

As filed with the U.S. Securities and Exchange Commission on October 5, 2023

Registration No. 333-268008

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-1/A
(Amendment No. 3)

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

ARCH THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction of
incorporation or organization)

3841
(Primary Standard Industrial
Classification Code Number)

46-0524102
(I.R.S. Employer
Identification Number)

235 Walnut St., Suite 6
Framingham, MA 01702
(617) 431-2313
(Address, including zip code, and telephone number, including
area code, of registrant's principal executive offices)

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Approximate date of commencement of proposed sale to the public: As soon as possible after the effective date hereof.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input checked="" type="checkbox"/>	Smaller reporting company <input checked="" type="checkbox"/>
	Emerging growth company <input type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said section 8(a), may determine.

EXPLANATORY NOTE

This registration statement contains two prospectuses:

- A prospectus that covers the offer and sale by the registrant of up to \$15,525,000 of Units (consisting of \$15,525,000 of shares of Common Stock and Investor Warrants to purchase up to \$15,525,000 of shares of Common Stock), up to \$13,500,000 of Pre-Funded Units (consisting of Pre-Funded Warrants to purchase up to \$13,500,000 of shares of Common Stock and Investor Warrants to purchase up to \$13,500,000 of shares of Common Stock), up to \$13,500,000 of shares of Common Stock underlying the Pre-Funded Warrants, up to \$15,525,000 of shares of Common Stock underlying the Investor Warrants, Underwriter Warrants to purchase up to \$970,313 of shares of Common Stock and up to \$970,313 of shares of Common Stock underlying the Underwriter Warrants (the “**Company Prospectus**”); and
- A prospectus that covers the resale of (i) 3,364,527 shares of Common Stock, (ii) up to 90,272,681 shares of Common Stock underlying warrants and (iii) up to 930,037 shares of Common Stock issuable upon conversion of convertible promissory notes (the “**Resale Prospectus**”).

The Company Prospectus immediately follows this Explanatory Note, and the Resale Prospectus immediately and sequentially follows the Company Prospectus.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED OCTOBER 5, 2023

PRELIMINARY PROSPECTUS

ARCH THERAPEUTICS, INC.

**6,750,000 Units (consisting of 6,750,000 Shares of Common Stock and Investor Warrants to Purchase up to 6,750,000 Shares of Common Stock)
Up to 6,750,000 Pre-Funded Units (consisting of Pre-Funded Warrants to Purchase up to 6,750,000 Shares of Common Stock and Investor Warrants to Purchase
up to 6,750,000 Shares of Common Stock)
Up to 6,750,000 Shares of Common Stock Underlying the Pre-Funded Warrants and
Up to 6,750,000 Shares of Common Stock Underlying the Investor Warrants**

We are offering units (“Units”), on a firm commitment basis, each Unit consisting of one share of our common stock, par value \$0.001 per share (“Common Stock”), and one warrant to purchase one share of our Common Stock (the “Investor Warrants”). The Units have no stand-alone rights and will not be certificated or issued as stand-alone securities. The shares of Common Stock can be purchased in this offering only with the accompanying Investor Warrants as part of a Unit (other than pursuant to the underwriters’ option to purchase additional shares of Common Stock and/or Investor Warrants). The shares of Common Stock and Investor Warrants comprising the Units are immediately separable and will be issued separately in this offering. Each Investor Warrant offered hereby is exercisable on the date of issuance at an exercise price per share of Common Stock equal to 100% of the public offering price of the Units in this offering, and will expire five years from the date of issuance. Pursuant to this prospectus, we are also offering the shares of Common Stock issuable upon exercise of the Investor Warrants.

We are also offering to each purchaser whose purchases of Units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding Common Stock immediately following the consummation of this offering, the opportunity to purchase, if the purchaser so chooses, pre-funded units (“Pre-Funded Units”) (each Pre-Funded Unit consisting of one pre-funded warrant (“Pre-Funded Warrant”) to purchase one share of Common Stock and one Investor Warrant to purchase one share of Common Stock) in lieu of Units that would otherwise result in the purchaser’s beneficial ownership exceeding 4.99% of our outstanding Common Stock (or at the election of the purchaser, 9.99%). Each Pre-Funded Warrant contained in a Pre-Funded Unit will be exercisable into one share of Common Stock, exercisable until all of the Pre-Funded Warrants are exercised in full. The purchase price of each Pre-Funded Unit will equal the price per Unit being sold to the public in this offering minus \$0.001, and the exercise price of each Pre-Funded Warrant included in the Pre-Funded Unit will be \$0.001 per share of Common Stock. This offering also relates to the shares of Common Stock issuable upon exercise of any Pre-Funded Warrants contained in the Pre-Funded Units sold in this offering. Each Investor Warrant contained in a Pre-Funded Unit has an exercise price equal to 100% of the public offering price of a Unit in this offering. The Investor Warrants contained in the Pre-Funded Units will be exercisable immediately and will expire five years from the date of issuance. Pursuant to this prospectus, we are also offering the shares of Common Stock issuable upon exercise of the Pre-Funded Warrants and Investor Warrants contained in the Pre-Funded Units.

Our Common Stock is currently quoted on the QB tier of the OTC Marketplace (“OTCQB”) under the symbol “ARTH”. The last reported sale price of our Common Stock on October 4, 2023, was \$1.20 per share. The public offering price per Unit and Pre-Funded Unit, and the exercise price of the Investor Warrants, as applicable, will be determined between us and the underwriters based on market conditions at the time of pricing, and may be at a discount to the then current market price. Therefore, the recent market price used throughout this preliminary prospectus may not be indicative of the final offering price. Currently, there is a very limited market for our Common Stock and no established public trading market for the Investor Warrants being offered in this offering. We do not intend to apply for listing of the Pre-Funded Warrants on any securities exchange or other nationally recognized trading system. There is no established public trading market for the Pre-Funded Warrants, and we do not expect a market to develop. We have applied to list our Common Stock and Investor Warrants on The Nasdaq Capital Market (the “Nasdaq Capital Market”) under the symbols “ARTH” and “ARTHW,” respectively. There is no assurance that our listing application will be approved by the Nasdaq Capital Market or The Nasdaq Global Market, NYSE or NYSE American (each of the NYSE American, The Nasdaq Global Market and NYSE, an “Alternate Exchange”), or, if successful, that an active trading market for our Common Stock and Investor Warrants will develop or be sustained. If we are unable to list our Common Stock on the Nasdaq Capital Market or an Alternate Exchange, we will not consummate this offering.

For each Pre-Funded Unit we sell, the number of Units we are offering will be decreased on a one-for-one basis. The Units and the Pre-Funded Units will not be issued or certificated. The shares of Common Stock or Pre-Funded Warrants, as the case may be, and the Investor Warrants can only be purchased together in this offering but the securities contained in the Units or Pre-Funded Units will be issued separately.

The final public offering price per Unit and Pre-Funded Unit, and the exercise price of the Investor Warrants, as applicable, will be determined through negotiation between the underwriters and us at the time of pricing, considering our historical performance and capital structure, prevailing market conditions, and overall assessment of our business, and may be at a discount to the current market price. The price at which our Common Stock was quoted on the OTCQB may not be indicative of the actual public offering price for the Units or of the price at which our Common Stock may trade on the Nasdaq Capital Market or an Alternate Exchange in the future.

In connection with this offering, we intend to effect a reverse stock split of our Common Stock at a ratio of between 1.5-for-1 and 20-for-1, with the exact ratio to be determined by our Board of Directors prior to effecting the reverse stock split. The information in this prospectus has not been adjusted to reflect the anticipated reverse stock split.

We are a “smaller reporting company” as defined under the federal securities laws and, as such, are eligible for reduced public company reporting requirements for this prospectus and future filings. See “**Prospectus Summary - Implications of Being a Smaller Reporting Company**”.

Investing in our securities involves a high degree of risk. Before making any investment in our securities, you should read and carefully consider the risks described in this prospectus under the heading “Risk Factors” beginning on page [15](#) of this prospectus.

You should rely only on the information contained in this prospectus or any prospectus supplement or amendment thereto. We have not authorized anyone to provide you with different information.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Unit	Per Pre-Funded Unit	Total
Public offering price(1)	\$	\$	\$
Underwriting discounts and commissions (2)	\$	\$	\$
Proceeds, before expenses, to us (3)	\$	\$	\$

- (1) Does not include additional compensation payable to the underwriters.
- (2) We have agreed to reimburse the underwriters for certain expenses in connection with this offering which are not included in the table above. In addition, we have agreed to issue to the Representative (as defined below), or its designees, warrants to purchase a number of shares of Common Stock equal to 5% of the total number of shares of Common Stock and Pre-Funded Warrants sold in this offering, including any shares sold in the over-allotment option, if any (the “**Underwriter Warrants**”). We refer you to the section entitled “**Underwriting**” for additional information regarding underwriting compensation.
- (3) Excludes potential proceeds from the exercise of the Warrants or the Pre-Funded Warrants being offered pursuant to this prospectus.

We have granted the underwriters an option, exercisable within 45 days from the date of this prospectus, to purchase from us, up to an additional 1,012,500 shares of Common Stock at the public offering price and/or Investor Warrants to purchase up to 1,012,500 shares of Common Stock (equal to 15% of the shares of Common Stock (and Pre-Funded Warrants, if any) and Investor Warrants sold in this offering), in any combination, at a price per Investor Warrant equal to the public offering price, less, in each case, the underwriting discounts and commissions, to cover over-allotments, if any. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable will be \$, and the total proceeds to us, before expenses, will be \$.

The underwriters expect to deliver the securities to the purchasers on or about , 2023.

Sole Book-Running Manager

Dawson James Securities, Inc.

The date of this prospectus is , 2023

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ABOUT THIS PROSPECTUS

This prospectus relates to the primary offering and sale by Arch Therapeutics, Inc. of 6,750,000 Units, each consisting of one share of Common Stock and one Investor Warrant to purchase one share of Common Stock. This prospectus also registers up to 337,500 shares (or 388,125 shares if the underwriters exercise their over-allotment option in full) of Common Stock issuable upon exercise of the Underwriter Warrants.

We are also offering to each purchaser whose purchase of Units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding Common Stock immediately following the consummation of this offering, if the purchaser so chooses, Pre-Funded Units (each Pre-Funded Unit consisting of one Pre-Funded Warrant to purchase one share of Common Stock and one Investor Warrant to purchase one share of Common Stock) in lieu of Units that would otherwise result in the purchaser's beneficial ownership exceeding 4.99% of our outstanding Common Stock (or at the election of the purchaser, 9.99%).

We have not, and the underwriters have not, authorized anyone to provide you with information that is different from that contained in this prospectus. When you make a decision about whether to invest in our securities, you should not rely upon any information other than the information in this prospectus. Neither the delivery of this prospectus nor the sale of our securities means that the information contained in this prospectus is correct after the date of this prospectus. This prospectus is not an offer to sell or the solicitation of an offer to buy our securities in any circumstances under which the offer or solicitation is unlawful.

For investors outside the United States: We have not, and the underwriters have not, taken any action that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities covered hereby and the distribution of this prospectus outside the United States.

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market share, is based on information from our own management estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third parties. Management estimates are derived from publicly available information, our knowledge of our industry and assumptions based on such information and knowledge, which we believe to be reasonable. Our management estimates have not been verified by any independent source, and we have not independently verified any third-party information. In addition, assumptions and estimates of our and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "**Risk Factors**." These and other factors could cause our future performance to differ materially from our assumptions and estimates. See "**Risk Factors**" and "**Cautionary Note Regarding Forward-Looking Statements**."

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to the registration statement of which this prospectus is a part were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to this registration statement of which this prospectus forms a part, and you may obtain copies of those documents as described below under the heading "**Where You Can Find More Information**" beginning on page [109](#) of this prospectus.

As used in this prospectus, unless the context indicates or otherwise requires, the "**Company**", "**we**", "**us**", "**our**" and "**Arch**" refer to Arch Therapeutics, Inc., a Nevada corporation, and its consolidated subsidiary, and the term "**ABS**" refers to Arch Biosurgery, Inc., a private Massachusetts corporation that, through a reverse merger acquisition completed on June 26, 2013, has become our wholly owned subsidiary.

AC5, AC5-G, AC5-V, AC5-P, Crystal Clear Surgery, NanoDrape and NanoBioBarrier and associated logos are trademarks and/or registered trademarks of Arch Therapeutics, Inc. and subsidiary. All other trademarks, trade names and service marks included in this prospectus are the property of their respective owners.

This prospectus and the information incorporated by reference into this prospectus contain references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus and the information incorporated by reference into this prospectus, including logos, artwork, and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other company.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve risks, uncertainties and assumptions. In some cases, you can identify forward-looking statements by terminology such as “if,” “shall,” “may,” “might,” “will likely result,” “should,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “project,” “intend,” “goal,” “objective,” “predict,” “potential” or “continue,” or the negative of these terms or other comparable terminology. All statements made in this prospectus other than statements of historical fact are statements that could be deemed forward-looking statements, including without limitation statements about our business plan, our plan of operations and our need to obtain future financing. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks in the section entitled “**Risk Factors**” beginning on page 15 of this prospectus, and the risks set out below, any of which may cause our or our industry’s actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. These risks include, by way of example and not in limitation, risks related to:

- Our ability to continue as a going concern;
- Our ability to obtain financing necessary to operate our business;
- Our limited operating history;
- Our ability to comply with the terms and covenants of our existing agreements and outstanding convertible notes, including the First Notes (as defined below) which are secured by security interests in substantially all of our assets;
- The dilutive effect of our outstanding warrants and convertible notes;
- The results of our research and development activities, including uncertainties relating to the preclinical and clinical testing of our product candidates;
- The commercialization of our primary product candidate;
- Our ability to develop, obtain required approvals for and commercialize our product candidates;
- Our ability to recruit and retain qualified key executives, and medical and science personnel;
- Our ability to develop and maintain an effective sales force to market our approved product candidates;
- Our ability to manage any future growth we may experience;
- Our ability to obtain and maintain protection of our intellectual property;
- Our dependence on third party manufacturers, suppliers, research organizations, academic institutions, testing laboratories and other potential collaborators;
- The size and growth of the potential markets for any of our approved product candidates, and the rate and degree of market acceptance of any of our approved product candidates;
- Our ability to successfully complete potential acquisitions and collaborative arrangements;
- Competition in our industry;
- The impact of the COVID-19 pandemic, and related responses of businesses and governments to the pandemic, on our operations and personnel, on commercial activity in the markets in which we operate and on our results of operations;
- General economic and business conditions; and
- Other factors discussed under the section entitled “**Risk Factors**.”

New risks emerge in our rapidly-changing industry from time to time. As a result, it is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business. If any such risks or uncertainties materialize or such assumptions prove incorrect, our results could differ materially from those expressed or implied by such forward-looking statements and assumptions. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity or performance. These forward-looking statements speak only as of the date of this prospectus. Except as required by applicable law, we do not intend to update any of these forward-looking statements.

PROSPECTUS SUMMARY

This summary highlights selected information from this prospectus and does not contain all of the information that is important to you in making an investment decision. This summary is qualified in its entirety by the more detailed information included elsewhere in this prospectus. Before making your investment decision with respect to our securities, you should carefully read this entire prospectus, including the information under “Risk Factors,” beginning on page 15 of this prospectus, “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” beginning on page 45, and the financial statements and the accompanying notes beginning on page F-1 of this prospectus.

Our Company

We are a biotechnology company marketing a number of products based on our innovative AC5® self-assembling technology platform. We believe these products are important advances in the field of stasis and barrier applications, which includes managing wounds created during surgery, trauma, interventional care or disease; stopping bleeding (hemostasis); and controlling leaking (sealant). We have recently devoted substantially all of our operational effort to the market adoption and commercial sales of AC5® Advanced Wound System, our first product. Our goal is to make care faster and safer for patients with products for use on external wounds, which we refer to as Dermal Sciences applications, and products for use inside the body, which we refer to as BioSurgery applications.

Our flagship products and product candidates are derived from our AC5® self-assembling peptide (“SAP”) technology platform and are sometimes referred to as AC5 or the “AC5 Devices.” These include AC5 Advanced Wound System and AC5® Topical Hemostat, which have received marketing authorization as medical devices in the United States and Europe, respectively, and which are intended for skin applications, such as management of complicated chronic wounds or acute surgical wounds. Marketing for AC5 Topical Hemostat in Europe has not initiated. Other products are in development for use in minimally invasive or open surgical procedures and include, for example, AC5-G™ for gastrointestinal endoscopic procedures and AC5-V™ and AC5® Surgical Hemostat for hemostasis inside the body, all of which are currently investigational devices limited by law to investigational use.

Products based on the AC5 platform contain a proprietary biocompatible peptide that is synthesized from proteogenic, naturally occurring L-amino acids. Unlike products that contain traditional peptide sequences, when applied to a wound, AC5-based products intercalate into the interstices of the tissue and self-assemble (i.e., self-build) into a protective physical-mechanical nanoscale structure that can provide a barrier to leaking substances, such as blood, while also acting as a biodegradable scaffold that enables healing. Self-assembly is a central component of the mechanism of action of our technology. Individual AC5 peptide units readily build themselves, or self-assemble, into an ordered network of nanofibrils when in aqueous solution by the following process:

- Peptide strands line up with neighboring peptide strands, interacting via hydrogen bonds (non-covalent bonds) to form a ribbon-like structure called a beta sheet.
- This process continues such that hundreds of strands organize with charged and polar side chains oriented on one face and non-polar side chains oriented on the opposite face of the beta sheets.
- Interactions of the resulting structure with water molecules and ions results in formation nanofibrils, which extend in length and can join together to form larger nanofibers.
- This network of AC5 peptide nanofibers forms the semi-solid physical-mechanical barrier that interacts with the extracellular matrix, is responsible for sealant, hemostatic and/or other properties that may be observed even in the presence of antithrombotic agents (i.e., blood thinners), and which subsequently becomes the scaffold that supports the repair and regeneration of damaged tissue.

Based on the intended application, we believe that the underlying AC5 SAP technology can impart important features and benefits to our products that may include, for instance, stopping bleeding (hemostasis), mitigating contamination, modulating inflammation, donating moisture, and enabling an appropriate wound microenvironment conducive to healing. Furthermore, we believe that AC5 SAP technology permits cell and tissue growth and is self-healing, in that it can dynamically self-repair around migrating cells. For instance, AC5 Advanced Wound System, which is indicated for the management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds, is shipped and stored at room temperature, is applied directly as a liquid, can conform to irregular wound geometry, self-assembles into a wound care matrix that can provide clinicians with multi-modal support, and does not possess sticky or glue-like handling characteristics. We believe these properties enhance its utility in several settings and contribute to its user-friendly profile.

We believe that our technology lends itself to a range of potential applications for wounds inside or on the body, including those for which a hemostatic agent or sealant is needed. For instance, the results of certain preclinical and clinical investigations that either we have conducted, or others have conducted on our behalf, have shown quick and effective hemostasis with the use of AC5 SAP technology, and that time to hemostasis (“TTH”) is comparable among test subjects regardless of whether such test subject had or had not been treated with therapeutic doses of anticoagulant or antiplatelet medications, commonly called “blood thinners.” Furthermore, the transparency and physical properties of certain AC5 Devices may enable a surgeon to operate through it in order to maintain a clearer field of vision and prophylactically stop or lessen bleeding as surgery starts, a concept that we call Crystal Clear Surgery™. An example of a product that contains related features and benefits is AC5 Topical Hemostat, which is indicated for use as a dressing and to control mild to moderate bleeding, each during the management of injured skin and the micro-environment of an acute surgical wound. AC5 Topical Hemostat has not yet been marketed in Europe but has received marketing authorization.

Sales and marketing efforts for our AC5 Advanced Wound System, which has received 510(k) marketing clearance from the FDA, address the demand for improved solutions to treat challenging chronic and acute surgical wounds, with a particular early focus on diabetic foot ulcers, venous leg ulcers and pressure ulcers. Chronic wounds are typically defined as wounds that have not healed after four weeks of standard care. Approximately 4 million to 6.5 million new onset chronic wounds are estimated to occur in the U.S. annually, including approximately 700,000 to 2 million diabetic foot ulcers, 2.5 million pressure ulcers, and 1.2 million venous leg ulcers. If untreated, improperly treated or unresponsive to treatment, these wounds can ultimately lead to amputation. The 5-year mortality rate among patients with chronic wounds, especially after an amputation, is significant.

Published data on AC5 Advanced Wound System shows encouraging outcomes, including limb salvage (avoided limb loss), among patients with multiple co-morbidities and challenging chronic wounds that failed to heal despite treatment with either traditional or other advanced wound care modalities over prolonged periods of time.

We currently maintain an internal commercial team focused on driving awareness and adoption of AC5 Advanced Wound System in several targeted channels with a particular focus on physician offices and government channels, such as Veterans Affairs (“VA”) hospitals and military treatment facilities (“MTFs”). We anticipate that material growth in the physician office setting will require product reimbursement. To that end, we submitted an application to the Centers for Medicare and Medicaid Services (“CMS”) in July 2022 for a unique product reimbursement code. Our application was subsequently approved with a go-live date of April 1, 2023. We have launched a temporary reimbursement support program in line with CMS guidance to support commercial use and adoption of AC5 Advanced Wound System both before and after the go-live date of our unique product code (A2020). In support of the VA and MTF market, we partnered with Lovell Government Services (“LGS”), a service-disabled veteran-owned small business, as its distributor in the government channel. As a direct result of its relationship with LGS, AC5 Advanced Wound System is listed on the four major government supply schedules (ECAT, DAPA, FSS and GSA) in order to allow doctors in any VA or MTF to order AC5 Advanced Wound System. We have also established and will continue to seek partnerships with reputable, value-added independent sales distributors on a case-by-case basis to expand the overall reach and footprint of its total sales organization. Presently, our commercialization efforts and resources remain dedicated to the U.S. market for advanced wound care.

Much of our operational efforts to date, which we often perform in collaboration with partners, have included selecting compositions and formulations for our initial products; conducting preclinical studies, including safety and other tests; conducting a human trial for safety and performance of AC5; developing and conducting a human safety study to assess for irritation and sensitization potential; securing marketing authorization for our first product in the United States and in Europe; supporting surgeons performing clinical case studies; obtaining post-marketing clinical data; developing, optimizing, and validating manufacturing methods and formulations, which are particularly important components of self-assembling peptide development; developing methods for manufacturing scale-up, reproducibility, and validation; engaging with regulatory authorities to seek early regulatory guidance as well as marketing authorization for our products; sourcing and evaluating commercial partnering opportunities in the United States and abroad; and developing and protecting the intellectual property rights underlying our technology platform.

Our long-term business plan includes the following goals:

- Continue to build recent commercial momentum and grow revenues by driving awareness, adoption and payment policies for AC5 Advanced Wound System with the now-effective CMS Level II Healthcare Common Procedure Coding System (“**HCPCS**”) code dedicated to the “AC5”;
- conducting biocompatibility, pre-clinical, and clinical studies on our products and product candidates;
- obtaining additional marketing authorization for products in the United States, Europe, and other jurisdictions as we may determine;
- continuing to develop third party relationships to manufacture, distribute, market and otherwise commercialize our products;
- continuing to develop academic, scientific and institutional relationships to collaborate on product research and development;
- expanding and maintaining protection of our intellectual property portfolio; and
- developing additional product candidates in Dermal Sciences, BioSurgery, and other areas.

In furtherance of our long-term business goals, we expect to continue to focus on the following activities during the next twelve months:

- seek additional funding as required to support the milestones described previously and our operations generally;
- work with our manufacturing partners to scale up production of product compliant with current good manufacturing practices (“**cGMP**”), which activities will be ongoing and tied to our development and commercialization needs;
- further clinical development of our product platform;
- assess our technology platform in order to identify and select product candidates for potential advancement into development;
- seek regulatory input to guide activities related to expanded and new product marketing authorizations;
- continue to expand and enhance our financial and operational reporting and controls;
- pursue commercial partnerships; and
- expand and enhance our intellectual property portfolio by filing new patent applications, obtaining allowances on currently filed patent applications, and/or adding to our trade secrets in self-assembly, manufacturing, analytical methods and formulation, which activities will be ongoing as we seek to expand our product candidate portfolio.

We believe that our current cash on hand as of September 15, 2023 is sufficient to meet our anticipated cash requirements into the first fiscal quarter of 2024, and we must obtain additional financing in order to continue to operate our business. Even if this offering is successful, depending upon additional input from EU and US regulatory authorities, however, we do not expect to generate sufficient revenues from operations before we need to raise additional capital. Further, our estimates regarding our use of cash could change if we encounter unanticipated difficulties or other issues arise, including without limitation those set forth in this prospectus under the heading “**Risk Factors**” beginning on page 15, in which case our current funds may not be sufficient to operate our business for the period we expect.

Additionally, we are bound by certain contractual terms and obligations that may limit or otherwise impact our ability to raise additional funding in the near-term including, but not limited to, provisions in the Bridge SPA (as defined below) and securities purchase agreement dated July 6, 2022, as amended (the “**2022 Notes SPA**”), associated with the sale of the 2022 Notes (as defined below) (the “**2022 Notes Financing**”), in each case as described in greater detail in the risk factor entitled “*The terms of the Bridge Offering and 2022 Notes Financing could impose additional challenges on our ability to raise funding in the future*” under the heading “**Risk Factors**” in this prospectus.

We have an aggregate of \$6,268,501 in principal outstanding as of September 15, 2023 under the 2022 Notes and an aggregate of \$587,959 in principal and accrued interest outstanding as of September 15, 2023 (calculated through maturity) under the Series 2 Notes (as defined below). The holders of the First Notes (as defined below) have been granted a security interest in substantially all of our assets pursuant to the terms of the security agreement dated July 6, 2022 (the “**Security Agreement**”), pursuant to which we provided a security interest in, and a lien on, substantially all of our assets as collateral for the repayment of the First Notes. If we fail to make payments on the First Notes when due or otherwise comply with the covenants contained in the First Notes, the First Note holders could declare us in default, in which event such holders would have the right to exercise their rights as a secured creditor with respect to our assets that secure the indebtedness, which would force us to suspend operations.

Proposed Listing on the Nasdaq Capital Market or an Alternate Exchange

Our Common Stock is presently quoted on the OTCQB under the trading symbol “ARTH.” In connection with this offering, we have applied to list our Common Stock and Investor Warrants on the Nasdaq Capital Market under the symbols “ARTH” and “ARTHW,” respectively. Although we have applied to list the Investor Warrants, there is no established public trading market for the Investor Warrants and without an active trading market, the liquidity of the Investor Warrants will be limited. No assurance can be given that our listing application for our Common Stock and Investor Warrants will be approved by the Nasdaq Capital Market or an Alternate Exchange. If our listing application is approved, our Common Stock will cease to be traded on the OTCQB. This offering will occur only if the Nasdaq Capital Market or an Alternate Exchange approves the listing of our Common Stock by October 31, 2023. The Nasdaq Capital Market and Alternate Exchange listing requirements include, among other things, a stock price threshold. As a result, prior to effectiveness, we will need to take the necessary steps to meet Nasdaq Capital Market listing requirements or the listing requirements of an Alternate Exchange, including but not limited to a reverse split of our outstanding shares of Common Stock.

Implications of Being a Smaller Reporting Company

We are a “smaller reporting company,” meaning that the market value of our Common Stock held by non-affiliates is less than \$700 million and our annual revenue is less than \$100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our stock held by non-affiliates is less than \$250 million as of the last business day of our second fiscal quarter or (ii) our annual revenue is less than \$100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700 million. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Corporate Information

Arch Therapeutics, Inc. (together with its subsidiary, the “**Company**” or “**Arch**”) arose from the June 26, 2013 merger (the “**Merger**”) of three entities previously known as Arch Biosurgery, Inc., Almah, Inc., and Arch Acquisition Corporation, respectively.

Arch Biosurgery, Inc. (“**ABS**”) is a biotechnology company that was incorporated under the laws of the Commonwealth of Massachusetts on March 6, 2006 as Clear Nano Solutions, Inc., changed its name from Clear Nano Solutions, Inc. to Arch Therapeutics, Inc. on April 7, 2008, and, as part of the Merger transaction, changed its name from Arch Therapeutics, Inc. to Arch Biosurgery.

Almah, Inc., was incorporated under the laws of the State of Nevada on September 16, 2009 and, as part of the Merger transaction, changed its name to Arch Therapeutics, Inc. and abandoned both its prior business plan and operations in order to adopt those of ABS.

Arch Acquisition Corporation, or Merger Sub, was a wholly owned subsidiary of Almah, Inc., formed for the purpose of the Merger transaction, pursuant to which Merger Sub merged with and into ABS, and ABS thereafter became the wholly owned subsidiary of the Company.

Prior to the completion of the Merger, we were a “shell company” under applicable rules of the SEC, and had no or nominal assets or operations.

Our principal executive offices are located at 235 Walnut St., Suite 6, Framingham, Massachusetts 01702. The telephone number of our principal executive offices is (617) 431-2313. Our website address is <http://www.archtherapeutics.com>. We have not incorporated by reference into this prospectus the information on, or that can be accessed through, our website, and you should not consider it to be a part of this document. You should not rely on any information on that website in making your decision to purchase shares of our Common Stock.

Recent Developments

Charter Amendments

On July 18, 2023, the board of directors of the Company (the “**Board**”) adopted resolutions by unanimous written consent, pursuant to which the Board determined that it is advisable and in the best interests of the Company to amend the Certificate of Incorporation of the Company (the “**Amendment**”) to (i) increase the total number of authorized shares of Common Stock from 12,000,000 to 350,000,000 (the “**Authorized Share Increase**”), (ii) authorize 5,000,000 shares of “blank check” preferred stock of the Company, thereby giving the Board the authority to designate from time to time one or more series of preferred stock (the “**Blank Check Preferred**”), and (iii) provide for a reverse stock split of the outstanding Common Stock, at a ratio within a range of 1.5-for-1 to 20-for-1, with the exact ratio to be determined by the Board subsequent to the applicable approval by the Company’s stockholders, within 1 year following the date of such approval, and without correspondingly decreasing the number of authorized shares of Common Stock (the “**Reverse Split**” and, together with the Authorized Share Increase and the Blank Check Preferred, the “**Charter Amendments**”). On August 22, 2023, stockholders representing a majority of the voting power of the then outstanding shares of voting stock of the Company (the “**Majority Stockholders**”) executed a written consent approving the Charter Amendments and the Company filed a preliminary Information Statement with the SEC with respect to the transactions contemplated hereby. The Company filed a definitive Information Statement with the SEC and mailed the definitive Information Statement to the Company’s stockholders notifying them of the action taken by written consent on September 1, 2023. Accordingly, the Company filed the Amendment with respect to the Authorized Share Increase and the Blank Check Preferred with the Secretary of State of Nevada on September 21, 2023. The Company intends to effect the Reverse Split prior to the pricing of this offering.

Bridge and Note Financings

Bridge Offering

Between July 7, 2023 and September 11, 2023, pursuant to a Securities Purchase Agreement dated July 7, 2023, as subsequently amended (the “**Bridge SPA**”), among the Company and certain institutional and accredited individual investors (collectively, the “**Bridge Investors**”) the Company issued and sold to the Bridge Investors an aggregate of (i) 3,344,321 shares (the “**Bridge Shares**”) of Common Stock; (ii) warrants (the “**Bridge Pre-Funded Warrants**”) to purchase an aggregate of 6,054,942 shares of Common Stock (the “**Bridge Pre-Funded Warrant Shares**”); and (iii) warrants (the “**Common Warrants**” and together with the Bridge Pre-Funded Warrants, the “**Bridge Warrants**”) to purchase an aggregate 18,798,526 shares of Common Stock (the “**Common Warrant Shares**” and together with the Bridge Pre-Funded Warrant Share, the “**Bridge Warrant Shares**”), at a purchase price of \$0.275 per Bridge Share and accompanying Common Warrant to purchase two shares of Common Stock, and \$0.274 per Bridge Pre-Funded Warrant to purchase one share of Common Stock and accompanying Common Warrant to purchase two shares of Common Stock. The Shares, Bridge Pre-Funded Warrants, and Common Warrants were issued as part of a private placement offering authorized by the Company’s board of directors (the “**Bridge Offering**”).

Pursuant to the lock-up agreement provided for by the Bridge SPA, the Bridge Investors agreed that they would either (A) purchase securities, for cash, in an offering conducted in conjunction with an uplist of the Common Stock to any of, and in compliance with the rules of, the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (the “**Uplist Transaction**”), which this offering is intended to be, with an aggregate purchase price equal to at least 4.3 multiplied by the aggregate purchase price paid by the Bridge Investor for the Bridge Shares and Bridge Warrants under the Bridge SPA or (B) be subject to a lock-up provision not to sell or otherwise transfer any of the Bridge Shares or Bridge Warrant Shares acquired by them in the Bridge Offering until the one-year anniversary of the Bridge Closing Date (as defined below). The aggregate gross proceeds for the sale of the Bridge Shares, Bridge Pre-Funded Warrants, and Common Warrants was approximately \$2.6 million, before deducting the placement agent’s fees and other estimated fees and offering expenses payable by the Company. The first closing of the sales of these securities under the Bridge SPA occurred on July 7, 2023 (the “**Bridge Closing Date**”).

Under the Bridge SPA, the Company also agreed that upon the closing of the next underwritten public offering of Common Stock (a **Qualifying Offering**), if the effective offering price to the public per share of Common Stock (the **Qualifying Offering Price**) is lower than the \$4.00 per share, then the Company shall issue additional Bridge Pre-Funded Warrants in an amount reflecting a reduction in the purchase price paid for the Bridge Shares and Bridge Pre-Funded Warrants that equals the proportion by which the Qualifying Offering Price is less than the \$4.00.

The Company retained Dawson James Securities, Inc. (**DJ**) as placement agent in connection with the Bridge Offering. The Company paid DJ a cash fee equal to 8.0% of the aggregate gross proceeds of the Bridge Offering and reimbursement of expenses of \$50,000. Additionally, on September 7, 2023 the Company issued to DJ, or its designees, warrants (the **Placement Agent Warrants**) to purchase an aggregate of 441,938 shares of Common Stock. The Placement Agent Warrants are exercisable at any time and from time to time, in whole or in part, during the five-year period commencing March 7, 2024, at a price per share equal to \$0.275.

Bridge Pre-Funded Warrants

The Bridge Pre-Funded Warrants (i) have a nominal exercise price of \$0.001 per share; (ii) are exercisable after the earlier of (A) the six-month anniversary after the date of issuance, (B) 120 days after the closing date of an Uplist Transaction, and (C) the date that a registration statement registering the Bridge Pre-Funded Warrant Shares is declared effective; (iii) are exercisable until all of the Bridge Pre-Funded Warrants are exercised in full; and (iv) have a provision preventing the exercisability of such Bridge Pre-Funded Warrants if, as a result of the exercise of the Bridge Pre-Funded Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder's, would be deemed to beneficially own more than either 4.99% or 9.99% of the Common Stock (the **Ownership Limitation**) immediately after giving effect to the exercise of the Bridge Pre-Funded Warrants.

Common Warrants

The Common Warrants (i) have an exercise price of \$1.00 per share; (ii) have a term of exercise equal to 5 years after their issuance date; (iii) are exercisable after the earlier of (A) the six-month anniversary after the date of issuance and (B) the date that a registration statement registering the Common Warrant Shares is declared effective; (iv) have a provision permitting voluntary adjustments to the exercise price by the Company, subject to the prior written consent of the Common Warrant holder; (v) are automatically exchanged upon the closing of an Uplist Transaction for a new warrant that is identical to the warrants (other than any pre-funded warrants), if any, being issued to investors in such Uplist Transaction, with the number of shares underlying such new warrant being equal to the number of Common Warrant Shares then underlying the Common Warrant multiplied by three and (vi) have a provision preventing the exercisability of such Common Warrants if, as a result of the exercise of the Common Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Company Common Stock would be aggregated with the holder's, would be deemed to beneficially own more than the Ownership Limitation immediately after giving effect to the exercise of the Common Warrants. **Accordingly, at the closing of this offering, the Common Warrants will be cancelled and exchanged for newly issued warrants identical to the Investor Warrants to purchase an aggregate of 56,395,578 shares of Common Stock at an exercise price per share equal to the exercise price per share of the Investor Warrants (the "Exchange Investor Warrants").**

Registration Rights Agreement

The Company also entered into a registration rights agreement with the Bridge Investors dated July 7, 2023, as subsequently amended (the **Registration Rights Agreement**), pursuant to which the Company is obligated, subject to certain conditions, to file with the Securities and Exchange Commission within the earlier of (i) 30 days following the closing date of the Uplist Transaction and (ii) October 31, 2023 one or more registration statements (any such registration statement, a **Resale Registration Statement**) to register the Shares, the Bridge Warrant Shares, the shares of Common Stock issuable upon exercise in full of the Exchange Investor Warrants (the **Exchange Investor Warrant Shares**) and the shares of Common Stock issuable upon exercise in full of the Participating Pre-Funded Warrant (as defined below) (the **Conversion Warrant Shares**) for resale under the Securities Act of 1933, as amended (the **Securities Act**). The Company's failure to satisfy certain filing and effectiveness deadlines with respect to a Resale Registration Statement and certain other requirements set forth in the Registration Rights Agreement may subject the Company to payment of monetary penalties.

Note Modification Agreements

On July 7, 2023, the Company entered into an amendment (“**Amendment No. 8 to the First Notes**”) with the holders of the Company’s outstanding Senior Secured Convertible Promissory Notes, as separately amended on February 14, 2023, March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 31, 2023, August 30, 2023 and September 30, 2023 (as amended, the “**First Notes**”), issued in connection with a private placement financing the Company completed on July 6, 2022 (the “**First Closing**”). On July 7, 2023, the Company also entered into an amendment (“**Amendment No. 8 to the Second Notes**”) with the holders of the Company’s outstanding Unsecured Convertible Promissory Notes, as separately amended on February 14, 2023, March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 31, 2023, August 30, 2023 and September 30, 2023 (as amended, the “**Second Notes**”), issued in connection with a private placement financing the Company completed on January 18, 2023 (the “**Second Closing**”). On July 7, 2023, the Company also entered into an amendment (“**Amendment No. 3 to the Third Notes**” and, together with Amendment No. 8 to the First Notes and Amendment No. 8 to the Second Notes, the “**Amendments to the 2022 Notes**”) with the holders of the Company’s outstanding Unsecured Convertible Promissory Notes, as separately amended on June 15, 2023, July 1, 2023, July 31, 2023, August 30, 2023 and September 30, 2023 (as amended, the “**Third Notes**” and, together with the First Notes and Second Notes, the “**2022 Notes**”), issued in connection with a private placement financing the Company completed on May 15, 2023 (the “**Third Closing**”).

Under the Amendments to the 2022 Notes, the following amendments to the 2022 Notes will be simultaneously effective upon the closing of the Uplist Transaction. The Specified Percentage (as defined below) of the then outstanding principal amount of the 2022 Notes shall automatically convert (the “**Automatic Conversion**”) into shares of Common Stock, with the conversion price for purposes of such Automatic Conversion being equal to the lower of (i) the per unit price at which any units (each unit being comprised of one share or share equivalent and accompanying warrants, if any) are sold in the Uplist Transaction or (ii) the price at which warrants issued in the Uplist Transaction are exercisable (but in no event increased above the conversion price in effect immediately prior to the pricing of the Uplist Transaction).

In addition, if the Holder (as defined below) (i) participates in the Uplist Transaction and in the Bridge Offering for a combined (taking into account the Holder’s aggregate investment in the Uplist Transaction and the Bridge Offering) amount equal to no less than fifty percent (50%) of the Holder’s original purchase price under the 2022 Notes and (ii) the Holder’s amount of participation in the Uplist Transaction is at least 4.3 times the Holder’s amount of participation in the Bridge Offering (such criteria in clauses (i) and (ii) above, the “**Participation Criteria**”), then the Holder shall receive a pre-funded warrant (the “**Participating Pre-Funded Warrant**”) to purchase a number of shares of Common Stock equal to the Specified Number (as defined below) times the dollar amount under the 2022 Notes that was converted in the Automatic Conversion. The Participating Pre-Funded Warrant (i) shall have an exercise price of \$0.001 per share, (ii) may be exercised on a cashless basis, (iii) shall be exercisable by the Holder at any time commencing on the 90th day after issuance, (iv) may be redeemed by the Company for cash at a redemption price of \$0.82 per share underlying the Participating Pre-Funded Warrant, with any such redemption made pro rata to all holders of the Participating Pre-Funded Warrants, (v) and shall contain a customary beneficial ownership limitation provision. Additionally, the holder of the Participating Pre-funded Warrants will agree that, until January 6, 2024, it shall not offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of, or announce the intention to otherwise dispose of, the Participating Pre-Funded Warrant.

“Specified Percentage” means the greater of: (i) the percentage specified by the Company by notice to the 2022 Note holders (the “**Holders**” and each a “**Holder**”) at least five business days prior to the closing of the Uplist Transaction, which percentage shall be the percentage necessary to ensure the applicable Nasdaq requirements regarding the Uplist Transaction are satisfied, and (ii) the percentage specified by the Holder by notice to the Company at least three business days prior to the closing of the Uplist Transaction (which percentage may be different for each 2022 Note as determined by each Holder thereof); provided, that in no event shall the Specified Percentage for the 2022 Notes (A) exceed twenty five percent (25%) unless otherwise agreed in writing by the Holder, or (B) exceed fifty percent (50%) unless otherwise agreed in writing by the Company.

“Specified Number” means, if the Specified Percentage is 50%, 2.4, which number shall be increased by 1.6% for each percentage point decrease in the Specified Percentage, such increase being compounded iteratively for each percentage point decrease in the Specified Percentage, with the result rounded to two decimal places.

Further, on September 30, 2023, the Company entered into an amendment (“**Amendment No. 11 to the First Notes**”) to the First Notes, an amendment (“**Amendment No. 11 to the Second Notes**”) to the Second Notes and an amendment (“**Amendment No. 6 to the Third Notes**” and, together with Amendment No. 11 to the First Notes and Amendment No. 11 to the Second Notes, the “**September Amendments to the 2022 Notes**”) to the Third Notes. The September Amendments to the 2022 Notes extend the deadline by which the Company must close the Uplist Transaction to October 31, 2023 and provide that upon the Automatic Conversion and to the extent that a Holder’s beneficial ownership would increase over the applicable Ownership Limitation, the Holder will receive pre-funded warrants (the “**2022 Note Conversion Pre-Funded Warrants**”) in lieu of shares of Common Stock otherwise issuable to the Holder in connection with the Automatic Conversion, which 2022 Note Conversion Pre-Funded Warrants shall have an exercise price of \$0.001 per share, may be exercised on a cashless basis, shall be exercisable immediately upon issuance and shall contain a customary beneficial ownership limitation provision.

Accordingly, it is currently anticipated that the Specified Percentage will be 50%, and thus, at the closing of this offering: (i) an aggregate of 1,567,127 shares of Common Stock (assuming no issuance of 2022 Note Conversion Pre-Funded Warrants) will be issued upon the Automatic Conversion of an aggregate of \$3,134,250 of principal amount under the 2022 Notes, representing 50% of the \$6,268,501 in principal amount currently outstanding under the 2022 Notes, based on the assumed offering price of \$2.00 per Unit in this offering; and (ii) assuming that all Holders fulfill the Participation Criteria, the Holders will be issued Participating Pre-Funded Warrants to purchase an aggregate of 7,522,203 shares of Common Stock, based on a Specified Number of 2.4 multiplied by the \$3,134,250 of principal amount converted in the Automatic Conversion.

Additionally, on July 7, 2023, the Company entered into an amendment (the “**Omnibus Amendment to Notes and Warrants**”) with the Holders of the 2022 Notes, amending the 2022 Notes and related warrants issued at each of the First Closing, Second Closing, and Third Closing (the “**First Warrants**”, “**Second Warrants**” and “**Third Warrants**”, respectively, and collectively, the “**2022 Warrants**”). Under the Omnibus Amendment to Notes and Warrants, the 2022 Notes and 2022 Warrants were amended (i) to modify the Most Favored Nation provisions therein to exclude the Bridge Offering and (ii) to prohibit the Company from engaging in any capital raising transactions, subject to certain exceptions, until the earlier of (A) July 7, 2027, and (B) the first date on which all Holders hold less than 20% of the original amount of the Participating Pre-Funded Warrants received by each Holder, respectively, in connection with the Automatic Conversion.

2022 Notes

The 2022 Notes bear interest on the unpaid principal balance at a rate equal to ten percent (10%) (computed on the basis of the actual number of days elapsed in a 360-day year) per annum accruing from the issuance date until the 2022 Notes become due and payable at maturity or upon their conversion, acceleration or by prepayment, and may become due and payable upon the occurrence of an event of default under the 2022 Notes. The 2022 Notes mature January 6, 2024. Any amount of principal or interest on the 2022 Notes which is not paid when due shall bear interest at the rate of the lesser of (i) eighteen percent (18%) per annum or (ii) the maximum amount allowed by law from the due date thereof until payment in full. As of September 15, 2023, the outstanding unpaid principal balance including all accrued interest under the 2022 Notes totaled \$6,935,071.

The 2022 Notes are convertible into shares of Common Stock at the option of each Holder from the date of issuance at \$9.14 (the “**Conversion Price**”), subject to adjustment, through the later of (i) January 6, 2024 (the “**Maturity Date**”) or (ii) the date of payment of the Default Amount (as defined in the 2022 Notes).

The 2022 Notes contain events of default, which include, among other things, (i) the Company’s failure to pay when due any principal or interest payment under the 2022 Notes; and (ii) our failure to complete an Uplist Transaction by October 31, 2023.

The 2022 Warrants (i) have an exercise price of \$9.94 per share; (ii) have a term of exercise equal to 5 years after their issuance date; (iii) became exercisable immediately after their issuance; and (iv) have a provision preventing the exercisability of such 2022 Warrants if, as a result of the exercise of the 2022 Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of our Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than the Ownership Limitation. As long as the 2022 Notes and 2022 Warrants remaining outstanding, upon the issuance of any security in connection with any potential future financing activity on terms more favorable than the existing terms, except for any offering conducted in connection with the Uplist Transaction which this offering is intended to be, the Company has an obligation to notify the holders of the 2022 Notes and 2022 Warrants of such more favorable terms, and to use best efforts to effect such terms in the 2022 Notes and 2022 Warrants.

As discussed above, it is currently anticipated that 50% of the of the \$6,268,501 unpaid principal balance currently outstanding under the 2022 Notes will convert into 1,567,127 shares of Common Stock (assuming no issuance of 2022 Note Conversion Pre-Funded Warrants) in connection with the Automatic Conversion.

Under the Second Amended and Restated Registration Rights Agreement, dated as of May 15, 2023, as amended, the Company is required to file a registration statement registering the securities issued in the Second Closing and Third Closing, including the applicable 2022 Notes and 2022 Warrants, no later than 45 days following the closing of the Uplist Transaction.

Series 1 and 2 Convertible Notes

On June 4, 2020 and November 6, 2020, the Company issued unsecured 10% Series 1 Convertible Notes (“**Series 1 Notes**”) and Series 2 Convertible Notes, as amended (“**Series 2 Notes**”, and collectively with the Series 1 Notes, the “**Series Convertible Notes**”). The maturity dates of the Series 1 Notes and Series 2 Notes are June 30, 2023 and November 30, 2023, respectively. On July 12, 2023, the Company secured countersigned notices of conversion from all remaining holders of the Series 1 Convertible Notes and provided instructions to its transfer agent to issue a total of 59,912 shares of Common Stock in full satisfaction of all previously outstanding Series 1 Convertible Notes, which had an aggregate of \$718,918 of principal and interest outstanding at the time of conversion.

As of September 15, 2023, there was \$587,959 of principal and accrued interest (through maturity) outstanding under the Series 2 Notes. The Series 2 Notes have a “Conversion Price” of \$50.00 and allow the Company to convert all obligations thereunder upon the Uplist Transaction, or the maturity date, using the Conversion Price and multiplying the obligations then outstanding by 4.5. **Accordingly, it is currently anticipated that an aggregate of 52,917 shares of Common Stock will be issued at the closing of this offering upon the conversion of the remaining outstanding amount under the Series 2 Notes.**

Bylaw Amendments

On July 18, 2023, the Board approved an amendment to the Amended and Restated Bylaws of the Company (the “**Bylaw Amendment**”), effective immediately. The Bylaw Amendment amended the Amended and Restated Bylaws (i) to allow stockholders of the Company to take action by written consent without a meeting with not less than the minimum number of votes that would be necessary to take such action if the matter was presented at a meeting of stockholders at which all shares entitled to vote thereon were present and voted, subject to certain limitations and (ii) to provide that in the absence of a quorum, the chairman of a stockholder meeting can adjourn the meeting, respectively.

Equity Incentive Plan

Effective August 13, 2023, the Board adopted and approved the Amended and Restated 2023 Equity Incentive Plan (the “**2023 Plan**”) and reserved 455,169 shares of Common Stock for issuance thereunder to employees, officers, directors and consultants of the Company. The stockholders of the Company approved the plan on August 22, 2023. The Plan has a term of 6 years and is intended to replace the Company’s 2013 Stock Incentive Plan, which expired on June 18, 2023.

The general purpose of the 2023 Plan is to provide a means whereby eligible employees, officers, non-employee directors, consultants, advisors, and other individual service providers may develop a sense of proprietorship and personal involvement in the Company’s development and financial success, and to encourage them to devote their best efforts to the Company, thereby advancing the Company’s interests and the interests of stockholders of the Company. The 2023 Plan permits the Company to grant a variety of forms of awards, including stock options, stock appreciation rights, restricted stock, restricted stock units, and dividend equivalent rights, to allow the Company to adapt its incentive compensation program to meet its needs.

In addition, the number of shares of Common Stock available for issuance under the 2023 Plan will automatically increase on October 1st of each fiscal year of the Company commencing with October 1, 2023, and on each October 1 thereafter until the 6th anniversary of the date of the 2023 Plan’s initial adoption by the Board, in an amount equal to five percent (5%) of the total number of shares of Common Stock outstanding on September 30th of the preceding fiscal year. Furthermore, effective at the close of business on the date of the closing (the “**Uplist Date**”) of the public offering in connection with which the Common Stock becomes tradeable on a national exchange and on the first day of each fiscal quarter of the Company thereafter until the earlier of (i) the five-year anniversary of the Uplist Date and (ii) October 31, 2028, the number of shares of Common Stock available for issuance under the 2023 Plan shall automatically increase by an amount equal to fifteen percent (15%) of the incremental number of shares of Common Stock, if any, issued by the Company (x) with respect to the “Bridge Offering,” including without limitation “Pre-Funded Warrant Shares” and “Common Warrant Shares,” the “Uplist Transaction” and/or a “Qualifying Offering” (as such terms are defined in the 2023 Plan), (y) with respect to the Uplist Date, since the date on which the stockholders ratified the 2023 Plan, and (z) with respect to each fiscal quarter thereafter, during the previous fiscal quarter (excluding in each case shares of Common Stock issued pursuant to awards under the 2023 Plan); provided, however, that shares of Common Stock issued in connection with any such Qualifying Offering shall not be taken into account except to the extent, if any, that such shares are issued with respect to shares of Common Stock issued in connection with the Bridge Offering and/or the Uplist Transaction.

The Offering

Units being offered	6,750,000 Units. Each Unit will consist of one share of Common Stock and one Investor Warrant to purchase one share of Common Stock. The Units have no stand-alone rights and will not be certificated or issued as stand-alone securities. The shares of Common Stock can be purchased in this offering only with the accompanying Investor Warrants as part of Units (other than pursuant to the underwriters' option to purchase additional shares of Common Stock and/or Investor Warrants), but the components of the Units will be immediately separable and will be issued separately in this offering.
Pre-Funded Units being offered	We are also offering to each purchaser whose purchases of Units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding Common Stock immediately following the consummation of this offering, the opportunity to purchase, if the purchaser so chooses, Pre-Funded Units (each Pre-Funded Unit consisting of one Pre-Funded Warrant to purchase one share of Common Stock and one Investor Warrant to purchase one share of Common Stock) in lieu of Units that would otherwise result in the purchaser's beneficial ownership exceeding 4.99% of our outstanding Common Stock (or at the election of the purchaser, 9.99%). Each Pre-Funded Warrant contained in a Pre-Funded Unit will be exercisable into one share of Common Stock, exercisable until all of the Pre-Funded Warrants are exercised in full. The purchase price of each Pre-Funded Unit will equal the price per Unit being sold to the public in this offering minus \$0.001, and the exercise price of each Pre-Funded Warrant included in the Pre-Funded Unit will be \$0.001 per share of Common Stock. This offering also relates to the shares of Common Stock issuable upon exercise of any Pre-Funded Warrants contained in the Pre-Funded Units sold in this offering. For each Pre-Funded Unit we sell, the number of Units we are offering will be decreased on a one-for-one basis. Because we will issue an Investor Warrant as part of each Unit or Pre-Funded Unit, the number of Investor Warrants sold in this offering will not change as a result of a change in the mix of the Units and Pre-Funded Units sold.
Common Stock outstanding prior to the offering(1)	4,689,446
Common Stock to be outstanding after the offering(1)	13,059,490 shares (14,071,990 shares if the underwriters exercise their option to purchase additional shares in full, and assuming, in each case, no sale of any Pre-Funded Units and no exercise of the Investor Warrants), which takes into account the issuance of an assumed 1,567,127 shares of Common Stock as a result of the Automatic Conversion under the 2022 Notes and 52,917 shares of Common Stock as a result of the conversion of the Series 2 Notes, at the closing of this offering and assumes no issuance of 2022 Note Conversion Pre-Funded Warrants as a result of the Automatic Conversion and no exercise of the Participating Pre-Funded Warrants and Exchange Investor Warrants to be issued at the closing of this offering.
Over-allotment Option	We have granted the underwriters an option, exercisable for 45 days after the date of this prospectus, to purchase up to an additional 1,012,500 shares of Common Stock and/or Investor Warrants to purchase up to an additional 1,012,500 shares of Common Stock (equal to 15% of the shares of Common Stock (and Pre-Funded Warrants, if any) and Investor Warrants sold in this offering), in any combination, at the public offering price per share of Common Stock and per Investor Warrant, respectively, less the underwriting discounts payable by us, solely to cover over-allotments, if any.
Description of Investor Warrants	<p>Each Unit and each Pre-Funded Unit includes an Investor Warrant to purchase one share of Common Stock. The Investor Warrants will have an exercise price per share of Common Stock equal to 100% of the offering price of the Unit in this offering, will be immediately separable from the Common Stock or Pre-Funded Warrant, as the case may be, will be exercisable on the date of issuance and will expire five years from the date of issuance. Each Investor Warrant is exercisable for one share of Common Stock, subject to adjustment in the event of stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our Common Stock. A holder may not exercise any portion of an Investor Warrant to the extent that the holder, together with its affiliates and any other person or entity acting as a group, would own more than 4.99% of our outstanding shares of Common Stock after exercise, as such ownership percentage is determined in accordance with the terms of the Investor Warrants, except that upon notice from the holder to us, the holder may waive such limitation up to a percentage not in excess of 9.99% of our outstanding shares of Common Stock.</p> <p>This prospectus also registers up to 6,750,000 shares of Common Stock issuable upon exercise of the Investor Warrants. To better understand the terms of the Investor Warrants, you should carefully read the “Description of Securities – Description of Investor Warrants to be Issued in this Offering” section of this prospectus. You should also read the form of Investor Warrant, which is filed as an exhibit to the registration statement that includes this prospectus.</p>

Description of Underwriter Warrants	Upon the closing of this offering, we will issue to the Representative, or its designees, warrants entitling it to purchase a number of shares of Common Stock equal to 5% of the total number of shares of Common Stock and Pre-Funded Warrants sold in this offering, including any shares sold in the over-allotment option, if any, at an exercise price equal to 125% of the public offering price of the Units (the “ Underwriter Warrants ”). The Underwriter Warrants shall be exercisable commencing six months after the effective date of the registration statement of which this prospectus is a part and will expire five years after the effective date of the registration statement of which this prospectus is a part. This prospectus also registers up to 337,500 shares (or 388,125 shares if the underwriters exercise their over-allotment option in full) of Common Stock issuable upon exercise of the Underwriter Warrants.
Use of proceeds	<p>We estimate that we will receive net proceeds from this offering of approximately \$11.6 million (assuming no sale of any Pre-Funded Warrants) or approximately \$13.5 million if the underwriters exercise their over-allotment option in full, based upon an assumed public offering price of \$2.00 per Unit and after deducting the underwriting discounts and commissions and estimating offering expenses payable by us.</p> <p>We intend to use the net proceeds we receive from this offering for product marketing and for general working capital purposes. See Use of Proceeds” beginning on page 41 of this prospectus for more information.</p>
Market for Common Stock	Our Common Stock is traded on the OTCQB under the symbol “ARTH.” On October 4, 2023, the closing price of our Common Stock was \$1.20 per share. The public offering price per Unit and Pre-Funded Unit, and the exercise price of the Investor Warrants, as applicable, will be determined between us and the underwriters based on market conditions at the time of pricing, and may be at a discount to the then current market price. Therefore, the recent market price used throughout this preliminary prospectus may not be indicative of the final offering price. We have applied to list our Common Stock on the Nasdaq Capital Market under the symbol “ARTH.” No assurance can be given that an active trading market will develop for the Common Stock. We believe that upon the completion of the offering contemplated by this prospectus, we will meet the standards for listing on the Nasdaq Capital Market or an Alternate Exchange. We cannot guarantee that we will be successful in listing our Common Stock on the Nasdaq Capital Market or an Alternate Exchange; however, we will not complete this offering unless we are so listed.
Market for Pre-Funded Warrants	There is no established public trading market for the Pre-Funded Warrants, and we do not expect a market to develop. We do not intend to apply for listing of the Pre-Funded Warrants on any securities exchange or other nationally recognized trading system.
Market for Investor Warrants	There is no established public trading market for the Investor Warrants. We have applied to list the Investor Warrants on the Nasdaq Capital Market under the symbol “ARTHW.” No assurance can be given that such listing will be approved or, if successful, that an active trading market for the Investor Warrants will develop or be sustained.
Risk Factors	See “ Risk Factors ” beginning on page 15 and other information in this prospectus for a discussion of the factors you should consider before you decide to invest in our securities.
Lock-ups	We, our directors and executive officers will enter into customary “lock-up” agreements pursuant to which such persons and entities will agree, for a period of six months after the closing of this offering, not to offer, issue, sell, contract to sell, encumber, grant any option for the sale of, or otherwise dispose of, any shares of Common Stock or any securities convertible into or exchangeable for our Common Stock. See “ Underwriting-Lock-Up Agreements. ”

- (1) Based on 4,689,446 shares of Common Stock outstanding on September 15, 2023. Excludes, as of such date, (i) options granted to employees, directors and consultants under our 2013 Stock Incentive Plan (the “**2013 Plan**”) to purchase up to an aggregate of 100,900 shares of Common Stock at exercise prices ranging from \$4.00 to \$130.00 per share and with a weighted average exercise price of \$37.57 per share; (ii) 26,283,816 shares of Common Stock issuable upon the exercise of outstanding warrants, having a weighted average exercise price of \$1.36 per share (which includes 18,798,526 Common Warrants that will automatically be cancelled and exchanged for 56,395,578 Exchange Investor Warrants at the closing of this offering); (iii) Series 2 Convertible Notes convertible into 52,917 shares of Common Stock at a conversion price of \$50.00 per share; (iv) 685,846 shares of Common Stock issuable upon conversion of the 2022 Notes at the exercise price of \$9.14 per share; (v) 7,522,203 shares of Common Stock to be issuable upon exercise of the Participating Pre-Funded Warrants expected to be issued at the closing of this offering; (vi) 56,395,578 shares of Common Stock to be issuable upon exercise of the Exchange Investor Warrants expected to be issued at the closing of this offering; (vii) 455,169 shares of Common Stock reserved for future issuance under the 2023 Plan; (viii) up to 6,750,000 shares (7,762,500 shares if the underwriters’ option to purchase additional Investor Warrants is exercised in full) of Common Stock issuable upon exercise of the Investor Warrants to be issued in this offering; and (ix) up to 337,500 shares (388,125 shares if the underwriters’ option to purchase additional shares of Common Stock is exercised in full) of Common Stock issuable upon exercise of the Underwriter Warrants to be issued to the Representative, or its designees, upon completion of this offering.

Except as indicated otherwise, the discussion above assumes no sale of any Pre-Funded Units, no issuance of any 2022 Note Conversion Pre-Funded Warrants and no exercise of the underwriters’ option to purchase up to 1,012,500 additional shares of Common Stock and/or Investor Warrants to purchase up to 1,012,500 additional shares of Common Stock.

RISK FACTORS

Investment in our securities involves a high degree of risk. You should carefully consider the risks that are summarized below and discussed in greater detail in the following pages, together with the other information contained in this prospectus, including our financial statements and the related notes appearing at the end of this prospectus, before making an investment decision. If any of the following risks and uncertainties actually occur, our business, financial condition, and results of operations could be negatively impacted, and you could lose all or part of your investment.

Risk Factor Summary

- There is substantial doubt about our ability to continue as a going concern, and we believe that our current cash on hand as of September 15, 2023 is not sufficient to meet our anticipated cash requirements through the end of the first quarter of fiscal 2024, and we must obtain additional financing in order to continue to operate the business.
- We have incurred significant losses since inception, we expect to continue to incur losses for the foreseeable future, and we may not generate sufficient revenue to achieve or maintain profitability.
- We will need to raise additional capital, which may not be available to us on acceptable terms, or at all. In addition, the terms of our previous financings could impose additional challenges on our ability to raise funding in the future.
- Our obligations under the First Notes, including our obligation to repay the outstanding balance under the First Notes upon such holder's demand for repayment upon the completion of an Uplist Transaction, are secured by security interests in substantially all of our assets and our failure to comply with the terms and covenants of the First Notes could result in our loss of substantially all of our assets.
- The holders of our 2022 Notes have certain additional rights upon an event of default under such notes, which could harm our business, financial condition, and results of operations and could require us to reduce or cease our operations.
- If we issue additional shares in the future, including issuances of shares upon exercise of our outstanding warrants or conversion of our outstanding convertible notes, our existing stockholders will be significantly diluted and our stock price may be negatively affected.
- If we do not successfully market our products, we will continue to incur losses and will never be profitable.
- Our business may be materially adversely affected by the coronavirus (COVID-19) pandemic. Should the pandemic or its aftereffects continue, our business operations could and will likely be delayed or interrupted.
- Our flagship product is novel without any history of use in the clinical fields in which it is marketed requiring education and training regarding its application to gain and maintain market acceptance by patients, physicians, healthcare payors or others in the medical community.
- Applications for regulatory marketing authorization for commercialization of our additional products or elements of our supply chain may not be accepted, or if accepted, may be voluntarily withdrawn or eventually rejected, and the future success of our business is significantly dependent on the success of our being able to obtain regulatory marketing authorization for our development stage candidates.
- Our additional product candidates are inherently risky because they are based on novel technologies and thus create significant challenges with respect to product development and optimization, engineering, manufacturing, scale-up, quality systems, pre-clinical in vitro and in vivo testing, government regulation and approval, third-party reimbursement and market acceptance.

- Any changes in our supply chain, including to the third-party contract manufacturers, service providers, or other vendors, or in the processes that they employ, could adversely affect us.
- If the FDA or similar foreign agencies or intermediaries impose requirements more onerous than we anticipate, our business could be adversely affected.
- We are subject to extensive and dynamic medical device regulations outside of the United States, which may impede or hinder the approval, marketing authorization or sale of our products and, in some cases, may ultimately result in an inability to obtain approval of certain products or may result in the recall or seizure of previously approved or authorized products.
- Any clinical trials that are planned or are conducted on our flagship product or additional product candidates may not start or may fail. Clinical trials are lengthy, complex and extremely expensive processes with uncertain expenditures and results and frequent failures.
- We cannot market and sell any additional product candidate in the United States or in any other country or region if we fail to obtain the necessary marketing authorization, clearances or certifications from applicable government agencies.
- The flagship product for which we obtained required regulatory marketing authorization is subject to post-approval regulation, and we may be subject to penalties if we fail to comply with such post-approval requirements.
- Use of third parties to manufacture our product and our additional product candidates may increase the risk that preclinical development, clinical development and potential commercialization of our product candidates could be delayed, prevented or impaired.
- We face competition from companies that have greater resources than we do, and we may not be able to effectively compete against these companies.
- If others claim we and/or the parties from whom we license some of our intellectual property are infringing on their intellectual property rights, we may be subject to costly and time-consuming litigation.
- There is not now, and there may not ever be, an active market for our Common Stock, which trades in the over-the-counter market in low volumes and at volatile prices. Although we have applied to list our Common Stock on the Nasdaq Capital Market there is no assurance that our application will be approved.
- Even if this offering is successful and our application to list our Common Stock and Investor Warrants on the Nasdaq Capital Market or an Alternate Exchange is approved, no assurance can be given that an active trading market for our Common Stock or Investor Warrants will develop or be maintained.

AC5, AC5-G, AC5-V, AC5-P, Crystal Clear Surgery, NanoDrape and NanoBioBarrier and associated logos are trademarks and/or registered trademarks of Arch Therapeutics, Inc. and subsidiary. For purposes herein, references to regulatory approval and marketing authorization may be used interchangeably.

Risks Related to our Business, Financial Position and Capital Requirements

There is substantial doubt about our ability to continue as a going concern. Even if this offering is successful, we will need additional funding to continue our operations and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts and could cause our business to fail.

We have only recently commenced commercial sales of our first product, AC5 Advanced Wound System, and we have incurred substantial net losses as a result. We believe that our current cash on hand as of September 15, 2023 is sufficient to meet our anticipated cash requirements into the first fiscal quarter of 2024, and we must obtain additional financing in order to continue to operate our business. Even if this offering is successful, we will need to secure additional resources to support our continued operations.

We have obtained additional cash from debt and equity financings during the last several fiscal quarters to continue operations and fund our planned future operations, which include research and development of our product candidates, steps related to seeking regulatory marketing authorization for our initial product candidates, and planning for their commercialization in the U.S. and Europe. Even with the additional funds received from these financings, there exists substantial doubt about our ability to continue as a going concern. In addition, our plans may change and/or we may use our capital resources more rapidly than we currently anticipate. We presently expect that our expenses will increase in connection with our ongoing activities to support our business operations, inclusive of regulatory submissions, marketing authorization, and commercialization of our product candidates and products, and, therefore, we will require additional funding.

Our future capital requirements will depend on many factors, including:

- the success of our marketing efforts;
- the success of our additional commercialization efforts;
- the scope, progress and results of our research and development collaborations;
- the extent of potential direct or indirect grant funding for our research and development activities;
- the scope, progress, results, costs, timing and outcomes of any regulatory process and clinical trials conducted for any of our product candidates;
- the timing of entering into, and the terms of, any collaboration agreements with third parties relating to any of our product candidates;
- the timing of and the costs involved in obtaining regulatory marketing authorization for our product candidates;
- the costs of operating, expanding and enhancing our operations to support our clinical activities and, if our product candidates are approved, commercialization activities;
- the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities;
- the costs associated with maintaining and expanding our product pipeline;
- the costs associated with expanding our geographic focus;
- operating revenues, if any, received from sales of our product candidates, if any are approved by the FDA or other applicable regulatory agencies;
- the cost associated with being a public company, including obligations to regulatory agencies, and increased investor relations and corporate communications expenses; and
- the costs of additional general and administrative personnel, including accounting and finance, legal and human resources employees.

We intend to obtain additional financing for our business through public or private securities offerings, the incurrence of additional indebtedness, or some combination of those sources. We may also seek funding through collaborative arrangements with strategic partners if we determine them to be necessary or appropriate, although these arrangements could require us to relinquish rights to our technology or product candidates and could result in our receipt of only a portion of any revenues associated with the partnered product. We cannot provide any assurance that additional financing from these sources will be available on favorable terms, if at all.

In addition, we are bound by certain contractual terms and obligations that may limit or otherwise impact our ability to raise additional funding in the near-term including, but not limited to, provisions in the Bridge SPA and 2022 Notes SPA, associated with the 2022 Notes Financing, in each case as described in greater detail in the risk factor entitled ***“The terms of the Bridge Offering and 2022 Notes Financing could impose additional challenges on our ability to raise funding in the future”*** below.

These restrictions and provisions could make it more challenging for us to raise capital through the incurrence of additional debt or through future equity issuances. Further, if we do raise capital through the sale of equity, or securities convertible into equity, the ownership of our then existing stockholders would be diluted, which dilution could be significant depending on the price at which we may be able to sell our securities. Also, if we raise additional capital through the incurrence of indebtedness, we may become subject to covenants restricting our business activities, and the holders of debt instruments may have rights and privileges senior to those of our equity investors. Finally, servicing the interest and principal repayment obligations under any debt facilities that we may enter into in the future could divert funds that would otherwise be available to support research and development, clinical or commercialization activities.

If we are unable to obtain adequate financing on a timely basis or on acceptable terms in the future, we would likely be required to delay, reduce or eliminate one or more of our product development activities, which could cause our business to fail.

We have incurred significant losses since inception. We expect to continue to incur losses for the foreseeable future, and we may never increase revenue or achieve or maintain profitability.

As noted above under the risk factor entitled ***“There is substantial doubt about our ability to continue as a going concern,”*** we have only recently commenced commercial sales of our first product, AC5 Advanced Wound System, and we have incurred substantial net losses as a result. Consequently, we have incurred losses in each year since our inception and we expect that losses will continue to be incurred in the foreseeable future in the operation of our business. To date, we have financed our operations primarily through equity and debt investments by founders, other investors and third parties, and we expect to continue to rely on these sources of funding, to the extent available in the foreseeable future. Losses from operations have resulted principally from costs incurred in research and development programs and from general and administrative expenses, including significant costs associated with establishing and maintaining intellectual property rights, significant legal and accounting costs incurred in connection with both the closing of the Merger and complying with public company reporting and control obligations, and personnel expenses. In addition, we expect to continue to incur additional general and administrative expenses due to the costs associated with being a public company, including obligations to regulatory agencies, and increased investor relations and corporate communications expenses. We have devoted much of our operational effort to date to the research and development of our core technology, including selecting our initial product composition, conducting safety and other related tests, conducting a human trial for safety and performance, developing methods for manufacturing scale-up, reproducibility and validation, and developing and protecting the intellectual property rights underlying our technology platform. We have recently devoted substantially all of our operational effort to continue the ongoing commercialization and market adoption of AC5 Advanced Wound System, our first product.

We expect to continue to incur significant expenses and anticipate that those expenses and losses may increase in the foreseeable future as we:

- commercialize AC5 Advanced Wound System;
- develop our additional product candidates, and the underlying technology, including advancing applications and conducting biocompatibility and other preclinical studies and clinical studies;
- raise capital needed to fund our operations;
- enhance investor relations and corporate communications capabilities;
- conduct clinical trials on products and product candidates;
- attempt to obtain regulatory marketing authorizations for product candidates;
- build relationships with additional contract manufacturing partners, and invest in product and process development through such partners;
- maintain, expand and protect our intellectual property portfolio;
- advance additional product candidates and technologies through our research and development pipeline;
- seek to market selected product candidates, which may require regulatory marketing authorization; and
- hire additional regulatory, clinical, quality control, scientific, financial, and management, consultants and advisors.

To become and remain profitable, we must successfully market AC5 Advanced Wound System and succeed in developing and eventually commercializing other product candidates with significant market potential. This will require us to be successful in a number of challenging activities, including successfully completing preclinical testing and clinical trials of product candidates, obtaining regulatory marketing authorization for our product candidates and manufacturing, marketing and selling any products for which we have or may obtain marketing authorization. We are only in the preliminary stages of many of those activities. We may never succeed in those activities and may never generate sufficient operating revenues to achieve profitability. Even if we do generate operating revenues sufficient to achieve profitability, we may not be able to sustain or increase profitability. Our failure to generate sufficient operating revenues to become and remain profitable would impair our ability to raise capital, expand our business or continue our operations, all of which would depress the price of our Common Stock. A further decline or lack of increase in the price of our Common Stock could cause our stockholders to lose all or a part of their investment in the Company.

The terms of the Bridge Offering and 2022 Notes Financing could impose additional challenges on our ability to raise funding in the future.

The Bridge SPA contains certain restrictions on the Company's ability to conduct subsequent sales of its equity securities and certain business activities. In particular, until July 7, 2024, the Company will be prohibited from effecting or entering into agreements to effect any issuance by the Company, or any of its subsidiaries, of Common Stock or Common Stock equivalents (or a combination of units thereof) involving a variable rate transaction.

The 2022 Notes SPA contains certain restrictions on our ability to conduct subsequent sales of our equity securities and certain business activities. In particular, until the 2022 Notes are paid in full and/or converted in full and the 2022 Warrants are exercised in full, we are prohibited from (i) changing the nature of business, (ii) selling, divesting, acquiring, or changing the structure of any material assets other than in the ordinary course of business; or (iii) negotiating or entering into certain variable rate debt transactions; in each instance without each applicable 2022 Note holder's prior written consent, which shall not be unreasonably withheld. In addition, the 2022 Notes, as amended, prohibit the Company from engaging in any capital raising transactions, subject to certain exceptions, until the earlier of (A) July 7, 2027, and (B) the first date on which all Holders hold less than 20% of the original amount of the Participating Pre-Funded Warrants received by each Holder, respectively, in connection with the Automatic Conversion.

Our obligations under the First Notes are secured by security interests in substantially all of our assets and our failure to comply with the terms and covenants of the First Notes could result in our loss of substantially all of our assets.

Our obligations under the First Notes and the related transaction documents are secured by a security interest in substantially all of our assets. As a result, if we default on our obligations under such First Notes, the First Note holders could foreclose on the security interests and liquidate some or all of our assets, which would harm our business, financial condition and results of operations and could require us to reduce or cease operations.

In connection with the First Closing, the First Note holders were granted a security interest in substantially all of our assets pursuant to the terms of the Security Agreement. If we fail to make payments on the First Notes when due or otherwise comply with the covenants contained in the First Notes, the First Note holders could declare us in default, in which event such holders would have the right to exercise their rights as a secured creditor with respect to our assets that secure the indebtedness, which would force us to suspend operations.

In addition, the 2022 Notes contain customary events of default, which include, among other things, (i) our failure to pay when due any principal or interest payment under the 2022 Notes; (ii) our insolvency; (iii) delisting of our Common Stock; (iv) our breach of any material covenant or other material term or condition under the 2022 Notes; and (v) our breach of any representations or warranties under the 2022 Notes which cannot be cured within five (5) days. Further, events of default under the 2022 Notes also include (i) the unavailability of Rule 144 at certain times; (ii) our failure to deliver the shares of Common Stock to the 2022 Note holder upon exercise by such holder of its conversion rights under the 2022 Notes; (iii) our loss of the "bid" price for our Common Stock and/or a market and such loss is not cured during the specified cure periods; and (iv) our failure to complete an Uplist Transaction by October 31, 2023.

The 2022 Note holders have certain additional rights upon an event of default under such notes, which could harm our business, financial condition, and results of operations and could require us to reduce or cease our operations.

Under the 2022 Notes, the holders have certain rights upon an event of default. Such rights include that, upon an event of default, the 2022 Notes will become immediately due and payable and we will be obligated to pay to each such note holder an amount equal to the Default Premium multiplied by the sum of the outstanding principal amount of such notes plus any accrued and unpaid interest on the unpaid principal amount of such notes to the date of payment, plus any Default Interest and any other amounts owed to the holder under the SPA, or the Default Amount; *provided that*, upon any subsequent event of default not in connection with the first event of default, such holder shall be entitled to an additional 5% to the Default Premium for each subsequent event of default. At the election of each 2022 Note holder, the Default Amount may be paid in cash or shares of Common Stock equal to the Default Amount divided by the \$9.14 (subject to adjustment as more specifically set forth in the 2022 Notes) at the time of payment.

In addition, the 2022 Notes are subject to prepayment penalties, subject to adjustment as a result of certain time-based prepayment premiums set forth in such notes; provided, that, the written consent of the lead investor is not required in connection with a prepayment made from the proceeds of an Uplist Transaction. The 2022 Notes bear interest on the unpaid principal balance at a rate equal to ten percent (10%) (computed on the basis of the actual number of days elapsed in a 360-day year) per annum accruing from July 6, 2022 until such notes become due and payable on the Maturity Date or upon their conversion, acceleration or by prepayment. Any amount of principal or interest on the 2022 Notes which is not paid when due will bear interest at the rate of the lesser of (i) eighteen percent (18%) per annum or (ii) the Default Interest.

We may not have sufficient funds to pay the Default Amount and, as described above, this could trigger rights under the security interest granted to the holders and result in the foreclosure of their security interests and liquidation of some or all of our assets. The exercise of any of these rights upon an event of default could substantially harm our financial condition, substantially dilute our other stockholders and force us to reduce or cease operations and cause our stockholders to lose all or a part of their investment in the Company.

General economic factors may adversely affect our financial performance.

General economic conditions may adversely affect our financial performance. In the United States, changes in interest rates, changes in fuel and other energy costs, weakness in the housing market, inflation or deflation or expectations of either inflation or deflation, higher levels of unemployment, decreases in discretionary consumer spending or consumer demand, unavailability or limitations of consumer credit, higher consumer debt levels or efforts by consumers to reduce debt levels, higher tax rates and other changes in tax laws, overall economic slowdown, changes in consumer desires affecting demand for the products we sell and other economic factors could adversely affect consumer demand for the products we sell, change the mix of products we sell to a mix with a lower average gross margin and result in slower inventory turnover. Higher interest rates, transportation costs, inflation, higher costs of labor, insurance and healthcare, foreign exchange rates fluctuations, higher tax rates and other changes in tax laws, changes in other laws and regulations and other economic factors in the United States or internationally can increase our cost of sales and operating, selling, general and administrative expenses, decrease sales, and otherwise adversely affect our operations and operating results. These factors affect not only our operations, but also the operations of suppliers from whom we purchase goods and services, a condition that can result in an increase in the cost to us of the goods we sell to customers.

The COVID-19 pandemic could continue to affect our suppliers and employees, and cause disruptions in current and future plans for operations and expansion.

The COVID-19 pandemic may continue to directly and indirectly adversely impact our business, financial condition and operating results. The extent to which this will continue will depend on numerous evolving factors that are highly uncertain, rapidly changing and cannot be predicted with precision or certainty at this time.

Our business may continue to be disrupted due to the costs incurred as a result of additional necessary actions and preparedness plans to help ensure the health and safety of our employees and continued operations, including enhanced cleaning processes, protocols designed to implement appropriate social distancing practices, and/or adoption of additional wage and benefit programs to assist employees. We also cannot predict the effect of the COVID-19 pandemic on our supply chain's reliability and costs.

In addition, our business and operations, and the operations of our suppliers, may continue to be adversely affected by the COVID-19 pandemic. The pandemic, including the related response, could cause disruptions due to potential suspension or slowdown of activities at our third-party suppliers, manufacturing delays, or increased prices implemented by our suppliers. The COVID-19 pandemic has disrupted nearly every aspect of the global supply chain, including the manufacturing or delivery of some of the key supplies used in our tests. We currently utilize third parties to, among other things, manufacture raw materials. If any third party involved in the production of our products, product candidates, or raw materials is adversely impacted by restrictions resulting from the coronavirus outbreak, our supply chain may be disrupted, limiting our ability to manufacture products for research and development operations, clinical trials and, in the case of AC5 Advanced Wound System) and AC5 Topical Hemostat, commercialization.

Finally, while we believe that we currently have sufficient supply of our products to continue commercialization efforts, our products and product candidates or the materials contained therein (such as the Active Pharmaceutical Ingredients ("APIs") for our AC5 product line) are manufactured from facilities in areas impacted by the coronavirus, which could result in shortages due to ongoing efforts to address the outbreak. If any of the foregoing were to occur, it could materially adversely affect our future revenues, financial condition, profitability, and cash flows.

Unfavorable global political or economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The global credit and financial markets have experienced severe volatility and disruptions in the past several years. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services.

Geopolitical conflicts could potentially affect our sales and disrupt our operations and could have a material adverse impact on the Company.

Geopolitical conflicts, including the recent war in Ukraine, could adversely impact our operations or those of our customers. The extent to which these events impact our operations and those of our customers will depend on future developments, which are highly uncertain and cannot be predicted with confidence. If the uncertainty surrounding geopolitical conflicts and in the global marketplace continues, or if we, or any of our customers encounter any disruptions to our or their respective operations or facilities, then we or they may be prevented or delayed from effectively operating our or their business, respectively, and the marketing and sale of our products and our financial results could be adversely affected.

Russia's invasion and military attacks on Ukraine have triggered significant sanctions from North American and European leaders. These events are currently escalating and creating increasingly volatile global economic conditions. Related sanctions, export controls or other actions have been or may in the future be initiated by nations including the United States, the European Union or Russia (e.g., potential cyberattacks, disruption of energy flows, etc.), which could adversely affect our business and/or our supply chain and other third parties with whom we conduct business. Furthermore, the current military conflict between Russia and Ukraine could disrupt or otherwise adversely impact our operations and those of third parties upon which we rely. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our operating history may hinder our ability to successfully meet our objectives.

We are transitioning from being strictly a development stage company subject to the risks, uncertainties and difficulties frequently encountered by early-stage companies in evolving markets to a combination commercial stage and development stage company. Our operations to date have been primarily limited to organizing and staffing, developing and securing our technology and undertaking funding preclinical studies of our lead product candidates, and funding one clinical trial. We have not demonstrated our ability to successfully complete large-scale, pivotal clinical trials, reliably obtain regulatory marketing authorizations, manufacture a commercial scale product or arrange for a third-party to do so on our behalf, and we have only recently begun to generate revenue from commercial sales of our first product, AC5 Advanced Wound System, and there can be no assurance that we will be successful in generating increased revenue.

Because of our limited operating history, we have limited insight into trends that may emerge and affect our business, and errors may be made in developing an approach to address those trends and the other challenges faced by development stage companies. Failure to adequately respond to such trends and challenges could cause our business, results of operations and financial condition to suffer or fail. Further, our limited operating history may make it difficult for our stockholders to make any predictions about our likelihood of future success or viability.

If we are not able to attract and retain qualified management and scientific personnel, we may fail to develop our technologies and product candidates.

Our future success depends to a significant degree on the skills, experience and efforts of the principal members of our scientific and management personnel. These members include Terrence Norchi, MD, our President and Chief Executive Officer. The loss of Dr. Norchi or any of our other key personnel could harm our business and might significantly delay or prevent the achievement of research, development or business objectives. Further, our operation as a public company will require that we attract additional personnel to support the establishment of appropriate financial reporting and internal controls systems. Competition for personnel is intense. We may not be able to attract, retain and/or successfully integrate qualified scientific, financial and other management personnel, which could materially harm our business.

If we fail to properly manage any growth we may experience, our business could be adversely affected.

We anticipate increasing the scale of our operations as we seek to develop our product candidates, including hiring and training additional personnel and establishing appropriate systems for a company with larger operations. The management of any growth we may experience will depend, among other things, upon our ability to develop and improve our operational, financial and management controls, reporting systems and procedures. If we are unable to manage any growth effectively, our operations and financial condition could be adversely affected.

We have identified material weaknesses in our internal control over financial reporting. These material weaknesses could continue to adversely affect our ability to report our results of operations and financial condition accurately and in a timely manner. If we fail to enhance appropriate internal controls in the future, we may not be able to report our financial results accurately, which may adversely affect our stock price and our business

Our management is responsible for establishing and maintaining adequate internal control over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with the generally accepted accounting principles generally accepted in the United States of America (“GAAP”). As a public company, we are required, on a quarterly basis, to evaluate the effectiveness of our internal controls and to disclose any changes and material weaknesses identified through such evaluation in those internal controls. Our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and the related regulations regarding our required assessment of our internal controls over financial reporting requires the commitment of significant financial and managerial resources. Internal control over financial reporting has inherent limitations, including human error, the possibility that controls could be circumvented or become inadequate because of changed conditions, and fraud.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Our management identified material weaknesses in our internal control over financial reporting relating to a lack of sufficient resources with an understanding of the technical guidance under GAAP related to accounting for complex financial instruments within the 2022 Notes and certain accounting practices relating to the recording of the insurance premium advanced by a third party. As a result of these material weaknesses, our management concluded that our internal control over financial reporting was not effective as of September 30, 2022.

We are working to remediate the material weaknesses as efficiently and effectively as possible. Accordingly, the Audit Committee in consultation with management has determined that these matters may be best addressed by: (i) reviewing accounting literature and other technical materials to ensure that the appropriate personnel have a full awareness and understanding of the applicable accounting pronouncements and how they are to be implemented; (ii) additional education on new and existing accounting pronouncements and their application and (iii) requiring senior accounting staff and outside consultants with technical accounting experience to review complex transactions to evaluate and approve the accounting treatment of such transactions. Accordingly, the Board has recommended to management and management has agreed that the Company’s accounting staff, including its Chief Financial Officer, undertake additional training on an accelerated basis and that such training, in view of the complexity of certain generally accepted accounting principles and other matters be ongoing and engage third party specialists on an as-needed basis to help supplement the Company’s internal resources.

If we are unable to enhance effective internal controls, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations as a publicly traded company or comply with the requirements of the SEC or the Sarbanes-Oxley Act of 2002. This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our stock, or investigation by regulatory authorities, all of which is exacerbated by the recent determination of a material weakness related to our internal controls over financial reporting as disclosed herein. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our stock and our business.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

We maintain sensitive data pertaining to our Company on our computer networks, including information about our research and development activities, our intellectual property and other proprietary business information. Our internal computer systems and those of third parties with which we contract may be vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures, despite the implementation of security measures. System failures, accidents or security breaches could cause interruptions to our operations, including material disruption of our research and development activities, result in significant data losses or theft of our intellectual property or proprietary business information, and could require substantial expenditures to remedy. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability and our research and development programs could be delayed, any of which would harm our business and operations.

Legal, political and economic uncertainty surrounding the exit of the United Kingdom from the European Union is a source of instability and uncertainty.

Legal, political and economic uncertainty surrounding the exit of the United Kingdom from the European Union (“**Brexit**”) is a source of instability and uncertainty.

The uncertainty concerning the U.K.’s legal, political and economic relationship with the E.U. after the transition period may be a source of instability in the international markets, create significant currency fluctuations, and/or otherwise adversely affect trading agreements or similar cross-border co-operation arrangements (whether economic, tax, fiscal, legal, regulatory or otherwise).

These developments, or the perception that any of them could occur, have had, and may continue to have, a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and limit the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the U.K. financial and banking markets, as well as on the regulatory process in Europe. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility.

If the U.K. and the E.U. are unable to negotiate acceptable trading and customs terms or if other E.U. Member States pursue withdrawal, barrier-free access between the U.K. and other E.U. Member States or among the European Economic Area (“**E.E.A.**”) overall could be diminished or eliminated. The long-term effects of Brexit will depend on any agreements (or lack thereof) between the U.K. and the E.U. and, in particular, any arrangements for the U.K. to retain access to E.U. markets after the transition period. Such a withdrawal from the E.U. is unprecedented, and it is unclear how the U.K. access to the European single market for goods, capital, services and labor within the E.U., or single market, and the wider commercial, legal and regulatory environment, will impact our U.K. operations.

We may also face new regulatory costs and challenges that could have an adverse effect on our operations and development programs. For example, the U.K. could lose the benefits of global trade agreements negotiated by the E.U. on behalf of its members, which may result in increased trade barriers that could make our doing business in the E.U. and the E.E.A. more difficult. There may continue to be economic uncertainty surrounding the consequences of Brexit, which could adversely affect our financial condition, results of operations, cash flows and market price of our Common Stock.

Risks Related to the Development and Commercialization of our Product Candidates

The commercial success of AC5 Advanced Wound System will depend upon the degree of its market acceptance by patients, physicians, healthcare payors and others in the medical community. If AC5 Advanced Wound System does not achieve an adequate level of market acceptance, we may not generate sufficient revenues to achieve or maintain profitability.

AC5 Advanced Wound System is a novel use in the clinical fields in which it is marketed and may not gain or maintain market acceptance by patients, physicians, healthcare payors or others in the medical community. Additionally, we believe that we will need to educate physicians and other healthcare providers about AC5 Advanced Wound System in order for these providers to administer AC5 Advanced Wound System. If we are unsuccessful in educating these practitioners about AC5 Advanced Wound System, we do not expect to achieve an appropriate level of market acceptance for AC5 Advanced Wound System. We could incur substantial and unanticipated additional expense in an effort to increase market acceptance, which would increase the cost of commercializing AC5 Advanced Wound System and could limit its commercial success and result in lower-than-expected revenues. We believe the degree of market acceptance of AC5 Advanced Wound System will depend on a number of factors, including:

- its efficacy and potential advantages over other treatments,
- the extent to which physicians are successful in treating patients with other products or treatments,
- the extent to which physicians and patients experience similar or improved clinical results to that reported on the approved product labeling,
- market acceptance of the cost at which we sell AC5 Advanced Wound System,
- the timing of the release of competitive products or treatments,
- our marketing and sales resources, the quantity of our supplies of AC5 Advanced Wound System and our ability to establish a distribution infrastructure for AC5 Advanced Wound System, and
- whether third-party and government payors cover or reimburse for AC5 Advanced Wound System, and if so, to what extent and in what amount.

If market acceptance of AC5 Advanced Wound System is adversely affected by any of these or other factors, then sales of AC5 Advanced Wound System may be reduced and our business will be materially harmed.

We are seeking reimbursement arrangements with privately managed care organizations and government payors and additional third-party payors. If we are unable to obtain adequate reimbursement from third-party payors, or acceptable prices, for AC5 Advanced Wound System, our revenues and prospects for profitability will suffer.

Our future revenues and ability to become profitable will depend heavily upon the availability of adequate reimbursement for the use of AC5 Advanced Wound System from government-funded and private third-party payors. Reimbursement by a third-party payor depends on a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan,
- safe, effective and medically necessary,
- appropriate for the specific patient,
- cost effective, and
- neither experimental nor investigational.

Obtaining reimbursement approval for AC5 Advanced Wound System from each government-funded and private third-party payor is a time-consuming and costly process, which in some cases requires us to provide to the payor supporting scientific, clinical and cost-effectiveness data for AC5 Advanced Wound System's use. We may not be able to provide data sufficient to gain acceptance with respect to reimbursement.

Even when a third-party payor determines that a product is generally eligible for reimbursement, third-party payors may impose coverage limitations that preclude payment for some product uses that are approved by the FDA or similar authorities or impose patient co-insurance or co-pay amounts that may result in lower market acceptance and which would lower our revenues. Some payors establish prior authorization programs and procedures requiring physicians to document several different parameters, which may impede patient access to therapy. Moreover, eligibility for coverage does not necessarily mean that AC5 Advanced Wound System will be reimbursed in all cases or at a rate that allows us to sell AC5 Advanced Wound System at an acceptable price adequate to make a profit or even cover our costs. If we are not able to obtain coverage and adequate reimbursement promptly from third-party payors for AC5 Advanced Wound System, our ability to generate revenues and become profitable will be compromised.

The scope of coverage and payment policies varies among private third-party payors, including indemnity insurers, employer group health insurance programs and managed care plans. These third-party payors may base their coverage and reimbursement on the coverage and reimbursement rate paid by carriers for Medicare beneficiaries, which are traditionally at a substantially discounted rate. Furthermore, many such payors are investigating or implementing methods for reducing healthcare costs, such as the establishment of capitated or prospective payment systems. Cost containment pressures have led to an increased emphasis on the use of cost-effective products by healthcare providers. If third-party payors do not provide adequate coverage or reimbursement for AC5 Advanced Wound System, it could have a negative effect on our revenues, results of operations and liquidity.

Applications for regulatory marketing authorization for commercialization of our additional product candidates or elements of our supply chain may not be accepted, or if accepted, may be voluntarily withdrawn or eventually rejected, and the future success of our business is significantly dependent on the success of our being able to obtain regulatory marketing authorization for our development stage candidates.

For example, on July 17, 2017, we filed a 510(k) notification with the FDA for AC5 Topical Gel. As previously announced on December 18, 2017, we voluntarily withdrew the submission after receiving a communication from the FDA near the end of the agency's 90-day review period for a final decision on 510(k) notifications. The communication contained questions for which a comprehensive response could not be provided in the limited review time remaining on the submission. Given that it was not possible to respond in the time available, the Company made the decision to withdraw the 510(k) notification but noted at the time that it remained committed to continued collaboration with the FDA to appropriately address the outstanding questions and planned to submit a new 510(k) notification as soon as possible following further discussion with the agency. On March 12, 2018, we announced that we were utilizing the FDA's pre-submission process to submit a proposed development strategy to the FDA to address the agency's comments on our 510(k) notification. As indicated in that March 12, 2018, announcement, we determined that providing additional data to the FDA would be the most expeditious path forward for addressing the FDA's comments, subject to any further comments that we may receive from the FDA.

On May 8, 2018, we announced that the Company would initiate the previously disclosed study designed to address FDA comments on Arch's previous 510(k) notification for our AC5 Topical Gel. The agency provided feedback via the pre-submission process and indicated that the proposed study design was acceptable to support our future marketing application. On June 15, 2018, we further announced that we completed enrollment for our human skin sensitization study and that applications of our AC5 Topical Gel were underway for all subjects.

On October 1, 2018, we announced that the Company submitted a 510(k) notification to the FDA for our AC5 Topical Gel (AC5) and received acknowledgment from the FDA that the submission has been received. On December 17, 2018, we announced that the 510(k) premarket notification for AC5 Topical Gel has been reviewed and cleared by the FDA.

Our business plan is dependent on the success of our development stage product candidates.

Our business is currently focused almost entirely on the development and commercialization of our initial product candidates and products ("AC5 Devices"). Our reliance on AC5 Devices means that, if we are not able to obtain both regulatory marketing authorization and market acceptance of those product candidates, our chances for success will be significantly reduced. We are also less likely to withstand competitive pressures if any of our competitors develop and obtain regulatory marketing authorization for similar products or for products that may be more attractive to the market. Our current dependence on AC5 Devices increases the risk that our business will fail if our development efforts for those products experience delays or other obstacles or are otherwise not successful.

The Chemistry, Manufacturing and Control ("CMC") process for our commercial product and product candidates may be challenging.

Because of the complexity of our lead product candidates, the CMC process, including but not limited to product scale-up activities and cGMP manufacturing for human use, may be difficult to complete successfully within the parameters required by the FDA or its foreign counterparts. Peptide formulation optimization is particularly challenging, and any delays could negatively impact our ability to conduct clinical trials and our subsequent commercialization timeline. Furthermore, we have, and the third parties with whom we may establish relationships may also have, limited experience with attempting to commercialize a self-assembling peptide as a medical device, which increases the risks associated with completing the CMC process successfully, on time, or within the projected budget. Failure to complete the CMC process successfully would impact our ability to complete product development activities, such as conducting clinical trials and submitting applications for regulatory approval, which could affect the long-term viability of our business.

Our AC5 Devices are inherently risky because they are based on novel technologies.

We are subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of AC5 Devices creates significant challenges with respect to product development and optimization, engineering, manufacturing, scale-up, quality systems, pre-clinical in vitro and in vivo testing, government regulation and approval, third-party reimbursement and market acceptance. Our failure to overcome any one of those challenges could harm our operations, commercialization efforts, ability to complete additional clinical trials, and overall chances for success.

Any changes in our supply chain, including to the third-party contract manufacturers, service providers, or other vendors, or in the processes that they employ could adversely affect us.

We are dependent on third parties in our supply chain, including manufacturers, service providers, and other vendors, and the processes that they employ to make major and minor components of our products, and this dependence exposes us to risks associated with regulatory requirements, delivery schedules, manufacturing capability, quality control, quality assurance and costs. We make periodic changes within our supply chain, for example, as our business needs evolve; and/or if a third party does not perform as agreed or desired; and/or if we decide to add an additional manufacturer, service provider, or vendor where we were previously single sourced; and/or if processes are altered to meet evolving scale requirements. For instance, the Company harmonized its U.S. and European product supply chains by adding a supplier and additional manufacturing processes to the list of approved suppliers and processes for the production of AC5 Advanced Wound System that is commercially available in the United States. The Company filed documentation with the FDA related to these supply chain changes and announced on March 23, 2020, that the FDA provided the required clearance to market with the supply chain and manufacturing process changes. We cannot yet provide assurance that the changes or resulting product will prove acceptable to us.

The manufacturing, production, and sterilization methods that we intend to be utilized are detailed and complex and are a difficult process to manage.

We intend to utilize third-party manufacturers to manufacture and sterilize our products. We believe that our proposed manufacturing methods make our choice of manufacturer and sterilizer critical, as they must possess sufficient expertise in synthetic organic chemistry and device manufacturing. If such manufacturers are unable to properly manufacture to product specifications or sterilize our products adequately, that could severely limit our ability to market our products.

Compliance with governmental regulations regarding the treatment of animals used in research could increase our operating costs, which would adversely affect the commercialization of our technology.

The Animal Welfare Act ("AWA") is the federal law that covers the treatment of certain animals used in research. Currently, the AWA imposes a wide variety of specific regulations that govern the humane handling, care, treatment and transportation of certain animals by producers and users of research animals, most notably relating to personnel, facilities, sanitation, cage size, and feeding, watering and shipping conditions. Third parties with whom we contract are subject to registration, inspections and reporting requirements under the AWA. Furthermore, some states have their own regulations, including general anti-cruelty legislation, which establish certain standards in handling animals. Comparable rules, regulations, and/or obligations exist in many foreign jurisdictions. If our contractors or we fail to comply with regulations concerning the treatment of animals used in research, we may be subject to fines and penalties and adverse publicity, and our operations could be adversely affected.

If the FDA or similar foreign agencies or intermediaries impose requirements more onerous than we anticipate, our business could be adversely affected.

The FDA and other regulatory authorities or related bodies separately determine the classification of our products and product candidates. The development plan for our lead product candidates is based on our anticipation of pursuing the medical device regulatory pathway, and in February 2015 we received confirmation from The British Standards Institution (“BSI”), a European notified body (which is a private commercial entity designated by the national government of a European Union (“EU”) member state as being competent to make independent judgments about whether a medical device complies with applicable regulatory requirements), confirmed that AC5 Topical Hemostat fulfills the definition of a medical device within the EU, and it was classified as such in consideration of the CE mark, receipt of which was announced by the Company on April 13, 2020. The FDA also determined AC5 Topical Gel, which was later renamed AC5 Advanced Wound System, to be a medical device. If the FDA or similar foreign agencies or intermediaries deem our products to be a member of a category other than a medical device, such as a drug or biologic, or impose additional requirements on our pre-clinical and clinical development than we presently anticipate, financing needs would increase, the timeline for product approval would lengthen, the program complexity and resource requirements would increase, and the probability of successfully commercializing a product would decrease. Any or all of those circumstances would materially adversely affect our business.

We are subject to extensive and dynamic medical device regulations outside of the United States, which may impede or hinder the approval, or sale of our products and, in some cases, may ultimately result in an inability to obtain approval of certain products or may result in the recall or seizure of products that were previously approved.

In the European Union, we are required to comply with applicable medical device directives, including the Medical Devices Directive, and obtain CE mark in order to market medical device products. The CE mark is applied following approval from an independent notified body or declaration of conformity. As is the case in the United States, the process of obtaining marketing approval or clearance from comparable agencies in foreign countries for new products, or with respect to enhancements or modifications to existing products, could:

- take a significant period of time;
- require the expenditure of substantial resources;
- involve rigorous pre-clinical and clinical testing;
- require extensive post-marketing surveillance;
- require changes to products; and
- result in limitations on the indicated uses of products.

In addition, exported devices are subject to the regulatory requirements of each country to which the device is exported. Most foreign countries possess medical devices regulations and require that they be applied to medical devices before they can be commercialized.

There can be no assurance that we will receive the required approvals for our products on a timely basis or that any approval will not be subsequently withdrawn or conditioned upon extensive post-market study requirements.

Our global regulatory environment is becoming increasingly stringent and unpredictable, which could increase the time, cost and complexity of obtaining marketing authorization for our products, as well as the clinical and regulatory costs of supporting those approvals. Several countries that did not have regulatory requirements for medical devices have established such requirements in recent years and other countries have expanded existing regulations. Certain regulators are exhibiting less flexibility by requiring, for example, the collection of local preclinical and/or clinical data prior to approval. While harmonization of global regulations has been pursued, requirements continue to differ significantly among countries. We expect the global regulatory environment to continue to evolve, which could impact our ability to obtain future approvals for our products and increase the cost and time to obtain such approvals. By way of example, the European Union regulatory bodies recently implemented a new Medical Device Regulation (“MDR”). The MDR changes several aspects of the existing regulatory framework, such as clinical data requirements, and introduces new ones, such as Unique Device Identification (“UDI”). We, and the Notified Bodies who will oversee compliance to the new MDR, face uncertainties in the upcoming years as the MDR is rolled out and enforced, creating risks in several areas, including the CE mark process, data transparency and application review timetables.

If we are not able to secure and maintain relationships with third parties that are capable of conducting clinical trials on our product candidates and support our regulatory submissions, our product development efforts, and subsequent marketing authorization could be adversely impacted.

Our management has limited experience in conducting preclinical development activities and clinical trials. As a result, we have relied and will need to continue to rely on third-party research institutions, organizations and clinical investigators to conduct our preclinical and clinical trials and support our regulatory submissions. If we are unable to reach agreement with qualified research institutions, organizations and clinical investigators on acceptable terms, or if any resulting agreement is terminated prior to the completion of our clinical trials, then our product development efforts could be materially delayed or otherwise harmed. Further, our reliance on third parties to conduct our clinical trials and support our regulatory submissions will provide us with less control over the timing and cost of those trials, the ability to recruit suitable subjects to participate in the trials, and the timing, cost, and probability of success for the regulatory submissions. Moreover, the FDA and other regulatory authorities require that we comply with standards, commonly referred to as good clinical practices (“GCP”), for conducting, recording and reporting the results of our preclinical development activities and our clinical trials, to assure that data and reported results are credible and accurate and that the rights, safety and confidentiality of trial participants are protected. Additionally, both we and any third-party contractor performing preclinical and clinical studies are subject to regulations governing the treatment of human and animal subjects in performing those studies. Our reliance on third parties that we do not control does not relieve us of those responsibilities and requirements. If those third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical development activities or clinical trials in accordance with regulatory requirements or stated protocols, we may not be able to obtain, or may be delayed in obtaining, marketing authorization for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. Any of those circumstances would materially harm our business and prospects.

Any clinical trials that are planned or are conducted on our flagship product and additional product candidates may not start or may fail.

Clinical trials are lengthy, complex and extremely expensive processes with uncertain expenditures and results and frequent failures. While we have completed our first clinical trial in Western Europe, clinical trials that are planned or which have or shall commence for any of our product candidates could be delayed or fail for a number of reasons, including if:

- FDA or other regulatory authorities, or other relevant decision-making bodies do not grant permission to proceed or place a trial on clinical hold due to safety concerns or other reasons;
- sufficient suitable subjects do not enroll, enroll more slowly than anticipated or remain in our trials;
- we fail to produce necessary amounts of the product or product candidate;
- subjects experience an unacceptable rate of efficacy of the product or product candidate;
- subjects experience an unacceptable rate or severity of adverse side effects, demonstrating a lack of safety of the product or product candidate;
- any portion of the trial or related studies produces negative or inconclusive results or other adverse events;
- reports from preclinical or clinical testing on similar technologies and products raise safety and/or efficacy concerns;
- third-party clinical investigators lose their licenses or permits necessary to perform our clinical trials, do not perform their clinical trials on the anticipated schedule or consistent with the clinical trial protocol, GCP or regulatory requirements, or other third parties do not perform data collection and analysis in a timely or accurate manner;
- inspections of clinical trial sites by the FDA or an institutional review board (“IRB”) or other applicable regulatory authorities find violations that require us to undertake corrective action, suspend or terminate one or more testing sites, or

- prohibit us from using some or all of the resulting data in support of our marketing applications with the FDA or other applicable agencies;
- manufacturing facilities of our third-party manufacturers are ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of cGMP or other applicable requirements;
- third-party contractors become debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements;
- the FDA or other regulatory authorities impose requirements on the design, structure or other features of the clinical trials for our product candidates that we and/or our third-party contractors are unable to satisfy;
- one or more IRB refuses to approve, suspends or terminates a trial at an investigational site, precludes enrollment of additional subjects, or withdraws its approval of the trial;
- the FDA or other regulatory authorities seek the advice of an advisory committee of physician and patient representatives that may view the risks of our product candidates as outweighing the benefits;
- the FDA or other regulatory authorities require us to expand the size and scope of the clinical trials, which we may not be able to do; or
- the FDA or other regulatory authorities impose prohibitive post-marketing restrictions on any of our product candidates that attain marketing authorization.

Any delay or failure of one or more of our clinical trials may occur at any stage of testing. Any such delay could cause our development costs to materially increase, and any such failure could significantly impair our business plans, which would materially harm our financial condition and operations.

We cannot market and sell any additional product candidate in the U.S. or in any other country or region if we fail to obtain the necessary marketing authorization, clearances or certifications from applicable government agencies.

We cannot sell our additional product candidates in any country until regulatory agencies grant marketing approval, clearance or other required certification(s). The process of obtaining such approval is lengthy, expensive and uncertain. If we are able to obtain such approvals for our lead product candidate or additional product candidates we may pursue, which we may never be able to do, it would likely be a process that takes many years to achieve.

To obtain marketing approvals in the U.S. for our product candidates, we believe that we must, among other requirements, complete carefully controlled and well-designed clinical trials sufficient to demonstrate to the FDA that the product candidate is safe and effective for each indication for which we seek approval. As described above, many factors could cause those trials to be delayed or to fail.

We believe that the pathway to marketing approval in the U.S. for our lead product candidate for internal use will likely be classified as a Class III medical device and require the process of FDA Premarket Approval (“**PMA**”). This approval pathway can be lengthy and expensive and is estimated to take from one to three years or longer from the time the PMA application is submitted to the FDA until approval is obtained, if approval can be obtained at all.

Similarly, to obtain approval to market our product candidates outside of the U.S., we will need to submit clinical data concerning our product candidates to and receive marketing approval or other required certifications from governmental or other agencies in those countries, which in certain countries includes approval of the price we intend to charge for a product. For instance, in order to obtain the certification needed to market our lead product candidate in the EU, we believe that we will need to obtain a CE mark for the product, which entails scrutiny by applicable regulatory agencies and bears some similarity to the PMA process, including completion of one or more successful clinical trials.

We may encounter delays or rejections if changes occur in regulatory agency policies, if difficulties arise within regulatory or related agencies such as, for instance, any delays in their review time, or if reports from preclinical and clinical testing on similar technology or products raise safety and/or efficacy concerns during the period in which we develop a product candidate or during the period required for review of any application for marketing approval or certification.

Any difficulties we encounter during the approval or certification process for any of our product candidates would have a substantial adverse impact on our operations and financial condition and could cause our business to fail.

We cannot guarantee that we will be able to effectively market our product candidates.

A significant part of our success depends on the various marketing strategies we plan to implement. Our business model has historically focused solely on product development, and we have never attempted to market any product. There can be no assurance as to the success of any such marketing strategy that we develop or that we will be able to build a successful sales and marketing organization. If we cannot effectively market those products we seek to market directly, such products' prospects will be harmed.

AC5 Advanced Wound System and any other product for which we obtain required regulatory marketing authorization are subject to post-approval regulation, and we may be subject to penalties if we fail to comply with such post-approval requirements.

AC5 Advanced Wound System and any other product for which we are able to obtain marketing approval or other required certifications, and for which we are able to obtain approval of the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and comparable foreign regulatory authorities, including through periodic inspections. These requirements include, without limitation, submissions of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents. Maintaining compliance with any such regulations that may be applicable to us or our product candidates in the future would require significant time, attention and expense. Even if marketing approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or other conditions of approval or may contain requirements for costly and time-consuming post-marketing approval testing and surveillance to monitor the safety or efficacy of the product. Discovery after approval of previously unknown problems with any approved product candidate or related manufacturing processes, or failure to comply with regulatory requirements, may result in consequences to us such as:

- restrictions on the marketing or distribution of a product, including refusals to permit the import or export of the product;
- the requirement to include warning labels on the products;
- withdrawal or recall of the products from the market;
- refusal by the FDA or other regulatory agencies to approve pending applications or supplements to approved applications that we may submit;
- suspension of any ongoing clinical trials;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals or certifications; or
- civil or criminal penalties.

If any of our product candidates achieve required regulatory marketing approvals or certifications in the future, the subsequent occurrence of any such post-approval consequences would materially adversely affect our business and operations.

Current or future legislation may make it more difficult and costly for us to obtain marketing approval or other certifications of our product candidates.

In 2007, the Food and Drug Administration Amendments Act of 2007 ("FDAAA") was adopted. This legislation grants significant powers to the FDA, many of which are aimed at assuring the safety of medical products after approval. For example, the FDAAA grants the FDA authority to impose post-approval clinical study requirements, require safety-related changes to product labeling and require the adoption of complex risk management plans. Pursuant to the FDAAA, the FDA may require that a new product be used only by physicians with specialized training, only in specified health care settings, or only in conjunction with special patient testing and monitoring. The legislation also includes requirements for disclosing clinical study results to the public through a clinical study registry, and renewed requirements for conducting clinical studies to generate information on the use of products in pediatric patients. Under the FDAAA, companies that violate these laws are subject to substantial civil monetary penalties. The requirements and changes imposed by the FDAAA, or any other new legislation, regulations or policies that grant the FDA or other regulatory agencies additional authority that further complicates the process for obtaining marketing approval and/or further restricts or regulates post-marketing approval activities, could make it more difficult and more costly for us to obtain and maintain approval of any of our product candidates.

Public perception of ethical and social issues may limit or discourage the type of research we conduct.

Our clinical trials involve human subjects, and third parties with whom we contract also conduct research involving animal subjects. Governmental authorities could, for public health or other purposes, limit the use of human or animal research or prohibit the practice of our technology. Further, ethical and other concerns about our or our third-party contractors' methods, particularly the use of human subjects in clinical trials or the use of animal testing, could delay our research and preclinical and clinical trials, which would adversely affect our business and financial condition.

Use of third parties to manufacture our additional product candidates may increase the risk that preclinical development, clinical development and potential commercialization of our product candidates could be delayed, prevented or impaired.

We have limited personnel with experience in medical device development and manufacturing, do not own or operate manufacturing facilities, and generally lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We currently outsource all or most of the clinical and commercial manufacturing and packaging of our product candidates to third parties. However, we have not established long-term agreements with any third-party manufacturers for the supply of any of our product candidates. There are a limited number of manufacturers that operate under cGMP regulations and that are capable of and willing to manufacture our lead product candidates utilizing the manufacturing methods that are required to produce our product candidates, and our product candidates will compete with other product candidates for access to qualified manufacturing facilities. If we have difficulty locating third-party manufacturers to develop our product candidates for preclinical and clinical work, then our product development programs will experience delays and otherwise suffer. We may also be unable to enter into agreements for the commercial supply of products with third-party manufacturers in the future or may be unable to do so when needed or on acceptable terms. Any such events could materially harm our business.

Reliance on third-party manufacturers entails risks to our business, including without limitation:

- the failure of the third-party to maintain regulatory compliance, quality assurance, and general expertise in advanced manufacturing techniques and processes that may be necessary for the manufacture of our product candidates;
- limitations on supply availability resulting from capacity and scheduling constraints of the third parties;
- failure of the third-party manufacturers to meet the demand for the product candidate, either from future customers or for preclinical or clinical trial needs;
- the possible breach of the manufacturing agreement by the third-party; and
- the possible termination or non-renewal of the agreement by the third-party at a time that is costly or inconvenient for us.

The failure of any of our contract manufacturers to maintain high manufacturing standards could result in harm to clinical trial participants or patients using the products. Such failure could also result in product liability claims, product recalls, product seizures or withdrawals, delays or failures in testing or delivery, cost overruns or other problems that could seriously harm our business or profitability. Further, our contract manufacturers will be required to adhere to FDA and other applicable regulations relating to manufacturing practices. Those regulations cover all aspects of the manufacturing, testing, quality control and recordkeeping relating to our product candidates and any products that we may commercialize in the future. The failure of our third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval or other required certifications of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business, financial condition and operations.

Materials necessary to manufacture our product candidates may not be available on time, on commercially reasonable terms, or at all, which may delay or otherwise hinder the development and commercialization of those products and product candidates.

We rely on the manufacturers of our product and product candidates to purchase from third-party suppliers the materials necessary to produce the compounds for preclinical and clinical studies and may continue to rely on those suppliers for commercial distribution if we obtain marketing approval or other required certifications for any of our product candidates. The materials to produce our products may not be available when needed or on commercially reasonable terms, and the prices for such materials may be susceptible to fluctuations. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently do not have any agreements relating to the commercial production of any of these materials. If these materials cannot be obtained for our preclinical and clinical studies, product testing and potential regulatory marketing authorization of our product candidates will be delayed, which would significantly impact our ability to develop our product candidates and materially adversely affect our ability to meet our objectives and obtain operations success.

We may not be successful in maintaining or establishing collaborations, which could adversely affect our ability to develop and, if required regulatory authorizations are obtained, commercialize our product candidates.

If required regulatory authorizations are obtained to market any of our product candidates, then we may consider entering into additional collaboration arrangements with medical technology, pharmaceutical or biotechnology companies and/or seek to establish strategic relationships with marketing partners for the development, sale, marketing and/or distribution of our products within or outside of the U.S. If we elect to expand our current relationships or seek additional collaborators in the future but are unable to reach agreements with such other collaborators, as applicable, then we may fail to meet our business objectives for the affected product or program. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement, and we may not be successful in our efforts, if any, to establish and implement additional collaborations or other alternative arrangements. The terms of any collaboration or other arrangements that we establish may not be favorable to us, and the success of any such collaboration will depend heavily on the efforts and activities of our collaborators. Any failure to engage successful collaborators could cause delays in our product development and/or commercialization efforts, which could harm our financial condition and operational results.

We compete with other pharmaceutical and medical device companies, including companies that may develop products that make our product and product candidates less attractive or obsolete.

The medical device, pharmaceutical and biotechnology industries are highly competitive. If our product candidates become available for commercial sale, we will compete in that competitive marketplace. There are several products on the market or in development that could be competitors with our lead product candidates. Further, most of our competitors have greater resources or capabilities and greater experience in the development, approval and commercialization of medical devices or other products than we do. We may not be able to compete successfully against them. We also compete for funding with other companies in our industry that are focused on discovering and developing novel improvements in surgical bleeding prevention.

We anticipate that competition in our industry will increase. In addition, the healthcare industry is characterized by rapid technological change, resulting in new product introductions and other technological advancements. Our competitors may develop and market products that render our lead product candidate or any future product candidate we may seek to develop non-competitive or otherwise obsolete. Any such circumstances could cause our operations to suffer.

If we fail to generate market acceptance of our product and product candidates and establish programs to educate and train surgeons as to the distinctive characteristics of our product and product candidates, we will not be able to generate revenues on our product candidates.

Acceptance in the marketplace of AC5 Advanced Wound System and our lead product candidates depends in part on our and our third-party contractors' ability to establish programs for the training of surgeons in the proper usage of those product candidates, which will require significant expenditure of resources. Convincing surgeons to dedicate the time and energy necessary to properly train to use new products and techniques is challenging, and we may not be successful in those efforts. If surgeons are not properly trained, they may ineffectively use our product candidates. Such misuse could result in unsatisfactory patient outcomes, patient injury, negative publicity or lawsuits against us. Accordingly, even if our product candidates are superior to alternative treatments, our success will depend on our ability to gain and maintain market acceptance for those product candidates among certain select groups of the population and develop programs to effectively train them to use those products. If we fail to do so, we will not be able to generate revenue from product sales and our business, financial condition and results of operations will be adversely affected.

The use of our product and product candidates in human subjects may expose us to product liability claims, and we may not be able to obtain adequate insurance or otherwise defend against any such claims.

We face an inherent risk of product liability claims and currently have product liability and clinical trial liability coverage. If claims against us exceed any applicable insurance coverage we may obtain, then our business could be adversely impacted. Regardless of whether we would be ultimately successful in any product liability litigation, such litigation could consume substantial amounts of our financial and managerial resources, which could significantly harm our business.

Risks Related to our Intellectual Property

If we are unable to obtain and maintain protection for intellectual property rights that we own, seek, or have licensed from other parties, the value of our technology and products will be adversely affected.

Our success will depend in large part on our ability to obtain and maintain protection in the U.S. and other countries for the intellectual property rights covering or incorporated into our technology and products. The ability to obtain patents covering technology in the field of medical devices generally is highly uncertain and involves complex legal, technical, scientific and factual questions. We may not be able to obtain and maintain patent protection relating to our technology or products. Many of our owned or licensed patent applications are pending. Even if issued, patents issued or licensed to us may be challenged, narrowed, invalidated, held to be unenforceable or circumvented, or determined not to cover our product candidates or our competitors' products, which could limit our ability to stop competitors from marketing identical or similar products. Because our patent portfolio includes certain patents and applications that are in-licensed on a non-exclusive basis, other parties may be able to develop, manufacture, market and sell products with similar features covered by the same patent rights and technologies, which in turn could significantly undercut the value of any of our product candidates and adversely affect our business. Our licensed MIT European patent No. 1879606 was opposed; however, this patent was maintained in amended form following an administrative hearing. Both parties appealed this decision. MIT granted European patent EP1879606, to which Arch Therapeutics has an exclusive license, was the subject of a hearing at the European Patent Office Board of Appeal (the "**Board of Appeal**") on November 26, 2021 as a result of an appeal by MIT to obtain broader claim scope than was upheld by the European Patent Opposition Division in 2016 and appeals by opponents for the upheld scope to be denied to MIT. At the oral proceedings, in light of concerns expressed by the Board of Appeal, MIT withdrew its appeal and the affected claims, resulting in a formal revocation of the European patent. There is a pending divisional patent application in which the concerns that the Board of Appeal expressed can be addressed. MIT can file further divisional patent applications to seek additional claim scope. There is no guarantee that any divisional patent application will result in a granted patent or that any granted patent will not be opposed and revoked. The Board of Appeal's decision is in relation to the granted European patent EP1879606 and the various national patents that are derived therefrom, and it has no legal significance outside of Europe except in Hong Kong. Further, we cannot be certain that we were the first to make the inventions claimed in the patents we own or license, or that protection of the inventions set forth in those patents was the first to be filed in the U.S. Third parties that have filed patents or patent applications covering similar technologies or processes may challenge our claim of sole right to use the intellectual property covered by the patents we own or exclusively license. Moreover, changes in applicable intellectual property laws or interpretations thereof in the U.S. and other countries may diminish the value of our intellectual property rights or narrow the scope of our patent protection. Any failure to obtain or maintain adequate protection for our intellectual property would materially harm our business, product development programs and prospects. In addition, our proprietary information, trade secrets and know-how are important components of our intellectual property rights. We seek to protect our proprietary information, trade secrets, know-how and confidential information, in part, with confidentiality agreements with our employees, corporate partners, outside scientific collaborators, sponsored researchers, consultants and other advisors. We also have invention or patent assignment agreements with our employees and certain consultants and advisors. If our employees or consultants breach those agreements, we may not have adequate remedies for any of those breaches. In addition, our proprietary information, trade secrets and know-how may otherwise become known to or be independently developed by others. Enforcing a claim that a party illegally obtained and/or for which a party is using our proprietary information, trade secrets and/or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek to defend, enforce and/or determine the scope of our intellectual property rights, and failure to obtain or maintain protection thereof could adversely affect our competitive business position and results of operations.

Many of our owned patent applications are pending, and our patent portfolio includes certain patents and applications that are in-licensed on a non-exclusive basis.

As of September 15, 2023, we either own or license from others a number of U.S. patents, U.S. patent applications, foreign patents and foreign patent applications.

We have also entered into a license agreement with MIT pursuant to which we have been granted exclusive rights under two portfolios of patents and non-exclusive rights under another three portfolios of patents.

The two portfolios exclusively licensed from MIT include approximately 30 patents and pending applications drawn to self-assembling peptides, formulations and methods of use thereof and self-assembling peptidomimetics and methods of use thereof in a total of nine jurisdictions. The portfolios include five issued U.S. patents (US 9,511,113; US 9,084,837; US 10,137,166; US 9,327,010; and US 9,364,513) that expire between 2026 and 2027 (absent any potential patent term extension), as well as additional patents that have been either allowed, issued or granted in foreign jurisdictions.

The portfolios non-exclusively licensed from MIT include a number of US and foreign applications, including three issued U.S. patents (US 7,846,891; US 7,713,923; and US 8,901,084) that expire between 2024 and 2026 (absent any potential patent term extension), as well as additional patents that have been either allowed, issued or granted in foreign jurisdictions.

If we lose certain intellectual property rights owned by third parties and licensed to us, our business could be materially harmed.

We have entered into certain in-license agreements with MIT and with certain other third parties and may seek to enter into additional in-license agreements relating to other intellectual property rights in the future. To the extent we and our product candidates rely heavily on any such in-licensed intellectual property, we are subject to our and the counterparty's compliance with the terms of such agreements in order to maintain those rights. Presently, we, our lead product candidates and our business plans are dependent on the patent and other intellectual property rights that are licensed to us under our license agreement with MIT. Although that agreement has a durational term through the life of the licensed patents, it also imposes or imposed certain diligence, capital raising, and other obligations on us, our breach of which could permit MIT to terminate the agreement. Further, we are responsible for all patent prosecution and maintenance fees under that agreement, and a failure to pay such fees on a timely basis could also entitle MIT to terminate the agreement. Any failure by us to satisfy our obligations under our license agreement with MIT or any other dispute or other issue relating to that agreement could cause us to lose some or all of our rights to use certain intellectual property that is material to our business and our lead product candidates, which would materially harm our product development efforts and could cause our business to fail.

If we infringe or are alleged to infringe the intellectual property rights of third parties, our business and financial condition could suffer.

Our research, development and commercialization activities, as well as any product candidates or products resulting from those activities, may infringe or be accused of infringing a patent or other intellectual property under which we do not hold a license or other rights. Third parties may own or control those patents or other rights in the U.S. or abroad and could bring claims against us that would cause us to incur substantial time, expense, and diversion of management attention. If a patent or other intellectual property infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales, if any, of the applicable product or product candidate that is the subject of the suit. In order to avoid or settle potential claims with respect to any of the patent or other intellectual property rights of third parties, we may choose or be required to seek a license from a third-party and be required to pay license fees or royalties or both. Any such license may not be available on acceptable terms, or at all. Even if we or our future collaborators were able to obtain a license, the rights granted to us or them could be non-exclusive, which could result in our competitors gaining access to the same intellectual property rights and materially negatively affecting the commercialization potential of our planned products. Ultimately, we could be prevented from commercializing one or more product candidates, or be forced to cease some aspects of our business operations, if, as a result of actual or threatened infringement claims, we are unable to enter into licenses on acceptable terms or at all or otherwise settle such claims. Further, if any such claims were successful against us, we could be forced to pay substantial damages. Any of those results could significantly harm our business, prospects and operations.

Risks Related to Ownership of our Common Stock and Investor Warrants

We have pursued an Uplist Transaction by filing an application to list our Common Stock to trade on the Nasdaq Capital Market. We may not satisfy the listing requirements and thereby consummate an Uplist Transaction, including the requirement to have sufficient capital to satisfy our working capital requirements for at least one year, and the minimum bid price requirement to list on the Nasdaq Capital Market. In the event we fail to list our Common Stock on the Nasdaq Capital Market, such failure may inhibit or preclude our ability to raise additional financing.

We have committed to pursue an Uplist Transaction. Accordingly, we have filed an application to list our Common Stock on the Nasdaq Capital Market. To successfully list our Common Stock, we are required to satisfy certain Nasdaq listing requirements, including having sufficient capital to satisfy our working capital requirements for at least one year, achieving a minimum bid price for our Common Stock, among other requirements relating to stockholder equity, market value of listed securities and number of market makers and stockholders. If we fail to meet any of those requirements, our application to list our Common Stock on the Nasdaq Capital Market will be denied. No assurances can be given that we will satisfy the listing requirements. If our application is not successful, our Board will weigh the available alternatives to successfully consummate an Uplist Transaction and list our Common Stock on the Nasdaq Capital Market. However, there can be no assurance that we will be able to successfully meet such listing requirements. If, for any reason, our listing application is not approved by Nasdaq and we are unable to otherwise consummate an Uplist Transaction on another national securities exchange or take action to successfully list our Common Stock on the Nasdaq Capital Market, our ability to raise additional capital may be adversely affected.

There is not now, and there may not ever be, an active market for our Common Stock, which trades in the over-the-counter market in low volumes and at volatile prices. Even if this offering is successful and our application to list our Common Stock on the Nasdaq Capital Market or an Alternate Exchange is approved, no assurance can be given that an active trading market for our Common Stock will develop or be maintained.

There currently is a limited market for our Common Stock. Although our Common Stock is quoted on the OTCQB, an over-the-counter quotation system, trading of our Common Stock is extremely limited and sporadic and generally at very low volumes. Further, the price at which our Common Stock may trade is volatile and we expect that it will continue to fluctuate significantly in response to various factors, many of which are beyond our control. The stock market in general, and securities of small-cap companies driven by novel technologies in particular, has experienced extreme price and volume fluctuations in recent years. Continued market fluctuations could result in further volatility in the price at which our Common Stock may trade, which could cause its value to decline. To the extent we seek to raise capital in the future through the issuance of equity, those efforts could be limited or hindered by low and/or volatile market prices for our Common Stock.

We have applied to list our Common Stock on the Nasdaq Capital Market under the symbol “ARTH.” No assurance can be given that our application will be approved or that, if approved, an active trading market for our securities will develop or be maintained. If our Common Stock is not approved for listing on the Nasdaq Capital Market or an Alternate Exchange, we will not complete this offering. Even if our Common Stock is approved for listing on the Nasdaq Capital Market or an Alternate Exchange, an active trading market for our Common Stock may not develop or be sustained. In the absence of an active trading market for our Common Stock, the ability of our stockholders to sell their securities could be limited. As a result, investors must bear the economic risk of holding their shares of our Common Stock for an indefinite period of time.

Under the 2022 Notes, we are obligated to complete an Uplist Transaction by October 31, 2023 to the Nasdaq Capital Market or an Alternate Exchange. In the event we are unable to uplist our Common Stock, we anticipate that our Common Stock will continue to be quoted on the OTCQB or another over-the-counter quotation system. In those venues, our stockholders may find it difficult to obtain accurate quotations as to the market value of their shares of our Common Stock and may find few buyers to purchase their stock and few market makers to support its price. There is no assurance that our Common Stock will ever be listed on a national securities exchange, that we will be able to comply with or continue to meet such applicable listing standards.

There is not now and may not be an active liquid trading market for our Investor Warrants.

There is no established public trading market for our Investor Warrants. Although we plan to apply to have the Investor Warrants listed on the Nasdaq Capital Market or Alternate Exchange under the symbol “ARTHW,” there is no assurance our application will be approved, or even if it is approved, that a public trading market will develop or if one develops that it will be maintained. Without a public market, the liquidity of the Investor Warrants will remain limited. However, if our Investor Warrants are not approved for listing on the Nasdaq Capital Market or an Alternate Exchange, we will still complete this offering.

Even if our planned Reverse Split achieves the requisite increase in the market price of our Common Stock, there can be no assurance that we will be approved for listing on the Nasdaq Capital Market or an Alternate Exchange or be able to comply with other continued listing standards of the Nasdaq Capital Market or an Alternate Exchange.

On August 22, 2023, the stockholders approved a reverse stock split between 1.5-for-1 to 20-for-1, with the exact ratio to be determined by the Board within 1 year following the date of such approval, and without correspondingly decreasing the number of authorized shares of Common Stock (the “Reverse Split”). Even if our planned Reverse Split increases the market price of our Common Stock sufficiently so that we comply with the minimum market price requirement, no assurance can be given that we will be able to comply with the other standards that we are required to meet in order to be approved for listing on the Nasdaq Capital Market or an Alternate Exchange or maintain a listing of our Common Stock on such exchange. Our failure to meet these requirements prior to listing will result in the offering not occurring and our failure to meet these requirements following listing may result in our Common Stock being delisted from the Nasdaq Capital Market or an Alternate Exchange.

The Reverse Split may decrease the liquidity of the shares of our Common Stock.

The liquidity of the shares of our Common Stock may be affected adversely by the Reverse Split given the reduced number of shares that will be outstanding following the Reverse Split. In addition, the Reverse Split may increase the number of stockholders who own odd lots (less than 100 shares) of our Common Stock, creating the potential for such stockholders to experience an increase in the cost of selling their shares and greater difficulty affecting such sales.

If this offering is successful, we will be subject to the continued listing requirements of the Nasdaq Capital Market or an Alternate Exchange. If we are unable to comply with such requirements, our Common Stock and Investor Warrants would be delisted from the Nasdaq Capital Market or such Alternate Exchange, which would limit investors' ability to effect transactions in our Common Stock and Investor Warrants and subject us to additional trading restrictions.

Even if this offering is successful and our application to list our Common Stock and Investor Warrants on the Nasdaq Capital Market or an Alternate Exchange is approved, if we fail to meet the Nasdaq Capital Market or such Alternate Exchange continued listing requirements, including stockholder equity requirements, our Common Stock and Investor Warrants could be subject to delisting by the Nasdaq Capital Market or such Alternate Exchange, which could reduce the liquidity of our Common Stock and Investor Warrants materially and result in a corresponding material reduction in the price of our Common Stock and Investor Warrants. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and business development opportunities. Such a delisting likely would impair your ability to sell or purchase our Common Stock and Investor Warrants when you wish to do so. Further, if we were to be delisted from the Nasdaq Capital Market or an Alternate Exchange, our Common Stock and Investor Warrants would no longer be recognized as a "covered security" and we would be subject to regulation in each state in which we offer our securities. Thus, delisting from the Nasdaq Capital Market or an Alternate Exchange could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly impact the ability of investors to trade our securities and would negatively impact the value and liquidity of our Common Stock and Investor Warrants.

Our Common Stock may experience extreme stock price volatility unrelated to our actual or expected operating performance, financial condition or prospects, making it difficult for prospective investors to assess the rapidly changing value of our Common Stock.

Recently, there have been instances of extreme stock price run-ups followed by rapid price declines and strong stock price volatility with a number of recent initial public offerings, especially among companies with relatively smaller public floats. As a relatively small-capitalization company with relatively small public float, we may experience greater stock price volatility, extreme price run-ups, lower trading volume and less liquidity than large-capitalization companies. In particular, our Common Stock may be subject to rapid and substantial price volatility, low volumes of trades and large spreads in bid and ask prices. Such volatility, including any stock-run up, may be unrelated to our actual or expected operating performance, financial condition or prospects, making it difficult for prospective investors to assess the rapidly changing value of our Common Stock.

In addition, if the trading volumes of our Common Stock are low, persons buying or selling in relatively small quantities may easily influence prices of our Common Stock. This low volume of trades could also cause the price of our Common Stock to fluctuate greatly, with large percentage changes in price occurring in any trading day session. Holders of our Common Stock may also not be able to readily liquidate their investment or may be forced to sell at depressed prices due to low volume trading. If high spreads between the bid and ask prices of our Common Stock exist at the time of a purchase, the stock would have to appreciate substantially on a relative percentage basis for an investor to recoup their investment. Broad market fluctuations and general economic and political conditions may also adversely affect the market price of our Common Stock.

As a result of this volatility, investors may experience losses on their investment in our Common Stock. A volatile market price of our Common Stock also could adversely affect our ability to issue additional shares of Common Stock or other securities and our ability to obtain additional financing in the future.

Substantial future sales of our shares of Common Stock or rights to purchase shares of our Common Stock, or the perception that such sales could occur, could cause the market price of our Common Stock to decline, even if our business is doing well.

As noted above under the risk factor entitled, ***“There is substantial doubt about our ability to continue as a going concern. Even if this offering is successful, we will need additional funding to continue our operations and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts and could cause our business to fail.”*** Sales of substantial amounts of our Common Stock in the public market or the perception that such sales could occur, could adversely affect the trading price of our Common Stock, and may make it more difficult for you to sell your Common Stock at a time and price that you deem appropriate. We are unable to predict the effect that such sales may have on the prevailing price of our Common Stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

We, our directors and executive officers have entered into or will enter into lock-up agreements with the underwriter of this offering pursuant to which they and we have agreed, or will agree, that, subject to certain exceptions, we will not issue or offer, and they will not sell, contract to sell, encumber, grant any option for the sale of, or otherwise dispose of any shares or any securities convertible into or exchangeable for shares of our Common Stock for a period of 6 months after the offering is completed. See the section titled **“Underwriting”** for more information. Sales of a substantial number of such shares upon expiration of, or the perception that such sales may occur, or early release of the securities subject to, the lock-up agreements, could cause our stock price to fall or make it more difficult for you to sell your Common Stock at a time and price that you deem appropriate. A decline in the price of our Common Stock might impede our ability to raise capital through the issuance of additional Common Stock or other equity securities.

In addition, in the future, we may issue additional shares of Common Stock, warrants or other equity or debt securities convertible into Common Stock in one or more transactions, at prices and in a manner we determine from time to time, in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our Common Stock or warrants to decline.

If we issue additional shares in the future, including issuances of shares upon exercise of our outstanding warrants and convertible notes, our existing stockholders will be significantly diluted.

As of September 21, 2023, our articles of incorporation authorize the issuance of up to 350,000,000 shares of Common Stock. The issuance of shares of our Common Stock upon the exercise of our outstanding warrants or conversion of outstanding convertible notes, summarized below, could result in substantial dilution to our stockholders, which may have a negative effect on the price of our Common Stock.

As of September 15, 2023, there were issued and outstanding: (i) options granted to employees, directors and consultants under our 2013 Plan to purchase up to an aggregate of 100,900 shares of Common Stock at exercise prices ranging from \$4.00 to \$130.00 per share and with a weighted average exercise price of \$37.57 per share; (ii) 26,283,816 shares of Common Stock issuable upon the exercise of outstanding warrants, having a weighted average exercise price of \$1.36 per share (which includes 18,798,526 Common Warrants that will automatically be cancelled and exchanged for 56,395,578 Exchange Investor Warrants at the closing of this offering); (iii) Series 2 Convertible Notes convertible into 52,917 shares of Common Stock at a conversion price of \$50.00 per share; (iv) 685,846 shares of Common Stock issuable upon conversion of the 2022 Notes at the exercise price of \$9.14 per share; (v) 7,522,203 shares of Common Stock to be issuable upon exercise of the Participating Pre-Funded Warrants expected to be issued at the closing of this offering; (vi) 56,395,578 shares of Common Stock to be issuable upon exercise of the Exchange Investor Warrants expected to be issued at the closing of this offering; (vii) 455,169 shares of Common Stock reserved for future issuance under the 2023 Plan; (viii) up to 6,750,000 shares (7,762,500 shares if the underwriters’ option to purchase additional Investor Warrants is exercised in full) of Common Stock issuable upon exercise of the Investor Warrants to be issued in this offering; and (ix) up to 337,500 shares (388,125 shares if the underwriters’ option to purchase additional shares of Common Stock is exercised in full) of Common Stock issuable upon exercise of the Underwriter Warrants to be issued to the Representative, or its designees, upon completion of this offering.

Additionally, the numbers issuable under the 2023 Plan will increase by specific amounts, as described above under **“Prospectus Summary—Recent Developments—Equity Incentive Plan.”** Any future grants of options, warrants or other securities exercisable or convertible into our Common Stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our Common Stock.

In addition to capital raising activities, other possible business and financial uses for our authorized Common Stock include, without limitation, future stock splits, acquiring other companies, businesses or products in exchange for shares of Common Stock, issuing shares of our Common Stock to partners in connection with strategic alliances, attracting and retaining employees by the issuance of additional securities under our various equity compensation plans, compensating consultants by issuing shares or options to purchase shares of our Common Stock, or other transactions and corporate purposes that our Board deems are in the Company’s best interest. Additionally, shares of Common Stock could be used for anti-takeover purposes or to delay or prevent changes in control or management of the Company. We cannot provide assurances that any issuances of Common Stock will be consummated on favorable terms or at all, that they will enhance stockholder value, or that they will not adversely affect our business or the trading price of our Common Stock. The issuance of any such shares will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our Common Stock. If we issue any such additional shares, such issuance will reduce the proportionate ownership and voting power of all current stockholders. Further, such issuance may result in a change of control of our Company.

We are a smaller reporting company, and we cannot be certain if the reduced disclosure requirements applicable to smaller reporting companies will make our Common Stock less attractive to investors.

We are currently a “smaller reporting company”, meaning that we are not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent company that is not a smaller reporting company and we either have a public float of less than \$250 million as of the last business day of our second fiscal quarter or annual revenues of less than \$100 million during our most recently completed fiscal year and a public float of less than \$700 million. Smaller reporting companies are able to provide simplified executive compensation disclosures in their filings; are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting; and have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports and in a registration statement under the Exchange Act on Form 10. Decreased disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects.

Financial Industry Regulatory Authority (“FINRA”) sales practice requirements may limit a stockholder’s ability to buy and sell our stock.

In addition to the “penny stock” rules described above, FINRA has adopted rules that require that, in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer’s financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA has indicated its belief that there is a high probability that speculative low-priced securities will not be suitable for at least some customers. These FINRA requirements make it more difficult for broker-dealers to recommend that at least some of their customers buy our Common Stock, which may limit the ability of our stockholders to buy and sell our Common Stock and could have an adverse effect on the market for our shares.

There may be additional risks because we completed a reverse merger transaction in June 2013.

Additional risks may exist because we completed a “reverse merger” transaction in June 2013. Securities analysts of major brokerage firms may not provide coverage of the Company because there may be little incentive to brokerage firms to recommend the purchase of our Common Stock. There may also be increased scrutiny by the SEC and other government agencies and holders of our securities due to the nature of the transaction, as there has been increased focus on transactions such as the Merger in recent years. Further, since the Company existed as a “shell company” under applicable rules of the SEC up until the closing of the Merger on June 26, 2013, there will be certain restrictions and limitations on the Company going forward relating to any potential future issuances of additional securities to raise funding and compliance with applicable SEC rules and regulations.

The elimination of monetary liability against our directors and officers under Nevada law and the existence of indemnification rights held by our directors, officers and employees may result in substantial expenditures by us and may discourage lawsuits against our directors, officers and employees.

Our articles of incorporation eliminate the personal liability of our directors and officers to our Company and our stockholders for damages for breach of fiduciary duty as a director or officer to the extent permissible under Nevada law. Further, our amended and restated bylaws provide that we are obligated to indemnify any of our directors or officers to the fullest extent authorized by Nevada law and, subject to certain conditions, advance the expenses incurred by any director or officer in defending any action, suit or proceeding prior to its final disposition.

Those indemnification obligations could result in our Company incurring substantial expenditures to cover the cost of settlement or damage awards against our directors or officers, which we may be unable to recoup. These provisions and resultant costs may also discourage us from bringing a lawsuit against any of our current or former directors or officers for breaches of their fiduciary duties and may similarly discourage the filing of derivative litigation by our stockholders against our directors and officers even if such actions, if successful, might otherwise benefit us or our stockholders.

We are subject to the reporting requirements of federal securities laws, compliance with which involves significant time, expense and expertise.

We are a public reporting company in the U.S., and, accordingly, are subject to the information and reporting requirements of the Exchange Act and other federal securities laws, including the obligations imposed by the Sarbanes-Oxley Act. The costs associated with preparing and filing annual, quarterly and current reports, proxy statements and other information with the SEC in the ordinary course, as well as preparing and filing audited financial statements, has caused, and could continue to cause, our operational expenses to remain at higher levels or continue to increase.

Shares of our Common Stock that have not been registered under federal securities laws are subject to resale restrictions imposed by Rule 144. In addition, any shares of our Common Stock that are held by affiliates, including any that are registered, will be subject to the resale restrictions of Rule 144.

Rule 144 imposes requirements on us and our stockholders that must be met in order to effect a sale thereunder. As a result, it will be more difficult for us to raise funding to support our operations through the sale of debt or equity securities unless we agree to register such securities under the Securities Act, which could cause us to expend significant additional time and cash resources and which we presently have no intention to pursue. Further, it may be more difficult for us to compensate our employees and consultants with our securities instead of cash. We were a shell company prior to the closing of the Merger, and such status could also limit our use of our securities to pay for any acquisitions we may seek to pursue in the future (although none are currently planned) and could cause the value of our securities to decline. In addition, any shares held by affiliates, including shares received in any registered offering, will be subject to certain additional requirements in order to effect a sale of such shares under Rule 144.

We do not intend to pay cash dividends on our Common Stock in the foreseeable future.

We have never declared or paid any dividends on our shares and do not anticipate paying any such dividends in the foreseeable future. Any future payment of cash dividends would depend on our financial condition, contractual restrictions, solvency tests imposed by applicable corporate laws, results of operations, anticipated cash requirements and other factors and will be at the discretion of our Board.

The market price of our Common Stock may be volatile which could subject us to securities class action litigation.

The market price for our Common Stock has been and may continue to be volatile and subject to wide fluctuations in response to factors including the following:

- sales or potential sales of substantial amounts of our Common Stock;
- delay or failure in initiating or completing preclinical or clinical trials or unsatisfactory results of these trials;
- announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions;
- developments concerning our product manufacturers;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- conditions in the pharmaceutical or biotechnology industries;
- governmental regulation and legislation;
- variations in our anticipated or actual operating results;
- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations; foreign currency values and fluctuations; and
- overall economic conditions.

In the past, securities class action litigation has been brought against companies following periods of volatility of its securities in the marketplace. The stock markets in general, and the market for pharmaceutical and biotechnology companies in particular, have historically experienced extreme price and volume fluctuations. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors could reduce the market price of our Common Stock, regardless of our actual operating performance. Due to the volatility of our stock price, we could be the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources.

Risks Related to This Offering

Management will have broad discretion as to the use of the proceeds from this offering, and we may not use the proceeds effectively.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section entitled **Use of Proceeds**,” and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our Common Stock. You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the net proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for us. Our failure to apply these funds effectively could have a material adverse effect on our business and cause the price of our Common Stock to decline.

You will experience immediate and substantial dilution in the net tangible book value per share of the Common Stock included in the Units or issuable upon exercise of the Pre-Funded Warrants in this offering.

The public offering price of the Units and Pre-Funded Units being offered in this offering is substantially higher than the net tangible book value per share of our Common Stock prior to the offering. Investors purchasing Units or Pre-Funded Units in this offering may pay an effective price per share of Common Stock that may substantially exceed the pro forma book value of our tangible assets after subtracting our liabilities. Based on an assumed public offering price of \$2.00 per Unit (the last reported sale price of our Common Stock on the OTCQB on September 19, 2023), if you purchase shares of our Common Stock in this offering, you will suffer immediate and substantial dilution of \$1.63 per share with respect to the net tangible book value of the Common Stock. See the section entitled **“Dilution”** below for a more detailed discussion of the dilution you will incur if you purchase securities in this offering. As a result of the dilution to investors purchasing securities in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of a liquidation of our company.

There is no public market for the Investor Warrants or the Pre-Funded Warrants.

There is no established public trading market for the Investor Warrants or the Pre-Funded Warrants, and we do not expect a market to develop for the Pre-Funded Warrants. We have applied to list the Investor Warrants on the Nasdaq Capital Market under the symbol “ARTHW.” No assurance can be given that such listing will be approved or, if successful, that an active trading market for the Investor Warrants will develop or be sustained. In addition, we do not intend to apply to list the Pre-Funded Warrants on any national securities exchange or other nationally recognized trading system. Without an active market, the liquidity of the Investor Warrants and the Pre-Funded Warrants will be limited.

The Investor Warrants and the Pre-Funded Warrants in this offering are speculative in nature.

Neither the Investor Warrants nor the Pre-Funded Warrants in this offering confer any rights of Common Stock ownership on its holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of Common Stock at a fixed price, as the case maybe. In addition, following this offering, the market value of the Investor Warrants, if any, is uncertain and there can be no assurance that the market value of the Investor Warrants will equal or exceed their imputed offering price. The Pre-Funded Warrants will not be listed or quoted for trading on any market or exchange.

USE OF PROCEEDS

We expect to receive net proceeds of approximately \$11.6 million from this offering or approximately \$13.5 million if the underwriters exercise their option to purchase additional shares of Common Stock and/or Investor Warrants in full, based on an assumed public offering price of \$2.00 per Unit (the last reported sale price of our Common Stock on the OTCQB on September 19, 2023), after deducting the estimated underwriting discounts and commissions and offering expenses payable by us. We currently intend to use the net proceeds we receive from this offering for product marketing and for general working capital purposes.

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot currently allocate specific percentages of the net proceeds that we may use for the purposes specified above, and we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering, or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures will depend upon numerous factors, including our sales and marketing efforts, demand for our products, our operating costs and the other factors described under “**Risk Factors**” in this prospectus. Accordingly, our management will have flexibility in applying the net proceeds from this offering. An investor will not have the opportunity to evaluate the economic, financial or other information on which we base our decisions on how to use the proceeds.

Each \$0.25 increase (decrease) in the assumed public offering price of \$2.00 per Unit (the last reported sale price of our Common Stock on the OTCQB on September 19, 2023), would increase (decrease) the net proceeds to us from this offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, by approximately \$1.6 million, assuming that the number of Units offered by us, as set forth on the cover page of this prospectus, remains the same. We may also increase or decrease the number of Units we are offering. An increase (decrease) of 1,000,000 in the number of Units we are offering would increase (decrease) the net proceeds to us from this offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, by approximately \$1.8 million, assuming the public offering price stays the same. We do not expect that a change in the offering price or the number of Units by these amounts would have a material effect on our intended uses of the net proceeds from this offering, although it may impact the amount of time prior to which we may need to seek additional capital.

MARKET PRICE OF AND DIVIDENDS ON COMMON STOCK AND RELATED MATTERS

Market Information

Our Common Stock is currently quoted on the OTCQB over-the-counter quotation system under the stock symbol “ARTH”. Our Common Stock began quotation on the OTCBB and the OTCQB on June 27, 2013 and since that date has been primarily traded on the OTCQB. There was no trading of our Common Stock on the OTCBB, OTCQB or any other over-the-counter market prior to January 2, 2013. Although our Common Stock is currently quoted on the OTCQB, there is a limited trading market for our Common Stock and there has been limited trading activity in our Common Stock to date. Because our Common Stock is thinly traded on the OTCQB, (i) any reported sale prices may not be a true market-based valuation of our Common Stock; and (ii) such over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

We have applied to list our Common Stock and Investor Warrants on the Nasdaq Capital Market under the symbols “ARTH” and “ARHTW”, respectively. There is no assurance that our listing application will be approved by the Nasdaq Capital Market, or, if successful, that an active trading market for our Common Stock or Investor Warrants will develop or be sustained. If we are unable to list our Common Stock on the Nasdaq Capital Market or an Alternate Exchange, we will not consummate this offering.

Dividends

We have never declared or paid any cash dividends or distributions on our Common Stock. We currently intend to retain our future earnings, if any, to support operations and to finance expansion, and, therefore, we do not anticipate paying any cash dividends on our Common Stock in the foreseeable future. Any future payment of dividends will depend upon our results of operations, financial condition, cash requirements and other factors deemed relevant by our Board.

Holders

As of September 15, 2023, there were approximately 131 holders of record of our Common Stock.

Transfer Agent and Registrar

The transfer agent and warrant agent for our Common Stock and Investor Warrants, respectively, is Empire Stock Transfer. Our transfer agent’s address is 1859 Whitney Mesa Drive, Henderson, Nevada 89014.

CAPITALIZATION

The following table sets forth our cash and capitalization as of June 30, 2023:

- on an actual basis;
- on a pro forma basis to give effect to (i) the issuance of 3,344,321 Bridge Shares (and the Common Warrants) and 6,054,942 Bridge Pre-Funded Warrants in the Bridge Offering between July 7, 2023 and September 11, 2023 for net proceeds of approximately \$2,340,843, and assuming the full exercise of all of the Bridge Pre-Funded Warrants, (ii) the conversion in full of the Series 1 Notes for the issuance of 59,912 shares of Common Stock on July 12, 2023, (iii) the expected full conversion of the Series 2 Notes into an aggregate of 52,917 shares of Common Stock at the closing of this offering and (iv) the issuance at the closing of this offering of an aggregate of 1,567,127 shares of Common Stock upon the Automatic Conversion of an aggregate of \$3,134,250 of principal amount under the 2022 Notes, assuming no issuance of any 2022 Note Conversion Pre-Funded Warrants, based on the assumed offering price of \$2.00 per Unit in this offering (the events in clauses (i) through (iv), the “**Pro Forma Events**”); and
- on a pro forma, as adjusted basis, to give effect to the issuance and sale by us of 6,750,000 Units in this offering based on an assumed public offering price of \$2.00 per Unit (assuming no sale of any Pre-Funded Units), after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and the receipt by us of the proceeds of such sale.

You should read this table together with “**Use of Proceeds**,” “**Management’s Discussion and Analysis of Financial Condition and Results of Operations**” and our audited and unaudited financial statements and related notes thereto included elsewhere in this prospectus.

	As of June 30, 2023		Pro Forma As Adjusted (unaudited) (1)
	Actual (unaudited)	Pro Forma (unaudited)	
Cash	\$ 86,542	\$ 2,427,385	\$ 14,072,385
Total liabilities	9,579,274	5,585,232	5,585,232
Stockholders’ deficit:			
Common stock, \$0.001 par value, 12,000,000 shares authorized as of June 30, 2023 (350,000,000 effective September 21, 2023), and 1,285,213 shares, actual, 12,364,432 shares, pro forma and 19,114,432 shares, pro forma as adjusted, issued as of June 30, 2023	1,285	12,364	19,114
Additional paid-in capital	\$ 51,582,100	\$ 57,322,701	\$ 68,960,951
Accumulated deficit	\$ (59,598,413)	\$ (59,015,208)	\$ (59,015,208)
Total stockholders’ (deficit) equity	\$ (8,015,028)	\$ (1,680,143)	\$ 9,964,857
Total capitalization	\$ 1,564,246	\$ 3,905,089	\$ 15,550,089

(1) A \$0.25 increase or decrease in the assumed public offering price of \$2.00 per Unit (the last reported sale price of our Common Stock on the OTCQB on September 19, 2023), would increase or decrease the pro forma as adjusted amount of each of cash, additional paid-in capital, total stockholders’ equity (deficit) and total capitalization by approximately \$1.6 million, assuming that the number of Units offered by us, as set forth on the cover page of this prospectus, remains the same (assuming no sale of any Pre-Funded Units) and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us and assuming no exercise of the Investor Warrants issued as part of the Units. An increase or decrease of 1,000,000 in the number of Units offered by us, as set forth on the cover page of this prospectus (assuming no sale of any Pre-Funded Units), would increase or decrease the pro forma as adjusted amount of each of cash, additional paid-in capital, total stockholders’ equity (deficit) and total capitalization by approximately \$1.8 million, assuming no change in the assumed public offering price per Unit and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us and assuming no exercise of the Investor Warrants issued as part of the Units.

Except as indicated otherwise, the total number of shares reflected in the discussion and tables above is based on 1,285,213 shares of our Common Stock outstanding as of June 30, 2023, and excludes, in each case: As of such date, (i) options granted to employees, directors and consultants under our 2013 Plan to purchase up to an aggregate of 100,900 shares of Common Stock at exercise prices ranging from \$4.00 to \$130.00 per share and with a weighted average exercise price of \$37.57 per share; (ii) 988,417 shares of Common Stock issuable upon the exercise of outstanding warrants, having a weighted average exercise price of \$17.05 per share; (iii) Series 2 Convertible Notes convertible into 52,917 shares of Common Stock at a conversion price of \$50.00 per share; (iv) Series 1 Convertible Notes convertible into 59,912 shares of Common Stock; (v) 685,846 shares of Common Stock issuable upon conversion of the 2022 Notes; (vi) 7,522,203 shares of Common Stock to be issuable upon exercise of the Participating Pre-Funded Warrants expected to be issued at the closing of this offering; (vii) 56,395,578 shares of Common Stock to be issuable upon exercise of the Exchange Investor Warrants expected to be issued at the closing of this offering; (viii) up to 6,750,000 shares (7,762,500 shares if the underwriters’ option to purchase additional Investor Warrants is exercised in full) of Common Stock issuable upon exercise of the Investor Warrants to be issued in this offering; and (ix) up to 337,500 shares (388,125 shares if the underwriters’ option to purchase additional shares of Common Stock is exercised in full) of Common Stock issuable upon exercise of the Underwriter Warrants to be issued to the Representative, or its designees, upon completion of this offering.

Except as indicated otherwise, the discussion and table above assume no sale of Pre-Funded Units and no exercise of the underwriters’ option to purchase up to 1,012,500 additional shares of Common Stock and/or Investor Warrants to purchase up to 1,012,500 additional shares of Common Stock.

DILUTION

If you invest in our securities in this offering, your interest will be diluted to the extent of the difference between the public offering price per share of Common Stock included in each Unit or issuable upon exercise of the Pre-Funded Warrants (attributing no value to the Investor Warrants) and the as adjusted net tangible book value per share of our Common Stock after this offering. We calculate net tangible book value per share by dividing the net tangible book value (tangible assets less total liabilities) by the number of outstanding shares of our Common Stock.

The net tangible book value (deficit) of our Common Stock as of June 30, 2023, was approximately \$(8.0 million), or approximately \$(6.24) per share of Common Stock. Net tangible book value per share represents the amount of our total tangible assets less total liabilities divided by the total number of our shares of Common Stock outstanding as of June 30, 2023.

Our pro forma net tangible book value (deficit) as of June 30, 2023 was \$(1.7 million), or \$(0.14) per share of Common Stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to (i) the issuance of 3,344,321 Bridge Shares (and the Common Warrants) and 6,054,942 Bridge Pre-Funded Warrants in the Bridge Offering between July 7, 2023 and September 11, 2023 for net proceeds of approximately \$2,334,788, and assuming the full exercise of all of the Bridge Pre-Funded Warrants, (ii) the conversion in full of the Series 1 Notes for the issuance of 59,912 shares of Common Stock on July 12, 2023, (iii) the expected full conversion of the Series 2 Notes into an aggregate of 52,917 shares of Common Stock at the closing of this offering and (iv) the issuance at the closing of this offering of an aggregate of 1,567,127 shares of Common Stock upon the Automatic Conversion of an aggregate of \$3,134,250 of principal amount under the 2022 Notes, assuming no issuance of any 2022 Note Conversion Pre-Funded Warrants, based on the assumed offering price of \$2.00 per Unit in this offering. Pro forma net tangible book value per share represents the pro forma net tangible book value divided by the total number of shares outstanding as of June 30, 2023, after giving effect to the pro forma adjustment described above.

After giving further effect to the sale of 6,750,000 shares of Common Stock included in the Units in this offering at an assumed public offering price of \$2.00 per share of Common Stock included in each Unit (assuming no sale of Pre-Funded Units), and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, and assuming no exercise of the Investor Warrants issued as part of the Units, our pro forma, as adjusted net tangible book value as of June 30, 2023 would have been approximately \$10.0 million, or approximately \$0.52 per share of Common Stock. This amount represents an immediate increase in actual book value of \$6.76 per share to our existing stockholders and immediate dilution of approximately \$1.48 per share to new investors in this offering (attributing no value to the Investor Warrants). We determine dilution by subtracting the as adjusted net tangible book value per share after this offering from the amount of cash that a new investor paid for a share of Common Stock included in each Unit in this offering. The following table illustrates this dilution:

Assumed public offering price per Unit	\$	2.00
Net tangible book value (deficit) per share as of June 30, 2023	\$	(6.24)
Pro forma net tangible book value (deficit) per share after giving effect to the Pro Forma Events		(0.14)
Increase in pro forma net tangible book value per share after giving effect to this offering (including the Pro Forma Events)		0.66
Pro forma, as adjusted net tangible book value per share as of June 30, 2023 after giving effect to this offering and the Pro Forma Events		0.52
Dilution per share to new investors in this offering		1.48

If the underwriters exercise their option to purchase additional shares of our Common Stock in full, the pro forma, as adjusted net tangible book value after this offering would be approximately \$0.59 per share, the increase in pro forma net tangible book value per share would be approximately \$6.83 and dilution per share to new investors would be approximately \$1.41 per share.

Each \$0.25 increase (decrease) in the assumed public offering price of \$2.00 per Unit (the last reported sale price of our Common Stock on the OTCQB on September 19, 2023), would increase (decrease) the net proceeds to us from this offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, by approximately \$1.6 million, assuming that the number of Units offered by us, as set forth on the cover page of this prospectus, remains the same (assuming no sale of any Pre-Funded Warrants) and assuming no exercise of the Investor Warrants issued as part of the Units. We may also increase or decrease the number of Units we are offering. An increase (decrease) of 1,000,000 in the number of Units we are offering would increase (decrease) the net proceeds to us from this offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, by approximately \$1.8 million, assuming the public offering price stays the same (assuming no sale of any Pre-Funded Warrants) and assuming no exercise of the Investor Warrants issued as part of the Units. We do not expect that a change in the offering price or the number of Units by these amounts would have a material effect on our intended uses of the net proceeds from this offering, although it may impact the amount of time prior to which we may need to seek additional capital.

The total number of shares reflected in the discussion and tables above is based on 1,285,213 shares of our Common Stock outstanding as of June 30, 2023, and excludes, in each case: As of such date, (i) options granted to employees, directors and consultants under our 2013 Plan to purchase up to an aggregate of 100,900 shares of Common Stock at exercise prices ranging from \$4.00 to \$130.00 per share and with a weighted average exercise price of \$37.57 per share; (ii) 988,417 shares of Common Stock issuable upon the exercise of outstanding warrants, having a weighted average exercise price of \$17.05 per share; (iii) Series 2 Convertible Notes convertible into 52,917 shares of Common Stock at a conversion price of \$50.00 per share; (iv) Series 1 Convertible Notes convertible into 59,912 shares of Common Stock; (v) 685,846 shares of Common Stock issuable upon conversion of the 2022 Notes; (vi) 7,522,203 shares of Common Stock to be issuable upon exercise of the Participating Pre-Funded Warrants expected to be issued at the closing of this offering; (vii) 56,395,578 shares of Common Stock to be issuable upon exercise of the Exchange Investor Warrants expected to be issued at the closing of this offering; (viii) up to 6,750,000 shares (7,762,500 shares if the underwriters' option to purchase additional Investor Warrants is exercised in full) of Common Stock issuable upon exercise of the Investor Warrants to be issued in this offering; and (ix) up to 337,500 shares (388,125 shares if the underwriters' option to purchase additional shares of Common Stock is exercised in full) of Common Stock issuable upon exercise of the Underwriter Warrants to be issued to the Representative, or its designees, upon completion of this offering.

Except as indicated otherwise, the discussion and table above assume no sale of Pre-Funded Units and no exercise of the underwriter's option to purchase up to 1,012,500 additional shares of Common Stock and/or Investor Warrants to purchase up to 1,012,500 additional shares of Common Stock.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the other sections of this prospectus, including our audited annual consolidated financial statements and related notes beginning on page F-1 of this prospectus. This discussion and analysis contains forward-looking statements, including information about possible or assumed results of our financial condition, operations, plans, objectives and performance that involve risks, uncertainties and assumptions. See “Cautionary Note Regarding Forward-Looking Statements” beginning on page 2 of this prospectus. Our actual results may differ materially from those anticipated or suggested in any forward-looking statements.

Corporate Overview

Arch Therapeutics, Inc. (together with its subsidiary, the “Company” or “Arch”) arose from the June 26, 2013 merger (the “Merger”) of three entities previously known as Arch Biosurgery, Inc., Almah, Inc., and Arch Acquisition Corporation, respectively.

Arch Biosurgery, Inc. (“ABS”) is a biotechnology company that was incorporated under the laws of the Commonwealth of Massachusetts on March 6, 2006 as Clear Nano Solutions, Inc., changed its name from Clear Nano Solutions, Inc. to Arch Therapeutics, Inc. on April 7, 2008, and, as part of the Merger transaction, changed its name from Arch Therapeutics, Inc. to Arch Biosurgery.

Almah, Inc., was incorporated under the laws of the State of Nevada on September 16, 2009 and, as part of the Merger transaction, changed its name to Arch Therapeutics, Inc. and abandoned both its prior business plan and operations in order to adopt those of ABS.

Arch Acquisition Corporation, or Merger Sub, was a wholly owned subsidiary of Almah, Inc., formed for the purpose of the Merger transaction, pursuant to which Merger Sub merged with and into ABS, and ABS thereafter became the wholly owned subsidiary of the Company.

The Company’s principal offices are located in Framingham, Massachusetts.

The Company has recently devoted substantially all of its operational effort to the market adoption and commercial sales of AC5® Advanced Wound System, its first product. To date, the Company has principally raised capital through debt borrowings, the issuance of convertible debt, and the issuance of units consisting of shares of the Company’s common stock, \$0.001 par value per share (“Common Stock”), and warrants.

The Company expects to incur substantial expenses for the foreseeable future relating to research, development and commercialization of current and potential products. However, there can be no assurance that the Company will be successful in securing additional capital when needed, on terms acceptable to the Company, if at all. Therefore, there exists substantial doubt about the Company’s ability to continue as a going concern for one year past the issuance of the financial statements. The consolidated financial statements do not include any adjustments related to the recoverability of assets that might be necessary despite this uncertainty.

Liquidity

We devote a significant amount of our efforts on fundraising, planning and conducting clinical trials, activities in connection with obtaining regulatory approval, and product research. We have principally raised capital through borrowings, the issuance of convertible debt, and units consisting of Common Stock and warrants to fund our operations. For the year ended September 30, 2022, we had a net loss of \$5,275,854 versus a net loss of \$6,240,482 in the prior year. The losses for each of the years ended September 30, 2022 and 2021 can be attributable to research and development expense, including regulatory approval and product research, and general and administrative costs, primarily relating to legal costs associated with intellectual property and patent application, general corporate legal expense all of which were partially offset by adjustments to the derivative liabilities and, for the fiscal year ended September 30, 2021, a gain on the forgiveness of the loan issued by First Republic Bank under the Paycheck Protection Program, established under the Coronavirus Aid, Relief, and Economic Security Act. For the nine months ended June 30, 2023, we had a net loss of \$4,525,640 versus a net loss of \$3,387,295 in the same period in fiscal year 2022. Cash used in operating activities decreased \$1,502,553 during the year ended September 30, 2022 to \$4,456,075, compared to \$5,958,628 for the year ended September 30, 2021. Cash used in operating activities during the nine months ended June 30, 2023 was \$2,147,480, compared to \$2,786,642 for the same period in fiscal year 2022.

Business Overview

We are a biotechnology company marketing and developing a number of products based on our innovative AC5® self-assembling technology platform. We believe these products can be important advances in the field of stasis and barrier applications, which includes managing wounds created during surgery, trauma, interventional care or disease; stopping bleeding (hemostasis); and controlling leaking (sealant). We have recently devoted substantially all of our operational effort to the market adoption and commercial sales of AC5 Advanced Wound System, our first product. Our goal is to make care faster and safer for patients with products for use on external wounds, which we refer to as Dermal Sciences applications, and products for use inside the body, which we refer to as BioSurgery applications.

Core Technology

Our flagship products and product candidates are derived from our AC5 self-assembling peptide (SAP) technology platform and are sometimes referred to as AC5 or the “AC5 Devices.” These include AC5 Advanced Wound System and AC5® Topical Hemostat, which have received marketing authorization as medical devices in the United States and Europe, respectively, and which are intended for skin applications, such as the management of complicated chronic wounds and acute surgical wounds. Marketing for AC5 Topical Hemostat in Europe has not initiated. Other products are in development for use in minimally invasive or open surgical procedures and include, for example, AC5-G™ for gastrointestinal endoscopic procedures and AC5-V® and AC5 Surgical Hemostat for hemostasis inside the body, all of which are currently investigational devices limited by law to investigational use.

Products based on the AC5 platform contain a proprietary biocompatible peptide that is synthesized from proteogenic, naturally occurring L-amino acids. Unlike products that contain traditional peptide sequences, when applied to a wound, AC5-based products intercalate into the interstices of the tissue and self-assemble (i.e., self-build) into a protective physical-mechanical nanoscale structure that can provide a barrier to leaking substances, such as blood, while also acting as a biodegradable scaffold that enables healing. Self-assembly is a central component of the mechanism of action of our technology. Individual AC5 peptide units readily build themselves, or self-assemble, into an ordered network of nanofibrils when in aqueous solution by the following process:

- Peptide strands line up with neighboring peptide strands, interacting via hydrogen bonds (non-covalent bonds) to form a ribbon-like structure called a beta sheet.
- This process continues such that hundreds of strands organize with charged and polar side chains oriented on one face and non-polar side chains oriented on the opposite face of the beta sheets.
- Interactions of the resulting structure with water molecules and ions results in formation nanofibrils, which extend in length and can join together to form larger nanofibers.
- This network of AC5 peptide nanofibers forms the semi-solid physical-mechanical barrier that interacts with the extracellular matrix, is responsible for sealant, hemostatic and/or other properties that may be observed even in the presence of antithrombotic agents (i.e., blood thinners), and which subsequently becomes the scaffold that supports the repair and regeneration of damaged tissue.

Based on the intended application, we believe that the underlying AC5 SAP technology can impart important features and benefits to our products that may include, for instance, stopping bleeding (hemostasis), mitigating contamination, modulating inflammation, donating moisture, and enabling an appropriate wound microenvironment conducive to healing. Furthermore, we believe that AC5 SAP technology permits cell and tissue growth and is self-healing, in that it can dynamically self-repair around migrating cells. For instance, AC5 Advanced Wound System, which is indicated for the management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds, is shipped and stored at room temperature, is applied directly as a liquid, can conform to irregular wound geometry, self-assembles into a wound care matrix that can provide clinicians with multi-modal support, and does not possess sticky or glue-like handling characteristics. We believe these properties enhance its utility in several settings and contribute to its user-friendly profile.

We believe that our technology lends itself to a range of potential applications for wounds inside or on the body, including those for which a hemostatic agent or sealant is needed. For instance, the results of certain preclinical and clinical investigations that either we have conducted, or others have conducted on our behalf, have shown quick and effective hemostasis with the use of AC5 SAP technology, and that time to hemostasis (“TTH”) is comparable among test subjects regardless of whether such test subject had or had not been treated with therapeutic doses of anticoagulant or antiplatelet medications, commonly called “blood thinners.” Furthermore, the transparency and physical properties of certain AC5 Devices may enable a surgeon to operate through it in order to maintain a clearer field of vision and prophylactically stop or lessen bleeding as surgery starts, a concept that we call Crystal Clear Surgery™. An example of a product that contains related features and benefits is AC5 Topical Hemostat, which is indicated for use as a dressing and to control mild to moderate bleeding, each during the management of injured skin and the micro-environment of an acute surgical wound. AC5 Topical Hemostat has not yet been marketed in Europe but has received marketing authorization.

Marketing

Sales and marketing efforts for our AC5 Advanced Wound System, which has received 510(k) marketing clearance from the FDA, address the demand for improved solutions to treat challenging chronic and acute surgical wounds, with a particular early focus on diabetic foot ulcers, venous leg ulcers and pressure ulcers. Chronic wounds are typically defined as wounds that have not healed after four weeks of standard care. Approximately 4 million to 6.5 million new onset chronic wounds are estimated to occur in the U.S. annually, including approximately 700,000 to 2 million diabetic foot ulcers, 2.5 million pressure ulcers, and 1.2 million venous leg ulcers. If untreated, improperly treated or unresponsive to treatment, these wounds can ultimately lead to amputation. The 5-year mortality rate among patients with chronic wounds, especially after an amputation, is significant.

Published data on AC5 Advanced Wound System shows encouraging outcomes, including limb salvage (avoided limb loss), among patients with multiple co-morbidities and challenging chronic wounds that failed to heal despite treatment with either traditional or other advanced wound care modalities over prolonged periods of time.

We currently maintain an internal commercial team focused on driving awareness and adoption of AC5 Advanced Wound System in several targeted channels with a particular focus on physician offices and government channels, such as Veterans Health Administration hospitals (“**VA Hospitals**”) and military treatment facilities (“**MTFs**”). We anticipate that material growth in the physician office setting will require product reimbursement. To that end, we submitted an application to the Centers for Medicare and Medicaid Services (“**CMS**”) in July 2022 for a unique product reimbursement code. Our application was subsequently approved with a go-live date of April 1, 2023. We have launched a temporary reimbursement support program in line with CMS guidance to support commercial use and adoption of AC5 Advanced Wound System both before and after the go-live date of our unique product code (A2020). In support of the VA and MTF market, we partnered with Lovell Government Services (“**LGS**”), a Service-Disabled Veteran-Owned Small Business, as its distributor in the government channel. As a direct result of its relationship with LGS, AC5 Advanced Wound System is listed on the four major government supply schedules (ECAT, DAPA, FSS and GSA) in order to allow doctors in any VA or MTF to order AC5 Advanced Wound System. We have also established and will continue to seek partnerships with reputable, value-added independent sales distributors on a case-by-case basis to expand the overall reach and footprint of its total sales organization. Presently, our commercialization efforts and resources remain dedicated to the U.S. market for advanced wound care.

Operations

Much of our operational efforts to date, which we often perform in collaboration with partners, have included selecting compositions and formulations for our initial products; conducting preclinical studies, including safety and other tests; conducting a human trial for safety and performance of AC5; developing and conducting a human safety study to assess for irritation and sensitization potential; securing marketing authorization for our first product in the United States and in Europe; supporting surgeons performing clinical case studies; obtaining post-marketing clinical data; developing, optimizing, and validating manufacturing methods and formulations, which are particularly important components of self-assembling peptide development; developing methods for manufacturing scale-up, reproducibility, and validation; engaging with regulatory authorities to seek early regulatory guidance as well as marketing authorization for our products; sourcing and evaluating commercial partnering opportunities in the United States and abroad; and developing and protecting the intellectual property rights underlying our technology platform.

Our long-term business plan includes the following goals:

- Continue to build recent commercial momentum and grow revenues by driving awareness, adoption and payment policies for AC5 Advanced Wound System with the now-effective CMS Level II Healthcare Common Procedure Coding System (“**HCPCS**”) code dedicated to the “AC5”;
- conducting biocompatibility, pre-clinical, and clinical studies on our products and product candidates;
- obtaining additional marketing authorization for products in the United States, Europe, and other jurisdictions as we may determine;
- continuing to develop third party relationships to manufacture, distribute, market and otherwise commercialize our products;
- continuing to develop academic, scientific and institutional relationships to collaborate on product research and development;
- expanding and maintaining protection of our intellectual property portfolio; and
- developing additional product candidates in Dermal Sciences, BioSurgery, and other areas.

In furtherance of our long-term business goals, we expect to continue to focus on the following activities during the next twelve months:

- seek additional funding as required to support the previously described milestones necessary to support our operations;

- work with our manufacturing partners to scale up production of product compliant with cGMP, which activities will be ongoing and tied to our development and commercialization needs;
- further clinical development of our product platform;
- assess our technology platform in order to identify and select product candidates for potential advancement into development;
- seek regulatory input to guide activities related to expanded and new product marketing authorizations;
- continue to expand and enhance our financial and operational reporting and controls;
- pursue commercial partnerships; and
- expand and enhance our intellectual property portfolio by filing new patent applications, obtaining allowances on currently filed patent applications, and/or adding to our trade secrets in self-assembly, manufacturing, analytical methods and formulation, which activities will be ongoing as we seek to expand our product candidate portfolio.

In addition to capital required for operating expenses, depending upon input from regulatory authorities, authorized representatives, patent and trademark offices, or other agencies in the US, EU or elsewhere, as well as for potential additional regulatory filings and approvals during the approximately next two years, additional capital will be required.

We have no commitments for any future capital. We will require significant additional financing to fund our planned operations, including further research and development relating to AC5, seeking regulatory approval of any product we may choose to develop, commercializing any product for which we are able to obtain regulatory approval or certification, seeking to license or acquire new assets or business, and maintaining our intellectual property rights, pursuing new technologies and for financing the investor relations and incremental administrative costs associated with being a public corporation. In addition, we are bound by certain contractual terms and obligations that may limit or otherwise impact our ability to raise additional funding in the near-term including, but not limited to, provisions in the Bridge SPA (as defined below) and securities purchase agreement dated July 6, 2022, as amended (the “**2022 Notes SPA**”), associated with the sale of the 2022 Notes (the “**2022 Notes Financing**”), in each case as described in greater detail in the risk factor entitled “*The terms of the Bridge Offering and 2022 Notes Financing could impose additional challenges on our ability to raise funding in the future*” under the heading “Risk Factors” in this prospectus.

The estimated capital requirements potentially could increase significantly if a number of risks relating to conducting these activities were to occur, including without limitation those set forth under the heading “**Risk Factors**” in this prospectus. We anticipate that our operating and other expenses will continue to increase as we continue to implement our business plan and pursue and achieve these goals. After giving effect to the funds received in past equity and debt financings and assuming our use of that funding at the rate we presently anticipate, as of September 15, 2023, we believe that our current cash on hand is sufficient to meet our anticipated cash requirements into the first fiscal quarter of 2024, and we must obtain additional financing in order to continue to operate our business. Even if this offering is successful, we could spend our financial resources much faster than we expect, in which case we would need to raise additional capital as our current funds may not be sufficient to operate our business for the entire duration of that period.

Preclinical Testing

We have engaged and continue to engage third parties in the United States and abroad to advise on and perform certain preclinical bench-top and animal research and development studies, typically with assistance from our team. These third parties can include contract research organizations, academic institutions, consultants, advisors, scientists, clinicians, and/or other collaborators.

We completed the biocompatibility studies required to receive marketing authorizations for AC5 Advanced Wound System in the United States and AC5 Topical Hemostat in Europe, and such test results support that the products are biocompatible. We will perform further biocompatibility testing that we deem necessary for additional indications, classifications, jurisdictions, and/or as required by regulatory authorities.

Acute and survival animal studies assessing the safety and performance of our technology have also demonstrated favorable outcomes in Dermal Sciences and BioSurgical applications.

Clinical Testing

We have engaged and continue to engage third parties in the United States and abroad to advise on and perform certain clinical studies and related activities, typically with assistance from our team. These third parties can include contract research organizations, academic institutions, consultants, advisors, scientists, clinicians, and/or other collaborators.

We completed two clinical studies. The first study, which met its primary and secondary endpoints, assessed the safety and performance of our product candidate in 46 patients with bleeding skin wounds that resulted from excision of skin lesions and followed for 30 days. The second study assessed our product candidate on skin, determining that it was neither an irritant nor a sensitizer, and no immunogenic response or serious or other adverse events attributable to our product were reported in any of the approximately 50 enrolled volunteers. The product candidate in these studies subsequently received marketing authorization and is presently known as AC5 Advanced Wound System in the United States and AC5 Topical Hemostat in Europe.

Post marketing clinical case reports have been published demonstrating both efficacy and safety in a range of challenging acute surgical or chronic wounds on patients.

Commercialization

Our commercialization efforts are currently focused on Dermal Sciences. Our BioSurgery products for internal use will require additional preclinical and clinical testing before we seek marketing authorization to commercialize them.

Our Dermal Sciences products are AC5 Advanced Wound System in the United States and AC5 Topical Hemostat in Europe, and the indication for use, or purpose, for each product follows, respectively:

- Under the supervision of a health care professional, AC5 Advanced Wound System is a topical dressing used for the management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds.
- AC5 Topical Hemostat is intended for use locally as a dressing and to control mild to moderate bleeding, each during the management of injured skin and the micro-environment of an acute surgical wound.

In practice, we envision that both products will be used in comparable wounds, including, in particular, acute or chronic wounds that require surgical intervention. Examples include, surgical excision of dead, contaminated, or damaged tissue, otherwise known as debridement, in chronic wounds; complicated wounds created during an acute surgical procedure; failed acute surgical wounds; wounds requiring wound bed preparation in advance of other procedures; wounds in need of an advanced dressing that incorporates an initial protective barrier function followed by a scaffolding or lattice function that enables healing.

We announced receipt of 510(k) premarket notification clearances for AC5 Advanced Wound System on December 17, 2018, providing marketing authorization, and on March 23, 2020, clearing use of an additional supplier and additional manufacturing processes. We announced receipt of the CE mark for AC5 Topical Hemostat on April 13, 2020.

The COVID-19 pandemic environment introduced new challenges related to product launch, marketing and sales, as clinicians and facilities are increasingly focused on managing resources, the disease, or its potential spread. We believe that these challenges have also highlighted some potential opportunities for our new technology to address certain poorly met needs. For instance, wound interventions are too often considered to be elective procedures instead of being treated essentially or emergently as National Pressure Ulcer Advisory Panel guidelines and others recommend, resulting in a projected increased risk to limb and life while elective procedures are delayed and not prioritized. Furthermore, the implications of these delays are a growing backlog of chronic wounds awaiting care and a worsening of such wounds, leading to greater morbidity, such as infection, necrosis, and amputation, and potentially mortality.

We expect our Dermal Sciences product commercialization to be gradual, initially, and moderately accelerate into new market channels. In addition to identifying and encouraging product use by key opinion leaders and early adopters, we will prioritize our focus on private and government facilities. VA Hospitals, for example, tend to have many patients whose needs we believe we can help address. We prioritized the launch of AC5 Advanced Wound System in the United States over that of AC5 Topical Hemostat in Europe to maximize operational efficiencies in light of the COVID-19 pandemic and have not yet determined when we will launch the product in Europe.

On December 13, 2021, we announced that in partnership with Lovell Government Services, our AC5 Advanced Wound System has been added to the Federal Supply Schedule and General Services Administration contracts and is approved for purchase by all federal government agencies, including the Department of VA, Indian Health Services, and Department of Defense Medical Treatment Facilities effective December 15, 2021.

On March 14, 2022, we announced the Company had entered into a distribution agreement with Centurion Therapeutics Inc. (**Centurion**), an exclusive strategic partner to the world's largest tissue bank, to expand sales opportunities for AC5 Advanced Wound System. Centurion distributes a comprehensive portfolio of aseptically processed human tissues to support surgeons in a broad array of specialties through over a hundred contracted wound care distributors nationwide. AC5 Advanced Wound System will be added to their advanced wound care product line as part of this distribution agreement.

We have engaged and continue to engage third parties in the United States and abroad to advise on and perform certain sales and marketing activities, typically with assistance from our team. These third parties can include contract organizations, consultants, advisors, scientists, clinicians, and/or other collaborators.

The COVID-19 Pandemic Impact on Commercialization

The COVID-19 pandemic environment introduced significant challenges related to product launch, marketing and sales, as clinicians and facilities became overburdened and increasingly focused on managing resources, the disease, and the virus spread. While the overall environment has improved, many negative effects linger. We have observed the following effects at different times, and anticipate that they will variously wax and wane over time:

- the volume of elective surgical procedures has been constrained periodically, with many institutions indefinitely suspending or eliminating such procedures at times;
- healthcare facilities often have been required to ration staff and resources, including ventilators, personal protective equipment (**PPE**), and operating rooms, thereby negatively impacting the focus on wound care;
- clinicians often have been required to divert their time and resources to urgent COVID-19 needs;
- clinicians often have been required to quarantine due to exposure to a COVID-19 positive individual or isolate because of contracting symptomatic or asymptomatic COVID-19 disease;
- some institutions have been periodically designated "COVID Hospitals";
- access to surgeons, potential strategic partners, and facilities outside of the United States has become curtailed;
- administrators who may be required to facilitate or approve new product intake are constrained by new and other pressing priorities; and
- both clinicians and patients often try to minimize possible COVID-19 exposure, resulting in reduced access to healthcare system and essential care treatments and services.

We believe that these challenges have also highlighted some potential opportunities for our new technology to address certain poorly met needs. For instance, wound interventions are too often considered to be elective procedures instead of being treated essentially or emergently as National Pressure Ulcer Advisory Panel guidelines and others recommend, resulting in a projected increased risk to limb and life while elective procedures are delayed and not prioritized. Furthermore, the implications of these delays are a growing backlog of chronic wounds awaiting care and a worsening of such wounds, leading to greater morbidity, such as infection, necrosis, and amputation, and potentially mortality.

While highlighted by the COVID-19 pandemic, we also believe that these challenges reveal an underlying problem in the healthcare system-clinicians and other providers are being asked to accomplish more in less time with fewer resources. These resources may include higher acuity settings, such as operating rooms; expensive wound care products that may not work as well as desired; nursing time to change wound dressings; and surgeon time for managing wounds during debridement; repeat patient visits over months and often years, and others. Our COVID-19 related discussions with surgeons, economic stakeholders and other decision-making personnel often include whether AC5 Advanced Wound System may enable them to accomplish more for their patients while deploying overall fewer resources and achieving desired outcomes.

Manufacturing

We work with contract manufacturing and related organizations, including those operating under cGMP, as is required by applicable regulatory agencies for production of product that can be used for preclinical and human testing as well as for commercial use. We also have engaged and continue to engage other third parties in the United States and abroad to advise on and perform certain manufacturing and related activities, typically with assistance from our team. These third parties include academic institutions, consultants, advisors, scientists, and/or other collaborators. The activities include development of our primary product candidates, as well as generation of appropriate analytical methods, scale-up, and other procedures for use by manufacturers and/or other members of our supply chain to produce or process our products at current and/or larger scale quantities for preclinical and clinical testing and ultimately, as required marketing authorizations are obtained, commercialization.

Our products are regulated as medical devices, and as such, many of our activities have focused on optimizing traditional parameters to target specifications, biocompatibility, physical appearance, stability, and handling characteristics, among other metrics, in order to achieve the desired product. We and our partners intend to continue to monitor manufacturing processes and formulation methods closely, as success or failure in establishing and maintaining appropriate specifications may directly impact our ability to conduct additional preclinical and clinical trials and/or deliver commercial product.

Merger with ABS and Related Activities

On June 26, 2013, the Company completed the Merger with ABS, pursuant to which ABS became a wholly owned subsidiary of the Company. In contemplation of the Merger, effective May 24, 2013, the Company increased its authorized shares of Common Stock from 375,000 shares to 1,500,000 shares and effected a forward stock split, by way of a stock dividend, of its issued and outstanding shares of Common Stock at a ratio of 11 shares to each one issued and outstanding share. Also, in contemplation of the Merger, effective June 5, 2013, the Company changed its name from Almah, Inc. to Arch Therapeutics, Inc. and changed the ticker symbol under which our Common Stock trades on the OTC Bulletin Board from “AACH” to “ARTH”.

Recent Events

On July 18, 2023, the board of directors of the Company (the “**Board**”) adopted resolutions by unanimous written consent, pursuant to which the Board determined that it is advisable and in the best interests of the Company to amend the Certificate of Incorporation of the Company (the “**Amendment**”) to (i) increase the total number of authorized shares of Common Stock from 12,000,000 to 350,000,000 (the “**Authorized Share Increase**”), (ii) authorize 5,000,000 shares of “blank check” preferred stock of the Company, thereby giving the Board the authority to designate from time to time one or more series of preferred stock (the “**Blank Check Preferred**”), and (iii) provide for a reverse stock split of the outstanding Common Stock, at a ratio within a range of 1.5-for-1 to 20-for-1, with the exact ratio to be determined by the Board subsequent to the applicable approval by the Company’s stockholders, within 1 year following the date of such approval, and without correspondingly decreasing the number of authorized shares of Common Stock (the “**Reverse Split**” and, together with the Authorized Share Increase and the Blank Check Preferred, the “**Charter Amendments**”). On August 22, 2023, stockholders representing a majority of the voting power of the then outstanding shares of voting stock of the Company (the “**Majority Stockholders**”) executed a written consent approving the Charter Amendments and the Company filed a preliminary Information Statement with the SEC with respect to the transactions contemplated hereby. The Company filed a definitive Information Statement with the SEC and mailed the definitive Information Statement to the Company’s stockholders notifying them of the action taken by written consent on September 1, 2023. Accordingly, the Company filed the Amendment with respect to the Authorized Share Increase and the Blank Check Preferred with the Secretary of State of Nevada on September 21, 2023. The Company intends to effect the Reverse Split prior to the pricing of this offering.

Reverse Stock Split

On January 17, 2023, the Company effected a prior reserve stock split (the “**Prior Reverse Stock Split**”) of the Common Stock at a ratio of 1-for-200. As a result of the Prior Reverse Stock Split, every two hundred (200) shares of Common Stock issued and outstanding were combined into one (1) share of Common Stock, with a proportionate 1:200 reduction in the Company’s authorized Common Stock. The Prior Reverse Stock Split affected all stockholders uniformly and did not alter any stockholder’s percentage interest in the Company’s equity, except to the extent that the Prior Reverse Stock Split would have resulted in some stockholders owning a fractional share. No fractional shares were issued in connection with the Prior Reverse Stock Split. Any fractional shares of Common Stock resulting from the Prior Reverse Stock Split were rounded up to the nearest whole post-Prior Reverse Stock Split share and no stockholders received cash in lieu of fractional shares. The Prior Reverse Stock Split did not change the par value of the Common Stock. All outstanding securities entitling their holders to purchase shares of Common Stock or acquire shares of Common Stock, including stock options, restricted stock units, and warrants, were adjusted as a result of the Prior Reverse Stock Split, as required by the terms of those securities. The Prior Reserve Stock Split was approved by the Company’s stockholders on September 29, 2022.

On January 13, 2023, the Company filed a Certificate of Amendment (the “**Certificate of Amendment**”) to the Company’s Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Nevada to increase the number of authorized shares of Common stock from 4,000,000 shares to 12,000,000 shares. The increase in the number of authorized shares was approved by the Company’s stockholders on September 29, 2022.

Bridge Offering

Between July 7, 2023 and September 11, 2023, pursuant to a Securities Purchase Agreement dated July 7, 2023, as subsequently amended (the “**Bridge SPA**”), among the Company and certain institutional and accredited individual investors (collectively, the “**Bridge Investors**”) the Company issued and sold to the Bridge Investors an aggregate of (i) 3,344,321 shares (the “**Bridge Shares**”) of Common Stock; (ii) warrants (the “**Bridge Pre-Funded Warrants**”) to purchase an aggregate of 6,054,942 shares of Common Stock (the “**Bridge Pre-Funded Warrant Shares**”); and (iii) warrants (the “**Common Warrants**”) and together with the Bridge Pre-Funded Warrants, the “**Bridge Warrants**”) to purchase an aggregate 18,798,526 shares of Common Stock (the “**Common Warrant Shares**” and together with the Bridge Pre-Funded Warrant Share, the “**Bridge Warrant Shares**”), at a purchase price of \$0.275 per Bridge Share and accompanying Common Warrant to purchase two shares of Common Stock, and \$0.274 per Bridge Pre-Funded Warrant to purchase one share of Common Stock and accompanying Common Warrant to purchase two shares of Common Stock. The Shares, Bridge Pre-Funded Warrants, and Common Warrants were issued as part of a private placement offering authorized by the Company’s board of directors (the “**Bridge Offering**”).

Pursuant to the lock-up agreement provided for by the Bridge SPA, the Bridge Investors agreed that they would either (A) purchase securities, for cash, in an offering conducted in conjunction with an uplist of the Common Stock to any of, and in compliance with the rules of, the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (the “**Uplist Transaction**”), which this offering is intended to be, with an aggregate purchase price equal to at least 4.3 multiplied by the aggregate purchase price paid by the Bridge Investor for the Bridge Shares and Bridge Warrants under the Bridge SPA or (B) be subject to a lock-up provision not to sell or otherwise transfer any of the Bridge Shares or Bridge Warrant Shares acquired by them in the Bridge Offering until the one-year anniversary of the Bridge Closing Date (as defined below). The aggregate gross proceeds for the sale of the Bridge Shares, Bridge Pre-Funded Warrants, and Common Warrants was approximately \$2.6 million, before deducting the placement agent’s fees and other estimated fees and offering expenses payable by the Company. The first closing of the sales of these securities under the Bridge SPA occurred on July 7, 2023 (the “**Bridge Closing Date**”).

Under the Bridge SPA, the Company also agreed that upon the closing of the next underwritten public offering of Common Stock (a “**Qualifying Offering**”), if the effective offering price to the public per share of Common Stock (the “**Qualifying Offering Price**”) is lower than the \$4.00 per share, then the Company shall issue additional Bridge Pre-Funded Warrants in an amount reflecting a reduction in the purchase price paid for the Bridge Shares and Bridge Pre-Funded Warrants that equals the proportion by which the Qualifying Offering Price is less than the \$4.00.

The Company retained Dawson James Securities, Inc. (“**DJ**”) as placement agent in connection with the Bridge Offering. The Company paid DJ a cash fee equal to 8.0% of the aggregate gross proceeds of the Bridge Offering and reimbursement of expenses of \$50,000. Additionally, on September 7, 2023 the Company issued to DJ, or its designees, warrants (the “**Placement Agent Warrants**”) to purchase an aggregate of 441,938 shares of Common Stock. The Placement Agent Warrants are exercisable at any time and from time to time, in whole or in part, during the five-year period commencing March 7, 2024, at a price per share equal to \$0.275.

Bridge Pre-Funded Warrants

The Bridge Pre-Funded Warrants (i) have a nominal exercise price of \$0.001 per share; (ii) are exercisable after the earlier of (A) the six-month anniversary after the date of issuance, (B) 120 days after the closing date of an Uplist Transaction, and (C) the date that a registration statement registering the Bridge Pre-Funded Warrant Shares is declared effective; (iii) are exercisable until all of the Bridge Pre-Funded Warrants are exercised in full; and (iv) have a provision preventing the exercisability of such Bridge Pre-Funded Warrants if, as a result of the exercise of the Bridge Pre-Funded Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder's, would be deemed to beneficially own more than either 4.99% or 9.99% of the Common Stock (the "**Ownership Limitation**") immediately after giving effect to the exercise of the Bridge Pre-Funded Warrants.

Common Warrants

The Common Warrants (i) have an exercise price of \$1.00 per share; (ii) have a term of exercise equal to 5 years after their issuance date; (iii) are exercisable after the earlier of (A) the six-month anniversary after the date of issuance and (B) the date that a registration statement registering the Common Warrant Shares is declared effective; (iv) have a provision permitting voluntary adjustments to the exercise price by the Company, subject to the prior written consent of the Common Warrant holder; (v) are automatically exchanged upon the closing of an Uplist Transaction for a new warrant that is identical to the warrants (other than any pre-funded warrants), if any, being issued to investors in such Uplist Transaction, with the number of shares underlying such new warrant being equal to the number of Common Warrant Shares then underlying the Common Warrant multiplied by three and (vi) have a provision preventing the exercisability of such Common Warrants if, as a result of the exercise of the Common Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Company Common Stock would be aggregated with the holder's, would be deemed to beneficially own more than the Ownership Limitation immediately after giving effect to the exercise of the Common Warrants. **Accordingly, at the closing of this offering, the Common Warrants will be cancelled and exchanged for newly issued warrants identical to the Investor Warrants to purchase an aggregate of 56,395,578 shares of Common Stock at an exercise price per share equal to the exercise price per share of the Investor Warrants (the "Exchange Investor Warrants").**

Registration Rights Agreement

The Company also entered into a registration rights agreement with the Bridge Investors dated July 7, 2023, as subsequently amended (the "**Registration Rights Agreement**"), pursuant to which the Company is obligated, subject to certain conditions, to file with the Securities and Exchange Commission within the earlier of (i) 30 days following the closing date of the Uplist Transaction and (ii) October 31, 2023 one or more registration statements (any such registration statement, a "**Resale Registration Statement**") to register the Shares, the Bridge Warrant Shares, the shares of Common Stock issuable upon exercise in full of the Exchange Investor Warrants (the "**Exchange Investor Warrant Shares**") and the shares of Common Stock issuable upon exercise in full of the Participating Pre-Funded Warrant (as defined below) (the "**Conversion Warrant Shares**") for resale under the Securities Act of 1933, as amended (the "**Securities Act**"). The Company's failure to satisfy certain filing and effectiveness deadlines with respect to a Resale Registration Statement and certain other requirements set forth in the Registration Rights Agreement may subject the Company to payment of monetary penalties.

Note Modification Agreements

On July 7, 2023, the Company entered into an amendment ("**Amendment No. 8 to the First Notes**") with the holders of the Company's outstanding Senior Secured Convertible Promissory Notes, as separately amended on February 14, 2023, March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 31, 2023, August 30, 2023 and September 30, 2023 (as amended, the "**First Notes**"), issued in connection with a private placement financing the Company completed on July 6, 2022 (the "**First Closing**"). On July 7, 2023, the Company also entered into an amendment ("**Amendment No. 8 to the Second Notes**") with the holders of the Company's outstanding Unsecured Convertible Promissory Notes, as separately amended on February 14, 2023, March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 31, 2023, August 30, 2023 and September 30, 2023 (as amended, the "**Second Notes**"), issued in connection with a private placement financing the Company completed on January 18, 2023 (the "**Second Closing**"). On July 7, 2023, the Company also entered into an amendment ("**Amendment No. 3 to the Third Notes**") and, together with Amendment No. 8 to the First Notes and Amendment No. 8 to the Second Notes, the "**Amendments to the 2022 Notes**") with the holders of the Company's outstanding Unsecured Convertible Promissory Notes, as separately amended on June 15, 2023, July 1, 2023, July 31, 2023, August 30, 2023 and September 30, 2023 (as amended, the "**Third Notes**" and, together with the First Notes and Second Notes, the "**2022 Notes**"), issued in connection with a private placement financing the Company completed on May 15, 2023 (the "**Third Closing**").

Under the Amendments to the 2022 Notes, the following amendments to the 2022 Notes will be simultaneously effective upon the closing of the Uplist Transaction. The Specified Percentage (as defined below) of the then outstanding principal amount of the 2022 Notes shall automatically convert (the “**Automatic Conversion**”) into shares of Common Stock, with the conversion price for purposes of such Automatic Conversion being equal to the lower of (i) the per unit price at which any units (each unit being comprised of one share or share equivalent and accompanying warrants, if any) are sold in the Uplist Transaction or (ii) the price at which warrants issued in the Uplist Transaction are exercisable (but in no event increased above the conversion price in effect immediately prior to the pricing of the Uplist Transaction).

In addition, if the Holder (as defined below) (i) participates in the Uplist Transaction and in the Bridge Offering for a combined (taking into account the Holder’s aggregate investment in the Uplist Transaction and the Bridge Offering) amount equal to no less than fifty percent (50%) of the Holder’s original purchase price under the 2022 Notes and (ii) the Holder’s amount of participation in the Uplist Transaction is at least 4.3 times the Holder’s amount of participation in the Bridge Offering (such criteria in clauses (i) and (ii) above, the “**Participation Criteria**”), then the Holder shall receive a pre-funded warrant (the “**Participating Pre-Funded Warrant**”) to purchase a number of shares of Common Stock equal to the Specified Number (as defined below) times the dollar amount under the 2022 Notes that was converted in the Automatic Conversion. The Participating Pre-Funded Warrant (i) shall have an exercise price of \$0.001 per share, (ii) may be exercised on a cashless basis, (iii) shall be exercisable by the Holder at any time commencing on the 90th day after issuance, (iv) may be redeemed by the Company for cash at a redemption price of \$0.82 per share underlying the Participating Pre-Funded Warrant, with any such redemption made pro rata to all holders of the Participating Pre-Funded Warrants, (v) and shall contain a customary beneficial ownership limitation provision. Additionally, the holder of the Participating Pre-funded Warrants will agree that, until January 6, 2024, it shall not offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of, or announce the intention to otherwise dispose of, the Participating Pre-Funded Warrant.

“Specified Percentage” means the greater of: (i) the percentage specified by the Company by notice to the 2022 Note holders (the “**Holders**” and each a “**Holder**”) at least five business days prior to the closing of the Uplist Transaction, which percentage shall be the percentage necessary to ensure the applicable Nasdaq requirements regarding the Uplist Transaction are satisfied, and (ii) the percentage specified by the Holder by notice to the Company at least three business days prior to the closing of the Uplist Transaction (which percentage may be different for each 2022 Note as determined by each Holder thereof); provided, that in no event shall the Specified Percentage for the 2022 Notes (A) exceed twenty five percent (25%) unless otherwise agreed in writing by the Holder, or (B) exceed fifty percent (50%) unless otherwise agreed in writing by the Company.

“Specified Number” means, if the Specified Percentage is 50%, 2.4, which number shall be increased by 1.6% for each percentage point decrease in the Specified Percentage, such increase being compounded iteratively for each percentage point decrease in the Specified Percentage, with the result rounded to two decimal places.

Further, on September 30, 2023, the Company entered into an amendment (“**Amendment No. 11 to the First Notes**”) to the First Notes, an amendment (“**Amendment No. 11 to the Second Notes**”) to the Second Notes and an amendment (“**Amendment No. 6 to the Third Notes**” and, together with Amendment No. 11 to the First Notes and Amendment No. 11 to the Second Notes, the “**September Amendments to the 2022 Notes**”) to the Third Notes. The September Amendments to the 2022 Notes extend the deadline by which the Company must close the Uplist Transaction to October 31, 2023 and provide that upon the Automatic Conversion and to the extent that a Holder’s beneficial ownership would increase over the applicable Ownership Limitation, the Holder will receive pre-funded warrants (the “**2022 Note Conversion Pre-Funded Warrants**”) in lieu of shares of Common Stock otherwise issuable to the Holder in connection with the Automatic Conversion, which 2022 Note Conversion Pre-Funded Warrants shall have an exercise price of \$0.001 per share, may be exercised on a cashless basis, shall be exercisable immediately upon issuance and shall contain a customary beneficial ownership limitation provision.

Accordingly, it is currently anticipated that the Specified Percentage will be 50%, and thus, at the closing of this offering: (i) an aggregate of 1,567,127 shares of Common Stock (assuming no issuance of 2022 Note Conversion Pre-Funded Warrants) will be issued upon the Automatic Conversion of an aggregate of \$3,134,250 of principal amount under the 2022 Notes, representing 50% of the \$6,268,501 in principal amount currently outstanding under the 2022 Notes, based on the assumed offering price of \$2.00 per Unit in this offering; and (ii) assuming that all Holders fulfill the Participation Criteria, the Holders will be issued Participating Pre-Funded Warrants to purchase an aggregate of 7,522,203 shares of Common Stock, based on a Specified Number of 2.4 multiplied by the \$3,134,250 of principal amount converted in the Automatic Conversion.

Additionally, on July 7, 2023, the Company entered into an amendment (the “**Omnibus Amendment to Notes and Warrants**”) with the Holders of the 2022 Notes, amending the 2022 Notes and related warrants issued at each of the First Closing, Second Closing, and Third Closing (the “**First Warrants**”, “**Second Warrants**” and “**Third Warrants**”, respectively, and collectively, the “**2022 Warrants**”). Under the Omnibus Amendment to Notes and Warrants, the 2022 Notes and 2022 Warrants were amended (i) to modify the Most Favored Nation provisions therein to exclude the Bridge Offering and (ii) to prohibit the Company from engaging in any capital raising transactions, subject to certain exceptions, until the earlier of (A) July 7, 2027, and (B) the first date on which all Holders hold less than 20% of the original amount of the Participating Pre-Funded Warrants received by each Holder, respectively, in connection with the Automatic Conversion.

2022 Notes

The 2022 Notes bear interest on the unpaid principal balance at a rate equal to ten percent (10%) (computed on the basis of the actual number of days elapsed in a 360-day year) per annum accruing from the issuance date until the 2022 Notes become due and payable at maturity or upon their conversion, acceleration or by prepayment, and may become due and payable upon the occurrence of an event of default under the 2022 Notes. The 2022 Notes mature January 6, 2024. Any amount of principal or interest on the 2022 Notes which is not paid when due shall bear interest at the rate of the lesser of (i) eighteen percent (18%) per annum or (ii) the maximum amount allowed by law from the due date thereof until payment in full. As of September 15, 2023, the outstanding unpaid principal balance including all accrued interest under the 2022 Notes totaled \$6,935,071.

The 2022 Notes are convertible into shares of Common Stock at the option of each Holder from the date of issuance at \$9.14 (the “**Conversion Price**”), subject to adjustment, through the later of (i) January 6, 2024 (the “**Maturity Date**”) or (ii) the date of payment of the Default Amount (as defined in the 2022 Notes).

The 2022 Notes contain events of default, which include, among other things, (i) the Company’s failure to pay when due any principal or interest payment under the 2022 Notes; and (ii) our failure to complete an Uplist Transaction by October 31, 2023.

The 2022 Warrants (i) have an exercise price of \$9.94 per share; (ii) have a term of exercise equal to 5 years after their issuance date; (iii) became exercisable immediately after their issuance; and (iv) have a provision preventing the exercisability of such 2022 Warrants if, as a result of the exercise of the 2022 Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of our Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than the Ownership Limitation. As long as the 2022 Notes and 2022 Warrants remaining outstanding, upon the issuance of any security in connection with any potential future financing activity on terms more favorable than the existing terms, except for any offering conducted in connection with the Uplist Transaction which this offering is intended to be, the Company has an obligation to notify the holders of the 2022 Notes and 2022 Warrants of such more favorable terms, and to use best efforts to effect such terms in the 2022 Notes and 2022 Warrants.

Under the Second Amended and Restated Registration Rights Agreement, dated as of May 15, 2023, as amended, the Company is required to file a registration statement registering the securities issued in the Second Closing and Third Closing, including the applicable 2022 Notes and 2022 Warrants, no later than 45 days following the closing of the Uplist Transaction.

As discussed above, it is currently anticipated that 50% of the of the \$6,268,501 unpaid principal balance currently outstanding under the 2022 Notes will convert into 1,567,127 shares of Common Stock (assuming no issuance of 2022 Note Conversion Pre-Funded Warrants) in connection with the Automatic Conversion.

Series 1 and 2 Convertible Notes

On June 4, 2020 and November 6, 2020, the Company issued unsecured 10% Series 1 Convertible Notes (“**Series 1 Notes**”) and Series 2 Convertible Notes, as amended (“**Series 2 Notes**”, and collectively with the Series 1 Notes, the “**Series Convertible Notes**”). The maturity dates of the Series 1 Notes and Series 2 Notes are June 30, 2023 and November 30, 2023, respectively. On July 12, 2023, the Company secured countersigned notices of conversion from all remaining holders of the Series 1 Convertible Notes and provided instructions to its transfer agent to issue a total of 59,912 shares of Common Stock in full satisfaction of all previously outstanding Series 1 Convertible Notes, which had an aggregate of \$718,918 of principal and interest outstanding at the time of conversion.

As of September 15, 2023, there was \$587,959 of principal and accrued interest (through maturity) outstanding under the Series 2 Notes. The Series 2 Notes have a “Conversion Price” of \$50.00 and allow the Company to convert all obligations thereunder upon the Uplist Transaction, or the maturity date, using the Conversion Price and multiplying the obligations then outstanding by 4.5. **Accordingly, it is currently anticipated that an aggregate of 52,917 shares of Common Stock will be issued at the closing of this offering upon the conversion of the remaining outstanding amount under the Series 2 Notes.**

Insurance Financing

On July 11, 2023, the Company entered into a finance agreement with First Insurance Funding in order to fund a portion of its insurance policies. The amount financed is approximately \$310,000 and incurs interest at a rate of 7.49%. Per the terms of its agreement with First Insurance Funding, the Company is required to make monthly payments of approximately \$32,000 through April 2024.

Warrant Exchange Agreement

On March 10, 2023, the Company entered into exchange agreements (the “**Exchange Agreements**”) with each holder (the “**Warrantholders**”) of the Company’s outstanding Series G Warrants to purchase shares of the Company’s Common Stock at an exercise price of \$140.00 per share and the Company’s outstanding Series H Warrants to purchase shares of Common Stock at an exercise price of \$80.00 per share. Pursuant to the Exchange Agreements, the Warrantholders exchanged 34,013 Series G Warrants for 3,402 shares of Common Stock and 43,077 Series H Warrants for 8,617 shares of Common Stock.

Reimbursements and Support Program

During the month of September 2022, the Company launched and announced a reimbursement support program designed to help drive increased commercial use of the company’s FDA-approved AC5 Advanced Wound System. During the fiscal year ended September 30, 2022, the Company invoiced and shipped a total of 33 units, of which 23 units were shipped in connection with the launch of the Company’s reimbursement support program. Under the terms of the program, the invoice amount may be adjusted through full or partial write-offs based on actual reimbursement amounts paid by CMS for AC5 units applied and billed by doctors. As such, revenue, if any, for the units shipped in connection with the Company’s reimbursement support program will be booked in future periods when all conditions have been satisfied.

Results of Operations

The following discussion of our results of operations should be read together with the consolidated financial statements included in this prospectus and the notes thereto. Our historical results of operations and the period-to-period comparisons of our results of operations that follow are not necessarily indicative of future results.

Nine Months Ended June 30, 2023 Compared to Nine Months Ended June 30, 2022

	June 30, 2023 (\$)	June 30, 2022 (\$)	Increase (Decrease) (\$)
Revenue	36,207	14,086	22,121
Operating Expense:			
Cost of revenues	54,882	51,363	3,519
Selling, general and administrative	3,225,753	3,308,227	(82,474)
Research and development	471,135	922,120	(450,985)
Loss from Operations	(3,715,563)	(4,267,624)	(552,061)
Other (Expense) Income	(810,077)	880,329	1,690,406
Net loss	(4,525,640)	(3,387,295)	(1,138,345)

Revenue

Revenue for the nine months ended June 30, 2023 was \$36,207, an increase of \$22,121 compared to revenue of \$14,086 for the nine months ended June 30, 2022. Revenue for the nine months ended June 30, 2023 and 2022 was primarily the result of transactions into VA Hospitals through our distribution partner, LGS.

Cost of Revenue

Cost of revenue during the nine months ended June 30, 2023 was \$54,882 an increase of \$3,519 compared to cost of revenue of \$51,363 for the nine months ended June 30, 2022. Cost of revenue includes product costs, third party warehousing, overhead allocation, royalty and shipping costs.

Selling, General and Administrative Expense

Selling, general and administrative expense during the nine months ended June 30, 2023 was \$3,225,753, a decrease of \$82,474 compared to \$3,308,227 for the nine months ended June 30, 2022. The decrease in selling, general and administrative expense for the nine months ended June 30, 2023 is primarily attributable to a decrease in compensation costs attributed to a reduction in headcount partially offset by an increase in legal and consulting costs.

Research and Development Expense

Research and development expense during the nine months ended June 30, 2023 was \$471,135 a decrease of \$450,985 compared to \$922,120 for the nine months ended June 30, 2022. The decrease in research and development expense is primarily attributable to a decrease in compensation costs attributed to a reduction in headcount.

Other (Expense) Income

Other expense during the nine months ended June 30, 2023 was \$810,077 an increase of \$1,690,406 compared to other income of \$880,329 for the nine months ended June 30, 2022. The increase in other (expense) income is primarily attributed to an increase in interest expense related to the 2022 Notes, Second Notes and Third Notes offset by a gain for the extinguishment of the Series G warrants and Series H warrants derivative liabilities during the nine months ended June 30, 2023 and the impact of the expiration of the Series F warrants during the nine months ended June 30, 2022.

Year Ended September 30, 2022 Compared to Year Ended September 30, 2021

	September 30, 2022	September 30, 2021	Increase (Decrease)
	(\$)	(\$)	(\$)
Revenue	15,652	11,565	4,087
Operating Expenses			
Cost of revenues	51,489	26,282	25,207
Selling, general and administrative	4,519,636	5,009,323	(489,687)
Research and development	1,153,333	1,353,084	(199,751)
Loss from Operations	(5,708,806)	(6,377,124)	668,318
Other income	432,952	136,642	296,310
Net loss	(5,275,854)	(6,240,482)	964,628

Revenue

Revenue for the year ended September 30, 2022 was \$15,652, an increase of \$4,087 compared to \$11,565 for the year ended September 30, 2021. Revenue for the year ended September 30, 2022 was the result of four transactions into multiple VA Hospitals consisting of ten (10) total units through our distribution partner, LGS. Revenue for the year ended September 30, 2021 was \$11,565, which was the result of a single transaction with an established key opinion leader and a single transaction into the Veterans Administration of one (1) unit through our distribution partner, LGS.

Cost of revenues

Cost of revenues during the year ended September 30, 2022 was \$51,489, an increase of \$25,207 compared to \$26,282 for the year ended September 30, 2021. Cost of revenue includes product costs, third party warehousing, overhead allocation, royalty and shipping costs.

Selling, General and Administrative Expense

General and administrative expense during the year ended September 30, 2022 were \$4,519,636 a decrease of \$489,687 compared to \$5,009,323 for the year ended September 30, 2021. The decrease in selling, general and administrative expense for the year ended September 30, 2022 is primarily attributable to decrease in legal and consulting costs partially offset by an increase in compensation costs attributed to an increase in headcount.

Research and Development Expense

Research and development expense during the year ended September 30, 2022 was \$1,153,333, a decrease of \$199,751 compared to \$1,353,084 for the year ended September 30, 2021. The decrease in research and development expense is primarily attributable to a decrease in compensation costs, partially offset by an inventory obsolescence charge of approximately \$248,000 for shelf-life, research and development and product samples.

Other Income

Other income during the year ended September 30, 2022 was \$432,952, an increase of \$296,310 compared to total other income of \$136,642 for the year ended September 30, 2021. The increase in other income is attributable to a change in fair market value of the derivative liabilities partially offset by an increase in interest expense and the gain on the forgiveness of PPP loan recorded in the year ended September 30, 2021.

Liquidity and Capital Resources

In the first quarter of 2021, the Company commenced commercial sales of our first product, AC5 Advanced Wound System. We devote a significant amount of our efforts on fundraising as well as planning and conducting product research and development and activities in connection with obtaining regulatory marketing authorization. We have principally raised capital through borrowings and the issuance of convertible debt and units consisting of Common Stock and warrants to fund our operations.

Working Capital

At June 30, 2023, we had total current assets of \$1,560,018 (including cash of \$86,542) and working capital deficit of \$8,019,256. Our working capital as of June 30, 2023 and September 30, 2022 are summarized as follows:

	June 30, 2023	September 30, 2022
Total Current Assets	\$ 1,560,018	\$ 2,598,195
Total Current Liabilities	9,579,274	3,320,494
Working Capital deficit	<u>\$ (8,019,256)</u>	<u>\$ (722,299)</u>

Total current assets as of June 30, 2023 were \$1,560,018, a decrease of \$1,038,177 compared to \$2,598,195 as of September 30, 2022. The decrease in current assets is primarily attributable to a decrease in cash and prepaid expenses. Our total current assets as of June 30, 2023 and September 30, 2022 were comprised primarily of cash, inventory and prepaid expenses and other current assets.

Total current liabilities as of June 30, 2023 were \$9,579,274, an increase of \$6,258,780 compared to \$3,320,494 as of September 30, 2022. The increase is primarily due to an increase in accounts payable, the current portion of the Series 2 Convertible Notes, the current portion of the 2022 Notes, current portion of the Unsecured convertible notes, which includes both the Second Notes, the Third Notes and the Exchanged Notes, Shareholder and Third Party advances related to bridge financing and the accrued interest associated with these notes partially offset by a decrease to the amount owed in connection with the financing of certain insurance premiums and the decrease in the fair value of the derivative liability resulting from the exchange of the Series G warrants into Common Stock.

At September 30, 2022, we had total current assets of \$2,598,195 (including cash of \$746,940) and negative working capital of \$722,299. Our working capital as of September 30, 2022 and September 30, 2021 is summarized as follows:

	September 30, 2022	September 30, 2021
Total Current Assets	\$ 2,598,195	\$ 3,667,745
Total Current Liabilities	3,320,494	1,727,547
Working Capital	<u>\$ (722,299)</u>	<u>\$ 1,940,198</u>

Total current assets as of September 30, 2022 were \$2,598,195, a decrease of \$1,069,550 compared to \$3,667,745 as of September 30, 2021. The decrease in current assets is primarily attributable to selling, general and administrative expense and research and development expense incurred in connection with activities to develop our primary product candidate, which was partially offset by our net proceeds from our 2022 Private Placement Financing. Our total current assets as of September 2022 and 2021 were comprised primarily of cash, inventory and prepaid expense.

Total current liabilities as of September 30, 2022 were \$3,320,494, an increase of \$1,592,947 compared to \$1,727,547 as of September 30, 2021. The increase is primarily due to an increase in accounts payable, current portion of the Series 1 Convertible Notes, current portion of the Series 1 accrued interest and the amount owed in connection with the financing of certain insurance premiums and the current portion of the derivative liability.

Cash Flow for the Nine Months Ended June 30, 2023 Compared to the Nine Months Ended June 30, 2022

	June 30, 2023	June 30, 2022
Cash Used in Operating Activities	\$ (2,147,480)	\$ (2,786,642)
Cash Provided by Financing Activities	1,487,082	575,000
Net decrease in Cash	<u>\$ (660,398)</u>	<u>\$ (2,211,642)</u>

Cash Used in Operating Activities

Cash used in operating activities decreased by \$639,162 to \$2,147,480 during the nine months ended June 30, 2023, compared to \$2,786,642 during the nine months ended June 30, 2022. The decrease in cash used in operating activities is primarily attributable the Company managing expenses and an increase in accounts payable and accrued interest.

Cash Used in Financing Activities

Cash provided by financing activities increased by \$912,082 to \$1,487,082 during the nine months ended June 30, 2023, compared to \$575,000 cash provided by financing activities during the nine months ended June 30, 2022. For the nine months ended June 30, 2023, the cash provided by financing activities was attributable to the Second Closing of the 2022 Convertible Note Offering, the Third Closing of the 2022 Convertible Note Offering and shareholder advances, which was partially offset by payments made in connection with the financing of certain insurance premiums. For the nine months ended June 30, 2022, the cash provided by financing activities resulted from net proceeds of \$575,000 raised from the advances from investors.

Cash Flow for the Year Ended September 30, 2022 Compared to the Year Ended September 30, 2021

	September 30, 2022	September 30, 2021
Cash Used in Operating Activities	\$ (4,456,075)	\$ (5,958,628)
Cash Used in Investing Activities	-	(3,275)
Cash Provided by Financing Activities	2,936,376	7,269,233
Net Increase (decrease) in Cash	\$ (1,519,699)	\$ 1,307,330

Cash Used in Operating Activities

Cash used in operating activities decreased \$1,502,553 to \$4,456,075 during the fiscal year ended September 30, 2022 compared to \$5,958,628 for the fiscal year ended September 30, 2021. The decrease in cash used in operating activities is primarily attributable to an increase in accounts payable, primarily attributable to increased legal fees, product costs and consulting fees, and accrued interest, which was partially offset by an increase in inventory.

Cash Used in Investing Activities

Cash used in investing activities decreased \$3,275 to \$0 during the fiscal year ended September 30, 2022, compared to \$3,275 during the fiscal year ended September 30, 2021. For the fiscal year ended September 30, 2021, cash used in investing activities is attributed to computer hardware purchases.

Cash Provided by Financing Activities

Cash provided by financing activities decreased \$4,332,857, to \$2,936,376 during the fiscal year ended September 30, 2022, compared to \$7,269,233 the fiscal year ended September 30, 2021. For the year ended September 30, 2022, the cash provided by financing activities resulted from net proceeds of \$2,969,586 raised from the issuance of senior secured convertible notes, warrants and inducement shares partially offset by repayment of financed insurance premium. For the year ended September 30, 2021, the cash provided by financing activities resulted from net proceeds of \$6,219,233 raised from issuance of Common Stock and warrants in the 2021 Financing and \$1,050,000 from the issuance of Series 2 Convertible Notes.

Cash Requirements

We anticipate that our operating expenses, interest expense and other expenses will increase significantly as we continue to implement our business plan and pursue our operational goals. Depending upon additional input from EU and US regulatory authorities, however, we do not expect to generate sufficient revenues from operations before we will need to raise additional capital. Further, our estimates regarding our use of cash could change if we encounter unanticipated difficulties or other issues arise, including without limitation those set forth under the heading “**Risk Factors**” in this prospectus in which case our current funds may not be sufficient to operate our business for the period we expect.

In the first quarter of 2021, the Company commenced commercial sales of our first product, AC5 Advanced Wound System. That revenue will not be sufficient to fund our business operations and we will need to obtain additional funding from external sources for the foreseeable future. We do not have any commitments for future capital. Significant additional financing will be required to fund our planned operations in the near term and in future periods, including research and development activities relating to our potential new product candidates, seeking regulatory approval of any other product candidates we may choose to develop, commercializing any product candidates for which we are able to obtain regulatory approval or certification, seeking to license or acquire new assets or businesses, and maintaining our intellectual property rights and pursuing rights to new technologies. We may not be able to obtain additional financing on commercially reasonable or acceptable terms when needed, or at all. If we cannot raise the money that we need in order to continue to develop our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations. If any of these were to occur, there is a substantial risk that our business would fail, and our stockholders could lose all of their investments.

As previously noted, since inception we have funded our operations primarily through equity and debt financings and we expect to continue to seek to do so in the future. If we obtain additional financing by issuing equity securities, our existing stockholders' ownership will be diluted. Additionally, the terms of securities we may issue in future capital-raising transactions may be more favorable for our new investors, and in particular may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have additional dilutive effects. If we obtain additional financing by incurring debt, we may become subject to significant limitations and restrictions on our operations pursuant to the terms of any loan or credit agreement governing the debt. Further, obtaining any loan, assuming a loan would be available when needed on acceptable terms, would increase our liabilities and future cash commitments. We may also seek funding from collaboration or licensing arrangements in the future, which may require that we relinquish potentially valuable rights to our product candidates or proprietary technologies or grant licenses on terms that are not favorable to us. Moreover, regardless of the manner in which we seek to raise capital, we may incur substantial costs in those pursuits, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other related costs. In addition, we are bound by certain contractual terms and obligations that may limit or otherwise impact our ability to raise additional funding in the near-term including, but not limited to, provisions in the Bridge SPA and 2022 Notes SPA, associated with the 2022 Notes Financing, in each case as described in greater detail in the risk factor entitled "***The terms of the Bridge Offering and 2022 Notes Financing could impose additional challenges on our ability to raise funding in the future***" under the heading "**Risk Factors**" in this prospectus.

Going Concern

We have commenced commercial sales of our first product, AC5 Advanced Wound System. From inception, we have had recurring losses from operations. The continuation of our business as a going concern is dependent upon raising additional capital and eventually attaining and maintaining profitable operations. As of June 30, 2023, there is substantial doubt about the Company's ability to continue as a going concern. The financial statements included in this prospectus do not include any adjustments that might be necessary should operations discontinue.

Critical Accounting Policies and Significant Judgments and Estimates

Pursuant to certain disclosure guidance issued by the SEC, the SEC defines "critical accounting policies" as those that require the application of management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. We do not believe the company has any accounts or circumstances that carry a significant level of estimation uncertainty. Our critical accounting policies that we anticipate will require the application of our most difficult, subjective or complex judgments are as follows:

Derivative Liabilities

The Company accounts for its warrants and other derivative financial instruments as either equity or liabilities based upon the characteristics and provisions of each instrument, in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 815, *Derivatives and Hedging*. Warrants classified as equity are recorded at fair value as of the date of issuance on the Company's consolidated balance sheets and no further adjustments to their valuation are made. Warrants classified as derivative liabilities and other derivative financial instruments that require separate accounting as liabilities are recorded on the Company's consolidated balance sheets at their fair value on the date of issuance and will be revalued on each subsequent balance sheet date until such instruments are exercised or expire, with any changes in the fair value between reporting periods recorded as other income or expense. Management estimates the fair value of these liabilities using option pricing models and assumptions that are based on the individual characteristics of the warrants or instruments on the valuation date, as well as assumptions for future financings, expected volatility, expected life, yield, and risk-free interest rate.

Inventories

Inventories are stated at the lower of cost or net realizable value. The cost of inventories comprises expenditures incurred in acquiring the inventories, the cost of conversion and other costs incurred in bringing them to their existing location and condition. The cost of raw materials, work-in-progress and finished goods and other products are determined on a First in First out (FiFo) basis. When determining net realizable value, appropriate consideration is given to obsolescence, excessive levels, deterioration, and other factors in evaluating net realizable value.

Complex Financial Instruments

The Company does not use derivative instruments to hedge exposures to cash flow, market, or foreign currency risks. The Company evaluates its financial instruments, including warrants, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. The Company values its derivatives using the Black-Scholes option-pricing model or other acceptable valuation models, including Monte-Carlo simulations. Derivative instruments are valued at inception, upon events such as an exercise of the underlying financial instrument, and at subsequent reporting periods. The classification of derivative instruments, including whether such instruments should be recorded as liabilities, is re-assessed at the end of each reporting period.

The Company reviews the terms of debt instruments, equity instruments, and other financing arrangements to determine whether there are embedded derivative features, including embedded conversion options that are required to be bifurcated and accounted for separately as a derivative financial instrument. Additionally, in connection with the issuance of financing instruments, the Company may issue freestanding options and warrants, including options or warrants to non-employees in exchange for consulting or other services performed.

The Company accounts for its common stock warrants in accordance with ASC 815, Derivatives and Hedging (**ASC 815**). Based upon the provisions of ASC 815, the Company accounts for common stock warrants as liabilities if the warrant requires net cash settlement or gives the holder the option of net cash settlement, or it fails the equity classification criteria. The Company accounts for common stock warrants as equity if the contract requires physical settlement or net physical settlement or if the Company has the option of physical settlement or net physical settlement and the warrants meet the requirements to be classified as equity. Common stock warrants classified as liabilities are initially recorded at fair value on the grant date and remeasured at fair value each balance sheet date with the offset adjustments recorded in change in fair value of warrant liability within the consolidated statements of operations. Common stock warrants classified as equity are initially measured at fair value on the grant date and are not subsequently remeasured.

Recent Accounting Guidance

In August 2020, the FASB issued ASU 2020-06, “*Debt with Conversion and other Options* (Subtopic 470-20) and *Derivatives and Hedging-Contracts in Entity’s Own Equity* (Subtopic 815-40)” (“**ASU 2020-06**”). The purpose of ASU 2020-06 is to address issues identified as a result of the complexity associated with applying generally accepted accounting principles (“**GAAP**”) for certain financial instruments with characteristics of liabilities and equity. The amendments in ASU 2020-06 are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2023. Early adoption is permitted but no earlier than fiscal years beginning after December 15, 2020. The Company adopted ASU 2020-06 during our first quarter of fiscal year 2022, and the impact was considered immaterial on our consolidated financial statements.

Off-Balance Sheet Arrangements

We have no significant off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to stockholders.

OUR BUSINESS

Corporate Overview

Arch Therapeutics, Inc. (together with its subsidiary, the “**Company**” or “**Arch**”) arose from the June 26, 2013 merger (the “**Merger**”) of three entities previously known as Arch Biosurgery, Inc., Almah, Inc., and Arch Acquisition Corporation, respectively.

Arch Biosurgery, Inc. (“**ABS**”) is a biotechnology company that was incorporated under the laws of the Commonwealth of Massachusetts on March 6, 2006 as Clear Nano Solutions, Inc., changed its name from Clear Nano Solutions, Inc. to Arch Therapeutics, Inc. on April 7, 2008, and, as part of the Merger transaction, changed its name from Arch Therapeutics, Inc. to Arch Biosurgery.

Almah, Inc., was incorporated under the laws of the State of Nevada on September 16, 2009 and, as part of the Merger transaction, changed its name to Arch Therapeutics, Inc. and abandoned both its prior business plan and operations in order to adopt those of ABS.

Arch Acquisition Corporation, or Merger Sub, was a wholly owned subsidiary of Almah, Inc., formed for the purpose of the Merger transaction, pursuant to which Merger Sub merged with and into ABS, and ABS thereafter became the wholly owned subsidiary of the Company.

The Company’s principal offices are located in Framingham, Massachusetts.

The Company has recently devoted substantially all of our operational effort to the market adoption and commercial sales of AC5 Advanced Wound System, its first product. To date, the Company has principally raised capital through debt borrowings, the issuance of convertible debt, and the issuance of units consisting of Common Stock and warrants.

The Company expects to incur substantial expenses for the foreseeable future relating to research, development and commercialization of current and potential products. However, there can be no assurance that the Company will be successful in securing additional capital when needed, on terms acceptable to the Company, if at all. Therefore, there exists substantial doubt about the Company’s ability to continue as a going concern for one year past the issuance of the financial statements. The consolidated financial statements do not include any adjustments related to the recoverability of assets that might be necessary despite this uncertainty.

Our Current Business

We are a biotechnology company marketing a number of products based on our innovative AC5® self-assembling technology platform. We believe these products are important advances in the field of stasis and barrier applications, which includes managing wounds created during surgery, trauma, interventional care or disease; stopping bleeding (hemostasis); and controlling leaking (sealant). We have recently devoted substantially all of our operational effort to the market adoption and commercial sales of AC5 Advanced Wound System, our first product. Our goal is to make care faster and safer for patients with products for use on external wounds, which we refer to as Dermal Sciences applications, and products for use inside the body, which we refer to as BioSurgery applications.

To date, the Company has principally raised capital through debt borrowings, the issuance of convertible debt and the issuance of units consisting of its common stock, par value \$0.001 per share (“**Common Stock**”), and warrants. The Company expects to incur substantial expenses for the foreseeable future relating to the research, development, clinical trials, and commercialization of its current and potential products. As of September 15, 2023, we believe that our cash on hand will meet our anticipated cash requirements into the first fiscal quarter of 2024, and we must obtain additional financing in order to continue to operate our business. The Company will be required to raise additional capital, obtain alternative means of financial support, or both, in order to continue to fund operations. There can be no assurance that the Company will be successful in securing additional resources when needed on terms acceptable to the Company, if at all. Therefore, there exists substantial doubt about the Company’s ability to continue as a going concern.

Core Technology

Our flagship products and product candidates are derived from our AC5 self-assembling peptide (“**SAP**”) technology platform and are sometimes referred to as AC5 or the “AC5 Devices.” These include AC5 Advanced Wound System and AC5® Topical Hemostat, which have received marketing authorization as medical devices in the United States and Europe, respectively, and which are intended for skin applications, such as the management of complicated chronic wounds and acute surgical wounds. Marketing for AC5 Topical Hemostat in Europe has not initiated. Other products are in development for use in minimally invasive or open surgical procedures, and include, for example, AC5-G™ for gastrointestinal endoscopic procedures and AC5-V® and AC5® Surgical Hemostat for hemostasis inside the body, all of which are currently investigational devices limited by law to investigational use.

Products based on the AC5 platform contain a proprietary biocompatible peptide that is synthesized from proteogenic, naturally occurring L-amino acids. Unlike products that contain traditional peptide sequences, when applied to a wound, AC5-based products intercalate into the interstices of the tissue and self-assemble (i.e., self-build) into a protective physical-mechanical nanoscale structure that can provide a barrier to leaking substances, such as blood, while also acting as a biodegradable scaffold that enables healing. Self-assembly is a central component of the mechanism of action of our technology. Individual AC5 peptide units readily build themselves, or self-assemble, into an ordered network of nanofibrils when in aqueous solution by the following process:

- Peptide strands line up with neighboring peptide strands, interacting via hydrogen bonds (non-covalent bonds) to form a ribbon-like structure called a beta sheet.
- This process continues such that hundreds of strands organize with charged and polar side chains oriented on one face and non-polar side chains oriented on the opposite face of the beta sheets.
- Interactions of the resulting structure with water molecules and ions results in formation nanofibrils, which extend in length and can join together to form larger nanofibers.
- This network of AC5 peptide nanofibers forms the semi-solid physical-mechanical barrier that interacts with the extracellular matrix, is responsible for sealant, hemostatic and/or other properties that may be observed even in the presence of antithrombotic agents (i.e., blood thinners), and which subsequently becomes the scaffold that supports the repair and regeneration of damaged tissue.

Based on the intended application, we believe that the underlying AC5 SAP technology can impart important features and benefits to our products that may include, for instance, stopping bleeding (hemostasis), mitigating contamination, modulating inflammation, donating moisture, and enabling an appropriate wound microenvironment conducive to healing. Furthermore, we believe that AC5 SAP technology permits cell and tissue growth and is self-healing, in that it can dynamically self-repair around migrating cells. For instance, AC5 Advanced Wound System, which is indicated for the management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds, is shipped and stored at room temperature, is applied directly as a liquid, can conform to irregular wound geometry, self-assembles into a wound care matrix that can provide clinicians with multi-modal support, and does not possess sticky or glue-like handling characteristics. We believe these properties enhance its utility in several settings and contribute to its user-friendly profile.

We believe that our technology lends itself to a range of potential applications for wounds inside or on the body, including those for which a hemostatic agent or sealant is needed. For instance, the results of certain preclinical and clinical investigations that either we have conducted, or others have conducted on our behalf, have shown quick and effective hemostasis with the use of AC5 SAP technology, and that time to hemostasis (“TTH”) is comparable among test subjects regardless of whether such test subject had or had not been treated with therapeutic doses of anticoagulant or antiplatelet medications, commonly called “blood thinners.” Furthermore, the transparency and physical properties of certain AC5 Devices may enable a surgeon to operate through it in order to maintain a clearer field of vision and prophylactically stop or lessen bleeding as surgery starts, a concept that we call Crystal Clear Surgery™. An example of a product that contains related features and benefits is AC5 Topical Hemostat, which is indicated for use as a dressing and to control mild to moderate bleeding, each during the management of injured skin and the micro-environment of an acute surgical wound. AC5 Topical Hemostat has not yet been marketed in Europe but has received marketing authorization.

Operations

Much of our operational efforts to date, which we often perform in collaboration with partners, have included selecting compositions and formulations for our initial products; conducting preclinical studies, including safety and other tests; conducting a human trial for safety and performance of AC5; developing and conducting a human safety study to assess for irritation and sensitization potential; securing marketing authorization for our first product in the United States and in Europe; supporting surgeons performing clinical case studies; obtaining post-marketing clinical data; developing, optimizing, and validating manufacturing methods and formulations, which are particularly important components of self-assembling peptide development; developing methods for manufacturing scale-up, reproducibility, and validation; engaging with regulatory authorities to seek early regulatory guidance as well as marketing authorization for our products; sourcing and evaluating commercial partnering opportunities in the United States and abroad; and developing and protecting the intellectual property rights underlying our technology platform.

Our long-term business plan includes the following goals:

- Continue to build recent commercial momentum and grow revenues by driving awareness, adoption and payment policies for AC5 Advanced Wound System with the now-effective Centers for Medicare and Medicaid Services (“CMS”) Level II Healthcare Common Procedure Coding System (“HCPCS”) code dedicated to the “AC5”;
- educating the wound care field and growing commercial sales;
- conducting biocompatibility, pre-clinical, and clinical studies on our products and product candidates;
- obtaining additional marketing authorization for products in the United States, Europe, and other jurisdictions as we may determine;
- continuing to develop third party relationships to manufacture, distribute, market and otherwise commercialize our products;
- continuing to develop academic, scientific and institutional relationships to collaborate on product research and development;
- expanding and maintaining protection of our intellectual property portfolio; and
- developing additional product candidates in Dermal Sciences, BioSurgery, and other areas.

In furtherance of our long-term business goals, we expect to continue to focus on the following activities during the next twelve months:

- seek additional funding as required to support the previously described milestones necessary to support operations;
- work with our manufacturing partners to scale up production of product compliant with cGMP, which activities will be ongoing and tied to our development and commercialization needs;
- further clinical development of our product platform;
- assess our technology platform in order to identify and select product candidates for potential advancement into development;
- seek regulatory input to guide activities related to expanded and new product marketing authorizations;
- continue to expand and enhance our financial and operational reporting and controls;
- pursue commercial partnerships; and
- expand and enhance our intellectual property portfolio by filing new patent applications, obtaining allowances on currently filed patent applications, and/or adding to our trade secrets in self-assembly, manufacturing, analytical methods and formulation, which activities will be ongoing as we seek to expand our product candidate portfolio.

We have no commitments for any future capital. We will require significant additional financing to fund our planned operations, including further research and development relating to AC5, seeking regulatory approval of any product we may choose to develop, commercializing any product for which we are able to obtain regulatory approval or certification, seeking to license or acquire new assets or business, and maintaining our intellectual property rights, pursuing new technologies and for financing the investor relations and incremental administrative costs associated with being a public corporation. We do not presently have, nor do we expect in the near future to have, sufficient revenue to fund our business from operations, and we will need to obtain substantially all of our necessary funding from external sources for the foreseeable future. We may not be able to obtain additional financing on commercially reasonable or acceptable terms when needed, or at all. If we cannot raise the money that we need in order to continue to develop our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations. If any of these were to occur, there is a substantial risk that our business would fail, and our stockholders could lose all of their investment.

Since inception, we have funded our operations primarily through debt borrowings, the issuance of convertible debt and the issuance of units consisting of Common Stock and warrants, and we may continue to seek to do so in the future. If we obtain additional financing by issuing equity securities, our existing stockholders’ ownership will be diluted. The terms of securities we may issue in future capital-raising transactions may be more favorable for our new investors. Further, newly issued securities may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have additional dilutive effects. If we obtain additional financing by incurring debt, we may become subject to significant limitations and restrictions on our operations pursuant to the terms of any loan or credit agreement governing the debt. Further, obtaining any loan, assuming a loan on acceptable terms would be available when needed, would increase our liabilities and future cash commitments. We may also seek funding from additional collaboration or licensing arrangements in the future, which may require that we relinquish potentially valuable rights to our product candidates or proprietary technologies or grant licenses on terms that are not favorable to us. Moreover, regardless of the manner in which we seek to raise capital, we may incur substantial costs in those pursuits, including investment-banking fees, legal fees, accounting fees, printing and distribution expenses and other related costs. In addition, we are bound by certain contractual terms and obligations that may limit or otherwise impact our ability to raise additional funding in the near-term including, but not limited to, provisions in the Bridge SPA and securities purchase agreement dated July 6, 2022, as amended (the “**2022 Notes SPA**”), associated with the sale of the 2022 Notes (the “**2022 Notes Financing**”), in each case as described in greater detail in the risk factor entitled ***The terms of the Bridge Offering and 2022 Notes Financing could impose additional challenges on our ability to raise funding in the future***” under the heading “Risk Factors” in this prospectus.

In addition to the foregoing, our estimated capital requirements potentially could increase significantly if a number of risks relating to conducting these activities were to occur, including without limitation those set forth under the heading “**Risk Factors**” in this prospectus.

Merger with ABS and Related Activities

On June 26, 2013, the Company completed the Merger with ABS, pursuant to which ABS became a wholly owned subsidiary of the Company. In contemplation of the Merger, effective May 24, 2013, the Company increased its authorized Common Stock from 75,000,000 shares to 300,000,000 shares and effected a forward stock split, by way of a stock dividend, of its issued and outstanding shares of Common Stock at a ratio of 11 shares to each one issued and outstanding share. Also, in contemplation of the Merger, effective June 5, 2013, the Company changed its name from Almah, Inc. to Arch Therapeutics, Inc. and changed the ticker symbol under which its Common Stock trades on the OTC Bulletin Board from “AACH” to “ARTH.”

Research and Development

Preclinical and clinical testing of our product candidates is required in order to receive regulatory marketing authorizations and to support products upon commercialization, and we anticipate that such testing will continue as deemed appropriate.

Preclinical Testing

We have engaged and continue to engage third parties in the United States and abroad to advise on and/or perform certain preclinical bench-top and animal research and development studies, typically with assistance from our team. These third parties include contract research organizations, academic institutions, consultants, advisors, scientists, clinicians, and/or other collaborators.

We have conducted and anticipate continuing to conduct in vivo and in vitro research and development studies on our products and product candidates. A co-founding inventor of certain of our technology, Dr. Rutledge Ellis-Behnke, performed a significant portion of the early preclinical animal experiments conducted with our technology. Some of the most significant findings from Dr. Ellis-Behnke's studies have been published. Additionally, through collaborations with the National University of Ireland system and related parties, preclinical bench-top and animal research and development studies were performed in Dublin, Cork and Galway, Ireland over an approximately eight-year period that concluded in the third quarter of fiscal 2018.

Before initiating our clinical trials and submitting marketing applications for a given product in most jurisdictions, we are required to have completed a biocompatibility assessment, which typically consists of a battery of in vitro and in vivo tests. Standard biocompatibility tests, as set forth in ISO 10993 issued by the International Organization for Standardization, may include:

- in vitro cytotoxicity;
- in vitro blood compatibility;
- in vitro Ames assay (mutagenic activity);
- irritation/intracutaneous reactivity;
- sensitization (allergenic reaction);
- implantation (performed on devices that contact the body's interior);
- pyrogenicity (causing fever or inflammation);
- systemic toxicity; and
- in vitro chromosome aberration assay (structural chromosome changes).

We completed the biocompatibility studies required to receive marketing authorizations for AC5 Advanced Wound System in the United States and AC5 Topical Hemostat in Europe, and such test results support that the products are biocompatible. We will perform further biocompatibility testing that we deem necessary for additional indications, classifications, jurisdictions, and/or as required by regulatory authorities.

Acute and survival animal studies assessing safety and performance of our technology have also demonstrated favorable outcomes in Dermal Sciences and BioSurgery applications.

Porcine studies, also known as swine or pig studies, are often selected due to the morphological, physiological, and biochemical similarities between porcine skin and human skin and are very useful to assess the performance of AC5 Advanced Wound System or AC5 Topical Hemostat as a barrier and advanced wound dressing, as well as their safety and effects on healing.

In an assessment versus saline in a porcine partial thickness excision wound model, tissue response to AC5 Advanced Wound System over a 28-day follow-up period was consistent with normal wound healing and included complete re-epithelialization, normal collagen organization, and minimal inflammation and TTH was faster.

In an assessment versus both a market leading skin substitute and saline in a porcine full thickness 10 mm punch biopsy wound model, AC5 Advanced Wound System was solely associated with complete epithelialization by the end of the 11-day study.

In an assessment versus each a market leading antimicrobial burn dressing, a hydrogel, and saline in a porcine second degree burn wound model, AC5 Advanced Wound System was associated with less progression of thermal damage and less inflammation over three days.

Arch Therapeutics' technology has also demonstrated hemostasis in liver and other organs in in vivo surgical models, including rapid hemostasis within 15 seconds. In a range of small and large animal models, our compositions have been shown to stop bleeding, seal leaking, allow for normal healing, and mitigate inflammation while being biocompatible.

AC5 Surgical Hemostat demonstrated rapid average TTH when applied to a range of animal tissues. Certain surgical procedure studies have assessed TTH when using AC5 Surgical Hemostat as well as using an active control, a saline control, a peptide control, and a cautery control. The results of those tests have shown a TTH of approximately 10 - 30 seconds when AC5 Surgical Hemostat was applied, compared to 80 seconds to significantly more than 300 seconds when various control substances were applied, depending on the nature of the control substance and procedure performed. In several studies comparing AC5 Surgical Hemostat to popular commercially available branded hemostatic agents (absorbable cellulose, flowable gelatin with and without thrombin, and fibrin) applied to stop the bleeding from full thickness penetrating wounds surgically created in rat livers, AC5 Surgical Hemostat achieved hemostasis in significantly less than 30 seconds, whereas control products took from over 50% - 400% longer to achieve hemostasis.

AC5 Surgical Hemostat was also demonstrated in preclinical tests to stop surgically induced liver bleeding in animals that had been treated with therapeutic amounts of anticoagulant and antiplatelet medications, collectively known as antithrombotic medications and commonly called "blood thinners." In one preclinical study, an independent third-party research group obtained positive data assessing the use of AC5 Surgical Hemostat in animals that had been treated with therapeutic doses of the antiplatelet medications Plavix® (clopidogrel) and aspirin, alone and in combination. The results of the study were consistent with data obtained from two prior preclinical studies, in which AC5 Surgical Hemostat quickly stopped bleeding from surgical wounds created in rats following treatment with clinically relevant doses of the anticoagulant medication heparin. In these studies, the average TTH after AC5 Surgical Hemostat was applied to bleeding liver wounds in animals that had received anticoagulant medication was comparable to the average TTH as measured in their non-anticoagulated counterparts.

AC5-V was assessed for its ability to provide hemostasis after bleeding was intentionally created at vascular reconstruction sites in preclinical studies. In an acute study in swine that had been premedicated with therapeutic doses of heparin before undergoing end-to-end femoral artery anastomosis and synthetic graft to vessel anastomosis in carotid and femoral arteries, AC5-V promoted effective hemostasis at the vascular anastomotic site and allowed for clear visualization of the surgical site.

In a 14-day survival study in sheep that had been premedicated with therapeutic doses of heparin before undergoing end-to-side anastomosis between synthetic vascular grafts and carotid arteries, AC5-V promoted effective hemostasis at the vascular anastomotic site, the graft remained patent during the study as assessed by angiography and ultrasound, clinical observations were normal during the study, and tissue response as assessed by histopathological examination at the end of the study was consistent with expectations for a biodegrading implant.

AC5-G was studied in swine to assess visualization, submucosal lift generation and durability, and hemostatic and sealant performance when used during endoscopic mucosal resections and endoscopic submucosal dissections as well as hemostatic performance during endoscopic management of gastrointestinal bleeding. AC5-G was easily delivered through a 25G endoscopic injection needle into the tissue and provided a durable submucosal lift in the gastric antrum that lasted beyond 2 hours. When delivered with the visualizing agent prior to tissue dissection, AC5-G allowed for easy visualization with both snare and electrosurgical knives, and no visible bleeding was observed following polyp removal. AC5-G was also shown to provide hemostasis in actively bleeding lesions when applied with or without the visualizing agent either topically to a bleeding site or when injected into the nearby mucosa. AC5-G was found to be useful in conjunction with clips as a potential sealant when applied following application of clips to a post-polypectomy site for the purpose of mitigating leaks and potentially enabling healing.

The AC5 self-assembling peptide was studied in an experimental intraocular inflammation model of injected Lipopolysaccharide (**LPS**), in which an intraocular application of the peptide with LPS was associated with a marked reduction in retinal inflammation. The density of activated retinal microglial cells was significantly lower in the eyes of the study animals with LPS and AC5 than in the eyes of the LPS-only control group. The results suggest that the AC5 self-assembling peptide may reduce inflammation and may represent a new class of devices that act as anti-inflammatory agents to control ocular inflammation.

Clinical Testing

We have engaged and continue to engage third parties in the United States and abroad to advise on and perform certain clinical studies and related activities, typically with assistance from our team. These third parties include contract research organizations, academic institutions, consultants, advisors, scientists, clinicians, and other collaborators.

In order to complete a clinical trial, we are required to enroll a sufficient number of patients to conduct the trial after obtaining each patient's informed consent in a form and substance that complies with FDA and/or other regulatory authority requirements as well as state and federal privacy and human subject protection regulations. Many factors could lead to delays or inefficiencies in conducting clinical trials, some of which are discussed under the heading "**Risk Factors**" in this prospectus. Further, we, the FDA or an institutional review board ("**IRB**") could suspend a clinical trial at any time for various reasons, including a belief that the risks to the subjects of the trial outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA clearance or approval to market the product in the U.S.

We completed two clinical studies. The first study, which met its primary and secondary endpoints, assessed the safety and performance of our product candidate in 46 patients with bleeding skin wounds that resulted from excision of skin lesions and followed for 30 days. The second study assessed our product candidate on skin, determining that it was neither an irritant nor a sensitizer, and no immunogenic response or serious or other adverse events attributable to our product were reported in any of the approximately 50 enrolled volunteers. The product candidate in these studies subsequently received marketing authorization and is presently known as AC5 Advanced Wound System in the United States and AC5 Topical Hemostat in Europe.

Post marketing clinical case reports have been published demonstrating both efficacy and safety in a range of challenging acute surgical or chronic wounds on patients.

Regulatory

We have engaged and continue to engage third parties in the United States ("**U.S.**") and abroad to advise on and/or perform certain regulatory activities, typically with assistance from our team. These third parties can include contract research organizations, academic institutions, consultants, advisors, scientists, clinicians, and other collaborators.

Our research, development and clinical programs, as well as our manufacturing and marketing operations that may be performed by us or third-party service providers on our behalf, are subject to extensive regulation in the United States and other countries. Notably, for example, AC5 Advanced Wound System is subject to regulation as a medical device under the U.S. Food Drug and Cosmetic Act (the "**FDCA**") as implemented and enforced by the FDA and equivalent regulations that are enforced by foreign agencies in any other countries in which we pursue commercialization. The FDA and its foreign counterparts generally govern the following activities that we do or will perform or that will be performed on our behalf, as well as potentially additional activities, to ensure that products we may manufacture, promote and distribute domestically or export internationally are safe and effective for their intended uses:

- product design, preclinical and clinical development and manufacture;
- product premarket clearance and approval;
- product safety, testing, labeling and storage;
- certain supply chain changes;
- record keeping procedures;
- product marketing, sales and distribution; and
- post-marketing surveillance, complaint handling, medical device reporting, reporting of deaths, serious injuries or device malfunctions and repair or recall of products.

Medical Device Classification in the United States and Europe

AC5 Advanced Wound System in the United States and AC5 Topical Hemostat in Europe are classified as medical devices. Generally, a product is a medical device if it requires neither metabolic nor chemical activity to achieve the desired effect. Furthermore, a medical device can achieve its desired effects without requiring a body (animal/human), whereas a drug or a biologic requires a body in order to operate. Self-assembly, which is the desired effect and can occur outside of a body, is accordingly consistent with the medical device definition.

Medical devices in the United States and Europe are classified along a spectrum on the basis of the amount of risk to the patient associated with the medical device and the controls deemed necessary to reasonably ensure their safety and effectiveness. Class III status, which is the higher-level classification for devices compared to Classes II and I, involves additional procedures and regulatory scrutiny of the product candidate to obtain approvals. Class III devices are those that are deemed to pose the greatest risks, such as life-sustaining, life-supporting or implantable devices, or that have a new intended use or that use advanced technology not substantially equivalent to that of a legally marketed device.

As a result of the intended use of and the novel technology on which our products and product candidates are based, in general, we anticipate that they would typically be regulated as either Class II or Class III medical device in these jurisdictions, depending upon the intended use. Specifically, AC5 Advanced Wound System is a Class II medical device in the United States, and AC5 Topical Hemostat is a Class IIb medical device in Europe.

In the United States, the FDA recognizes these classes of medical devices:

- Class I, requiring general controls, including labeling, device listing, reporting and, for some products, adherence to good manufacturing practices through the FDA's quality system regulations and pre-market notification;
- Class II, requiring general controls and special controls, which may include performance standards and post-market surveillance; or
- Class III, requiring general controls and approval of a premarket approval application ("PMA"), which may include post-market approval conditions and post-market surveillance.

European regulatory authorities, likewise, recognize several classes of medical devices. Classification involves rules found in the European Union Medical Device Directive and is driven in part by the device's degree of contact with the patient, invasiveness, active nature, and indications for use. The medical device classes recognized in the EU are:

- Class IIa, which are considered low-medium risk devices and require certification by a notified body;
- Class IIb, which are considered medium-high risk devices and require certification by a notified body; and
- Class III, which are considered high-risk devices and require certification by a notified body.

United States Class III and certain Class II medical device approvals and European Union Class III and certain Class IIa and IIb medical device approvals may require the successful completion of human clinical trials.

U.S. Regulatory Marketing Authorization Process

Products that are regulated as medical devices and that require review by the FDA are subject to either a premarket notification, also known as a 510(k), which must be submitted to the FDA for clearance, or a PMA application, which the FDA must approve prior to marketing in the United States. The FDA ultimately determines the appropriate regulatory path. For purposes herein, references to regulatory approval and marketing authorization may be used interchangeably.

We believe that the additional products we are currently pursuing for internal use will require a PMA approval prior to commercialization. However, we commercialized an initial product for external use that has been cleared through the 510(k) process. To obtain 510(k) marketing clearance for a medical device, an applicant must submit a premarket notification to the FDA demonstrating that the device is "substantially equivalent" to a predicate device or devices, which is typically a legally marketed Class II device in the United States. A device is substantially equivalent to a predicate device if it has the same intended use and (i) the same technological characteristics, or (ii) has different technological characteristics and the information submitted demonstrates that the device is as safe and effective as a legally marketed device and does not raise different questions of safety or effectiveness. In some cases, the submission must include data from human clinical studies. Marketing may commence when the FDA issues a clearance letter finding substantial equivalence. Depending upon a product's underlying technology and intended use, as well as on FDA processes and procedures, seeking and obtaining a 510(k) can be a lengthy process.

A PMA, which is required for most Class III medical devices, must be submitted to the FDA if a device cannot be cleared through another approval process or is not otherwise exempt from the FDA's premarket clearance requirements. The PMA approval process can be lengthy and expensive. A PMA must generally be supported by extensive data, including without limitation technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use. Clinical trials for a Class III medical device typically require an application for an investigational device exemption ("IDE"), which would need to be approved in advance by the FDA for a specified number of patients and study sites. Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements, and must be conducted under the oversight of an institutional review board ("IRB") for the relevant clinical trial sites and comply with applicable FDA regulations, including those relating to good clinical practices ("GCP").

The PMA process is estimated to take from one to three years or longer, from the time the PMA application is submitted to the FDA until an approval is obtained. During the review period, the FDA will typically request additional information or clarification of the information previously provided. Also, experts from outside the FDA may be convened to review and evaluate the PMA and provide recommendations to the FDA as to the approvability of the device, although the FDA may or may not accept any such recommendations. In addition, the FDA will generally conduct a pre-approval inspection of the manufacturing facility or facilities involved with producing the device to ensure compliance with the cGMP regulations. Upon approval of a PMA, the FDA may require that certain conditions of approval, such as conducting a post-market approval clinical trial, be met.

Further, if post-approval modifications are made, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling or design, then new PMAs or PMA supplements would be required. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is typically limited to information needed to support the changes from the device covered by the original PMA and accordingly may not require as extensive clinical and other data.

We have not submitted to the FDA a PMA or commenced the required clinical trials for an internal use product. Even if we conduct successful preclinical and clinical studies and submit a PMA for an approval or premarket application for clearance, the FDA may not permit commercialization of our product candidate for the desired internal use indications, on a timely basis, or at all. Our inability to achieve regulatory approval for AC5 in the United States for an internal use product, a large market for hemostatic products, would materially adversely affect our ability to grow our business.

European Union Marketing Authorization (CE Mark) Process

A notified body is a private commercial entity designated by the national government of an European Union ("EU") member state as being competent to make independent judgments about whether a medical device complies with applicable regulatory requirements in the EU. Our notified body is The British Standards Institution ("BSI").

The EU has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices, and it has further revised its rules and regulations with increasingly stringent requirements. Each EU member state has implemented legislation applying these directives and standards at a national level. Many countries outside of the EU have also voluntarily adopted laws and regulations that mirror those of the EU with respect to medical devices, potentially increasing the time and cost necessary to potentially achieve an approval in different jurisdictions.

Devices that comply with the requirements of the laws of the selected member state applying the applicable EU directive are entitled to bear a CE *Conformité Européenne* mark and can be distributed throughout the member states of the EU, as well as in other countries that have mutual recognition agreements with the EU or have adopted the EU's regulatory standards.

Under applicable European Medical Device Directives (MDD), a CE mark is a symbol placed on a product that declares that the product is compliant with the essential requirements of applicable EU health, safety and environmental protection legislation. In order to receive a CE mark for a product candidate, the company producing the product candidate must select a country in which to apply. Each country in the EU has one competent authority ("CA") that implements the national regulations by interpreting the EU directives. CAs also designate and regulate Notified Bodies. An assessment by a notified body in the selected country within the EU is required in order to commercially distribute the device. In addition, compliance with ISO 13485 issued by the International Organization for Standardization, among other standards, establishes the presumption of conformity with the essential requirements for CE mark. Certification to the ISO 13485 standard demonstrates the presence of a quality management system that can be used by a manufacturer for design and development, production, installation and servicing of medical devices and the design, development and provision of related services.

While there are many similarities between the processes required to obtain marketing authorization in the United States and Europe, there are several key differences between the jurisdictions, as well. Obtaining a CE mark is not equivalent to obtaining FDA clearance or approval. For instance, FDA requirements for products typically vary based on whether the submission is for a premarket notification (510(k)) or a premarket approval (PMA) whereas EU requirements for product submissions are primarily based on class. Furthermore, EU submissions must meet precise essential requirements, although the data demonstrating such compliance can vary by class of device. Additionally, a CE mark affixed to a product serves as a declaration by the responsible party that the product conforms to applicable provisions and that relevant conformity assessment procedures have been completed with respect to the product.

In 2017, the European Union regulatory bodies implemented a new Medical Device Regulation (“MDR”). The MDR changes several aspects of the existing regulatory framework, such as clinical data requirements, and introduces new ones, such as Unique Device Identification (“UDI”). We, and the Notified Bodies who will oversee compliance to the new MDR, face uncertainties in the upcoming years as the MDR is rolled out and enforced, creating risks in several areas, including the CE mark process, data transparency and application review timetables.

Post-Approval Regulation

After a medical device obtains approval from the applicable regulatory agency and is launched in the market, numerous post-approval regulatory requirements would apply. Many of those requirements are similar among the United States and EU member states and include:

- product listing and establishment registration;
- requirements that manufacturers, including third-party manufacturers, follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling and other advertising regulations, including prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- approval of product modifications that affect the safety or effectiveness of any of our devices that may achieve approval;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply, when necessary, to protect the public health or to provide additional safety and effectiveness data for the device;
- the recall authority of the applicable government agency and regulations pertaining to voluntary recalls; and
- reporting requirements, including reports of incidents in which a product may have caused or contributed to a death or serious injury or in which a product malfunctioned, and notices of corrections or removals.

Failure by us, our third-party manufacturers or our other suppliers to comply with applicable regulatory requirements could result in enforcement action by various regulatory authorities, which may result in monetary fines, the imposition of operating restrictions, product recalls, criminal prosecution or other sanctions.

Regulation by Other Foreign Agencies

International sales of medical devices outside the EU may be subject to government regulations in each country in which the device is marketed and sold, which vary substantially from country to country. The time required to obtain approval by a non-EU foreign country may be longer or shorter than that required for FDA or CE mark clearance or approval, and the requirements may substantially differ.

Marketing Authorization (510k) for AC5 Advanced Wound System in the United States

On July 25, 2017, we announced that we had made a 510(k) submission to the FDA for AC5 Topical Gel. On December 18, 2017, we voluntarily withdrew the application after receiving questions from the FDA for which an adequately comprehensive response could not be provided within the FDA’s congressionally-mandated 90-day review period. On October 1, 2018, we announced that we both completed the necessary steps required to file a new 510(k) submission to the FDA for AC5 Topical Gel and filed that 510(k) submission during the third calendar quarter. As previously disclosed, these steps included developing a required study protocol and submitting it to the FDA in a pre-submission letter in the first calendar quarter, completing the pre-submission process, initiating the study in the second calendar quarter of 2018 and completing the study. On December 17, 2018, we announced that the 510(k) premarket notification for AC5 Topical Gel had been reviewed and cleared by the FDA, allowing for the product to be marketed.

In line with plans to better harmonize our United States and European product supply chains by using an additional supplier and additional manufacturing processes in the production of AC5 Topical Gel, Arch filed documentation with the FDA seeking such clearance in the United States for these additions, each of which had been incorporated into the technical documentation for the European CE mark filing. On March 23, 2020, we announced that the 510(k) premarket notification for AC5 Topical Gel had been reviewed and cleared by the FDA, allowing for the product to be marketed in the United States with the aforementioned additions. AC5 Topical Gel was subsequently renamed to AC5 Advanced Wound System in the United States.

Marketing Authorization (CE mark) for AC5 Topical Hemostat in Europe

During November 2018 we submitted the required documents for AC5 Topical Hemostat to its notified body seeking a CE mark. During August 2019, we received and responded to customary written and verbal questions related to the technical file, and that BSI had provided and assessed during the review period were acceptable so far. In that announcement, we further expressed our belief that the delay by the regulatory authority in completing the CE mark technical file review appeared to be due to a backlog of work for EU notified bodies related to both Brexit and the implementation of the new EU Medical Devices Regulation.

During April 2020, we received the CE (*Conformité Européenne*) mark for AC5 Topical Hemostat, allowing for commercialization in Europe as a dressing and to control bleeding in external skin wounds in both outpatient and in-patient settings.

Commercialization

Our commercialization efforts are currently focused on Dermal Sciences. Our BioSurgery products for internal use will require additional preclinical and clinical testing before we seek marketing authorization to commercialize them.

Our Dermal Sciences products are AC5 Advanced Wound System in the United States and AC5 Topical Hemostat in Europe, and the indication for use, or purpose, for each product follows, respectively:

- Under the supervision of a health care professional, AC5 Advanced Wound System is a topical dressing used for the management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds.
- AC5 Topical Hemostat is intended for use locally as a dressing and to control mild to moderate bleeding, each during the management of injured skin and the micro-environment of an acute surgical wound.

We have prioritized the launch of AC5 Advanced Wound System in the United States over that of AC5 Topical Hemostat in Europe, where we have not launched, for the foreseeable future to maximize operational efficiencies considering the COVID-19 pandemic.

We expect the Dermal Sciences product commercialization ramp to be initially gradual and then moderately accelerate as we identify and encourage product use by key opinion leaders and early adopters in developing market channels. We are actively concentrating our marketing and selling efforts on doctor's offices, other ambulatory settings, and government facilities, such as hospitals in the Veterans Health Administration ("**VA Hospitals**") and Medical Treatment Facilities. These settings tend to have many patients whose needs we believe can be addressed by AC5 Advanced Wound System because it is a synthetic self-assembling wound care product that provides clinicians with multi-modal support and utility across all phases of wound healing. Numerous published case studies and accolades highlight the efficacy and safety of AC5 in the treatment of challenging chronic and acute surgical wounds, including limb salvage and healing after other modalities have failed.

Securing reimbursement for AC5 Advanced Wound System in ambulatory settings, such as doctor's offices, is an important part of our commercial strategy. Consequently, we applied to the CMS for a dedicated HCPCS Level II billing code specific to AC5 Advanced Wound System on June 29, 2022, which if granted, would better enable providers to bill third party payors for AC5 that is used in doctors' offices. We believe that there is a growing trend toward the use of synthetic wound care products, including those that have been commonly referred to as synthetic skin substitutes. A dedicated HCPCS code is an important step toward, although not a guarantee of, coverage and reimbursement, and it would enhance our ability to work directly with payors as we expand access in outpatient settings and continue to advocate for clinically appropriate usage of our technology for patients. Our application was subsequently approved with a go-live date of April 1, 2023. We have launched a temporary reimbursement support program in line with CMS guidance to support commercial use and adoption of AC5 Advanced Wound System both before and after the go-live date of our unique product code (A2020).

To support commercialization in government facilities, AC5 Advanced Wound System has been added to the Federal Supply Schedule (FSS), General Services Administration (GSA) schedule and the Defense Logistics Agency's Medical Electronic Catalog Program (ECAT) and Distribution and Pricing Agreement (DAPA), enabling purchase by federal government agencies, including the Department of Veterans Affairs (VA), Indian Health Services (IHS), and Department of Defense (DOD) Medical Treatment Facilities effective December 15, 2021.

We envision hiring additional internal sales representatives to help commercialize the Dermal Sciences products.

We have engaged and continue to engage third parties in the United States and abroad to advise on and perform certain sales and marketing activities, typically with assistance from our team. These third parties can include contract organizations, consultants, advisors, scientists, clinicians, and/or other collaborators.

While our core team oversees initial inventory distribution from the warehouse to the customer, our commercialization plans include entering into collaboration agreements with contract sales partners, including independent sales representatives and distributors, and potentially strategic partners. We anticipate that we will enter and periodically terminate certain agreements based on performance or other business criteria.

We are committed to continuous improvement processes. We collect feedback and data when feasible and appropriate to develop and commercialize products that serve patients and doctors; to develop marketing messages; to learn about product use; to evaluate product performance in different settings; to improve our products; to address reimbursement needs, and to support collaborations that we may have or may establish. Data has been and will continue to be collected by informal feedback, observational case reports and/or clinical trials.

We received the CE mark for AC5 Topical Hemostat in April 2020. We announced receipt of 510(k) premarket notification clearances for AC5 Advanced Wound System in December 2018, providing marketing authorization, and on March 23, 2020, clearing use of an additional supplier and additional manufacturing processes.

The COVID-19 Pandemic Impact on Commercialization

The COVID-19 pandemic environment introduced significant challenges related to product launch, marketing and sales, as clinicians and facilities became overburdened and increasingly focused on managing resources, the disease, and the virus spread. While the overall environment has improved, many negative effects linger. We have observed the following effects at different times, and anticipate that they will variously wax and wane over time:

- the volume of elective surgical procedures has been constrained periodically, with many institutions indefinitely suspending or eliminating such procedures at times;
- healthcare facilities often have been required to ration staff and resources, including ventilators, personal protective equipment ("PPE"), and operating rooms, thereby negatively impacting the focus on wound care;
- clinicians often have been required to divert their time and resources to urgent COVID-19 needs;
- clinicians often have been required to quarantine due to exposure to a COVID-19 positive individual or isolate because of contracting symptomatic or asymptomatic COVID-19 disease;
- some institutions have been periodically designated "COVID Hospitals";
- access to surgeons, potential strategic partners, and facilities outside of the United States has become curtailed;
- administrators who may be required to facilitate or approve new product intake are constrained by new and other pressing priorities; and
- both clinicians and patients often try to minimize possible COVID-19 exposure, resulting in reduced access to healthcare system and essential care treatments and services.

We believe that these challenges have also highlighted some potential opportunities for our new technology to address certain poorly met needs. For instance, wound interventions are too often considered to be elective procedures instead of being treated essentially or emergently as National Pressure Ulcer Advisory Panel guidelines and others recommend, resulting in a projected increased risk to limb and life while elective procedures are delayed and not prioritized. Furthermore, the implications of these delays are a growing backlog of chronic wounds awaiting care and a worsening of such wounds, leading to greater morbidity, such as infection, necrosis, and amputation, and potentially mortality.

While highlighted by the COVID-19 pandemic, we also believe that these challenges reveal an underlying problem in the healthcare system-clinicians and other providers are being asked to accomplish more in less time with fewer resources. These resources may include higher acuity settings, such as operating rooms; expensive wound care products that may not work as well as desired; nursing time to change wound dressings; and surgeon time for managing wounds during debridement; repeat patient visits over months and often years, and others. Our COVID-19- related discussions with surgeons, economic stakeholders and other decision-making personnel often include whether AC5 Advanced Wound System may enable them to accomplish more for their patients while deploying overall fewer resources and achieving desired outcomes.

Manufacturing

We work with contract manufacturing and related organizations, including those operating under current good manufacturing practices (“cGMP”), as is required by applicable regulatory agencies for production of product that can be used for preclinical and human testing as well as for commercial use. We also have engaged and continue to engage other third parties in the United States and abroad to advise on and perform certain manufacturing and related activities, typically with assistance from our team. These third parties include academic institutions, consultants, advisors, scientists, and/or other collaborators. The activities include development of our primary product candidates, as well as generation of appropriate analytical methods, scale-up, and other procedures for use by manufacturers and/or other members of our supply chain to produce or process our products at current and/or larger scale quantities for preclinical and clinical testing and ultimately, as required marketing authorizations are obtained, commercialization.

Our products are regulated as medical devices, and as such, many of our activities have focused on optimizing traditional parameters to target specifications, biocompatibility, physical appearance, stability, and handling characteristics, among other metrics, to achieve the desired product. We and our partners intend to continue to monitor manufacturing processes and formulation methods closely, as success or failure in establishing and maintaining appropriate specifications may directly impact our ability to conduct additional preclinical and clinical trials and/or deliver commercial product.

We believe that the manufacturing methods used for a product, including the type and source of ingredients and the burden of waste byproduct elimination, are important determinants of its opportunity for profitability. Industry participants are keenly aware of the downsides of products that rely on expensive biotechnology techniques and facilities for manufacture, onerous and expensive programs to eliminate complex materials, or ingredients that are sourced from the complicated process of human or other animal plasma separation, since those products typically are expensive, burdensome to produce, and at greater risk for failing regulatory oversight.

The manufacturing methods that we use and intend to use to produce our current products and potential future product candidates rely on detailed, complex and difficult to manage synthetic organic chemistry processes. Although use of those methods requires that we engage manufacturers that possess the expertise, skill and know-how involved with those methods, the required equipment to use those methods is widely available. Furthermore, improvements in relevant synthetic manufacturing techniques over the past two decades have reduced their complexity and cost, while increasing large-scale cGMP capacity. Moreover, our current products and currently planned product candidates will be synthesized from naturally occurring ingredients that are not sourced from humans or other animals but do exist in their natural state in humans. That type of ingredient may be more likely to be categorized as “generally recognized as safe”, or “GRAS”, by the FDA.

Industry and Competition

Arch is developing technology for Dermal Sciences and BioSurgery applications, including wound care, surgical procedures on and in the body, and endoscopic gastrointestinal procedures. We seek to provide a product set with broad utility in external and internal applications. Features of the technology highlight its potential utility in a range of settings, including traditional open procedures and the often more challenging minimally invasive surgeries.

Common features of our current and planned products, as described herein, are driven by the mechanism of action, which itself is derived from the underlying physicochemical properties or our self-assembling peptide technology and our product safety and performance specifications. Those features, which include, among others, that they possess barrier properties and can create an environment permissive to healing, can deliver a benefit in the treatment of external and internal wounds that are open, exposed, bleeding, leaking, and/or at risk for excessive inflammation or contamination.

Dermal Sciences

We have received marketing authorizations for AC5 Advanced Wound System in the United States and AC5 Topical Hemostat in Europe. Compared to most other advanced wound dressings on the market, ours can be used throughout all phases of wound healing (i.e., inflammatory, proliferative, and remodeling).

Wounds can vary widely in terms of degree of bleeding and oozing, chronicity, acuity, complications, anatomic location, biochemistry, microenvironment, bioburden and other factors that may inhibit an ideal response. Patients can also vary widely in terms of co-morbidities, compliance, setting of their care, ability to contribute to their own care, and other risk factors. And the approach by surgeons to clinical practice can vary widely in terms of debridement strategy, timing and/or use of advanced modalities, choice and use of consumables, follow-up, and dressing change frequency, and more. Our products are designed to self-assemble on the wound site in response to locally present stimuli (ions), despite these diverse situations, with the objective of providing greater utility to clinicians and enabling better outcomes for patients.

The incidence and prevalence of both acute surgical and chronic wounds is noteworthy. According to a 2020 report by Steiner et al for The Healthcare Cost and Utilization Project, approximately 17 million hospital visits (inpatient and ambulatory) in 2014 resulted in almost 22 million invasive therapeutic surgeries. While more acute surgical wounds occur per year versus chronic wounds, the nature of chronic wounds provides additional greater challenges due to the prolonged duration of the healing period, the frequency of interventions needed to help the wound heal, and the often-underlying medical problem that placed the patient at risk for the wound in the first place, which is itself a hindrance to the healing process.

Chronic wounds affect approximately 2% of the United States Population, accounting for an estimated 6-7 million people.

Diabetic foot ulcers develop in approximately 2 million Americans each year, according to The Health Innovation Program, University of Wisconsin, while the annual incidence across developed countries is estimated to be 2-4%, according to Woods et al in 2020. Pressure ulcers develop in over 2.5 million Americans each year, according to the United States Agency for Healthcare Research & Quality.

Venous leg ulcers, representing the most common chronic wounds, occur in approximately 2.2% of Americans over age 65 each year, according to Rice et al in 2014, which equates to roughly 1.2 million new wounds per year among just that population, while Qiu et al in 2021 provided an estimated prevalence of 2-4%. The Centers for Disease Control and Prevention estimates that approximately 56 million Americans are over age 65. Additional chronic wounds not accounted for above can include, among others, surgical wounds that become chronic wounds, typically in patients with co-morbidities.

The morbidity and mortality associated with wounds, and particularly chronic wounds, is problematic. A 2017 article by Järbrink et al noted that chronic wounds may not heal for several years or, in some cases, decades, during which time the patient may suffer from severe pain, emotional and physical distress, less mobility and greater social isolation, while the family may suffer from other stresses and challenges. Woods et al in 2020 stated that only 2/3 of diabetic foot ulcers heal within 12 months. Some wounds just do not heal, remaining stagnant or progressing to limb loss or worse. Järbrink et al noted in 2017 that ulcers precede 85% of all amputations.

The Health Innovation Program, University of Washington, cited that of patients with diabetic foot ulcers in the United States, more than 50% will die within five years and 5% will have an amputation (<https://hip.wisc.edu/DiabeticFootUlcers>). A common phrase in medicine, which we often cite, is, "Save a limb, save a life." Even the amputations that are required to save a patient from a non-healing, progressing chronic wound are associated with additional significant morbidity and mortality. In an examination of mortality rates after amputations from a chronic wound, Meshkin et al performed a systematic literature review and found that of the sixty-one studies yielding approximately 36,000 patients who previously received a nontraumatic major lower extremity amputation, approximately 34% died by year one, 55% died by year two, and 64% died by year five. Stern et al in 2017 reported an even higher mortality rate one year after amputation of approximately 48%.

According to the US Market Report for Wound and Tissue Management, 2018 by iData Research, advanced wound dressings account for approximately \$2 billion in annual revenues while the overall wound care market is projected to surpass \$10 billion in the United States, yet this represents a relatively small percentage of the overall cost to care for wounds, including chronic wounds, such as venous leg ulcers, diabetic foot ulcers, and pressure ulcers.

As such, the total expenditure required to treat wounds is an important consideration in assessing market opportunity, product need, industry dynamics, and needs of insurers. Several wound related phenomenon influence the overall cost and challenge of wound care. For instance, many surgeons believe that a chronic wound is essentially a chronic infection, which raises costs and complicates treatment plans, and that healing requires aggressive debridement (surgical removal of damaged, dead, lacerated, devitalized, or contaminated tissue), which narrows the scope of which wound care products can be used at the time of the procedure as a useful tool to support healing.

According to a 2018 report by Nussbaum et al., data from calendar year 2014 estimated that Medicare alone spent between \$28.1 to \$96.8 billion for all wound care types, and that nearly 15% (8.2 million) of Medicare beneficiaries were diagnosed with at least one type of wound or wound-related infection. Furthermore, a 2017 report by Chan et al indicated that the mean one-year cost of care from the perspective of a health-care public payer was \$44,200 for a diabetic foot ulcer, \$15,400 for a pressure ulcer and \$11,000 for a leg ulcer. Woods et al in 2020 estimated that the cost per admission among patients with diabetic foot ulcers was \$8,145 if the wound was not infected and \$11,290 if the wound was infected. Han et al noted in 2017 that lessening a hospital admission by just one day represents an enormous cost savings and is separately beneficial to the patient.

A common wound care topic, which has been further highlighted during the COVID-19 pandemic, is how to provide high quality care in lower acuity settings. It is less expensive, more convenient, and potentially better for the patient if a wound care procedure, such as debridement, can be safely performed in a doctor's office or wound clinic in lieu of a hospital operating room. For example, a report by Rogers et al in 2020 discussed changing sites of service to the lowest acuity setting in which care could be safely delivered. As such, we believe that wound care products should be designed to enable clinicians to "do more with less", such as debride in a clinic or office a wound that otherwise may have required an operating room visit.

While the wound care opportunity is large for safe, efficacious, and novel products, the competitive landscape is also crowded and challenging. For instance, while many of the commercially marketed advanced wound care dressings or other products, may provide utility in certain situations and possess some novel features, surgeons often describe an inability to differentiate one from the other. In addition, many advanced products are expensive when accounting for wound surface area coverage, are not user friendly, and/or may need to rely on the passage of several weeks of time for the wound bed to adequately be prepared before they can be used, which itself adds burden to their use.

We believe that the aforementioned elevated wound incidence and prevalence, consequential morbidity and mortality, prolonged healing times and exorbitant cost of overall care underscores the potential opportunity for the overall market and for our products. We believe that the addressable market opportunity for advanced wound care products in the US alone can exceed \$20 billion if improvements enable the best products to increase penetration at the expense of less effective wound care products and categories, lessen expensive non-product-related treatment costs for insurers (e.g., skin grafts, dressing changes, etc.), and deliver improved outcomes more quickly and in lower acuity settings.

We believe that AC5 Advanced Wound System is sufficiently differentiated to replace certain competitive products, complement other products and procedures by potentially enabling the wound bed to be ready sooner, and enable more procedures to be done sooner and/or in settings where they could not be performed easily before.

Features and benefits of AC5 Advanced Wound System may include that it:

- is a self-assembling wound care matrix and may provide better outcomes across all phases of wound;
- conforms to irregularly shaped wound geometry;
- may be used in either lower acuity (e.g., clinics) or higher acuity (e.g., operating rooms) settings;
- can be used in conjunction with aggressive surgical debridement;
- can be used on a wound whether or not it is bleeding;
- is agnostic to the presence of anti-thrombotic therapy (aka, blood thinners);
- can be used on a chronic, stalled wound that has been previously unresponsive to or failed other treatment regimens;
- provides a protective barrier to mitigate contamination and modulating inflammation;
- donates moisture to the wound;
- can create wound microenvironment conducive to healing;
- aids in epithelial cell migration;
- creates an extracellular matrix-like structure to enable cell and tissue growth;
- is self-healing, in that it can dynamically self-repair around migrating cells;
- may reduce healing time and patient burden;
- is user-friendly, easy to prepare, and easy to apply;
- may be stored at ambient temperature; and
- may reduce treatment costs while improving outcomes in certain patients.

BioSurgery

We are developing BioSurgery products for internal use, including for hemostasis and sealant applications, and gastrointestinal endoscopic surgical procedures, and we believe that our technology will be useful in addressing the constant demand for better performance and safety in minimally invasive surgery ("MIS"), traditional surgery, Natural Orifice Translumenal Endoscopic Surgery, commonly referred to as "NOTES", and other procedures.

While developing our products, we engaged commercial strategy and marketing consultants and communicated directly with care providers to understand the needs of potential customers and to assess product feature preferences.

Surgeons, operating room managers, sales representatives and hospital decision-makers identified several characteristics deemed desirable, including that a product is:

- reliable;
- able to protect the wounds in tissues and organs where used;
- laparoscopic friendly;
- easily handled and applied;
- able to promote a clear field of vision and not obstruct view;
- sufficiently flowable;
- non-sticky (to tissue or equipment);
- permits normal healing;
- agnostic to the presence of antithrombotic medications (“blood thinners”) to whether the patient has bleeding abnormalities;
- non-toxic; and
- not sourced from human or other animal blood or tissue components.

We believe that long-term trends, which support a need for products to better support clinicians in surgical procedures, include:

- a persistent drive to migrate the site of surgical care from inpatient hospital operating room to progressively lower acuity same-day ambulatory settings due to cost and other potential negative impacts of unnecessary hospitalizations, such as infection risk or occupying scarce resources that may be more usefully deployed elsewhere;
- increased use of anticoagulants and other anti-thrombotic agents (also known as blood thinners) due to co-morbidities, but which predispose patients to bleeding;
- the increasingly difficult nature of procedures expected to be performed by surgeons with the least invasive method feasible in the less expensive settings accessible; and
- the desire to lower procedure time to increase operating room throughput, increase shift volume, and lessen in-procedure time for patient’s well-being;

We believe that a motivating factor for some of these trends may be the increased costs associated with procedures performed in hospital operating rooms, which have been estimated to cost between \$2,000 and \$10,000 per hour, according to MedMarket Diligence and others.

These costs likely drive the desire for increased operating room throughput and increased volume of procedures performed in outpatient settings. Both of those trends highlight the need for highly effective products that can decrease operating room time for inpatient procedures and help to increase the safety of performing more types of procedures in less expensive outpatient settings.

Since the early days of modern MIS in the 1990s, the percent of surgeries performed minimally invasively has increased significantly, such that it is now widespread and common. Laparoscopic surgery is among the most recognized types of MIS, although there are many additional types. Advantages of MIS tend to include less scarring, less post-operative pain, less need for pain medications, shorter recovery times, and faster discharge times. However, such procedures often present the surgeon with less margin for error and less capacity to deal with certain risks, such as excessive bleeding, without having to convert the surgery to a traditional open procedure.

A trend to make traditional minimally invasive surgery even less invasive is known NOTES. In NOTES procedures, an endoscope is passed through a natural orifice, such as the mouth, urethra, anus, or vagina, and then through an internal incision in the stomach, vagina, bladder or colon. NOTES advantages include those of MIS to a potentially even greater degree, as well as the lack of external incisions and external scars, improved visibility, and the possibility to avoid managing potential obstacles to surgery, such as extensive adhesions from prior procedures. However, compared to MIS, margin for error in NOTES is even less. NOTES may be performed by surgeons or endoscopists, yet the techniques can be challenging to learn and are in their early stages of development. Practitioners may seek additional tools, including BioSurgery products where relevant, to enable them to operate efficiently, effectively, and safely.

We consider these items while developing our BioSurgery products with the objective of meeting these needs.

We are developing products for hemostasis and sealant applications. Many of the hemostasis products currently available do not possess certain features and handling characteristics that are ideal for use in a laparoscopic setting. For instance, many available products are difficult to use in MIS or NOTES because they tend to be sticky, powdery, fabric-based or are otherwise difficult to insert into and control through the small gauge, yet long, catheters used during these procedures. We believe that the novel features and differentiating characteristics of our BioSurgery products will make them more suitable for such surgeries compared to many or most of the presently available alternatives.

According to a 2015 MedMarket Diligence, LLC report, the market for hemostatic agents and sealants achieved approximately \$4.2 billion in worldwide sales in 2015 and was projected to reach \$4.8 billion in 2017 and surpass \$7.5 billion in 2022. While the majority of those sales are for hemostats, we believe that the projected growth rate for sealants in multiple applications, such as the gastrointestinal track, could become greater as additional products become available.

In spite of the large size of the market for these products, many available hemostatic agents and sealants possess a combination of limitations, including slow onset of action, general unreliability, user-unfriendliness, and risk for adverse effects, such as healing problems, adhesion formation, infection and other safety concerns. Many of the deficiencies of currently available hemostatic agents and sealants are comparable to those of their earlier-generation counterparts, as revolutionary advances in underlying technologies have been elusive.

Participants in the hemostatic and sealant market include large medical device and biopharmaceutical companies, as well as various smaller companies. Commercially available hemostatic agents can cost between \$50 and \$500 per procedure, with the higher value-added products generally priced at the upper end of that range. We believe, however, that approaches to many surgical problems have evolved and will continue to do so, such that what may recently appeared to be an interesting market may be less so in the future if the required tools also evolve. For instance, the endovascular approach to vascular reconstruction may lessen the need for hemostatic agents in certain procedures.

We are also developing products for gastrointestinal and NOTES procedures, endoscopic mucosal resections (“**EMR**”) and endoscopic submucosal dissections (“**ESD**”). Surgical endoscopists are removing more complicated tumors and lesions from the gastrointestinal tract via EMR and ESD, which are endoscopic techniques to remove early-stage cancer and precancerous growths from the lining of the digestive tract through long narrow equipment, which consist of ports, catheters, lights, monitors, and video cameras. This represents the least invasive interventional approach known.

The EMR/ESD market is immature and growing, we believe, because of an increasing elderly population and incidence of gastrointestinal malignancies. The opportunity is noteworthy in North America, Europe, and Asia, where a higher prevalence of certain gastrointestinal malignancies and lower screening rates leads to later discovery and removal of tumors than would be desired. We believe that overall costs of care associated with these procedures, when compared to that of more invasive alternatives, and potentially faster recovery times will encourage a growth trend. It should be noted that these procedures do require that the doctor possess additional non-routine skill and equipment thereby tempering potential adoption curves.

A particular need for which we are developing AC5-G is a product that provides both a durable and safe lift while being inherently hemostatic. The concept is to inject AC5-G beneath a polyp or tumor to be resected or dissected, thus creating separation between the lesion and the underlying healthy tissue.

Incomplete lesion removal, bleeding and perforation are known challenges and risks of EMR/ESD. The objective of a lift is to minimize the risk for perforation into the peritoneum, which can cause significant morbidity and mortality, and increase the probability of visualizing and removing the entire desired lesion. The lift should also be durable, potentially lasting at least two hours, such that the frequency of repeat injections and perforation risk is minimized. Normal and abnormal tissues can also bleed during these procedures, and it can be challenging and time consuming to stop. Surgeons have expressed a desire for an improved agent that can prophylactically or actively address such bleeding. Surgeons have further expressed interest in sealant properties in the event that a perforation occurs during the procedure.

Several companies have products that provide either a lift or are hemostatic. Based on early indicators, we believe that AC5-G provides properties for both lift and hemostasis. AC5-G was featured in a video presentation during the Emerging Technology Session of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) 2020 Annual Meeting, which took place from August 11-13, 2020.

Potential Disadvantages of our Current and Planned Products Compared to the Competition

Some potential disadvantages of our products compared to currently marketed products follow:

- The favorable handling characteristics of AC5 Devices result, in part, from their non-sticky and non-glue-like nature. However, if a surgeon or healthcare provider requires a product to adhere tissues together, or provide similar glue-like action, then AC5 Devices in their current form would not achieve that effect.
- While we project that our products will be sufficiently economical to manufacture at scale, they may not be able to compete from a price perspective with inexpensive products.
- We have generated less data in humans compared to many successful products in the Dermal Sciences or BioSurgery categories.
- While we believe that the flowable nature of our products before they assemble into a dense nanofiber network can provide a meaningful advantage, some surgeons may prefer a solid product in certain applications.

Other Governmental Regulations and Environmental Matters

We are or may become subject to various laws and regulations regarding laboratory practices and the use of animals in testing, as well as environmental laws and regulations governing, among other things, any use and disposal by us of hazardous or potentially hazardous substances in connection with our research. At this time, costs attributable to environmental compliance are not material. In each of these areas, applicable U.S. and foreign government agencies have broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on our business. Additionally, if we are able to successfully obtain approvals for, and commercialize our product candidates, then the Company and our products may become subject to various federal, state and local laws targeting fraud, abuse, privacy and security in the healthcare industry.

Intellectual Property

We are focused on the development of self-assembling compositions, particularly self-assembling peptide compositions, and methods of making and using such compositions primarily in healthcare applications. Suitable applications of these compositions include limiting or preventing the movement of bodily fluids and contaminants within or on the human body, preventing adhesions, treatment of leaky or damaged tight junctions, and reinforcement of weak or damaged vessels, such as aneurysms. Our strategy to date has been to develop an intellectual property portfolio in high-value jurisdictions that tend to uphold intellectual property rights and apply business judgment rules to determine which patent applications to pursue and, if granted, which patents to maintain. The information provided is subject to change if pending patent applications are abandoned, issued patents are allowed to lapse, or new applications are filed.

As of September 15, 2023, we either own or license from others a number of U.S. patents, U.S. patent applications, foreign patents and foreign patent applications.

Six patent portfolios assigned to Arch Biosurgery, Inc. include approximately 50 patents and pending applications in approximately 20 jurisdictions, including approximately 11 patents and pending applications in the US. These portfolios cover self-assembling peptides, formulations and methods of use thereof and self-assembling peptidomimetics and methods of use thereof, including approximately eight issued US patents (US 9,415,084; US 9,162,005; US 9,789,157; US 9,821,022; US 9,339,476; US 10,314,886; US 10,682,386, and 10,869,907) that expire between 2026 and 2034 (absent any potential patent term extension), as well as approximately 30 patents that have been either allowed, issued or granted in foreign jurisdictions.

We have also entered into a license agreement with Massachusetts Institute of Technology and Versitech Limited (“MIT”) pursuant to which we have been granted exclusive rights under two portfolios of patents and non-exclusive rights under another three portfolios of patents.

The two portfolios exclusively licensed from MIT include approximately 30 patents and pending applications drawn to self-assembling peptides, formulations and methods of use thereof and self-assembling peptidomimetics and methods of use thereof in a total of nine jurisdictions. The portfolios include five issued US patents (US 9,511,113; US 9,084,837; US 10,137,166; US 9,327,010; and US 9,364,513) that expire between 2026 and 2027 (absent any potential patent term extension), as well as additional patents that have been either allowed, issued or granted in foreign jurisdictions.

The portfolios non-exclusively licensed from MIT include a number of US and foreign applications, including three issued US patents (US 7,846,891; US 7,713,923; and US 8,901,084) that expire between 2024 and 2026 (absent any potential patent term extension), as well as additional patents that have been either allowed, issued or granted in foreign jurisdictions.

Our license agreement with MIT imposes or imposed certain diligence, capital raising, and other obligations on us, including obligations to raise certain amounts of capital by specific dates. Additionally, we are responsible for all patent prosecution and maintenance fees under that agreement. Our breach of any material terms of our license agreement with MIT could permit the counterparty to terminate the agreement, which could result in our loss of some or all of our rights to use certain intellectual property that is material to our business and our lead product candidate. Our loss of any of the rights granted to us under our license agreement with MIT could materially harm our product development efforts and could cause our business to fail.

AC5, AC5-G, AC5-V, AC5-P, Crystal Clear Surgery, NanoDrape and NanoBioBarrier and associated logos are trademarks and/or registered trademarks of Arch Therapeutics, Inc. and of Arch Biosurgery, Inc.

Employees

As of September 15, 2023, we had ten employees, all of whom are full-time, and make extensive use of third-party contractors, consultants, and advisors to perform many of our present activities. We expect to increase the number of our employees as we increase our operations.

Properties

We do not own any real property. In April 2015, we moved our corporate offices to a property in Framingham, Massachusetts. In July 2017, we entered into a three-year operating lease commencing October 1, 2017 and ending on September 30, 2020 at our current location. During August 2020, we extended the lease through September 30, 2021 at our current location. During October 2021, we extended the lease through March 31, 2022 at our current location. Effective April 1, 2022, our lease is month to month at our current location.

Legal Proceedings

In the ordinary course of business, we may become a party to legal proceedings involving various matters. We are unaware of any such legal proceedings presently pending to which we or our subsidiary is a party or of which any of our property is the subject that management deems to be, individually or in the aggregate, material to our financial condition or results of operations.

Dr. Avtar Dhillon served as our Chairman of the Board from April 2013 through July 2018, and as an advisor to us from July 2018 until his termination on August 6, 2021. As previously disclosed, in August 2021, the U.S. Department of Justice (the “DOJ”) filed a criminal complaint against Dr. Avtar Dhillon, alleging, among other things, his participation in a securities fraud scheme whereby he concealed his ownership of millions of shares of two microcap companies (including the Company) and then secretly directed the shares’ sale, generating approximately \$2.19 million in proceeds. On December 7, 2022, Dr. Avtar Dhillon pleaded guilty to one count of conspiracy to commit securities fraud, one count of securities fraud, and two counts of obstructing a proceeding of the SEC. Sentencing is scheduled for May 23, 2024. At the same time, the SEC charged Dr. Avtar Dhillon with violations of the antifraud and certain other provisions of federal securities laws in connection with the sales of securities of certain public companies, including his sale of shares of the Company. On October 20, 2022, the United States District Court for the Central District of California entered a final judgment as to Dr. Avtar Dhillon, in favor of the SEC, pursuant to which he is (1) prohibited from acting as an officer or director of any issuer that has a class of securities registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”) or that is required to file reports pursuant to Section 15(d) of the Exchange Act and (2) permanently restrained and enjoined from violating, directly or indirectly, (i) Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, (ii) Section 17(a) of the Securities Act, and (iii) Section 17(b) of the Securities Act. The Company has fully cooperated with the DOJ and the SEC and has not been implicated in or charged with any wrongdoing.

DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Set forth below is certain information regarding our current directors and executive officers:

Name	Position	Age	Director/Officer Since
Dr. Terrence W. Norchi	President, Chief Executive Officer and Chairman of the Board of Directors	58	April 2013
Michael S. Abrams	Chief Financial Officer	52	May 2021
Daniel M. Yrigoyen	Vice President of Sales	53	July 2021
Punit Dhillon	Director	42	July 2018
Laurence Hicks	Director	57	September 2021
Dr. Guy L. Fish	Director	63	December 2021

Dr. Terrence W. Norchi. Terrence W. Norchi, MD, our co-founder, serves as our President and Chief Executive Officer, and Chairman of the Board. Dr. Norchi also served as our Interim Chief Financial Officer through June 26, 2013. Dr. Norchi has served in similar positions since co-founding ABS, our predecessor company in 2006. Prior to ABS, Dr. Norchi was a portfolio manager of one of the world's largest healthcare mutual funds and a pharmaceutical analyst at Putnam Investments from April 2002 to September 2004. Prior to that, he served as the senior global biotech and international pharmaceutical equity analyst at Citigroup Asset Management, and as a sell-side analyst covering non-U.S. pharmaceutical equities at Sanford C. Bernstein in New York City. Dr. Norchi earned an M.B.A. from the Massachusetts Institute of Technology, Sloan School of Management in 1996. Dr. Norchi earned an M.D. degree in 1990 from Northeast Ohio Medical University and completed his internal medicine residency in 1994 at Baystate Medical Center, Tufts University School of Medicine, where he was selected to serve as the Chief Medical Resident. Dr. Norchi brings to our Board and management team invaluable experience and knowledge of our core technology and proposed product candidates as a result of his first-hand experience with the development of that technology, having ushered it from the research laboratory to its current stage of development. His investing experience as a former public company analyst and a portfolio manager provides further insights and value as the company advances toward commercialization. Dr. Norchi serves on the Board of Advisors of the Boston Museum of Science.

Michael S. Abrams. Mr. Abrams has served as the Chief Financial Officer of the Company since May 2021. Prior to joining the Company, Mr. Abrams was the turnaround Chief Financial Officer for RiseIT Solutions, Inc. from February 2019 to April 2021, where he helped return the business to profitability. Prior to RiseIT Solutions, from August 2009 to February 2019, Mr. Abrams served as the Chief Financial Officer and director of FitLife Brands, Inc., a publicly traded entity focused on the development of functional nutritional supplements that promote an active, healthy lifestyle. From August 2004 to December 2016, Mr. Abrams served as Partner and Managing Director of Burnham Hill Capital Group, a private privately held financial services holding company. Mr. Abrams graduated with an MBA with Honors from the Booth School of Business at the University of Chicago and received his BBA with Honors from the University of Massachusetts at Amherst as a William F. Field Alumni scholar, an award given annually to the top finance student in the class.

Daniel M. Yrigoyen. Mr. Yrigoyen has served as the Vice President of Sales of the Company since July 2021. Prior to joining the Company, Mr. Yrigoyen was Vice President, Sales & Channel Distribution for Medela, Inc. from April 2016 to July 2021. Prior to Medela, Mr. Yrigoyen served as General Manager for multiple business units at Hollister, Inc., where he was responsible for the expansion of the wound care product portfolio and led the effort to launch several new and innovative wound care products into the US market. Following these efforts, Mr. Yrigoyen joined the Hollister Global Marketing Organization, where he led similar expansion efforts within key markets of Hollister's international business. Mr. Yrigoyen was an employee at Hollister for over 20 years and brings significant healthcare and distribution experience to the Company. Yrigoyen graduated with an MBA from the Kellogg School of Management at Northwestern University.

Punit Dhillon. Mr. Dhillon joined our Board of Directors in July 2018. Mr. Dhillon was appointed CEO and Chair of Skye Bioscience, Inc. (OTCQB: SKYE) in August 2020 and brings over 20 years of global industry experience to Arch's Board. He is the co-founder and former President & CEO of OncoSec Medical Incorporated (NASDAQ: ONCS), a leading biopharmaceutical company developing cancer immunotherapies for the treatment of solid tumors, where he served as an executive until March 2018 and a director until February 2020. Prior to that, Mr. Dhillon served as the Vice President of Finance and Operations at Inovio Pharmaceuticals, Inc. (NASDAQ: INO), a DNA vaccine development company, from September 2003 until March 2011. Mr. Dhillon is also a director and Audit Committee Chair of Emerald Health Therapeutics, Inc. (CSE: EMH). Mr. Dhillon also co-founded and is the director of YELL Canada, a registered Canadian charity that partners with schools to support entrepreneurial learning. Mr. Dhillon has a Bachelor of Arts with honors in Political Science and a minor in Business Administration from Simon Fraser University. Mr. Dhillon's experience in the medical device and life sciences industry provides value to his role as a member of the Board.

Laurence Hicks. Mr. Hicks joined our Board of Directors in September 2021. He has been the chief executive officer of Healthcare Components Group, a global manufacturer of OEM and replacement parts used for the manufacture and repair of medical devices, since 2021. From 2016 until 2021, when it merged into Healthcare Components Group, Mr. Hicks was chief executive officer of 2506052 Ontario Inc., a holding company for American Optics, Endoscopy Replacement Parts and Micro Optics Europe, which sell components used in the manufacturing and repair of endoscopes worldwide. He has held medical device leadership roles at ACMI, Karl Storz Endoscopy and NeuroTherm. Mr. Hicks' experience in the medical device industry provides value to his role as a member of the Board.

Dr. Guy L. Fish. Dr. Fish joined our Board of Directors in December 2021. He is currently employed by the Greater Lawrence Family Health Centers, a nationally recognized Federally Qualified Health Center, where he has served as the Chief Executive Officer since 2021. Dr. Fish is also the President and Co-Founder of Ivy Consulting Partners, Inc., a boutique consultancy focused on healthcare, corporate and leadership development, and business strategy, a role he has held since 1999. Dr. Fish served as the Chief Executive Officer at Cellanix LLC, a cancer diagnostic company, from 2019 to 2020. From 2002 to 2021, Dr. Fish served in various executive positions at Fletcher Spaght, Inc., a strategy management firm focused on health care innovator companies. From 2006 to 2019, Dr. Fish served as an investor and Senior Vice President at Fletcher Spaght Ventures. Dr. Fish has served as a member of the board of directors of Etiometry, Inc. since 2019, PhaseBio Pharmaceuticals, Inc. (NASDAQ:PHAS) from 2009 to 2018, and Metabolon, Inc. from 2010 to 2017. Dr. Fish holds an MBA degree from Yale University School of Management and a M.D. degree from Yale University School of Medicine. Dr. Fish holds a bachelor's degree in biochemistry from Harvard University. The Company believes that Dr. Fish is qualified to serve on the Board as a result of his extensive leadership experience in the medical field, as well as his record of accomplishment in business strategy and operations.

Board of Director Composition

Our Board currently consists of four members. We have no formal policy regarding board diversity. Our priority in selection of board members is identification of members who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business and understanding of the competitive landscape.

Term of Office of Directors

Our directors are appointed and serve until their successor has been duly elected and qualified, or until the earlier of their death, resignation or removal.

Involvement in Certain Legal Proceedings

No director, executive officer or control person of the Company has been involved in any legal proceeding listed in Item 401(f) of Regulation S-K in the past 10 years.

Director Independence

Our Board of Directors has determined that Mr. Punit Dhillon, Mr. Laurence Hicks and Dr. Guy Fish would qualify as "independent" as that term is defined by Nasdaq Listing Rule 5605(a)(2). On August 15, 2022, we have established separately designated audit, corporate governance and nominating, and compensation board committees. Mr. Dhillon, Mr. Hicks, and Dr. Fish all qualify as "independent" under Nasdaq Listing Rules applicable to all such board committees. Dr. Terrence W. Norchi would not qualify as "independent" under Nasdaq Listing Rules applicable to the Board of Directors generally or to separately designated board committees because he currently serves as our President and Chief Executive Officer.

Subject to some exceptions, Nasdaq Listing Rule 5605(a)(2) provides that an independent director is a person other than an executive officer or other employee of the Company or any other individual having a relationship which, in the opinion of our Board of Directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Under Nasdaq Listing Rule 5605(a)(2) and subject to certain exceptions, a director will not be deemed to be independent if (a) the director is, or at any time during the past three years was, an employee of ours; (b) the director or a member of the director's immediate family or a person living with such director (collectively, a "**Related Party**") has received more than \$120,000 in compensation from us during any twelve-month period within the preceding three years, other than compensation for service as a director or as a non-executive employee (in the case of Related Party), benefits under a tax-qualified retirement plan or non-discretionary compensation; (c) a Related Party is, or in the past three years has been, an executive officer of ours; (d) the director or a Related Party is an executive officer, partner or controlling shareholder of a company that makes payments to, or receives payments from, us in an amount which, in any twelve-month period during our past three fiscal years, exceeds the greater of 5% of the recipient's consolidated gross revenues for that year or \$200,000 (except for payments arising solely from investments in our securities or payments under non-discretionary charitable contribution matching programs); (e) the director or a Related Party is employed as an executive officer of another company where at any time during the preceding three years one of our executive officers served on the compensation committee of such company; and (f) the director or a Related Party is a current partner of our independent public accounting firm, or has worked for such firm in any capacity on our audit at any time during the past three years.

Committees of the Board of Directors

Our Board has established an Audit Committee, a Compensation Committee, and a Nominating and Corporate Governance Committee. Our Board may establish other committees to facilitate the management of our business. The composition and functions of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our Board. Each of these committees operate under a charter that has been approved by our Board, which will be available on our website.

Audit Committee

On August 15, 2022, our Board of Directors established a separate standing audit committee within the meaning of Section 3(a)(58)(A) of the Exchange Act. The Audit Committee consists of Mr. Punit Dhillon, serving as the Chairman of the Audit Committee, Mr. Laurence Hicks, and Dr. Guy Fish. Our Board has determined that the three directors currently serving on our Audit Committee are independent within the meaning of the Nasdaq Marketplace Rules and Rule 10A-3 under the Exchange Act. Our Board of Directors has determined that Mr. Dhillon is an “audit committee financial expert” as defined by applicable Securities and Exchange Commission (“SEC”) rules.

The Audit Committee oversees and monitors our financial reporting process and internal control system, reviews and evaluates the audit performed by our registered independent public accountants and reports to our Board any substantive issues found during the audit. The Audit Committee is directly responsible for the appointment, compensation and oversight of the work of our registered independent public accountants. The Audit Committee reviews and approves all transactions with affiliated parties.

Compensation Committee

Our Compensation Committee consists of Dr. Fish, Mr. Hicks and Mr. Dhillon, with Mr. Hicks serving as the Chairman of the Compensation Committee. Our Board has determined that the three directors currently serving on our Compensation Committee are independent under the listing standards, are “non-employee directors” as defined in rule 16b-3 promulgated under the Exchange Act and are “outside directors” as that term is defined in Section 162(m) of the Internal Revenue Code of 1986, as amended.

The Compensation Committee provides advice and makes recommendations to the Board in the areas of employee salaries, benefit programs and director compensation. The Compensation Committee also reviews and approves corporate goals and objectives relevant to the compensation of our Chief Executive Officer and other officers and makes recommendations in that regard to the Board as a whole.

Nominating and Corporate Governance Committee

Our Nominating and Corporate Governance Committee consists of Dr. Fish, Mr. Hicks and Mr. Dhillon, with Dr. Fish serving as the Chairman of the Nominating and Corporate Governance Committee. The Nominating and Corporate Governance Committee nominates individuals to be elected to the Board by our stockholders. The Nominating and Corporate Governance Committee considers recommendations from stockholders if submitted in a timely manner in accordance with the procedures set forth in our bylaws and will apply the same criteria to all persons being considered. All members of the Nominating and Corporate Governance Committee are independent directors as defined under the Nasdaq listing standards.

Board Leadership Structure and Role in Risk Oversight

Currently, Dr. Norchi serves as the Company’s Chief Executive Officer and Chairman of the Board. Periodically, our Board will assess the roles of Chairman and Chief Executive Officer and the Board leadership structure to ensure the interests of the Company and our stockholders are best served. Our Board believes the current combination of the two roles is satisfactory at present. Dr. Norchi, as our Chief Executive Officer and Chairman, has extensive knowledge of all aspects of the Company and its business. We have no policy requiring the combination or separation of leadership roles and our governing documents do not mandate a particular structure. This has allowed, and will continue to allow, our Board the flexibility to establish the most appropriate structure for the Company at any given time.

While management is responsible for assessing and managing risks for the Company, our Board is responsible for overseeing management’s efforts to assess and manage risk. This oversight is conducted primarily by our full Board, which has responsibility for general oversight of risks. Our Board satisfies this responsibility through regular reports directly from officers responsible for oversight of particular risks within the Company. Our Board believes that full and open communication between management and the Board is essential for effective risk management and oversight.

Code of Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, principal executive officer, principal financial officer, principal accounting officer and all of our other officers and employees and can be found on our website, <http://www.archtherapeutics.com> on our “Corporate Governance” webpage, which can be accessed from the “Investors” tab of our website. We will also provide a copy of our code of business conduct and ethics to any person without charge upon his or her request. Any such request should be directed to our Chief Financial Officer at 235 Walnut Street, Suite 6, Framingham, Massachusetts 01702. We intend to make all required disclosures concerning any amendments to or waivers from our code of business conduct and ethics on our website.

Liability and Indemnification of Directors and Officers

The NRS empower us to indemnify our directors and officers against expenses relating to certain actions, suits or proceedings as provided for therein. In order for such indemnification to be available, the applicable director or officer must not have acted in a manner that constituted a breach of his or her fiduciary duties and involved intentional misconduct, fraud or a knowing violation of law, or must have acted in good faith and reasonably believed that his or her conduct was in, or not opposed to, our best interests. In the event of a criminal action, the applicable director or officer must not have had reasonable cause to believe his or her conduct was unlawful.

We have not entered into separate indemnification agreements with our directors and officers. Our amended and restated bylaws provide that we shall indemnify any director or officer to the fullest extent authorized by the laws of the State of Nevada. Our amended and restated bylaws further provide that we shall pay the expenses incurred by an officer or director (acting in his capacity as such) in defending any action, suit or proceeding in advance of the final disposition of such action, suit or proceeding, subject to the delivery to us by or on behalf of such director or officer of an undertaking to repay the amount of such expenses if it shall ultimately be determined that he or she is not entitled to be indemnified by us as authorized in our bylaws or otherwise.

The NRS further provide that a corporation may purchase and maintain insurance or make other financial arrangements on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise for any liability asserted against him and liability and expenses incurred by him in his capacity as a director, officer, employee or agent, or arising out of his status as such, whether or not the corporation has the authority to indemnify him against such liability and expenses. We have secured a directors’ and officers’ liability insurance policy. We expect that we will continue to maintain such a policy.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

EXECUTIVE COMPENSATION

The following table summarizes all compensation recorded by us in each of the fiscal years ended September 30, 2023, and September 30, 2022 for (i) our principal executive officer; (ii) our two next most highly compensated executive officers whose total compensation exceeded \$100,000 during our last completed fiscal year; and (iii) certain of our other executive officers, whose compensation is voluntarily provided.

Summary Compensation Table

Name	Fiscal Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards (\$)(1)	All other Compensation (\$)	Total (\$)
Dr. Terrence W. Norchi,	2023	450,500	-	-	40,500	-	491,000
<i>President and Chief Executive Officer</i>	2022	450,500	-	-	-	-	450,500
Michael S. Abrams	2023	325,000	-	-	29,160	-	354,160
<i>Chief Financial Officer</i>	2022	325,000	-	-	-	-	325,000
Daniel Yrigoyen	2023	325,000	-	-	16,200	-	341,200
<i>VP of Sales</i>	2022	316,667	-	-	9,075	-	325,742

(1) Represents the aggregate grant date fair values of awards granted during the fiscal year ended September 30, 2023 and 2022 under ASC Topic 718, which is calculated as of the grant date using a Black-Scholes option-pricing model. Accordingly, the dollar amounts listed do not necessarily reflect the dollar amount of compensation that may be realized by our executive officers. For information on the valuation assumptions with respect to option grants made during the fiscal year ended September 30, 2022 refer to Note 14 “**Stock-Based Compensation**” in our consolidated financial statements in this prospectus.

Employment Agreements with Named Executive Officers

Terrence W. Norchi

On June 25, 2013, we entered into an executive employment agreement with Dr. Terrence W. Norchi, our President and Chief Executive Officer and a member of our Board, which became effective as of June 26, 2013. Dr. Norchi’s employment agreement continues until terminated by Dr. Norchi, or us and provided for an initial annual base salary of \$275,000, and eligibility to receive an annual cash bonus in an amount up to 30% of Dr. Norchi’s then-current annual base salary. In addition, Dr. Norchi’s employment agreement provides that his annual base salary will be reviewed from time to time in accordance with the established procedures of the Company for adjusting salaries for similarly situated employees. Annual bonuses are awarded at the sole discretion of our Board. If Dr. Norchi’s employment is terminated by us (unless such termination is “For Cause” (as defined in his employment agreement)), or by Dr. Norchi for “Good Reason” (as defined in his employment agreement), then Dr. Norchi, upon signing a release in favor of the Company, will be entitled to severance in an amount equal to 12 months of Dr. Norchi’s then-current annual base salary, payable in the form of salary continuation, plus, if Dr. Norchi elects and subject to certain other conditions, payment of Dr. Norchi’s premiums to continue his group health coverage under COBRA until the earlier of (i) 12 months following the date of such termination; or (ii) the date Dr. Norchi becomes covered under another employer’s health plan. In addition, Dr. Norchi’s employment agreement provides that, in the event of a change of control of the Company, termination by Dr. Norchi for Good Reason, termination by the Company for any reason other than For Cause, or termination as a result of Dr. Norchi’s death, all unvested shares under outstanding equity grants to Dr. Norchi, if any, shall automatically accelerate and become fully vested. On March 13, 2014, Dr. Norchi’s employment agreement was amended to increase his annual base salary to \$325,000, retroactively effective as of February 1, 2014, and increase his cash bonus eligibility from 30% of his annual base salary to 35% of his annual base salary. In connection with the Board’s annual review of Dr. Norchi’s base salary, Dr. Norchi’s annual base salary was increased to \$425,000 effective July 1, 2017. In connection with the Board’s annual review of Dr. Norchi’s base salary, Dr. Norchi’s annual base salary was increased to \$450,500 effective August 1, 2019.

Dr. Norchi's employment agreement provides the following definitions of "For Cause" and "Good Reason": (a) "For Cause" is (i) the commission by the executive of a crime involving dishonesty, breach of trust, or physical harm to any person, (ii) executive's engagement by the executive in conduct that is in bad faith and materially injurious to the Company, (iii) commission by the executive of a material breach of the employment agreement which is not cured within 20 days after the executive receives written notice of such breach, (iv) willful refusal by the executive to implement or follow a lawful policy or directive of the Company, which breach is not cured by the executive within 20 days after receiving written notice from the Company, (v) or executive's engagement in misfeasance or malfeasance demonstrated by a pattern of failure to perform job duties diligently and professionally (other than any such failure resulting from Executive's incapacity due to physical or mental illness); and (b) "Good Reason" is, without the executive's written consent, (1) a material reduction in executive's annual base salary, except for reductions that are comparable to reductions generally applicable to similarly situated executives of the Company, (2) the relocation of executive to a facility or location that is more than 50 miles from his primary place of employment and such relocation results in an increase in executive's one-way driving distance by more than 50 miles, or (3) a material and adverse change in executive's authority, duties, or responsibilities with the Company or a material and adverse change in executive's reporting relationship within the Company.

In connection with our entry into the executive employment agreement with Dr. Norchi, effective on June 26, 2013, Dr. Norchi's former employment agreement with ABS was terminated pursuant to a termination agreement and release between Dr. Norchi and ABS.

Michael S. Abrams

On March 31, 2021, we entered into an executive employment agreement with Mr. Abrams, our Chief Financial Officer and Treasurer. The agreement continues until terminated by us or by Mr. Abrams. Pursuant to the terms of the agreement, Mr. Abrams is entitled to an initial annual base salary of \$325,000 and is eligible to receive an annual cash bonus in an amount of up to 30% of Mr. Abrams' then-current annual base salary. Annual bonuses are awarded at the sole discretion of our Board of Directors. In addition, Mr. Abrams' employment agreement provides that his annual base salary will be reviewed by the Board (or any committee thereof), with such input as it may request from the Company's Chief Executive Officer, from time to time but at least on an annual basis, in accordance with the established procedures of the Company for adjusting salaries for similarly situated employees. If Mr. Abrams' employment is terminated by us at any time after 30 days after the start date (unless such termination is "For Cause" (as defined in his employment agreement)), or by Mr. Abrams for "Good Reason" (as defined in his employment agreement), then Mr. Abrams, upon signing a release in favor of the Company, would be entitled to severance in an amount equal to six months of Mr. Abrams' then-current annual base salary, payable in the form of salary continuation, plus, if Mr. Abrams elects and subject to certain other conditions, payment of Mr. Abrams' premiums to continue his group health coverage under COBRA until the earlier of (i) 12 months following the date of such termination; or (ii) the date Mr. Abrams becomes covered under another employer's health plan. In addition, Mr. Abrams' employment agreement provides that, in the event of a change of control of the Company or his employment is terminated by the Company for any reason other than For Cause, all unvested shares under outstanding equity grants to Mr. Abrams, if any, shall automatically accelerate and become fully vested.

The agreement provides the following definitions of "For Cause" and "Good Reason": (a) "For Cause" is (i) Mr. Abrams commits a crime involving dishonesty, breach of trust, or physical harm to any person; (ii) Mr. Abrams willfully engages in conduct that is in bad faith and materially injurious to the Company, including without limitation misappropriation of trade secrets, fraud or embezzlement; (iii) Mr. Abrams commits a material breach of this Agreement or the Proprietary Information Agreement, which breach is not cured within twenty calendar days after written notice to Executive from the Company (to the extent curable); (iv) Mr. Abrams willfully refuses to implement or follow a lawful policy or directive of the Company, which breach is not cured within twenty calendar days after written notice to Executive from the Company; or (v) Mr. Abrams engages in misfeasance or malfeasance demonstrated by a pattern of failure to perform job duties diligently and professionally. The Company may terminate Mr. Abrams' employment For Cause at any time, without any advance notice. The Company shall pay Mr. Abrams all compensation to which Mr. Abrams is entitled up through the date of termination, subject to any other rights or remedies of the Company under law, and thereafter all obligations of the Company under this Agreement shall cease.

Daniel M. Yrigoyen

On July 12, 2021, we entered into an executive employment agreement with Mr. Yrigoyen, our Vice President of Sales. The agreement continues until terminated by us or by Mr. Yrigoyen. Pursuant to the terms of the agreement, Mr. Yrigoyen is entitled to an initial annual base salary of \$225,000 and is eligible to receive regular commission payments of up to \$8,333.33 per month, depending on the achievement of established objectives; *provided, however*, that for the first nine (9) months of employment, Mr. Yrigoyen shall be entitled to receive the full commission of \$8,333.33 per month regardless of whether the applicable performance objectives are met; this provision was subsequently extended indefinitely pending review from time to time in connection with the Company's ongoing commercialization effort.

In addition, Mr. Yrigoyen's employment agreement provides that his annual base salary will be reviewed by the Board (or any committee thereof), with such input as it may request from the Company's Chief Executive Officer, from time to time but at least on an annual basis, in accordance with the established procedures of the Company for adjusting salaries for similarly situated employees. If Mr. Yrigoyen's employment is terminated by us at any time after 30 days after the start date (unless such termination is "For Cause" (as defined in his employment agreement)), or by Mr. Yrigoyen for "Good Reason" (as defined in his employment agreement), then Mr. Yrigoyen, upon signing a release in favor of the Company, would be entitled to severance in an amount equal to six months of Mr. Yrigoyen's then-current annual base salary, payable in the form of salary continuation, plus, if Mr. Yrigoyen elects and subject to certain other conditions, payment of Mr. Yrigoyen's premiums to continue his group health coverage under COBRA until the earlier of (i) 12 months following the date of such termination; or (ii) the date Mr. Yrigoyen becomes covered under another employer's health plan. In addition, Mr. Yrigoyen's employment agreement provides that, in the event of a change of control of the Company or his employment is terminated by the Company for any reason other than For Cause, all unvested shares under outstanding equity grants to Mr. Yrigoyen, if any, shall automatically accelerate and become fully vested.

The agreement provides the following definitions of "For Cause" and "Good Reason": (a) "For Cause" is (i) Mr. Yrigoyen commits a crime involving dishonesty, breach of trust, or physical harm to any person; (ii) Mr. Yrigoyen willfully engages in conduct that is in bad faith and materially injurious to the Company, including without limitation misappropriation of trade secrets, fraud or embezzlement; (iii) Mr. Yrigoyen commits a material breach of this Agreement or the Proprietary Information Agreement, which breach is not cured within twenty calendar days after written notice to Executive from the Company (to the extent curable); (iv) Mr. Yrigoyen willfully refuses to implement or follow a lawful policy or directive of the Company, which breach is not cured within twenty calendar days after written notice to Mr. Yrigoyen from the Company; or (v) Mr. Yrigoyen engages in misfeasance or malfeasance demonstrated by a pattern of failure to perform job duties diligently and professionally. The Company may terminate Mr. Yrigoyen's employment For Cause at any time, without any advance notice. The Company shall pay Mr. Yrigoyen all compensation to which Mr. Yrigoyen is entitled up through the date of termination, subject to any other rights or remedies of the Company under law, and thereafter all obligations of the Company under this Agreement shall cease.

Outstanding Equity Awards At Fiscal Year-End

The following table summarizes the aggregate number of option and stock awards held by our named executive officers at September 30, 2023:

Name	Option Awards				Stock Awards	
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)
Dr. Terrence W. Norchi	2,500	- (1)	70.00	03/23/2024		
	2,000	- (2)	38.00	01/21/2025		
	1,775	- (3)	56.00	08/17/2025		
	6,250	- (4)	78.00	05/02/2026		
	3,250	- (5)	130.00	02/02/2027		
	1,800	- (6)	85.00	07/18/2028		
	5,000	- (7)	45.84	12/19/2029		
	5,000	- (8)	20.56	09/26/2031		
	3,334	1,666 (9)	20.56	09/26/2031		
	1,737	4,513 (10)	8.02	11/9/2032		
Michael S. Abrams	2,084	416 (11)	26.58	05/02/2031		
	1,167	583 (12)	20.56	09/26/2031		
	1,250	3,250 (13)	8.02	11/9/2032		
Daniel M. Yrigoyen	542	208 (14)	18.00	06/29/2031		
	667	333 (15)	20.56	09/26/2031	750 (16)	19,500
	334	416 (17)	12.10	05/23/2032		
	695	1,805 (18)	8.02	11/9/2032		

- (1) Represents an option to purchase 2,500 shares of Common Stock with a grant date of March 23, 2014. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, 25% of the shares shall vest 12 months following the date of grant and 1/24th of the remaining shares shall vest on each of the monthly anniversaries of the grant date, commencing April 23, 2015.
- (2) Represents an option to purchase 2,000 shares of Common Stock with a grant date of January 22, 2015. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, 25% of the shares shall vest 12 months following the date of grant and 1/24th of the remaining shares shall vest on each of the monthly anniversaries of the grant date, commencing February 22, 2016.
- (3) Represents an option to purchase 1,775 shares of Common Stock with a grant date of August 18, 2015. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, and 1/36th of the remaining shares shall vest on each of the monthly anniversaries of the grant date, commencing September 18, 2015.
- (4) Represents an option to purchase 6,250 shares of Common Stock granted on May 3, 2016. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vesting immediately, the remaining unvested Shares subject to the Option shall vest on each of the next thirty-six (36) monthly anniversaries of the date of grant.
- (5) Represents an option to purchase 3,250 shares of Common Stock granted on February 3, 2017. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vesting immediately, the remaining unvested Shares subject to the Option shall vest on each of the next thirty-six (36) monthly anniversaries of the date of grant.
- (6) Represents an option to purchase 1,800 shares of Common Stock with a grant date of July 19, 2018. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, and 1/36th of the remaining shares shall vest on each of the monthly anniversaries of the grant date, commencing August 19, 2018.
- (7) Represents an option to purchase 5,000 shares of Common Stock with a grant date of December 20, 2019. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, and 1/36th of the remaining shares shall vest on each of the monthly anniversaries of the grant date, commencing January 20, 2019.
- (8) Represents an option to purchase 5,000 shares of Common Stock with a grant date of September 27, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with 33% of the shares vested immediately on the date of grant and the remaining shares to vest in 24 equal installments commencing on the first anniversary on the date of grant.
- (9) Represents an option to purchase 5,000 shares of Common Stock with a grant date of September 27, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.
- (10) Represents an option to purchase 6,250 shares of Common Stock with a grant date of November 10, 2022. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.
- (11) Represents an option to purchase 2,500 shares of Common Stock with a grant date of May 3, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with 30% of the shares vested immediately on the date of grant and the remaining shares to vest in 24 equal installments commencing on the first anniversary on the date of grant.
- (12) Represents an option to purchase 1,750 shares of Common Stock with a grant date of September 27, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.
- (13) Represents an option to purchase 4,500 shares of Common Stock with a grant date of November 10, 2022. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.
- (14) Represents an option to purchase 750 shares of Common Stock with a grant date of July 30, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant and the remaining shares to vest in 24 equal installments commencing on the first anniversary on the date of grant.
- (15) Represents an option to purchase 1,000 shares of Common Stock with a grant date of September 27, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.
- (16) Represents an option to purchase 750 shares of Common Stock with a grant date of July 30, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant and the remaining shares to vest in 24 equal installments commencing on the first anniversary on the date of grant.
- (17) Represents an option to purchase 750 shares of Common Stock with a grant date of May 24, 2022. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.
- (18) Represents an option to purchase 2,500 shares of Common Stock with a grant date of November 10, 2022. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.

Compensation of Directors

On March 23, 2014, our Board adopted a director compensation policy for non-employee directors. That policy provides that effective the first calendar quarter of 2014, the person serving as the Chairman of our Board receives an aggregate annual cash fee of \$190,000 for that chairperson role, and all other non-employee directors receive an annual cash fee of \$50,000.

The following table summarizes all compensation paid to our non-employee directors during the fiscal year ended September 30, 2023:

Director Compensation Table

	Fees Earned or Paid In Cash (\$)	Stock Awards (\$)	Option Awards (\$)	All other Compensation (\$)	Total (\$)
Punit Dhillon (1)	12,500	-	8,100	-	20,600
Laurence Hicks (2)	-	-	8,100	-	8,100
Guy L. Fish (3)	-	-	8,100	-	8,100

(1)Mr. Dhillon was appointed as a member of the Board on July 19, 2018. The aggregate number of shares of Common Stock underlying option awards outstanding as of September 30, 2023 held by Mr. Dhillon was 6,250.

(2)Mr. Hicks was appointed as a member of the Board on September 27, 2021. The aggregate number of shares of Common Stock underlying option awards outstanding as of September 30, 2023 held by Mr. Hicks was 2,500.

(3)Dr. Fish was appointed as a member of the Board on December 31, 2021. The aggregate number of shares of Common Stock underlying option awards outstanding as of September 30, 2023 held by Dr. Fish was 2,500.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Related Party Transactions

During fiscal years 2023 and 2022, other than with respect to matters relating to the Company's compensation arrangements with its executive officers, there were no transactions between the Company or any of its subsidiaries and any "Related Person" (as that term is defined in Item 404 of Regulation S-K) that would be required to be reported pursuant to Item 404 of Regulation S-K other than the following:

On June 22, 2020, the Company entered into a Series J Warrant Issuance Agreement (the "**Keyes Sulat Agreement**") with the Keyes Sulat Revocable Trust (the "**Trust**"), also a holder of outstanding Series D Warrants, resulting in approximately \$82,000 of proceeds as a result of the full exercise of the Trust's Series D Warrants. Under the terms of the Keyes Sulat Agreement, in exchange for fully exercising the Trust's remaining Series D Warrants for 2,273 shares of Common Stock on June 22, 2020, the Trust was issued Series J Warrants to purchase 1,705 shares of Common Stock at an exercise price of \$50.00 over a 1 year term. James R. Sulat, a former member of the Board, is a co-trustee of the Trust, of which members of Mr. Sulat's immediate family are beneficiaries. Mr. Sulat disclosed his interest in the Trust to the Board prior to its approval of the transaction and abstained from voting on the transaction. As of September 15, 2023, no Series J Warrants remain outstanding.

On July 6, 2022 a Board member, Laurence Hicks, and executive officers, Terrence W. Norchi and Michael S. Abrams, invested in the First Closing. The investment made in the First Closing made by the Board member and executive officers totaled \$80,000.

On August 30, 2023 a Board member, Laurence Hicks, and executive officers, Terrence W. Norchi and Michael S. Abrams, invested in the Bridge Offering. The investment made in the Bridge Offering made by the Board member and executive officers totaled approximately \$7,500.

Review, Approval or Ratification of Transactions with Related Persons

Due to the small size of our Company, at this time we have determined to rely on our full Board to review related party transactions and identify and prevent conflicts of interest. Our Board reviews a transaction in light of the affiliations of the director, officer, employee or stockholder and the affiliations of such person's immediate family. Transactions are presented to our Board for approval before they are entered into or, if that is not possible, for ratification after the transaction has occurred. If our Board finds that a conflict of interest exists, then it will determine the appropriate remedial action, if any. Our Board approves or ratifies a transaction if it determines that the transaction is consistent with the best interests of the Company and its stockholders. The procedures described above have been approved by resolutions adopted by our Board.

Subject to some exceptions, Nasdaq Listing Rule 5605(a)(2) provides that an independent director is a person other than an executive officer or other employee of the Company or any other individual having a relationship which, in the opinion of our Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Under Nasdaq Listing Rule 5605(a)(2) and subject to certain exceptions, a director will not be deemed to be independent if (a) the director is, or at any time during the past three years was, an employee of ours; (b) the director or a member of the director's immediate family or a person living with such director (collectively, a "**Related Party**") has received more than \$120,000 in compensation from us during any twelve-month period within the preceding three years, other than compensation for service as a director or as a non-executive employee (in the case of Related Party), benefits under a tax-qualified retirement plan or non-discretionary compensation; (c) a Related Party is, or in the past three years has been, an executive officer of ours; (d) the director or a Related Party is an executive officer, partner or controlling shareholder of a company that makes payments to, or receives payments from, us in an amount which, in any twelve-month period during our past three fiscal years, exceeds the greater of 5% of the recipient's consolidated gross revenues for that year or \$200,000 (except for payments arising solely from investments in our securities or payments under non-discretionary charitable contribution matching programs); (e) the director or a Related Party is employed as an executive officer of another company where at any time during the preceding three years one of our executive officers served on the compensation committee of such company; and (f) the director or a Related Party is a current partner of our independent public accounting firm, or has worked for such firm in any capacity on our audit at any time during the past three years.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding the beneficial ownership of our Common Stock by (i) each person who, to our knowledge, beneficially owns more than 5% of our Common Stock; (ii) each of our directors and named executive officers; and (iii) all of our directors and executive officers as a group. Unless otherwise indicated in the footnotes to the following table, the address of each person named in the table is: c/o Arch Therapeutics, Inc., 235 Walnut St., Suite #6, Framingham, Massachusetts 01702. The information set forth in the table below is based on 4,689,446 shares of our Common Stock outstanding on September 15, 2023. Shares of our Common Stock subject to options, warrants, or other rights currently exercisable or exercisable within 60 days of September 15, 2023 are deemed to be beneficially owned and outstanding for computing the share ownership and percentage of the person holding such options, warrants or other rights, but are not deemed outstanding for computing the percentage of any other person.

The number of shares beneficially owned after the offering assumes (i) the sale of 6,750,000 shares of Common Stock included in the Units in this offering at an assumed public offering price of \$2.00 per Unit (assuming no sale of Pre-Funded Units, even though it is currently anticipated that all of the stockholders listed below who would otherwise own more than 9.99% of our Common Stock will purchase Pre-Funded Units in lieu of Units to the extent needed to stay below 9.99%); (ii) that the Specified Percentage will be 50%, and thus, at the closing of this offering an aggregate of 1,567,127 shares of Common Stock (assuming no issuance of 2022 Note Conversion Pre-Funded Warrants) will be issued upon the Automatic Conversion of an aggregate of \$3,134,250 of principal amount under the 2022 Notes, representing 50% of the \$6,268,501 in principal amount currently outstanding under the 2022 Notes, based on the assumed offering price of \$2.00 per Unit in this offering; (iii) that all Holders of 2022 Notes will fulfill the Participation Criteria by investing in this offering 4.3 times the Holder's amount of participation in the Bridge Offering; (iv) no exercise of the Investor Warrants, Participating Pre-Funded Warrants or Exchange Investor Warrants issued at the closing of this offering; and (v) the issuance of 52,917 shares of Common Stock as a result of the conversion of the Series 2 Notes, at the closing of this offering. The percentage of shares beneficially owned after the offering is based on an assumed 13,059,490 shares of Common Stock to be outstanding, based on the assumptions set forth in the previous sentence.

The following table is presented after taking into account the applicable ownership limitation to which certain holders of our securities are subject to. In general, the ownership limitation prevents holders from exercising the warrant to the extent such exercise would result in the holder owning more shares than a certain ownership percentage, which is initially set below 5%, and such ownership limitation may be waived at the holder's discretion, provided that such waiver will not become effective until the 61st day after delivery of such waiver notice.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned (1)	Number of Shares Beneficially Owned after the Offering**	Percentage of Shares Beneficially Owned after the Offering
<i>5%+ Stockholders:</i>				
Oasis Capital, LLC (2)	300,000	6.40%	1,588,180	12.16%
Bigger Capital Fund, LP & District 2 Capital Fund LP (3)	300,000	6.40%	1,412,500	10.82%
Walleye Opportunities Master Fund Ltd (4)	300,000	6.40%	1,050,000	8.04%
Cavalry Fund I LP (5)	300,000	6.40%	1,195,000	9.15%
Brandt & Mona Wilson (6)	300,000	6.40%	1,050,000	8.04%
Ana and Michael Parker (7)	300,000	6.40%	698,895	5.35%
Andrew Stahl (8)	300,000	6.40%	1,050,000	8.04%
Sixth Borough Capital Fund, LP (9)	300,000	6.40%	515,000	3.94%
<i>Named Executive Officers and Directors:</i>				
Terrence Norchi (10)	113,194	2.39%	132,250	**%
Punit Dhillon (11)	5,868	*	5,868	**%
Laurence Hicks (12)	21,902	*	36,986	**%
Michael Abrams (13)	23,195	*	38,279	**%
Daniel Yrigoyen (14)	3,194	*	3,194	**%
Guy Fish (15)	2,014	*	2,014	**%
Named Officers and Directors as a Group	169,367	3.56%	209,591	1.6%

* Less than 1%.

**Excluding any shares and/or Investor Warrants issued in connection with the over-allotment option, if any.

Shares of our Common Stock subject to options, warrants, or other rights currently exercisable or convertible or exercisable or convertible within 60 days of September 15, 2023, are deemed to be beneficially owned and outstanding for computing the share ownership and percentage of the person holding such options, warrants or other rights, but are not deemed outstanding for computing the percentage of any other person.

- (1) Except as otherwise indicated, we believe that each of the beneficial owners of the Common Stock listed previously, based on information furnished by such owners, has sole investment and voting power with respect to the shares listed as beneficially owned by such owner, subject to community property laws where applicable. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities.

- (2) Represents 300,000 shares of Common Stock owned by Oasis Capital, LLC. Excludes (a) 131,292 shares of Common Stock issuable upon conversion of the First Notes (the “**First Conversion Shares**”); (b) 120,725 First Warrants; (c) 27,353 shares of Common Stock issuable upon conversion of the Second Notes (the “**Second Conversion Shares**”); (d) 50,302 Second Warrants; (e) 76,886 shares of Common Stock issuable upon conversion of the Third Notes (the “**Third Conversion Shares**”); (f) 141,396 Third Warrants; (g) 1,005,251 Bridge Pre-Funded Warrants with unsatisfied exercise restrictions; and (h) 2,552,766 Common Warrants with unsatisfied exercise restrictions, all of which are subject to conversion or exercise restrictions that prohibit conversion or exercise until such time as the holder would not beneficially own, after such conversion or exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder’s delivery of such waiver notice. As of September 15, 2023, Oasis Capital, LLC has not waived such limitation. The number of shares beneficially owned after the offering assumes the above referenced stockholder’s participation in the Uplist Transaction; however, no assurance can be given that the stockholder will participate as we are assuming.
- (3) Represents 300,000 shares of Common Stock owned by, and split evenly between, Bigger Capital Fund, LP and District 2 Capital Fund LP with a common control person. Excludes (a) 131,292 First Conversion Shares; (b) 120,726 First Warrants; (c) 27,354 Second Conversion Shares; (d) 50,302 Second Warrants; (e) 989,459 Bridge Pre-Funded Warrants with unsatisfied exercise restrictions; and (f) 2,552,652 Common Warrants with unsatisfied exercise restrictions held in the aggregate by Bigger Capital Fund, LP and District 2 Capital Fund LP, all of which are subject to conversion or exercise restrictions that prohibit conversion or exercise until such time as the holder would not beneficially own, after such conversion or exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder’s delivery of such waiver notice. As of September 15, 2023, neither Bigger Capital Fund, LP, nor District 2 Capital Fund LP has waived such limitation. The number of shares beneficially owned after the offering assumes the above referenced stockholder’s participation in the Uplist Transaction; however, no assurance can be given that the stockholder will participate as we are assuming.
- (4) Represents 300,000 shares of Common Stock owned by Walleye Opportunities Master Fund Ltd. Excludes (a) 976,278 Bridge PreFunded Warrants with unsatisfied exercise restrictions; and (b) 2,552,556 Common Warrants with unsatisfied exercise restrictions, all of which are subject to exercise restrictions that prohibit exercise until such time as the holder would not beneficially own, after such exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder’s delivery of such waiver notice. As of September 15, 2023, Walleye Opportunities Master Fund Ltd has not waived such limitation. The number of shares beneficially owned after the offering assumes the above referenced stockholder’s participation in the Uplist Transaction; however, no assurance can be given that the stockholder will participate as we are assuming.
- (5) Represents 300,000 shares of Common Stock owned by Cavalry Fund I LP. Excludes (a) 52,517 First Conversion Shares; (b) 48,290 First Warrants; (c) 10,941 Second Conversion Shares; (d) 20,121 Second Warrants; (e) 985,064 Bridge Pre-Funded Warrants with unsatisfied exercise restrictions; and (f) 2,552,620 Common Warrants with unsatisfied exercise restrictions, all of which are subject to conversion or exercise restrictions that prohibit conversion or exercise until such time as the holder would not beneficially own, after such conversion or exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder’s delivery of such waiver notice. As of September 15, 2023, Cavalry Fund I LP has not waived such limitation. The number of shares beneficially owned after the offering assumes the above referenced stockholder’s participation in the Uplist Transaction; however, no assurance can be given that the stockholder will participate as we are assuming.
- (6) Represents 300,000 shares of Common Stock owned individually by Brandt and Mona Wilson. Excludes (a) 976,278 Bridge PreFunded Warrants with unsatisfied exercise restrictions; and (b) 2,552,556 Common Warrants with unsatisfied exercise restrictions, all of which are subject to exercise restrictions that prohibit exercise until such time as the holder would not beneficially own, after such exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder’s delivery of such waiver notice. As of September 15, 2023, neither Brandt Wilson nor Mona Wilson had waived such limitation. The number of shares beneficially owned after the offering assumes the above referenced stockholder’s participation in the Uplist Transaction; however, no assurance can be given that the stockholder will participate as we are assuming.
- (7) Represents (i) 235,445 shares of Common Stock owned individually by Ana Parker, Michael A. Parker’s spouse; (ii) 38,055 shares of Common Stock owned individually by Mr. Parker; (iii) 25,000 shares of Common Stock owned through Tungsten, of which Mr. Parker is the sole manager and (iv) 1,500 shares of restricted stock granted to Mr. Parker on September 27, 2021. Excludes (a) 82,465 Bridge Pre-Funded Warrants with unsatisfied exercise restrictions; (b) 549,486 Common Warrants with unsatisfied exercise restrictions; (c) 103,559 First Conversion Shares; (d) 48,290 shares of Common Stock issuable upon exercise of the First Warrants (the “**First Warrant Shares**”); (e) any of the 17,143 shares of Common Stock that may be acquired upon the exercise of Series I Warrants (which expire October 18, 2024); or (f) any of the 23,438 shares that may be acquired upon the exercise of Series K Warrants (which expire on August 11, 2026), since such warrants cannot be exercised until such time as the holder would not beneficially own, after such exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case such waiver will become effective sixty-one (61) days after the holder’s delivery of such waiver notice. As of September 15, 2023, neither Ms. Parker nor Mr. Parker have waived such limitation. The number of shares beneficially owned after the offering assumes the above referenced stockholder’s participation in the Uplist Transaction; however, no assurance can be given that the stockholder will participate as we are assuming.

- (8) Represents 300,000 shares of Common Stock owned individually by Andrew Stahl. Excludes (a) 976,278 Bridge PreFunded Warrants with unsatisfied exercise restrictions; and (b) 2,552,556 Common Warrants with unsatisfied exercise restrictions, all of which are subject to exercise restrictions that prohibit exercise until such time as the holder would not beneficially own, after such exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of September 15, 2023, Mr. Stahl had not waived such limitation. The number of shares beneficially owned after the offering assumes the above referenced stockholder's participation in the Uplist Transaction; however, no assurance can be given that the stockholder will participate as we are assuming.
- (9) Represents 300,000 shares of Common Stock owned by Sixth Borough Capital Fund, LP. Excludes (a) 63,869 Bridge PreFunded Warrants with unsatisfied exercise restrictions; and (b) 727,738 Common Warrants with unsatisfied exercise restrictions, all of which are subject to exercise restrictions that prohibit exercise until such time as the holder would not beneficially own, after such exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of September 15, 2023, Sixth Borough Capital Fund, LP has not waived such limitation. The number of shares beneficially owned after the offering assumes the above referenced stockholder's participation in the Uplist Transaction; however, no assurance can be given that the stockholder will participate as we are assuming.
- (10) Represents (a) 50,000 shares of Common Stock held by Twelve Pins Partners, LLC, with respect to which Dr. Norchi is the sole member and holds sole voting and investment control; (b) 7,098 shares issued to Dr. Norchi upon the closing of the Merger in exchange for the cancellation of shares of Common Stock and convertible notes of ABS owned by him immediately prior to the closing of the Merger; (c) 5,650 shares of restricted stock granted to Dr. Norchi on May 3, 2016; (d) 3,250 shares of restricted stock granted to Dr. Norchi on February 3, 2017; (e) 1,800 shares of restricted stock granted to Dr. Norchi on July 19, 2018; (f) 2,626 First Conversion Shares; (g) 2,415 First Warrants; and (h) 363 shares of Common Stock issued in connection with the first Closing (the "**First Inducement Shares**"); (i) 33,130 shares subject to options exercisable within 60 days after September 15, 2023; and (j) 6,862 shares of common stock purchased. Excludes 13,724 Common Warrants with unsatisfied exercise restrictions. Dr. Norchi disclaims beneficial ownership of the securities held by Twelve Pins Partners, LLC except to the extent of his pecuniary interest therein. The number of shares beneficially owned after the offering assumes the above referenced stockholder's participation in the Uplist Transaction; however, no assurance can be given that the stockholder will participate as we are assuming.
- (11) Represents 5,868 shares of Common Stock subject to options exercisable within 60 days after September 15, 2023.
- (12) Represents 3,368 shares of Common Stock subject to options exercisable within 60 days after September 15, 2023. Includes (i) 137 shares of Common Stock, (ii) 3,939 First Conversion Shares, (iii) 3,622 First Warrant Shares, (iv) 544 First Inducement Shares; and (v) 10,292 shares of common stock held by Drake Partners Equity LLC, in which Mr. Hicks has an ownership interest. Excludes 20,584 Common Warrants with unsatisfied exercise restrictions held by Drake Partners Equity LLC, in which Mr. Hicks has an ownership interest. The number of shares beneficially owned after the offering assumes the above referenced stockholder's participation in the Uplist Transaction; however, no assurance can be given that the stockholder will participate as we are assuming.
- (13) Represents (i) 3,939 First Conversion Shares; (ii) 3,622 First Warrant Shares; (iii) 544 First Inducement Shares; (iv) 10,292 shares of common stock purchased, and (v) 4,798 shares of Common Stock subject to options exercisable within 60 days after September 15, 2023. Excludes 20,584 Common Warrants with unsatisfied exercise restrictions. The number of shares beneficially owned after the offering assumes the above referenced stockholder's participation in the Uplist Transaction; however, no assurance can be given that the stockholder will participate as we are assuming.
- (14) Represents 750 shares of restricted stock granted to Mr. Yrigoyen on July 30, 2021, and 2,444 shares of Common Stock subject to options exercisable within 60 days after September 15, 2023.
- (15) Represents 2,014 shares of Common Stock subject to options exercisable within 60 days after September 15, 2023.

SHARES ELIGIBLE FOR FUTURE SALE

Overview

As of the date of this offering our Common Stock has only been traded on the OTCQB Market. In connection with this offering, we have applied to list our Common Stock on the Nasdaq Capital Market. No assurance can be given that our application will be approved. Sales of substantial amounts of our Common Stock in the public market, including shares issued upon the exercise of outstanding options or warrants, or the perception that such sales could occur, could adversely affect prevailing market prices of our Common Stock. Upon completion of this offering, we will have an aggregate of 13,059,490 shares of Common Stock issued and outstanding, assuming no sale of Pre-Funded Units, no exercise of outstanding options or warrants (including the Investor Warrants included in the Units sold in this offering), that the underwriters do not exercise their over-allotment option and the issuance of an assumed 1,567,127 shares of Common Stock as a result of the Automatic Conversion under the 2022 Notes and 52,917 shares of Common Stock as a result of the conversion of the Series 2 Notes, at the closing of this offering. All of the shares of Common Stock sold in this offering, including the shares of Common Stock issuable upon exercise of the Investor Warrants included in the Units sold in this offering, will be freely transferable without restriction or further registration under the Securities Act by persons other than by our affiliates. In addition, for each Bridge Investor that purchases Units in this offering with an aggregate purchase price equal to at least 4.3 multiplied by the aggregate purchase price paid by the Bridge Investor for the Bridge Shares and Bridge Warrants under the Bridge SPA, their Bridge Shares and the shares underlying their Bridge Warrants will not be subject to the Bridge Lock-Up (defined below), and are expected to be freely transferable without restriction or further registration due to their inclusion in the Resale Prospectus. Further, all of the other securities registered under the Resale Prospectus will be freely transferable without restriction upon the effectiveness of the registration statement of which this prospectus forms a part. Those securities are comprised of an aggregate of (i) 3,364,527 shares of Common Stock and (ii) 72,404,192 shares of common stock underlying warrants (such amount assuming all of the Common Warrants are exchanged into the Exchange Investor Warrants at the closing of this offering).

Lock-Up Agreements

We, our directors and executive officers have agreed, subject to limited exceptions, for a period of six months after the closing of this offering, not to offer, issue, sell, contract to sell, encumber, grant any option for the sale of, or otherwise dispose of, any shares of Common Stock or any securities convertible into or exchangeable for our Common Stock either owned as of the date of the underwriting agreement or thereafter acquired without the prior written consent of Dawson James Securities, Inc. (“**Dawson**”). Dawson may, in its sole discretion and at any time or from time to time before the termination of the lock-up period, without notice, release all or any portion of the securities subject to lock-up agreements.

Bridge Lock-Up

Pursuant to the lock-up agreement provided for by the Bridge SPA (the “**Bridge Lock-Up**”), the Bridge Investors agreed that they would either (A) purchase securities, for cash, in the Uplist Transaction, which this offering is intended to be, with an aggregate purchase price equal to at least 4.3 multiplied by the aggregate purchase price paid by the Bridge Investor for the Bridge Shares and Bridge Warrants under the Bridge SPA or (B) be subject to a lock-up provision not to sell or otherwise transfer any of the Bridge Shares or Bridge Warrant Shares acquired by them in the Bridge Offering until the one-year anniversary of the Bridge Closing Date. It is currently anticipated that all Bridge Investors will purchase sufficient securities in this offering so as to not be subject to the Bridge Lock-Up.

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements for at least 90 days, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates, is entitled to sell those shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then that person would be entitled to sell those shares upon expiration of the lock-up agreements described above, without complying with any of the requirements of Rule 144.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell upon expiration of the lock-up agreements described below, within any three-month period, a number of shares that does not exceed the greater of:

- 1% of the number of shares of our Common Stock then outstanding, which will equal an assumed approximately 130,595 shares immediately after this offering; or
- if and when our Common Stock is listed on the Nasdaq Capital Market or Alternate Exchange, the average weekly trading volume of our Common Stock on such market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

DESCRIPTION OF SECURITIES

Authorized Capital Stock

Pursuant to our amended and restated articles of incorporation, as amended, as of September 21, 2023, our authorized capital stock consists of 350,000,000 shares of Common Stock. The following description summarizes the material terms of our capital stock. Because it is only a summary, it may not contain all the information that is important to you. In connection with this offering, we intend to effect a reverse stock split of our Common Stock at a ratio of between 1.5-for-1 and 20-for-1, with the exact ratio to be determined by our Board of Directors prior to effecting the reverse stock split.

Preferred Stock

We are authorized to issue up to 5,000,000 shares of preferred stock, par value \$0.001 per share, from time to time in one or more series. As of the date of this prospectus, there are no shares of our preferred stock outstanding.

The shares of preferred stock may be issued in series, and each such series shall have such voting powers, full or limited, or no voting powers, and such designations, preferences and relative participating, optional or other special rights, and qualifications, limitations or restrictions thereof, as shall be stated and expressed in the certificate of designation relating to such series, as approved by the board of directors and filed with the Nevada Secretary of State. Pursuant to our articles of incorporation, our Board of Directors is expressly vested with the authority, without further action by the stockholders, to determine and fix in the resolution or resolutions providing for the issuances of preferred stock the voting powers, designations, preferences and rights, and the qualifications, limitations or restrictions thereof, of each such series to the full extent now or hereafter permitted by the laws of the State of Nevada.

Prior to the issuance of any series of preferred stock, we will further amend our articles of incorporation, as amended, by way of a certificate of designation designating such series and its terms. We will file a copy of the certificate of designation that contains the terms of each such series of preferred stock with the Nevada Secretary of State and the SEC each time we issue a new series of preferred stock. Each certificate of designation will establish the number of shares included in a designated series and fix the designation, powers, privileges, preferences and rights of the shares of each series as well as any applicable qualifications, limitations or restrictions, including, as applicable:

- the designation, stated value and liquidation preference of the series;
- the number of shares authorized within the series;
- the offering price;
- the dividend rate or rates (or method of calculation), the date or dates from which dividends shall accrue, and whether such dividends shall be cumulative or noncumulative and, if cumulative, the dates from which dividends shall commence to cumulate;
- any redemption or sinking fund provisions;
- the amount that shares of the series shall be entitled to receive in the event of our liquidation, dissolution or winding-up;
- the terms and conditions, if any, on which shares of the series shall be convertible or exchangeable for shares of our stock of any other class or classes, or other series of the same class;
- the voting rights, if any, of shares of the series; the status as to reissuance or sale of shares of the series redeemed, purchased or otherwise reacquired, or surrendered to us on conversion or exchange;
- the conditions and restrictions, if any, on the payment of dividends or on the making of other distributions on, or the purchase, redemption or other acquisition by us or any subsidiary, of the common stock or of any other class of our shares ranking junior to the shares of the series as to dividends or upon liquidation;
- the conditions and restrictions, if any, on the creation of indebtedness by us or by any subsidiary, or on the issuance of any additional stock ranking on a parity with or prior to the shares of the series as to dividends or upon liquidation; and
- any additional dividend, liquidation, redemption, sinking or retirement fund and other rights, preferences, privileges, limitations and restrictions of the series.

The issuance of any preferred stock could adversely affect the rights of the holders of common stock and, therefore, reduce the value of the common stock. The ability of our Board of Directors to issue preferred stock could discourage, delay or prevent a takeover or other corporate action.

Common Stock Issued and Outstanding; Common Stock Registered Hereby

As of September 15, 2023, there were issued and outstanding 4,689,446 shares of Common Stock. Of our authorized and unissued shares of Common Stock, we are registering under the registration statement of which this prospectus forms a part 6,750,000 shares of Common Stock to be issued as part of the Units (or upon exercise of the Pre-Funded Warrants to be issued as part of the Pre-Funded Units, in lieu thereof).

The holders of our Common Stock, par value \$0.001 per share, are entitled to one vote per share on all matters submitted to a vote of our stockholders, including the election of directors. Our articles of incorporation do not provide for cumulative voting in the election of directors, and our amended and restated bylaws provide that directors are elected by a plurality vote of the votes cast and entitled to vote on the election of directors at any meeting for the election of directors at which a quorum is present. Matters other than the election of directors to be voted on by stockholders are generally approved if, at a duly convened stockholder meeting, the number of votes cast in favor of the action exceeds the number of votes cast in opposition to the action, unless a different vote for the action is required by applicable law, our articles of incorporation or our amended and restated bylaws. Applicable Nevada law requires any amendment to our articles of incorporation to be approved by stockholders holding shares entitling them to exercise at least a majority of the voting power of the Company. The holders of our Common Stock will be entitled to cash dividends as may be declared, if any, by our Board from funds available. Upon liquidation, dissolution or winding up of our Company, the holders of our Common Stock will be entitled to receive pro rata all assets available for distribution to the holders. All rights of our holders of Common Stock described in this paragraph could be subject to any preferential voting, liquidation or other rights of any series of preferred stock that we may authorize and issue in the future. Our amended and restated articles of incorporation do not currently authorize us to issue any class of preferred stock. Our Common Stock is presently traded on the QB tier of the OTC Marketplace under the trading symbol "ARTH". We have applied to list our Common Stock on the Nasdaq Capital Market under the symbol "ARTH." No assurance can be given that our application will be approved. If our Common Stock is not approved for listing on the Nasdaq Capital Market or an Alternate Exchange, we will not complete this offering.

Units to be Issued in this Offering

Each of the Units we are offering (subject to adjustment) consists of one share of Common Stock and one Investor Warrant to purchase one share of our Common Stock. Each Unit will be sold at a purchase price of \$ per Unit. Units will not be issued or certificated. The shares of Common Stock and the Investor Warrants comprising the Units are immediately separable and will be issued separately and uncertificated.

Pre-Funded Units to be Issued in this Offering

We are also offering to each purchaser whose purchase of Units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding Common Stock immediately following the consummation of this offering, if the purchaser so chooses, Pre-Funded Units (each Pre-Funded Unit consisting of one Pre-Funded Warrant to purchase one share of Common Stock and one Investor Warrant to purchase one share of Common Stock) in lieu of Units that would otherwise result in the purchaser's beneficial ownership exceeding 4.99% of our outstanding Common Stock (or at the election of the purchaser, 9.99%). The purchase price of each Pre-Funded Unit will equal the price per Unit being sold to the public in this offering minus \$0.001.

Pre-Funded Warrants to be Issued in this Offering

The following summary of certain terms and provisions of the Pre-Funded Warrants offered hereby is not complete and is subject to, and qualified in its entirety by the provisions of the form of Pre-Funded Warrant, which will be filed as an exhibit to the registration statement of which this prospectus is a part. Prospective investors should carefully review the terms and provisions set forth in the form of Pre-Funded Warrant.

Pre-Funded Warrants provide any purchaser in this offering with the ability to purchase Pre-Funded Units (each Pre-Funded Unit consisting of one Pre-Funded Warrant to purchase one share of Common Stock and one Investor Warrant to purchase one share of Common Stock) in lieu of Units that would otherwise result in the purchaser's beneficial ownership exceeding 4.99% of our outstanding Common Stock (or, at the election of the purchaser, 9.99%). This is accomplished through purchasing Pre-Funded Warrants at a price equal to the purchase price for Units, less \$0.001, which \$0.001 is the exercise price for the Pre-Funded Warrants. Each Pre-Funded Warrant is exercisable into one share of Common Stock as offered hereunder. Thus, the purchaser is paying essentially the purchase price for a Unit at closing of the offering but is not deemed to beneficially own the shares of Common Stock included in the Units until the purchaser exercises the Pre-Funded Warrant. Once purchased, the purchase price of the Pre-Funded Warrants is not refundable. While the Pre-Funded Warrants permit waiver of provisions by us and the holder of the Pre-Funded Warrants, this would not affect the pre-funding as that is the purchase price of the instrument which is paid at the time of closing and becomes part of our proceeds received from this offering. In addition, the Pre-Funded Warrants are perpetual and do not have an expiration date.

Duration and Exercise Price

Each Pre-Funded Warrant will have an outstanding exercise price per share equal to \$0.001. The Pre-Funded Warrants will be immediately exercisable and may be exercised at any time until the Pre-Funded Warrants are exercised in full. The exercise price and number of shares of Common Stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting Common Stock and the exercise price. The Pre-Funded Warrants will be issued separately from the accompanying Investor Warrants included in the Pre-Funded Units, and may be transferred separately immediately thereafter.

Exercisability

The Pre-Funded Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of Common Stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the Pre-Funded Warrant to the extent that the holder would own more than 4.99% of the outstanding Common Stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding Common Stock after exercising the holder's Pre-Funded Warrants up to 9.99% of the number of shares of Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Pre-Funded Warrants. Purchasers of Pre-Funded Units in this offering may also elect prior to the issuance of the Pre-Funded Warrants to have the initial exercise limitation set at 9.99% of our outstanding Common Stock.

Cashless Exercise

If, at the time a holder exercises its Pre-Funded Warrants, there is no effective registration statement registering, or the prospectus contained therein is not available for an issuance of the shares of Common Stock underlying the Pre-Funded Warrants to the holder, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to exercise its Pre-Funded Warrants on a cashless basis and receive upon such exercise (either in whole or in part) the net number of shares of Common Stock determined according to a formula set forth in the Pre-Funded Warrant.

Fundamental Transactions

If a fundamental transaction occurs, then the successor entity will succeed to, and be substituted for us, and may exercise every right and power that we may exercise and will assume all of our obligations under the Pre-Funded Warrants with the same effect as if such successor entity had been named in the Pre-Funded Warrant itself. If holders of our Common Stock are given a choice as to the securities, cash or property to be received in a fundamental transaction, then the holder shall be given the same choice as to the consideration it receives upon any exercise of the Pre-Funded Warrant following such fundamental transaction.

Transferability

Subject to applicable laws, a Pre-Funded Warrant may be transferred at the option of the holder upon surrender of the Pre-Funded Warrant to us together with the appropriate instruments of transfer.

Fractional Shares

No fractional shares of Common Stock will be issued upon the exercise of the Pre-Funded Warrants. Rather, the number of shares of Common Stock to be issued will be rounded up to the nearest whole number.

Trading Market

There is no established trading market for the Pre-Funded Warrants on any securities exchange or nationally recognized trading system, and we do not expect an active trading market to develop. We do not intend to list the Pre-Funded Warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the Pre-Funded Warrants will be extremely limited.

Right as a Shareholder

Except as otherwise provided in the Pre-Funded Warrants or by virtue of the holder's ownership of shares of Common Stock, such holder of Pre-Funded Warrants does not have the rights or privileges of a holder of Common Stock, including any voting rights, until such holder exercises such holder's Pre-Funded Warrants.

Investor Warrants to be Issued in this Offering

The following summary of certain terms and provisions of the Investor Warrants offered hereby is not complete and is subject to, and qualified in its entirety by the provisions of the form of Investor Warrant, which will be filed as an exhibit to the registration statement of which this prospectus is a part. Prospective investors should carefully review the terms and provisions set forth in the form of Investor Warrant.

The Investor Warrants issued in this offering entitle the registered holders to purchase Common Stock at an exercise price equal to \$ per share (100% of the public offering price of the Units in this offering), subject to adjustment as discussed below, immediately following the issuance of such Investor Warrants and terminating at 5:00 p.m., New York City time, five years after the date of issuance.

The exercise price and number of shares of Common Stock issuable upon exercise of the Investor Warrants may be adjusted in certain circumstances, including in the event of a stock dividend or recapitalization, reorganization, merger or consolidation. However, the Investor Warrants will not be adjusted for issuances of shares of Common Stock at prices below its exercise price.

Exercisability. The Investor Warrants are exercisable immediately upon issuance and at any time up to the date that is five years from the date of issuance. The Investor Warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of Common Stock purchased upon such exercise. Each Investor Warrant entitles the holder thereof to purchase one share of our Common Stock. Investor Warrants are not exercisable for a fraction of a share and may only be exercised into whole numbers of shares. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price and round down to the nearest whole share. Unless otherwise specified in the Investor Warrant, the holder will not have the right to exercise the Investor Warrants, in whole or in part, if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or 9.99% at the holder's election) of the number of our shares of Common Stock outstanding immediately after giving effect to the exercise, as such percentage is determined in accordance with the terms of the Investor Warrant. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon at least 61 days' prior notice from the holder to us.

Exercise Price. The exercise price per share of Common Stock purchasable upon exercise of the Investor Warrants is \$ (100% of the public offering price of one Unit in this offering), and is subject to adjustments for stock splits, reclassifications, subdivisions, and other similar transactions.

Listing; Transferability. We have applied for listing of the Investor Warrants on the Nasdaq Capital Market under the symbol "ARTHW ." No assurance can be given that our listing application will be approved. Subject to applicable laws, the Investor Warrants may be transferred at the option of the holders upon surrender of the Investor Warrants to us, together with the appropriate instruments of transfer.

Fundamental Transactions. If a fundamental transaction occurs, then the successor entity will succeed to, and be substituted for us, and may exercise every right and power that we may exercise and will assume all of our obligations under the Investor Warrants with the same effect as if such successor entity had been named in the Investor Warrant itself. If holders of our Common Stock are given a choice as to the securities, cash or property to be received in a fundamental transaction, then the holder shall be given the same choice as to the consideration it receives upon any exercise of the Investor Warrant following such fundamental transaction.

Rights as a Shareholder. Except by virtue of such holder's ownership of our Common Stock, the holder of Investor Warrants does not have rights or privileges of a shareholder, including any voting rights, until the holder exercises such Investor Warrant.

Underwriter Warrants to be Issued Upon Closing of this Offering

Upon the closing of this offering, there will be up to 337,500 shares of Common Stock issuable upon exercise of the Underwriter Warrants, not including any shares and/or Investor Warrants sold in the over-allotment option, if any. See the section entitled "**Underwriting - Underwriter Warrants**" for a description of the Underwriter Warrants we have agreed to issue to the Representative, or its designees, in this offering, subject to the completion of the offering.

Transfer Agent

The transfer agent for our Common Stock is Empire Stock Transfer. Our transfer agent's address is 1859 Whitney Mesa Drive, Henderson, Nevada 89014.

Anti-Takeover Provisions of Nevada State Law

Some features of the Nevada Revised Statutes ("NRS"), which are further described below, may have the effect of deterring third parties from making takeover bids for control of us or may be used to hinder or delay a takeover bid. This would decrease the chance that our stockholders would realize a premium over market price for their shares of Common Stock as a result of a takeover bid.

Acquisition of Controlling Interest

The NRS contain provisions governing acquisition of a controlling interest of a Nevada corporation. These provisions provide generally that any person or entity that acquires a certain percentage of the outstanding voting shares of a Nevada corporation may be denied voting rights with respect to the acquired shares, unless certain criteria are satisfied. Our amended and restated bylaws provide that these provisions will not apply to us or to any existing or future stockholder or stockholders.

Combination with Interested Stockholder

The NRS contain provisions governing combinations of a Nevada corporation that has 200 or more stockholders of record with an “interested stockholder.” These provisions only apply to a Nevada corporation that, at the time the potential acquirer became an interested stockholder, has a class or series of voting shares listed on a national securities exchange, or has a class or series of voting shares traded in an “organized market” and satisfies certain specified public float and stockholder levels. As we do not now meet those requirements, we do not believe that these provisions are currently applicable to us. However, to the extent they become applicable to us in the future, they may have the effect of delaying or making it more difficult to affect a change in control of the Company in the future.

A corporation affected by these provisions may not engage in a combination within two years after the interested stockholder acquires his, her or its shares unless the combination or purchase is approved by the board of directors before the interested stockholder acquired such shares. Generally, if approval is not obtained, then after the expiration of the two-year period, the business combination may be consummated with the approval of the board of directors before the person became an interested stockholder or a majority of the voting power held by disinterested stockholders, or if the consideration to be received per share by disinterested stockholders is at least equal to the highest of:

- the highest price per share paid by the interested stockholder within the three years immediately preceding the date of the announcement of the combination or within three years immediately before, or in, the transaction in which he, she or it became an interested stockholder, whichever is higher;
- the market value per share on the date of announcement of the combination or the date the person became an interested stockholder, whichever is higher; or
- if higher for the holders of preferred stock, the highest liquidation value of the preferred stock, if any.

Generally, these provisions define an interested stockholder as a person who is the beneficial owner, directly or indirectly of 10% or more of the voting power of the outstanding voting shares of a corporation, and define combination to include any merger or consolidation with an interested stockholder, or any sale, lease, exchange, mortgage, pledge, transfer or other disposition, in one transaction or a series of transactions with an interested stockholder of assets of the corporation:

- having an aggregate market value equal to 5% or more of the aggregate market value of the assets of the corporation;
- having an aggregate market value equal to 5% or more of the aggregate market value of all outstanding shares of the corporation; or
- representing 10% or more of the earning power or net income of the corporation.

UNDERWRITING

We are offering the units described in this prospectus through the underwriters named below. We have entered into an underwriting agreement dated October [], 2023 with Dawson James Securities, Inc. as the representative of the several underwriters named below (“**Dawson**” or the “**Representative**”), in connection with this offering. Dawson is acting as the sole book-running manager in this offering. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and the underwriters have agreed to purchase, at the public offering price, less the underwriting discounts and commissions, as set forth on the cover page of this prospectus, the number of Units and Pre-Funded Units set forth opposite their respective names below.

Underwriters	Number of Units	Number of Pre-Funded Units
Dawson James Securities, Inc.		
Total		

The underwriters are committed to purchase all the Units and Pre-Funded Units offered by us if they buy any of them. However, the underwriters are not obligated to purchase the shares and Investor Warrants covered by the underwriters’ over-allotment option described below. The underwriters are offering the Units and Pre-Funded Units, subject to prior sale, when, as and if issued to and accepted by them. The underwriting agreement provides that the obligations of the underwriters to purchase the Units and Pre-Funded Units included in this offering are subject to approval of legal matters by their counsel and to other conditions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

We have been advised by the underwriters that it intends to make a market in our shares of Common Stock but that they are not obligated to do so and may discontinue making a market at any time without notice.

In connection with this offering, the underwriters or securities dealers may distribute prospectuses electronically.

Option to Purchase Additional Shares and/or Investor Warrants

We have granted the underwriters an option, exercisable for 45 days after the date of this prospectus, to purchase up to an additional shares of Common Stock and/or Investor Warrants to purchase up to an additional shares of Common Stock (equal to 15% of the shares of Common Stock (and Pre-Funded Warrants, if any) and Investor Warrants sold in this offering), in any combination, at the public offering price per share of Common Stock and per Investor Warrant, respectively, less the underwriting discounts payable by us, solely to cover over-allotments, if any. If any additional shares of Common Stock and/or Investor Warrants are purchased, the underwriters will offer these shares of Common Stock and/or Investor Warrants on the same terms as those on which the other securities are being offered in this offering.

Discounts, Commissions and Expenses

The underwriters propose to offer the Units and Pre-Funded Units to the public at the public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of \$ per Unit. The underwriters may offer the Units and Pre-Funded Units through one or more of their affiliates or selling agents. If all the Units and Pre-Funded Units are not sold at the public offering price, the underwriters may change the offering price and the other selling terms. After this offering, the public offering price and concession may be changed by the underwriters. No such change will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

The underwriting discount is equal to the public offering price per share less the amount paid by the underwriters to us per Unit. The underwriting discount was determined through an arm’s length negotiation between us and the Representative. The underwriters’ commissions and discounts will be 8% of the gross proceeds of this offering (or 4% on any orders from investors introduced to the offering by the Company), or \$ per Unit based on the public offering price set forth on the cover page of this prospectus.

The following table shows the public offering price, underwriting discounts and commissions and proceeds, before expenses, to us assuming both no exercise and full exercise by the underwriters of their over-allotment option:

	Per Unit	Per Pre-Funded Unit	Total Without Option	With Option
Public offering price	\$	\$	\$	\$
Underwriting discounts and commissions	\$	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$	\$

We have agreed to pay the Representative’s expenses relating to the offering, irrespective of whether the offering is consummated, including, without limitation, SEC and FINRA-related fees, stock exchange listing fees, disbursements relating to background checks of our officers and directors, fees and disbursements relating to the registration or qualification under the “blue sky” securities laws (including fees of the Representative’s counsel), roadshow fees and expenses, costs relating to printing and mailing of underwriting documents, registration statements and prospectuses, costs and expenses of a public relations firm, and fees of the Representative’s legal counsel and other agents and representatives, in an aggregate amount not to exceed \$150,000.

We estimate that the total expenses of the offering payable by us, excluding the total underwriting discount will be approximately \$775,000.

Indemnification

Pursuant to the underwriting agreement, we have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments that the underwriters or such other indemnified party may be required to make in respect of those liabilities.

Underwriter Warrants

We have agreed to issue to Dawson (or its permitted designees) warrants to purchase up to a number of shares of our Common Stock equal to 5% of the total number of shares of Common Stock and Pre-Funded Warrants sold in this offering, including any shares sold in the over-allotment option, if any (the “**Underwriter Warrants**”). The Underwriter Warrants will be exercisable at any time, and from time to time, in whole or in part, commencing six months from the effective date of the registration statement of which this prospectus is a part, will have a term of five years from the date of the commencement of sales related to this offering and will have an exercise price equal to 125% of the public offering price of the Units set forth on the cover of this prospectus. The Underwriter Warrants may be exercised on a cashless basis. The Underwriter Warrants are not redeemable by us.

This prospectus also covers the sale of the Underwriter Warrants and the shares of Common Stock underlying such Underwriter Warrants. The Underwriter Warrants and the underlying securities have been deemed compensation by FINRA, and are therefore subject to the transfer restrictions under FINRA Rule 5110(e)(1). In accordance with FINRA Rule 5110(e)(1), neither the Underwriter Warrants nor any securities issued upon exercise of the Underwriter Warrants may be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of such securities for a period of 180 days beginning on the date of commencement of sales of the offering, except (i) the transfer of any security to any FINRA member firm participating in this offering and its officers or partners, its registered persons or affiliates, if all securities so transferred remain subject to the lock-up restriction described above for the remainder of the time period; (ii) the exercise or conversion of any security, if all securities received remain subject to the lock-up restriction set forth above for the remainder of the time period; or (iii) the transfer or sale of the security back to our company in a transaction exempt from registration with the SEC. The Underwriter Warrants and the underlying securities will have resale registration rights including one demand and unlimited “piggy-back” rights for periods of five and seven years, respectively, from the commencement of sales of this offering at our expense. In compliance with FINRA Rule 5110(g)(8), the Dawson registration rights are limited to demand and “piggy back” rights for periods of five and seven years, respectively, from the effective date of the registration statement of which this prospectus forms a part and such demand rights may be exercised on only one occasion. In addition, so long as the Underwriter Warrants are held by Dawson or its designees, they will only be exercisable for a period of five years from the date of this prospectus in accordance with FINRA Rule 5110(g)(8)(A).

Lock-Up Agreements

We, our directors and executive officers have agreed, subject to limited exceptions, for a period of six months after the closing of this offering, not to offer, issue, sell, contract to sell, encumber, grant any option for the sale of, or otherwise dispose of, any shares of Common Stock or any securities convertible into or exchangeable for our Common Stock either owned as of the date of the underwriting agreement or thereafter acquired without the prior written consent of Dawson. Dawson may, in its sole discretion and at any time or from time to time before the termination of the lock-up period, without notice, release all or any portion of the securities subject to lock-up agreements.

Exclusivity Tail

We have entered into an engagement letter with Dawson to serve as our lead underwriter in the Primary Offering (the “**Engagement Letter**”). The Engagement Letter is on a month-to-month basis, renewing automatically for successive month periods, unless earlier terminated in accordance with the terms of the Engagement Letter (the “**Engagement Period**”). We have agreed that until the Engagement Period terminates, Dawson will act as our exclusive underwriter, agent, or advisor if we proceed with an any alternative offering, whether registered or unregistered, of our equity securities or a reverse merger during the Engagement Period.

Upon the closing of an offering or if an offering is not consummated before the Engagement Period, we have also agreed to pay Dawson a tail fee equal to the compensation equivalent for this offering, if any investor, who was brought over-the-wall or introduced to us by Dawson during the term of its engagement, provides us with capital in any financing of equity, equity-linked or debt or other capital raising transaction during the 12 month period following the closing of an offering or the expiration or termination of our engagement of Dawson.

Right of First Refusal

We have granted a right of first refusal to Dawson pursuant to which it has the right to act as the sole managing underwriter and sole book runner, sole placement agent, or sole sales agent, for any and all future public or private equity, equity-linked or debt (excluding commercial bank debt) offerings of the Company, or any successor to or any subsidiary of the Company, at any time prior to the 12 month anniversary of the closing date of this offering. In accordance with FINRA Rule 5110(g)(6)(A), such right of first refusal shall not have a duration of more than three years from the commencement of sales of this offering. Additionally, in accordance with FINRA Rule 5110(g)(5)(B), such right of first refusal shall automatically terminate in the event the letter of engagement is terminated for cause.

Other Relationships

Dawson previously served as our placement agent for the Bridge Offering. Pursuant to the engagement letter that we entered into with Dawson on June 21, 2023 (the “**Bridge Engagement Letter**”), we agreed, among other things, to (i) pay Dawson 10% of the gross proceeds in the First Closing from certain institutional investors, and (ii) issue Dawson, or its designees, warrants to purchase up to 10% of the aggregate number of shares sold to the institutional investors in the First Closing, or warrants to purchase up to 31,510 shares of Common Stock. The First Placement Agent Warrants have substantially the same terms as the First Warrants, except that the exercise price of the First Placement Agent Warrants is \$10.06 per share and are not exercisable until six (6) months from the date of issuance.

In connection with the Second Closing, we agreed, among other things, to (i) pay Dawson 8% of the gross proceeds in the Bridge Offering, and (ii) issue to Dawson, or its designees, warrants to purchase up to 5% of the aggregate number of securities sold in the Bridge Offering, with a total of 441,938 warrants being issued.

In connection with the Bridge Offering, the total fees paid to Dawson was \$193,977 and the total expenses reimbursed was \$50,000.

The underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

Nasdaq Listing

Our shares of Common Stock are quoted on the OTCQB under the symbol “ARTH” and there is no established public trading market for the Investor Warrants. We have applied to list our Common Stock and Investor Warrants on the Nasdaq Capital Market under the symbol “ARTH” and “ ARTHW ,” respectively. There is no assurance, however, that our Common Stock or Investor Warrants will ever be listed on the Nasdaq Capital Market or an Alternate Exchange. We will not consummate this offering unless our Common Stock is approved for listing on the Nasdaq Capital Market or an Alternate Exchange.

Price Stabilization, Short Positions

In connection with this offering, the underwriters may engage in activities that stabilize, maintain or otherwise affect the price of our shares of Common Stock during and after this offering, including:

- stabilizing transactions;
- short sales;
- purchases to cover positions created by short sales;
- imposition of penalty bids; and
- syndicate covering transactions.

Stabilizing transactions consist of bids or purchases made for the purpose of preventing or retarding a decline in the market price of our shares of Common Stock while this offering is in progress. Stabilization transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. These transactions may also include making short sales of our shares of Common Stock, which involve the sale by the underwriters of a greater number of shares of Common Stock than they are required to purchase in this offering and purchasing shares of Common Stock on the open market to cover short positions created by short sales. Short sales may be “covered short sales,” which are short positions in an amount not greater than the underwriters’ option to purchase additional shares referred to above, or may be “naked short sales,” which are short positions in excess of that amount.

The underwriters may close out any covered short position by either exercising their option, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option.

Naked short sales are short sales made in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares of Common Stock in the open market that could adversely affect investors who purchased in this offering.

The underwriters also may impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the Representative has repurchased shares sold by or for the account of that underwriter in stabilizing or short covering transactions.

These stabilizing transactions, short sales, purchases to cover positions created by short sales, the imposition of penalty bids and syndicate covering transactions may have the effect of raising or maintaining the market price of our Common Stock or preventing or retarding a decline in the market price of our Common Stock. As a result of these activities, the price of our Common Stock may be higher than the price that otherwise might exist in the open market. The underwriters may carry out these transactions on Nasdaq, in the over-the-counter market or otherwise. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of the shares. Neither we, nor the underwriters make any representation that the underwriters will engage in these stabilization transactions or that any transaction, once commenced, will not be discontinued without notice.

Determination of Offering Price

The public offering price for our securities in this offering will be determined by negotiation among us and the Representative. The principal factors to be considered in determining the public offering price include:

- the information set forth in this prospectus and otherwise available to the Representative;
- our history and prospects and the history and prospects for the industry in which we compete;
- our past and present financial performance;
- our prospects for future earnings and the present state of our development;
- the general condition of the securities market at the time of this offering;
- the recent market prices of, and demand for, publicly traded shares of generally comparable companies; and
- other factors deemed relevant by the Representative and us.

The estimated public offering price set forth on the cover page of this prospectus and throughout this prospectus is subject to change as a result of market conditions and other factors. We offer no assurances that the public offering price will correspond to the price at which our securities will trade on the Nasdaq Capital Market or an Alternate Exchange subsequent to this offering. Neither we nor the underwriters can assure investors that an active trading market will develop for our shares of Common Stock or that the shares of Common Stock will trade in the public market at or above the public offering price.

Affiliations

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and their affiliates may from time to time in the future engage with us and perform services for us or in the ordinary course of their business for which they will receive customary fees and expenses. In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of ours. The underwriters and their respective affiliates may also make investment recommendations and/or publish or express independent research views in respect of these securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in these securities and instruments.

Electronic Distribution

A prospectus in electronic format may be made available on the Internet sites or through other online services maintained by the underwriters participating in this offering, or by its affiliates. In those cases, prospective investors may view offering terms online and, depending upon the particular underwriter, prospective investors may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' websites and any information contained in any other website maintained by the underwriters is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or each underwriter in its capacity as underwriter and should not be relied upon by investors.

Selling Restrictions

Canada. The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding the underwriters' conflicts of interest in connection with this offering.

European Economic Area. In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "**Relevant Member State**") an offer to the public of any securities may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any securities may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of securities shall result in a requirement for the publication by us or the underwriters of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an “offer to the public” in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any securities to be offered so as to enable an investor to decide to purchase any securities, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression “Prospectus Directive” means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State, and the expression “2010 PD Amending Directive” means Directive 2010/73/EU.

United Kingdom. The underwriters have represented and agreed that:

- they have only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 (the FSMA)) received by them in connection with the issue or sale of the securities in circumstances in which Section 21(1) of the FSMA does not apply to us; and
- they have complied and will comply with all applicable provisions of the FSMA with respect to anything done by them in relation to the securities in, from or otherwise involving the United Kingdom.

Switzerland. The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (the SIX) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (CISA). Accordingly, no public distribution, offering or advertising, as defined in CISA, its implementing ordinances and notices, and no distribution to any non-qualified investor, as defined in CISA, its implementing ordinances and notices, shall be undertaken in or from Switzerland, and the investor protection afforded to acquirers of interests in collective investment schemes under CISA does not extend to acquirers of securities.

Australia. No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission (ASIC), in relation to the offering.

This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the Corporations Act) and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the securities may only be made to persons (the Exempt Investors) who are “sophisticated investors” (within the meaning of section 708(8) of the Corporations Act), “professional investors” (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the securities without disclosure to investors under Chapter 6D of the Corporations Act.

The securities applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring securities must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Notice to Prospective Investors in the Cayman Islands. No invitation, whether directly or indirectly, may be made to the public in the Cayman Islands to subscribe for our securities.

Taiwan. The securities have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the securities in Taiwan.

Notice to Prospective Investors in Hong Kong. The contents of this prospectus have not been reviewed by any regulatory authority in Hong Kong. You are advised to exercise caution in relation to the offer. If you are in any doubt about any of the contents of this prospectus, you should obtain independent professional advice. Please note that (i) our shares may not be offered or sold in Hong Kong, by means of this prospectus or any document other than to “professional investors” within the meaning of Part I of Schedule 1 of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) (SFO) and any rules made thereunder, or in other circumstances which do not result in the document being a “prospectus” within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong) (CO) or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO, and (ii) no advertisement, invitation or document relating to our shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere) which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to the shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” within the meaning of the SFO and any rules made thereunder.

Notice to Prospective Investors in the People's Republic of China. This prospectus may not be circulated or distributed in the PRC and the shares may not be offered or sold, and we will not offer or sell, to any person for re-offering or resale directly or indirectly to any resident of the PRC, except pursuant to applicable laws, rules and regulations of the PRC. For the purpose of this paragraph only, the PRC does not include Taiwan and the special administrative regions of Hong Kong and Macau.

LEGAL MATTERS

Lowenstein Sandler LLP, Roseland, New Jersey, is acting as counsel in connection with the registration of our securities under the Securities Act. The validity of the securities being offered hereby has been passed upon for us by McDonald Carano LLP, Reno, Nevada. ArentFox Schiff LLP, Washington, D.C., advised the underwriters in connection with the offering of the securities.

EXPERTS

Baker Tilly US, LLP, an independent registered public accounting firm, has audited our consolidated financial statements as of and for the years ended September 30, 2022 and 2021, as stated in its report appearing herein, and such audited consolidated financial statements have been so included in reliance upon the report of such firm given upon its authority as experts in accounting and auditing. The report on the consolidated financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains a website, at <http://www.sec.gov>, that contains registration statements, reports, proxy statements and other information regarding registrants that file electronically with the SEC, including us. Our website address is <http://www.archtherapeutics.com>. We have not incorporated by reference into this prospectus the information on, or that can be accessed through, our website, and you should not consider it to be a part of this document. You should not rely on any information on that website in making your decision to purchase shares of our Common Stock.

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the securities being offered by this prospectus. This prospectus is part of that registration statement. This prospectus does not contain all of the information set forth in the registration statement or the exhibits to the registration statement. For further information with respect to us and the securities we are offering pursuant to this prospectus, you should refer to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract, agreement or other document referred to are not necessarily complete, and you should refer to the copy of that contract or other documents filed as an exhibit to the registration statement. You may read or obtain a copy of the registration statement at the SEC's website referred to above.

Arch Therapeutics, Inc.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of Arch Therapeutics, Inc. and Subsidiary

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Arch Therapeutics, Inc. and Subsidiary (the Company) as of September 30, 2022 and 2021, the related consolidated statements of operations, changes in stockholders' deficit, and cash flows for each of the two years in the period ended September 30, 2022, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of September 30, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended September 30, 2022, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that Arch Therapeutics, Inc. and Subsidiary will continue as a going concern. As discussed in Notes 1 and 2 to the consolidated financial statements, the Company has an accumulated deficit, has suffered significant net losses and negative cash flows from operations, only recently commenced generating limited operating revenues and has limited working capital that raises substantial doubt about its ability to continue as a going concern. Management's plans regarding these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accounting for Complex Financial Instruments

As described in Note 10, the Company entered a transaction (the 2022 Note Offering) that included the issuance of \$4.23 million in aggregate principal of senior secured convertible promissory notes, 63,833 shares of Common Stock, warrants to purchase 425,554 shares of the Company's common stock (the 2022 Warrants) and warrants to purchase 31,510 shares of the Company's common stock (the 2022 Placement Agent Warrants). In addition, in conjunction with the 2022 Note Offering, certain Series 2 note holders exchanged their notes in the aggregate amount of approximately \$700,000 of principal and interest (the Series 2 exchange), for senior secured convertible promissory notes of the Company.

We identified the accounting for these complex financial instruments, including the evaluation for potential embedded derivatives, accounting for the Series 2 exchange, and the classification of the 2022 Warrants and the 2022 Placement Agent Warrants as a critical audit matter. The application of the accounting guidance applicable to the transaction, including the evaluation for potential embedded derivatives, accounting for the Series 2 exchange, and the classification of the related warrants is complex, and therefore, applying such guidance to the contract terms is complex and requires significant management judgement. Auditing these elements involved especially complex auditor judgement due to the nature of the terms of these instruments, and the effort required to address these matters, including the extent of specialized skills and knowledge required.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others:

- Inspecting the agreements associated with the transaction and evaluating the completeness and accuracy of the Company's technical accounting analysis and application of the relevant accounting literature.
- Utilizing personnel with specialized knowledge and skills in technical accounting to assist in assessing management's analysis of the senior secured convertible promissory notes and 2022 Warrants and 2022 Placement Agent warrants, and the Series 2 exchange, including the evaluation of potential embedded derivatives, and the classification of the 2022 Warrants and 2022 Placement Agent warrants including: (i) evaluating the contracts to identify relevant terms that affect the recognition in the consolidated financial statements, and (ii) assessing the appropriateness of conclusions reached by management.

/s/ Baker Tilly US, LLP

We have served as the Company's auditor since 2013.

Tewksbury, Massachusetts

December 28, 2022, except for the effects of the reverse share split described in Note 2, as to which the date is January 23, 2023.

Arch Therapeutics, Inc. and Subsidiary
Consolidated Balance Sheets
As of September 30, 2022 and 2021

	September 30, 2022	September 30, 2021
ASSETS		
Current assets:		
Cash	\$ 746,940	\$ 2,266,639
Inventory	1,414,848	1,093,765
Prepaid expenses and other current assets	436,407	307,341
Total current assets	<u>2,598,195</u>	<u>3,667,745</u>
Long-term assets:		
Property and equipment, net	2,044	5,240
Other assets	3,500	3,500
Total long-term assets	<u>5,544</u>	<u>8,740</u>
Total assets	<u>\$ 2,603,739</u>	<u>\$ 3,676,485</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 1,328,000	\$ 408,083
Accrued expenses and other liabilities	318,505	319,464
Insurance premium financing	247,933	—
Current portion of Series 1 convertible notes	550,000	—
Current portion of accrued interest	127,781	—
Current portion of derivative liability	748,275	1,000,000
Total current liabilities	<u>3,320,494</u>	<u>1,727,547</u>
Long-term liabilities:		
Series 1 convertible notes	—	550,000
Series 2 convertible notes	450,000	1,050,000
Senior secured convertible notes, net of discount and issuance costs	2,362,273	—
Accrued interest	204,575	167,137
Derivative liability	459,200	1,207,475
Total long-term liabilities	<u>3,476,048</u>	<u>2,974,612</u>
Total liabilities	<u>6,796,542</u>	<u>4,702,159</u>
Commitments and contingencies (Note 15)		
Stockholders' equity (deficit):		
Common stock, \$0.001 par value, 12,000,000 shares authorized as of September 30, 2022 and 2021, 1,249,432 and 1,185,849 shares issued as of September 30, 2022 and 2021, and 1,249,682 and 1,183,599 outstanding as of September 30, 2022 and 2021	1,249	1,184
Additional paid-in capital	50,878,721	48,770,061
Accumulated deficit	(55,072,773)	(49,796,919)
Total stockholders' deficit	<u>(4,192,803)</u>	<u>(1,025,674)</u>
Total liabilities and stockholders' deficit	<u>\$ 2,603,739</u>	<u>\$ 3,676,485</u>

The accompanying notes are an integral part of these consolidated financial statements.

Arch Therapeutics, Inc. and Subsidiary
Consolidated Statements of Operations
For the Years Ended September 30, 2022 and 2021

	Fiscal Year Ended September 30, 2022	Fiscal Year Ended September 30, 2021
Revenue	\$ 15,652	\$ 11,565
Operating expenses:		
Cost of revenues	51,489	26,282
Selling, general and administrative expenses	4,519,636	5,009,323
Research and development expenses	1,153,333	1,353,084
Total costs and expenses	5,724,458	6,388,689
Loss from operations	(5,708,806)	(6,377,124)
Other (expense) income:		
Interest expense	(567,048)	(150,531)
Gain on forgiveness of loan	—	178,229
Decrease to fair value of derivative	1,000,000	108,944
Total other income	432,952	136,642
Net loss	\$ (5,275,854)	\$ (6,240,482)
Loss per share - basic and diluted		
Net loss per common share - basic and diluted	\$ (4.40)	\$ (5.67)
Weighted common shares - basic and diluted	1,199,574	1,100,007

The accompanying notes are an integral part of these consolidated financial statements.

Arch Therapeutics, Inc. and Subsidiary
Consolidated Statements of Changes in Stockholders' Deficit
For the Years Ended September 30, 2022 and 2021

<i>Fiscal Year Ended September 30, 2022</i>	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balance at September 30, 2021	1,183,599	\$ 1,184	\$ 48,770,061	\$ (49,796,919)	\$ (1,025,674)
Net loss	—	—	—	(5,275,854)	(5,275,854)
Issuance of common stock and warrants, net of financing costs	63,833	64	1,609,077	—	1,609,141
Vesting of restricted stock Issued	2,000	2	(2)	—	—
Stock-based compensation expense	—	—	499,584	—	499,584
Balance at September 30, 2022	<u>1,249,432</u>	<u>\$ 1,249</u>	<u>\$ 50,878,721</u>	<u>\$ (55,072,773)</u>	<u>\$ (4,192,803)</u>
<i>Fiscal Year Ended September 30, 2021</i>	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balance at September 30, 2020	965,224	\$ 965	\$ 42,054,981	\$ (43,556,437)	(1,500,491)
Net loss	—	—	—	(6,240,482)	(6,240,482)
Issuance of common stock and warrants, net of financing costs	215,625	216	6,219,017	—	6,219,233
Vesting of restricted stock issued	2,750	3	(3)	—	—
Stock-based compensation expense	—	—	496,066	—	496,066
Balance at September 30, 2021	<u>1,183,599</u>	<u>\$ 1,184</u>	<u>\$ 48,770,061</u>	<u>\$ (49,796,919)</u>	<u>\$ (1,025,674)</u>

The accompanying notes are an integral part of these consolidated financial statements.

Arch Therapeutics, Inc. and Subsidiary
Consolidated Statements of Cash Flows
For the Years Ended September 30, 2022 and 2021

	Fiscal Year Ended September 30, 2022	Fiscal Year Ended September 30, 2021
Cash flows from operating activities:		
Net loss	\$ (5,275,854)	\$ (6,240,482)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	3,196	2,587
Stock-based compensation	499,583	496,066
Decrease to fair value of derivative	(1,000,000)	(108,944)
Inventory obsolescence charge	248,073	181,988
Accretion of discount and debt issuance costs on 2022 Notes	302,049	—
Gain on forgiveness of loan	—	(178,229)
Changes in operating assets and liabilities:		
(Increase) decrease in:		
Inventory	(569,156)	(307,760)
Prepaid expenses and other current assets	225,124	(91,668)
Increase (decrease) in:		
Accounts payable	846,869	66,033
Accrued interest	265,000	151,285
Accrued expenses and other liabilities	(959)	70,496
Net cash used in operating activities	(4,456,075)	(5,958,628)
Cash flows from investing activities:		
Purchases of property and equipment	—	(3,275)
Net cash used in investing activities	—	(3,275)
Cash flows from financing activities:		
Repayment of insurance premium financing	(106,257)	—
Proceeds received from convertible notes	—	1,050,000
Proceeds received from senior secured convertible notes	3,525,000	—
Proceeds from issued common stock and warrants, net of financing costs	—	6,219,233
Payment of 2022 Financing debt issuance costs	(482,367)	—
Net cash provided by financing activities	2,936,376	7,269,233
Net (decrease) increase in cash	(1,519,699)	1,307,330
Cash, beginning of year	2,266,639	959,309
Cash, end of year	\$ 746,940	\$ 2,266,639
Non-cash financing activities:		
Financing of insurance premium	\$ 354,190	\$ —
Issuance of restricted stock	\$ 8,959	\$ —
Fair value of 2022 Warrants issued (see Note 10)	\$ 1,470,133	\$ —
Fair value of 2022 Inducement Shares issued (see Note 10)	\$ 314,523	\$ —
Exchange of Series 2 Convertible Notes into Senior Secured Notes (See Note 10)	\$ 699,781	\$ —
Issuance of restricted stock in consideration for services performed	\$ 30,840	\$ 103,750
Fair Value of 2022 Placement Agent Warrants (see Note 10)	\$ 219,894	\$ —
Unpaid issuance costs in accounts Payable	\$ 73,048	\$ —

The accompanying notes are an integral part of these consolidated financial statements.

Notes to the Consolidated Financial Statements

1. DESCRIPTION OF BUSINESS

Arch Therapeutics, Inc. (together with its subsidiary, the “Company” or “Arch”) was incorporated under the laws of the State of Nevada on September 16, 2009, under the name “Almah, Inc.”. Effective June 26, 2013, the Company completed a merger (the “Merger”) with Arch Biosurgery, Inc. (formerly known as Arch Therapeutics, Inc.), a Massachusetts corporation (“ABS”), and Arch Acquisition Corporation (“Merger Sub”), the Company’s wholly owned subsidiary formed for the purpose of the transaction, pursuant to which Merger Sub merged with and into ABS and ABS thereby became the wholly owned subsidiary of the Company. As a result of the acquisition of ABS, the Company abandoned its prior business plan and changed its operations to the business of a biotechnology company. The Company’s principal offices are located in Framingham, Massachusetts.

ABS was incorporated under the laws of the Commonwealth of Massachusetts on March 6, 2006, as Clear Nano Solutions, Inc. On April 7, 2008, ABS changed its name from Clear Nano Solutions, Inc. to Arch Therapeutics, Inc. Effective upon the closing of the Merger, ABS changed its name from Arch Therapeutics, Inc. to Arch Biosurgery, Inc.

In the first quarter of 2021, the Company commenced commercial sales of our first product, AC5® Advanced Wound System, and has devoted substantially all of the Company’s operational effort to the research, development and regulatory programs necessary to turn the Company’s core technology into commercial products. To date, the Company has principally raised capital through the issuance of convertible debt, and the issuance of units consisting of its common stock, \$0.001 par value per share (“Common Stock”), and warrants to purchase Common Stock (“warrants”).

The Company expects to incur substantial expenses for the foreseeable future relating to research, development and commercialization of its potential future products. However, there can be no assurance that the Company will be successful in securing additional resources when needed, on terms acceptable to the Company, if at all. Therefore, there exists substantial doubt about the Company’s ability to continue as a going concern. The consolidated financial statements do not include any adjustments related to the recoverability of assets that might be necessary despite this uncertainty.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accompanying consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America (“US GAAP”).

Basis of Presentation

The consolidated financial statements include the accounts of Arch Therapeutics, Inc. and its wholly owned subsidiary, Arch Biosurgery, Inc., a biotechnology company. All intercompany accounts and transactions have been eliminated in consolidation.

On January 6, 2023, the directors of the Company authorized a reverse share split of the issued and outstanding Common Shares in a ratio of 200:1, effective January 17, 2023 (the “Reverse Share Split”). All information included in these consolidated financial statements has been adjusted, on a retrospective basis, to reflect the Reverse Share Split, unless otherwise stated.

Use of Estimates

Management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from those estimates.

Recently Issued and Adopted Accounting Guidance

In August 2020, the FASB issued ASU 2020-06, “*Debt with Conversion and other Options* (subtopic 470-20) and *Derivatives and Hedging-Contracts in Entity’s Own Equity* (Subtopic 815-40)” (“ASU 2020-06”). The purpose of ASU 2020-06 is to address issues identified as a result of the complexity associated with applying generally accepted accounting principles (“GAAP”) for certain financial instruments with characteristics of liabilities and equity. The amendments in ASU 2020-06 are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2023. Early adoption is permitted but no earlier than fiscal years beginning after December 15, 2020. The Company early adopted ASU 2020-06 using the full retrospective method, during our first quarter of fiscal year 2022, and the impact was considered immaterial on our consolidated financial statements.

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Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. The Company had no cash equivalents as of September 30, 2022 and 2021.

Inventories

Inventories are stated at the lower of cost or net realizable value. The cost of inventories comprises expenditures incurred in acquiring the inventories, the cost of conversion and other costs incurred in bringing them to their existing location and condition. The cost of raw materials, goods-in-process and finished goods are determined on a First in First out (FIFO) basis. When determining net realizable value, appropriate consideration is given to obsolescence, excessive levels, deterioration, and other factors.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist primarily of cash. The Company maintains its cash in bank deposits accounts, which, at times, may exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk on cash.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful life of the related asset. Upon sale or retirement, the cost and accumulated depreciation are eliminated from their respective accounts, and the resulting gain or loss is included in income or loss for the period. Repair and maintenance expenditures are charged to expense as incurred.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment when circumstances indicate the carrying value of an asset may not be recoverable in accordance with FASB ASC Topic 360, *Property, Plant and Equipment*. For assets that are to be held and used, impairment is recognized when the estimated undiscounted cash flows associated with the asset or group of assets is less than their carrying value. If impairment exists, an adjustment is made to write the asset down to its fair value, and a loss is recorded as the difference between the carrying value and fair value. Fair values are determined based on quoted market values, discounted cash flows or internal and external appraisals, as applicable. Assets to be disposed of are carried at the lower of carrying value or estimated net realizable value. For the years ended September 30, 2022 and 2021 there has not been any impairment of long-lived assets.

Leases

The Company determines if an arrangement is a lease at its inception. Operating lease right-of-use ("ROU") assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As our lease does not provide an implicit interest rate, the Company used an incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Income Taxes

In accordance with FASB ASC Topic 740, *Income Taxes* ("ASC 740"), the Company recognizes deferred tax assets and liabilities for the expected future tax consequences or events that have been included in our consolidated financial statements and/or tax returns. Deferred tax assets and liabilities are based upon the differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities and for loss and credit carryforwards using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

The Company provides reserves for potential payments of tax to various tax authorities related to uncertain tax positions when management determines that it is more likely than not that a loss will be incurred related to these matters and the amount of the loss is reasonably determinable.

Revenue

In accordance with FASB ASC Topic 606, *Revenue Recognition*, the Company recognizes revenue through a five-step process: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) a performance obligation is satisfied.

The Company's source of revenue is product sales. Contracts with customers contain a single performance obligation and the Company recognizes revenue from product sales when the Company has satisfied our performance obligation by transferring control of the product to the customers. Control of the product transfers to the customer upon shipment from the Company's third-party warehouse. The Company launched a reimbursement support program in September 2022. Under the terms of the program, the invoice amount may be adjusted through full or partial write-offs based on actual reimbursement amounts paid by for Medicare and Medicaid Services ("CMS") for AC5 units applied and billed by doctors. As such, revenue, if any, for the units shipped in connection with the Company's reimbursement support program will be booked in future periods when all conditions have been satisfied.

Cost of Revenues

Cost of revenues includes product costs, warehousing, overhead allocation and royalty expenses.

Research and Development

The Company expenses internal and external research and development costs, including costs of funded research and development arrangements, in the period incurred.

Accounting for Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with the guidance of FASB ASC Topic 718, *Compensation-Stock Compensation* (“ASC 718”), which requires all share-based payments be recognized in the consolidated financial statements based on their fair values. In accordance with ASC 718, the Company has elected to use the Black-Scholes option pricing model to determine the fair value of options granted and recognizes the compensation cost of share-based awards on a straight-line basis over the vesting period of the award.

The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by the fair value of the common stock and a number of other assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. The expected life for awards uses the simplified method for all “plain vanilla” options, as defined in ASC 718-10-S99, and the contractual term for all other employee and non-employee awards. The risk-free interest rate assumption is based on observed interest rates appropriate for the terms of our awards. The dividend yield assumption is based on history and the expectation of paying no dividends. Stock-based compensation expense, when recognized in the consolidated financial statements, is based on awards that are ultimately expected to vest.

Fair Value Measurements

The Company measures both financial and nonfinancial assets and liabilities in accordance with FASB ASC Topic 820, *Fair Value Measurements and Disclosures*, including those that are recognized or disclosed in the consolidated financial statements at fair value on a recurring basis. The standard created a fair value hierarchy which prioritizes the inputs to valuation techniques used to measure fair value into three broad levels as follows: Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities; Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and Level 3 inputs are unobservable inputs that reflect the Company’s own views about the assumptions market participants would use in pricing the asset or liability.

At September 30, 2022 and 2021, the carrying amounts of cash, accounts payables and accrued expenses and other liabilities approximate fair value because of their short-term nature. The carrying amounts for the Convertible Notes (See Notes 11 and 12) approximate fair value because borrowing rates and the terms are similar to comparable market participants. The carrying amounts of the Derivative Liabilities (See Note 7) are valued using Level 3 inputs and are recognized in the consolidated financial statements at fair value.

Derivative Liabilities

The Company accounts for its warrants and other derivative financial instruments as either equity or liabilities based upon the characteristics and provisions of each instrument, in accordance with FASB ASC Topic 815, *Derivatives and Hedging* (“ASC 815”). Warrants classified as equity are recorded at fair value as of the date of issuance on the Company’s consolidated balance sheets and no further adjustments to their valuation are made. Warrants classified as derivative liabilities and other derivative financial instruments that require separate accounting as liabilities are recorded on the Company’s consolidated balance sheets at their fair value on the date of issuance and will be revalued on each subsequent balance sheet date until such instruments are exercised or expire, with any changes in the fair value between reporting periods recorded as other income or expense. Management estimates the fair value of these liabilities using option pricing models and assumptions that are based on the individual characteristics of the warrants or instruments on the valuation date, as well as assumptions for future financings, expected volatility, expected life, yield, and risk-free interest rate.

Complex Financial Instruments

The Company does not use derivative instruments to hedge exposures to cash flow, market, or foreign currency risks. The Company evaluates its financial instruments, including warrants, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. The Company values its derivatives using the Black-Scholes option-pricing model or other acceptable valuation models, including Monte-Carlo simulations. Derivative instruments are valued at inception, upon events such as an exercise of the underlying financial instrument, and at subsequent reporting periods. The classification of derivative instruments, including whether such instruments should be recorded as liabilities, is re-assessed at the end of each reporting period.

The Company reviews the terms of debt instruments, equity instruments, and other financing arrangements to determine whether there are embedded derivative features, including embedded conversion options that are required to be bifurcated and accounted for separately as a derivative financial instrument. Additionally, in connection with the issuance of financing instruments, the Company may issue freestanding options and warrants, including options or warrants to non-employees in exchange for consulting or other services performed.

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The Company accounts for its common stock warrants in accordance with Accounting Standards Codification (“ASC”) 815 *Derivatives and Hedging* (“ASC 815”). Based upon the provisions of ASC 815, the Company accounts for common stock warrants as liabilities if the warrant requires net cash settlement or gives the holder the option of net cash settlement, or it fails the equity classification criteria. The Company accounts for common stock warrants as equity if the contract requires physical settlement or net physical settlement or if the Company has the option of physical settlement or net physical settlement and the warrants meet the requirements to be classified as equity. Common stock warrants classified as liabilities are initially recorded at fair value on the grant date and remeasured at fair value each balance sheet date with the offset adjustments recorded in change in fair value of warrant liability within the consolidated statements of operations. Common stock warrants classified as equity are initially measured at fair value on the grant date and are not subsequently remeasured.

[Financial Statement Reclassification](#)

Certain balances in the prior year consolidated financial statements have been reclassified for comparison purposes to conform to the presentation in the current year consolidated financial statements. These reclassifications had no effect on the reported results of operations or financial position.

[Subsequent Events](#)

The Company evaluated all events or transactions through December 28, 2022, the date which these consolidated financial statements were issued. Please note the following matters deemed to be subsequent events.

[CMS HCPCS Code Status](#)

On December 5, 2022, the Company announced that the Centers for Medicare and Medicaid Services (“CMS”) made a preliminary recommendation to establish a dedicated Healthcare Common Procedure Coding System (“HCPCS”) Level II billing code specific to AC5® Advanced Wound System (“AC5”). The preliminary recommendation was discussed at CMS’ First Biannual 2022 HCPCS Public Meeting, which was held on November 30, 2022. The HCPCS code would better enable providers to bill third party payors for AC5® Advanced Wound System that is used in doctors’ offices. Although the establishment of a dedicated HCPCS code does not guarantee coverage or reimbursement, a HCPCS code specific to AC5® Advanced Wound System would also enhance the Company’s ability to work directly with payors and expand access in outpatient settings.

[Going Concern Basis of Accounting](#)

As reflected in the consolidated financial statements, the Company has an accumulated deficit as of September 30, 2022, has suffered significant net losses and negative cash flows from operations, only recently commenced generating limited operating revenues, and has limited working capital. The continuation of the Company’s business as a going concern is dependent upon raising additional capital, the ability to successfully market and sell its product and eventually attaining and maintaining profitable operations. In particular, as of September 30, 2022, the Company will be required to raise additional capital, obtain alternative means of financial support, or both, in order to continue to fund operations, and therefore there is substantial doubt about the Company’s ability to continue as a going concern. The Company expects to incur substantial expenses into the foreseeable future for the research, development and commercialization of its current and potential products. In addition, the Company will require additional financing in order to seek to license or acquire new assets, research and develop any potential patents and the related compounds, and obtain any further intellectual property that the Company may seek to acquire. Finally, some of our product candidates or the materials contained therein (such as the Active Pharmaceutical Ingredients for our AC5® product line), are manufactured from facilities in areas impacted by the outbreak of the COVID-19, which could result in shortages due to ongoing efforts to address the outbreak. Historically, the Company has principally funded operations through debt borrowings, the issuance of convertible debt, and the issuance of units consisting of common stock and warrants. Provisions in the Securities Purchase Agreements that the Company entered into on June 28, 2018 (“2018 SPA”), and July 6, 2022 (“2022 SPA”) restrict the Company’s ability to effect or enter into an agreement to effect any issuance by the Company or its subsidiary of Common Stock or securities convertible, exercisable or exchangeable for Common Stock (or a combination of units thereof) involving a Variable Rate Transaction (as defined in the 2018 SPA and 2022 SPA) including, but not limited to, an equity line of credit or “At-the-Market” financing facility until the institutional investors in the 2018 SPA collectively own less than 20% of the Series F Warrants and the Series G Warrants purchased by them pursuant to the and 2018 SPA, respectively and for a period of six months pursuant to the 2022 SPA. In addition, under the 2022 SPA, we are required to complete an uplist to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American by February 15, 2023. See Note 6 for more information on the 2018 Financing, including the terms of the Series F Warrants and Series G Warrants, and Note 10 for more information on the 2022 Note Financing, including the terms of the 2022 Warrants and 2022 Placement Agent Warrants.

The 2021 SPA contains certain restrictions on our ability to conduct subsequent sales of our equity securities (See Note 9). The continued spread of COVID-19 and uncertain market conditions may also limit the Company’s ability to access capital. If the Company is unable to obtain adequate capital, the Company may be required to reduce the scope, delay, or eliminate some or all of its planned activities. These conditions, in the aggregate, raise substantial doubt as to the Company’s ability to continue as a going concern.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The consolidated financial statements do not include any adjustments that might result from this uncertainty.

3. PROPERTY AND EQUIPMENT

At September 30, 2022 and 2021, property and equipment consisted of:

	Estimated Useful Life (in years)	September 30, 2022	September 30, 2021
Furniture and fixtures	5	\$ 9,357	\$ 9,357
Leasehold improvements	Life of Lease	8,983	8,983
Computer equipment	3	14,416	14,416
Lab equipment	5	1,000	1,000
		33,756	33,756
Less – accumulated depreciation		31,712	28,516
Property and equipment, net		<u>\$ 2,044</u>	<u>\$ 5,240</u>

For the years ended September 30, 2022 and 2021 depreciation expense recorded was \$,196 and \$2,587, respectively.

4. INVENTORIES

Inventories consist of the following:

	September 30, 2022	September 30, 2021
Finished Goods	\$ 9,063	\$ 249,571
Goods-in-process	1,405,785	844,194
Total	<u>\$ 1,414,848</u>	<u>\$ 1,093,765</u>

The Company capitalizes inventory that has been produced for commercial sale and has been determined to have a probable future economic benefit. The determination of whether or not the inventory has a future economic benefit requires estimates by management, to the extent that inventory is expected to expire prior to being sold or used for research and development or used for samples, the Company will write down the value of inventory. In evaluating the net realizable value of the inventory, appropriate consideration is given to obsolescence, excessive levels, deterioration, and other factors.

5. INSURANCE PREMIUM FINANCING

In July 2022, the Company entered into a finance agreement with First Insurance Funding in order to fund a portion of its insurance policies. The amount financed is approximately \$354,000 and incurs interest at a rate of 2.99%. The Company is required to make monthly payments of approximately \$35,000 through April 2023. The outstanding balance as of September 30, 2022 was approximately \$248,000.

6. REGISTERED DIRECT OFFERINGS

On September 30, 2016, the Company filed a registration statement with the SEC utilizing a “shelf” registration process, which was subsequently declared effective by the SEC on October 20, 2016 (such registration statement, the “*Shelf Registration Statement*”). Under the Shelf Registration Statement, the Company may offer and sell any combination of its Common Stock, warrants, debt securities, subscription rights, and/or units comprised of the foregoing to raise up to \$50,000,000 in gross proceeds.

On February 20, 2017, the Company entered into a Securities Purchase Agreement (the “2017 SPA”) with six accredited investors (collectively, the “2017 Investors”) providing for the issuance and sale by the Company to the 2017 Investors of an aggregate of 50,833 units at a purchase price of \$120.00 per unit in a registered offering (the “2017 Financing”). The securities comprising the units sold in the 2017 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant equal to 55% of the shares of Common Stock at an exercise price of \$150.00 per share (“Series F Warrant”) at any time prior to the fifth anniversary of the issuance date of the Series F Warrant subject to certain restrictions on exercise (the “2017 Warrants”) and the shares issuable upon exercise of the 2017 Warrants (the “2017 Warrant Shares”).

On June 28, 2018, the Company entered into a Securities Purchase Agreement (“2018 SPA”) with eight accredited investors (collectively, the “2018 Investors”) providing for the issuance and sale by the Company to the 2018 Investors of an aggregate of 45,350 units at a purchase price of \$100.00 per unit in a registered offering (“2018 Financing”). The securities comprising the units sold in the 2018 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant to purchase up to a number of shares of the Company’s Common Stock equal to 75% of the shares of Common Stock at an exercise price of \$140.00 per share (“Series G Warrant”) at any time prior to the fifth anniversary of the issuance date of the Series G Warrant subject to certain restrictions on exercise (the “2018 Warrants”) and the shares issuable upon exercise of the 2018 Warrants (the “2018 Warrant Shares”).

On May 12, 2019, the Company entered into a Securities Purchase Agreement (“2019 SPA”) with five accredited investors (collectively, the “2019 Investors”) providing for the issuance and sale by the Company to the 2019 Investors of an aggregate of 43,077 units at a purchase price of \$65.00 per unit in a registered offering (“2019 Financing”). The securities comprising the units sold in the 2019 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant to purchase one share of Common Stock at an exercise price of \$80.00 per share (“Series H Warrant”) at any time prior to the fifth anniversary of the issuance date of the Series H Warrant subject to certain restrictions on exercise (the “2019 Warrants”) and the shares issuable upon exercise of the 2019 Warrants (the “2019 Warrant Shares”).

During the years ended September 30, 2022 and 2021, no Series F, Series G or Series H Warrants had been exercised. As of September 30, 2022, up to 34,013 and 43,077 shares may be acquired upon the exercise of the Series G and Series H Warrants, respectively.

During the year ended September 30, 2022, all 27,958 remaining Series F Warrants expired.

7. Derivative Liabilities

The Company accounted for the Series F Warrants, Series G Warrants and the Series H Warrants in accordance with ASC 815-10. Since the Company may be required to purchase its Series F Warrants, Series G Warrants and Series H Warrants for an amount of cash equal to \$ 36.00, \$22.00 and \$10.66, respectively, for each share of Common Stock (“Minimum”) they are recorded as liabilities at the greater of the Minimum or fair value. They are marked to market each reporting period through the Consolidated Statement of Operations. During the year ended September 30, 2022, the Company recognized income of \$1,000,000 for the expiration of the Series F Warrants.

On the respective closing dates, the derivative liabilities related to the Series G Warrants and Series H Warrants were recorded at an aggregate fair value of \$1,628,113. Given that the fair value of the derivative liabilities was less than the net proceeds, the remaining proceeds were allocated to Common Stock and additional-paid-in-capital. For the fiscal year ended September 30, 2021, the Company recorded income of \$108,944 in connection with the decrease in the fair value of the derivative liability.

Fair Value Measurements Using Significant Unobservable Inputs - Year Ended September 30, 2022 (Level 3)

	Series F	Series G	Series H
Beginning balance at September 30, 2021	\$ 1,000,000	\$ 748,275	\$ 459,200
Issuances	—	—	—
Adjustments for the expiration of warrant	(1,000,000)	—	—
Ending balance at September 30, 2022	<u>\$ —</u>	<u>\$ 748,275</u>	<u>\$ 459,200</u>

Fair Value Measurements Using Significant Unobservable Inputs— Year Ended September 30, 2021 (Level 3)

	Series F	Series G	Series H
Beginning balance at September 30, 2020	\$ 1,000,000	\$ 748,275	\$ 568,144
Issuances	—	—	—
Adjustments to estimated fair value	—	—	(108,944)
Ending balance at September 30, 2021	<u>\$ 1,000,000</u>	<u>\$ 748,275</u>	<u>\$ 459,200</u>

The derivative liabilities are recorded as liabilities at September 30, 2022 using the greater of the minimum value or the Black Scholes Model with the following assumptions. As of September 30, 2022, the derivative liabilities are recorded at their minimum value.

	Series G	Series H
Closing price per share of Common Stock		
Exercise price per share	\$ 140.00	\$ 80.00
Expected volatility	132.97%	122.50%
Risk-free interest rate	4.05%	4.14%
Dividend yield	—	—
Remaining expected term of underlying securities (years)	0.69	1.57

During the year ended September 30, 2022, the Series F Warrants expired.

The derivative liabilities are recorded as liabilities at September 30, 2021 using the greater of the minimum value or the Black Scholes Model with the following assumptions. As of September 30, 2021, the derivative liabilities are recorded at their minimum value.

	Series F	Series G	Series H
Closing price per share of Common Stock	\$ 0.12	\$ 0.12	\$ 0.12
Exercise price per share	\$ 150.00	\$ 140.00	\$ 80.00
Expected volatility	90.28%	87.40%	86.59%
Risk-free interest rate	0.04%	0.19%	0.41%
Dividend yield	—	—	—
Remaining expected term of underlying securities (years)	0.34	1.70	2.58

8. OCTOBER 2019 REGISTERED DIRECT OFFERING

On October 16, 2019, the Company entered into a Securities Purchase Agreement (the “*October 2019 SPA*”) with seven accredited investors (collectively, the “*October 2019 Investors*”) providing for the issuance and sale by the Company to the 2019 Investors of an aggregate of 71,429 units at a purchase price of \$35.00 per unit in a registered offering (“*October 2019 Financing*”). The securities comprising the units sold in the October 2019 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant to purchase one share of Common Stock at an exercise price of \$44.00 per share (“*Series I Warrant*”) at any time prior to the fifth anniversary of the issuance date of the Series I Warrant subject to certain restrictions on exercise and the shares issuable upon exercise of the Series I Warrants (collectively, the “*October 2019 Warrant Shares*”). As of October 18, 2019, the Company recorded the 71,429 shares as Common Stock. Pursuant to the Engagement Agreement (as defined below), the Company also agreed to issue to the Placement Agent, or its designees, warrants to purchase up to 5,358 shares (the “*Placement Agent Warrants*”). The 2019 Placement Agent Warrants have substantially the same terms as the Series I Warrants, except that the exercise price of the Placement Agent Warrants is \$43.75 per share and the term of the Placement Agent Warrants is five years.

The gross proceeds to the Company from the October 2019 Financing, which were received as of October 18, 2019, were approximately \$2.5 million before deducting financing costs of approximately \$333,000 which includes approximately \$158,000 of placement fees. The number of shares of the Company’s Common Stock into which each of the Series I Warrants is exercisable and the exercise price therefore are subject to adjustment, as set forth in the Series I Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise).

The Company engaged H.C. Wainwright as its exclusive institutional investor placement agent (the “*Placement Agent*”) in connection with the October 2019 SPA pursuant to an engagement agreement dated as of October 10, 2019 (the “*2019 Engagement Agreement*”). In consideration for the services provided by the Placement Agent, the Placement Agent was entitled to receive cash fees ranging from 6.0% to 8.2% of the gross proceeds received by the Company, as well as reimbursement for all reasonable expenses incurred by it in connection with its engagement. The Company received gross proceeds of approximately \$2.5 million in the aggregate, resulting in a fee of approximately \$158,000.

During the year ended September 30, 2022, no Series I Warrants or Placement Agent Warrants have been exercised. As of September 30, 2022, up to 71,429 and 5,358 shares may be acquired upon the exercise of the Series I Warrants and Placement Agent Warrants, respectively.

Common Stock

At October 18, 2019 the Closing Date of the October 2019 Financing, the Company issued 71,429 shares of Common Stock.

Equity Value of Warrants

The Company accounted for the Series I Warrants and the Placement Agent Warrants relating to the aforementioned October 2019 Registered Direct Offering in accordance with ASC 815-40. Because the Series I Warrants and the Placement Agent Warrants are indexed to the Company’s stock, they are classified within stockholders’ equity (deficit) in the accompanying consolidated financial statements.

9. 2021 REGISTERED DIRECT OFFERING

On February 11, 2021, the Company entered into a Securities Purchase Agreement (the “*2021 SPA*”) with certain institutional and accredited investors (collectively, “*2021 Investors*”) providing for the issuance and sale by the Company to the 2021 Investors of an aggregate of 215,625 shares (the “*Shares*”) of the Company’s Common Stock, and warrants (the “*Series K Warrants*”) to purchase an aggregate of 161,719 shares (the “*Warrant Shares*”) of Common Stock, at a combined offering price of \$32.00 per share (the “*2021 Financing*”). The Series K Warrants have an exercise price of \$34.00 per share and are exercisable for a period of 5.5 years. The aggregate gross proceeds for the sale of the Shares and Series K Warrants were approximately \$6.9 million, before deducting the Placement Agent’s fees and expenses and other offering expenses payable by the Company, of approximately \$700,000. Pursuant to an engagement agreement dated as of February 8, 2021 (the “*2021 Engagement Agreement*”), by and between the Company and the Placement Agent, the Company agreed to pay the Placement Agent cash fees equal to (i) 7.5% of the gross proceeds received by the Company from certain investors in the 2021 Financing, and (ii) 6.0% of the gross proceeds received by the Company from certain investors that had pre-existing relationships with the Company. In addition, the Placement Agent received a one-time non-accountable expense fee of \$10,000, up to \$50,000 for fees and expenses of legal counsel and other out-of-pocket expenses and \$10,000 for clearing expenses. Pursuant to the 2021 Engagement Agreement, the Company also agreed to issue to the Placement Agent, or its designees, warrants to purchase up to 7.5% of the aggregate number of Shares sold to the 2021 Investors, or warrants to purchase up to 16,172 shares (the “*2021 Placement Agent Warrants*”) of the Company’s Common Stock. The 2021 Placement Agent 2 Warrants have substantially the same terms as the Series K Warrants, except that the exercise price of the 2021 Placement Agent Warrants is \$40.00 per share. The 2021 Engagement Agreement contained indemnity and other customary provisions for transactions of this nature.

The 2021 SPA contained certain restrictions on the Company’s ability to conduct subsequent sales of the Company’s equity securities. In particular, we were prohibited from entering into or effecting a Variable Rate Transaction (as defined in the 2021 SPA) until February 11, 2022; provided, however, the Company may enter into and effect an at-the-market offering facility with the Placement Agent.

The number of shares of the Company’s Common Stock into which each of the Series K Warrants is exercisable and the exercise price therefore are subject to adjustment, as set forth in the Series K Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise). During the fiscal year ended September 30, 2022, no Series K Warrants or 2021 Placement Agent Warrants had been exercised. As of September 30, 2022, up to 161,719 and 16,172 shares may be acquired upon the exercise of the Series K Warrants and Placement Agent Warrants, respectively.

Common Stock

On February 17, 2021 the Closing Date of the 2021 Financing, the Company issued 215,625 shares of Common Stock.

Equity Value of Warrants

The Company accounted for the Series K Warrants and the Placement Agent 2 Warrants relating to the aforementioned February 2021 Registered Direct Offering in accordance with ASC 815-40, *Derivatives and Hedging*. Because the Series K Warrants and the Placement Agent 2 Warrants are indexed to the Company’s stock, they are classified within stockholders’ equity (deficit) in the accompanying consolidated financial statements.

10. 2022 CONVERTIBLE NOTE OFFERING

On July 7, 2022, the Company announced that it had entered into a Securities Purchase Agreement (the “2022SPA”) with certain institutional and accredited individual investors (collectively, the “2022 Investors”) providing for the issuance and sale by the Company to the 2022 Investors of (i) Senior Secured Convertible Promissory Notes (each a “2022 Note” and collectively, the “2022 Notes”) in the aggregate principal amount of \$4.23 million, which includes an aggregate \$0.705 million original issue discount in respect of the 2022 Notes; (ii) Warrants (the “2022 Warrants”), to purchase an aggregate of 425,554 shares (the “2022 Warrant Shares”) of Common Stock; and (iii) 63,833 shares of Common Stock (the “2022 Inducement Shares”) equal to 15% of the principal amount of the 2022 Notes divided by the closing price of the Common Stock immediately prior to the Closing Date (as defined below). The 2022 Notes, 2022 Warrants and 2022 Inducement Shares were issued as part of a convertible note offering authorized by the Company’s board of directors (the “2022 Note Offering”). The aggregate gross proceeds for the sale of the 2022 Notes, 2022 Warrants and 2022 Inducement Shares was approximately \$3.5 million, before deducting debt issuance costs of \$775,000 consisting of fair value of the placement agent’s warrants of approximately \$220,000 and other estimated fees and offering expenses payable by the Company of approximately \$555,000. The closing of the sales of these securities under the 2022 SPA occurred on July 6, 2022 (the “2022 Closing Date”).

The 2022 Notes bear interest on the unpaid principal balance at a rate equal to ten percent (10%) (computed on the basis of the actual number of days elapsed in a 360-day year) per annum accruing from the Closing Date until the 2022 Notes become due and payable at maturity or upon their conversion, acceleration or by prepayment, and may become due and payable upon the occurrence of an event of default under the 2022 Notes. Any amount of principal or interest on the 2022 Notes which is not paid when due shall bear interest at the rate of the lesser of (i) eighteen percent (18%) per annum or (ii) the maximum amount allowed by law from the due date thereof until payment in full.

The 2022 Notes are convertible into shares of Common Stock at the option of each holder of the 2022 Notes from the date of issuance at \$1.14 (the “Conversion Price”) through the later of (i) January 6, 2024 (the “Maturity Date”) and (ii) the date of payment of the Default Amount (as defined in the 2022 Note); *provided, however*, certain 2022 Notes include a provision preventing such conversion if, as a result, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than 4.99% of the outstanding shares of the Common Stock (as applicable, the “Ownership Limitation”) immediately after giving effect to the Conversion; and *provided further*, the holder, upon notice to us, may increase or decrease the Ownership Limitation; *provided that* (i) the Ownership Limitation may only be increased to a maximum of 9.99% of the outstanding shares of the Common Stock; and (ii) any increase in the Ownership Limitation will not become effective until the 61st day after delivery of such waiver notice. The Conversion Price is subject to adjustment as set forth in the 2022 Notes.

The 2022 Notes contain customary events of default, which include, among other things, (i) our failure to pay when due any principal or interest payment under the 2022 Notes; (ii) our insolvency; (iii) delisting of our Common Stock; (iv) our breach of any material covenant or other material term or condition under the 2022 Notes; and (v) our breach of any representations or warranties under the 2022 Notes which cannot be cured within five (5) days. Further, events of default under the 2022 Notes also include (i) the unavailability of Rule 144 on or after six (6) months from the First Closing Date or January 6, 2023; (ii) our failure to deliver the shares of Common Stock to the 2022 Note holder upon exercise by such holder of its conversion rights under the 2022 Note; (iii) our loss of the “bid” price for its Common Stock and/or a market and such loss is not cured during the specified cure periods; and (iv) our failure to complete an uplisting of our Common Stock to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American by February 15, 2023 (an “Uplist Transaction”).

The 2022 Warrants (i) have an exercise price of \$9.94 per share; (ii) have a term of exercise equal to 5 years after their issuance date; (iii) became exercisable immediately after their issuance; and (iv) have a provision preventing the exercisability of such 2022 Warrant if, as a result of the exercise of the 2022 Warrant, the holder, together with its affiliates and any other persons whose beneficial ownership of our Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than the Ownership Limitation. The holder, upon notice to us, may increase or decrease the Ownership Limitation; *provided that* (i) the Ownership Limitation may only be increased to a maximum of 9.99% of the outstanding shares of our Common Stock; and (ii) any increase in the Ownership Limitation will not become effective until the 61st day after delivery of such waiver notice. The number of shares of Common Stock into which each of the 2022 Warrants is exercisable and the exercise price therefor are subject to adjustment as set forth in the 2022 Warrants, including standard antidilution provisions, and adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise). In the event of a Fundamental Transaction (as defined in the 2022 Warrants) holders of the 2022 Warrants would be entitled to receive alternate consideration in connection with such Fundamental Transaction, but only to the extent that holders of our Common Stock were entitled to receive the same. Moreover, as long as the 2022 Notes and 2022 Warrants remaining outstanding, upon the issuance of any security in connection with any potential future financing activity on terms more favorable than the existing terms, the Company has an obligation to notify the holders of the 2022 Notes and 2022 Warrants of such more favorable terms and to use best efforts to effect such terms in the 2022 Notes and 2022 Warrants. Finally, because of the Company’s net loss position, the shares underlying the 2022 Notes on an as converted basis are excluded from the calculation of basic and fully diluted earnings per share. Similarly, because of the Company’s net loss position, there was no impact on the calculation of basic and fully diluted earnings per share related to the classification of the 2022 Warrants as participating securities.

The Company retained a placement agent in connection with the private placement of \$2.4 million of the 2022 Notes to the institutional investors. The Company paid the 2022 Placement Agent 10% of the gross proceeds in the 2022 Placement Agent from certain institutional investors, or \$240,000 and we also reimbursed the 2022 Placement Agent approximately \$58,000 for non-accountable banking fees, legal fees and other expenses. In addition, we issued 2022 Placement Agent Warrants to purchase an aggregate of 31,510 shares of Common Stock. An additional \$1.1 million was raised in connection with the placement of the private placement notes, which included certain accredited investors some of which were Board members and executive officers of the Company. Board member, Laurence Hicks, and executive officers, Terrence W. Norchi and Michael S. Abrams, invested in the 2022 Senior Secured Convertible Notes. The investment made in the 2022 Senior Secured Convertible Notes made by the Board member and executive officers totaled \$80,000.

In addition, as a part of the 2022 Convertible Notes Offering, certain holders (the “*Series Holders*”) of the Company’s 10% Series 2 Convertible Notes (the “*Series Notes*”) agreed to exchange their Series 2 Notes for promissory notes of the Company on substantially similar terms to those of the 2022 Notes (the “*Subordinated Notes*”). The Subordinated Notes are convertible into 76,563 shares of Common Stock at a conversion price of \$9.14. The holders of the Subordinated Notes did not receive warrants or inducement shares. In connection with the issuance of the Subordinated Notes, the Series Holders entered into a subordination agreement on July 6, 2022 (the “*Closing Date*”) to subordinate their rights in respect of the Subordinated Notes to the rights of the Investors in respect of the 2022 Notes. As of July 7, 2022, approximately \$600,000 of the Series 2 Notes and accrued interest of approximately \$100,000 were included in the exchange.

Further, in connection with the 2022 Note Financing, we are required to complete an Uplist Transaction by February 15, 2023 under the terms of the 2022 Notes. If we are unable to complete an Uplist Transaction, then the 2022 Notes will become immediately due and payable and we will be obligated to pay to each 2022 Note holder an amount equal to 125%, multiplied by the sum of the outstanding principal amount of the 2022 Notes plus any accrued and unpaid interest on the unpaid principal amount of the 2022 Notes to the date of payment, plus any default interest and any other amounts owed to the holder, payable in cash or shares of Common Stock.

During the fiscal year ended September 30, 2022, the Company recorded interest expense on the 2022 Notes of approximately \$21,000 consisting of accrued interest of approximately \$119,000 and accretion of original issue discount debt discount and issuance costs of approximately \$302,000.

Allocation of Proceeds

The Company accounted for the Senior Secured Convertible Notes, the 2022 Warrants, and the 2022 Inducement Shares relating to the aforementioned July 2022 Senior Secured Convertible Promissory Notes in accordance with ASC 470-20-25-2 “Debt” which states that the allocation of the proceeds from the financing shall be based on the relative fair values of the securities issued at the time of the issuance. The 2022 Inducement Shares and the 2022 Warrants, which are indexed to the Company’s stock, are classified within stockholders’ equity (deficit) in the accompanying consolidated financial statements. The allocated value of the 2022 Inducement Shares and the 2022 Warrants are \$314,523 and \$1,470,133, respectively. The allocated value of the Senior Secured Convertible Notes are \$1,740,344 were allocated as long-term liabilities in the accompanying consolidated financial statements. The fair value of the 2022 Placement Agent Warrants of \$219,894 are being accounted for as debt issuance costs and are classified within stockholders’ equity (deficit) in the accompanying consolidated financial statements. As of September 30, 2022, the net carrying amount of the Senior Secured Convertible Notes was \$2,362,273 with unamortized debt discount and issuance costs of \$2,567,507.

The 2022 Warrants and the 2022 Placement Agent Warrants were valued as of July 6, 2022 using the Black Scholes Model with the following assumptions:

	2022 Investor Warrants	2022 Placement Agent Warrants
Closing price per share of Common Stock	\$ 9.98	\$ 9.98
Exercise price per share	\$ 9.94	\$ 10.06
Expected volatility	88.44%	88.44%
Risk-free interest rate	2.96%	2.96%
Dividend yield	—	—
Remaining expected term of underlying securities (years)	5.0	5.0

11. SERIES 1 AND SERIES 2 CONVERTIBLE NOTES

On June 4, 2020 and November 6, 2020, the Company issued unsecured 10% Series 1 Convertible Notes (“*Series 1 Notes*”) and Series 2 Convertible Notes (“*Series 2 Notes*”, and collectively with the Series 1 Notes, the “*Convertible Notes*”) in the aggregate principal amount of \$550,000 and \$1,050,000, respectively. The maturity dates of the Series 1 Notes and Series 2 Notes are June 30, 2023 and November 30, 2023, respectively. The Convertible Notes provide, among other things, for (i) a term of approximately three years; (ii) the Company’s ability to prepay the Convertible Notes, in whole or in part, at any time; (iii) the automatic conversion of the Convertible Notes upon a Change of Control (all capitalized terms not otherwise defined to have the meaning ascribed to such terms of the Convertible Notes) into shares of the Company’s Common Stock, at a per share price of \$54.00 and \$50.00 (the “*Conversion Price*”) for the Series 1 Notes and Series 2 Notes, respectively; (iv) the ability of the holders of the Convertible Note (a “*Holder*”) to convert the principal of the Convertible Notes, along with accrued interest, in whole or in part, into shares of Common Stock at the respective Conversion Price; (v) the Company’s ability to convert all Note Obligations outstanding upon a Qualified Equity Financing into shares of Common Stock at the respective Conversion Price; (vi) the Company’s ability to convert the principal of the Convertible Notes, along with accrued interest, in whole or in part, into shares of Common Stock at the respective Conversion Price in the event the volume weighted average price (“*VWAP*”) of the Common Stock equals or exceeds \$64.00 per share for at least fifteen consecutive Trading Days; (vii) the Company’s ability to convert all outstanding Note Obligations into shares of Common Stock at the respective Conversion Price (an “*In-Kind Note Repayment*”) in lieu of repaying the Note Obligations outstanding on the Maturity Date, provided, however, that in the case of an In-Kind Note Repayment, the outstanding Note Obligations will be calculated by increasing by thirty-five percent the aggregate sum of the unpaid Principal Amount held by each Holder and the accrued interest at a rate of ten percent per annum, subject to, with respect to any portion of the Principal Amount that is converted or prepaid before the twelve month anniversary of the Issuance Date, a minimum interest payment equal to ten percent of the amount that is converted or prepaid. As consideration for agreeing to subordinate, the premium applicable in connection with an In-Kind Note Repayment at maturity was increased from thirty-five percent to sixty percent.

Beginning June 22, 2015 and through June 30, 2015, the Company entered into a series of substantially similar subscription agreements with 20 accredited investors providing for the issuance and sale by the Company to the 2015 Investors, in a private placement, of an aggregate of 71,954 Units at a purchase price of \$44.00 per Unit. Each Unit consisted of a share of Common Stock and a Series D Warrant to purchase a share of Common Stock at an exercise price of \$50.00 per share at any time prior to the fifth anniversary of the issuance date of the Series D Warrant and the shares issuable upon exercise of the Series D Warrants.

On June 3, 2020, the Company entered into an agreement (the “*Agreement*”) with the holders of a majority (the “*Majority Holders*”) of the outstanding warrants classified as “*Series D Warrants*”, resulting in approximately \$850,000 of proceeds as a result of the full exercise of all Series D Warrants. Under the terms of the Agreement, in exchange for fully exercising their remaining Series D Warrants for 23,636 shares of Common Stock on June 4, 2020, the Majority Holders were issued warrants to purchase 17,727 shares of Common Stock at an exercise price of \$50.00 over a 1-year term (“*Series J Warrants*”). On November 6, 2020, as consideration for an investment in the Convertible Notes, the Company entered into an amendment to the Series J Warrants with a holder of a Series J Warrant exercisable for up to 16,875 shares of Common Stock, to extend the term of the Series J Warrant from one year to thirty months.

On June 22, 2020, the Company entered into a Series J Warrant Issuance Agreement (the “*Keyes Sulat Agreement*”) with the Keyes Sulat Revocable Trust (the “*Trust*”), also a holder of outstanding Series D Warrants, resulting in approximately \$82,000 of proceeds as a result of the full exercise of the Trust’s Series D Warrants. Under the terms of the Keyes Sulat Agreement, in exchange for fully exercising the Trust’s remaining Series D Warrants for 2,273 shares of Common Stock on June 22, 2020, the Trust was issued Series J Warrants to purchase 1,705 shares of Common Stock at an exercise price of \$50.00 over a one-year term. James R. Sulat, a former member of the Board, is a co-trustee of the Trust, of which members of Mr. Sulat’s immediate family are beneficiaries. Mr. Sulat disclosed his interest in the Trust to the Board prior to its approval of the transaction and abstained from voting on the transaction.

As described in Note 10, above, as a part of the 2022 Convertible Notes Offering, certain holders of the Series Notes agreed to exchange Notes with principal amounts of \$600,000 and accrued interest of approximately \$100,000 for promissory notes of the Company on substantially similar terms to those of the 2022 Notes (the “*Exchanged Notes*”). As of July 6, 2022, \$699,781 of principal and accrued interest of the Series 2 notes was exchanged for the Senior Secured Convertible Notes. In connection with the issuance of the Exchanged Notes, the Series Holders entered into a subordination agreement on the *Closing Date* to subordinate their rights to the rights of the Investors in respect of the 2022 Notes.

During the fiscal years ended September 30, 2022 and 2021, the Company recorded interest expense on the Series 1 and Series 2 Convertible Notes of approximately \$146,000 and \$150,000, respectively.

12. INCOME TAXES

The principal components of the Company's net deferred tax assets consisted of the following at September 30:

	2022	2021
Net operating loss carryforwards	\$ 11,485,524	\$ 10,022,020
Capitalized expenditures	1,535,736	1,703,849
Research and development credit carryforwards	946,243	946,158
Stock based compensation	1,427,946	2,352,432
Property and Equipment	2,616	2,740
Accrued expenses	162,191	57,812
Inventory allowance	70,805	62,946
Gross deferred tax assets	15,631,061	15,147,957
Deferred tax asset valuation allowance	(15,631,061)	(15,147,957)
Net deferred tax assets	\$ -	\$ -

The provision (benefit) for income taxes differs from the tax computed with the statutory federal income tax rate as follows:

	2022	2021
Expected income tax (benefit) at federal statutory rate	21.00%	21.00%
<u>Increase/(Decrease) due to:</u>		
State income taxes – net of federal benefit	3.65%	5.80%
<u>Permanent Differences:</u>		
Key man life insurance	---%	(0.01)%
Stock Based Compensation	(18.10)%	---%
R&D, taken as a credit	(0.23)%	(0.29)%
Adjustment to fair value of derivative	3.98%	0.37%
PPP Loan Forgiveness	---%	0.60%
Other	(1.14)%	(1.41)%
Change in Valuation Allowance	(9.16)%	(26.06)%
Total Income Tax Provision / (Benefit)	---%	---%

As of September 30, 2022 and 2021, the Company had federal net operating loss carryforwards totaling approximately \$42,695,000 and \$37,018,000, respectively, which may be available to offset future taxable income. The pre-2018 federal net operating loss carryforwards total approximately \$21,750,000, and begin to expire in 2026. Due to the CARES Act, federal net operating losses generated in tax years beginning after December 31, 2017 can be carried forward indefinitely. As of September 30, 2022 and 2021, the Company has federal net operating loss carryforwards with an indefinite life of \$20,945,000 and \$15,268,000. As of September 30, 2022 and 2021, the Company had federal research and experimentation credit carryforwards of \$626,000 and \$643,000, respectively, which may be available to offset future income tax liabilities and which would begin to expire in 2028.

As of September 30, 2022 and 2021, the Company had state net operating loss carryforwards of approximately \$40,367,000 and \$36,033,000, respectively, which may be available to offset future taxable income and which would begin to expire in 2030. As of September 30, 2022 and 2021, the Company had state research and development credit carryforwards of \$406,000 and \$384,000, respectively, which may be able to offset future income tax liabilities and which would begin to expire in 2023.

As the Company has not yet achieved profitable operations, management believes the tax benefits as of September 30, 2022 and 2021 did not satisfy the realization criteria set forth in FASB ASC Topic 740, *Income Taxes*, and therefore has recorded a valuation allowance for the entire deferred tax asset. The valuation allowance increased in 2022 by approximately \$483,000 and increased in 2021 by approximately \$1,626,000. The Company's effective income tax rate differed from the federal statutory rate due to state taxes and the Company's full valuation allowance and stock based compensation, the latter of which reduced the Company's effective federal income tax rate to zero.

The Company experienced an ownership change as a result of the Merger described in Note 1, causing a limitation on the annual use of the net operating loss carryforwards, which are subject to a substantial annual limitation due to the ownership change limitations set forth in Internal Revenue Code Section 382 and similar state provisions. A formal Section 382 study has not been performed.

As of September 30, 2022, the Company is open to examination in the U.S. federal and certain state jurisdictions for tax years ended September 30, 2022, 2021, 2010 and 2019. In addition, any loss years remain open to the extent that losses are available for carryover to future years. Therefore, the tax years ended 2006 through 2022 remain open for examination by the IRS.

The Coronavirus Aid, Relief and Economic Security (CARES) Act was enacted on March 27, 2020. The CARES Act affected items such as carryback periods for net operating losses, modifications to the net interest deduction limitations and changes to tax depreciation methods. The company has taken the CARES Act into consideration for the tax year ended September 30, 2022 and continues to evaluate the impact of the CARES act on the business.

13. PAYROLL PROTECTION PROGRAM LOAN

On April 25, 2020, the Company executed a promissory note (the “*PPP Note*”) evidencing an unsecured loan in the amount of \$176,300 under the Paycheck Protection Program (the “*PPP Loan*”). The Paycheck Protection Program (or “*PPP*”) was established under the Cares Act and is administered by the U.S. Small Business Administration (“*SBA*”). The Loan has been made through First Republic Bank (the “*Lender*”).

The PPP Loan had a two-year term and bears interest at a rate of 1.00% per annum. Monthly principal and interest payments are deferred until the SBA makes a decision on our loan forgiveness application. Unless the PPP Loan is forgiven, the Company would have been required to make monthly payments of principal and interest of approximately \$20,000 to the Lender.

The PPP Note contains customary events of default relating to, among other things, payment defaults, providing materially false and misleading representations to the SBA or Lender, or breaching the terms of the PPP Loan documents. The occurrence of an event of default may result in the immediate repayment of all amounts outstanding, collection of all amounts owing from the Company, or filing suit and obtaining judgment.

Under the terms of the CARES Act, PPP Loan recipients can apply for and be granted forgiveness for all or a portion of the loan granted under the PPP. Such forgiveness will be determined, subject to limitations, based on the use of loan proceeds for payment of payroll costs and any payments of mortgage interest, rent, and utilities. However, no assurance is provided that forgiveness for any portion of the PPP Loan will be obtained. During November 2020, the Company applied for forgiveness of the PPP Loan. On May 28, 2021, the Company received notice that the SBA completed review and all principal and interest has been forgiven. For the fiscal year ended September 30, 2021, approximately \$178,000 was recorded to Gain on forgiveness of loan in Other Income in the consolidated statements of operations.

14. STOCK-BASED COMPENSATION

2013 Stock Incentive Plan

On June 18, 2013, the Company established the 2013 Stock Incentive Plan (the “*2013 Plan*”). Under the 2013 Plan, during the fiscal year ended September 30, 2021, a maximum number of 155,571 shares of the Company’s authorized and available common stock could be issued in the form of options, stock appreciation rights, sales or bonuses of restricted stock, restricted stock units or dividend equivalent rights, and an award may consist of one such security or benefit, or two or more of them in any combination or alternative. The 2013 Plan provides that on the first business day of each fiscal year commencing with fiscal year 2014, the number of shares of our common stock reserved for issuance under the 2013 Plan for all awards except for incentive stock option awards will be subject to increase by an amount equal to the lesser of (A) 15,000 Shares, (B) four (4) percent of the number of shares outstanding on the last day of the immediately preceding fiscal year of the Company, or (C) such lesser number of shares as determined by the Company’s Board of Directors (the “*Board*”). The exercise price of each option shall be the fair value as determined in good faith by the Board at the time each option is granted. On October 1, 2021, the aggregate number of authorized shares under the Plan was further increased by 15,000 shares to a total of 170,571 shares.

The exercise price of each option is equal to the closing price of a share of our common stock on the date of grant.

Share-based awards

During the year ended September 30, 2022, the Company granted 2,375 options to employees and directors and 4,250 options to consultants to purchase shares of common stock under the 2013 Plan.

Share-based compensation expense for awards granted during the year ended September 30, 2022 was based on the grant date fair value estimated using the Black-Scholes Option Pricing Model. The following assumptions were used to calculate the fair value of share-based compensation for the year ended September 30, 2022; expected volatility, 79.44% - 119.44%, risk-free interest rate, 0.13% - 2.85%, expected dividend yield, 0%, expected term, 5.6 years.

Common Stock Options

Stock compensation activity under the 2013 Plan for the year ended September 30, 2022 follows:

	Option Shares Outstanding	Weighted Average Exercise Price	Average Remaining Contractual Term (years)	Weighted Aggregate Intrinsic Value
Outstanding at September 30, 2021	124,495	\$ 58.00	1.83	\$ 140,151
Awarded	6,625	\$ 6.00		
Forfeited/Cancelled	(32,494)	\$ 70.00		
Outstanding at September 30, 2022	98,626	\$ 52.00	1.46	\$ 16,900
Vested at September 30, 2022	82,522	\$ 58.00	1.52	\$ —
Vested and expected to vest at September 30, 2022	98,626	\$ 52.00	1.46	\$ 16,900

As of September 30, 2022, 41,366 shares are available for future grants under the 2013 Plan. Share-based compensation expense recorded in the Company's Consolidated Statements of Operations for the year ended September 30, 2022 and 2021 resulting from stock options awarded to the Company's employees, directors and consultants was approximately \$459,000 and \$391,000, respectively. Of this amount during the years ended September 30, 2022 and 2021, \$148,000 and \$124,000, respectively, were recorded as research and development expenses, and \$311,000 and \$267,000, respectively were recorded as general and administrative expenses in the Company's Consolidated Statements of Operations.

During the years ended September 30, 2022 and 2021, no stock options awarded under the 2013 Stock Incentive Plan were exercised for cash. During the years ended September 30, 2022 and 2021, no stock options awarded under the 2013 Stock Incentive Plan were exercised on a cashless basis.

As of September 30, 2022, there is approximately \$181,000 of unrecognized compensation expense related to unvested stock-based compensation arrangements granted under the 2013 Plan. That cost is expected to be recognized over a weighted average period of 2.47 years.

Restricted Stock

On October 14, 2020, the Company awarded 250 shares of Restricted Stock to a consultant. The shares subject to this grant were awarded under the 2013 Plan and vested 90 days from the date of the award.

On January 27, 2021, the Company awarded 2,500 shares of Restricted Stock to a consultant. The shares subject to this grant were awarded under the 2013 Plan and vested immediately.

On July 30, 2021, the Company awarded 750 shares of Restricted Stock to an employee. The shares subject to this grant were awarded under the 2013 Plan and 250 shares vest on each of the following dates: January 12, 2022, July 12, 2022 and January 12, 2023.

On September 27, 2021, the Company awarded 1,500 shares of Restricted Stock to a consultant. The shares subject to this grant were awarded under the 2013 Plan and 1/12 of the shares will vest on each of the next twelve monthly anniversaries.

Restricted stock activity in shares under the 2013 Plan for the years ended September 30, 2022 and 2021 follows:

	2022	2021
Non Vested at September 30, 2021 and 2020	2,250	
Awarded	—	5,000
Vested	(2,000)	(2,750)
Forfeited	—	—
Non Vested at September 30, 2022 and 2021	250	2,250

The weighted average restricted stock award date fair value information for the years ended September 30, 2022 and 2021 follows:

	2022	2021
Non Vested at September 30, 2021 and 2020	\$ 20.00	\$ —
Awarded		26.00
Vested	(20.00)	(32.00)
Forfeited		—
Non Vested at September 30, 2022 and 2021	\$ 18.00	\$ 20.00

For the years ended September 30, 2022 and 2021 compensation expense recorded for the restricted stock awards was approximately \$0,000 and \$105,000, respectively. As of September 30, 2022, there is approximately \$3,000 of unrecognized compensation expense related to unvested stock-based compensation arrangements granted under the 2013 Plan.

15. COMMITMENTS AND CONTINGENCIES

In the ordinary course of business, the Company enters into various agreements containing standard indemnification provisions. The Company's indemnification obligations under such provisions are typically in effect from the date of execution of the applicable agreement through the end of the applicable statute of limitations. The aggregate maximum potential future liability of the Company under such indemnification provisions is uncertain. As of September 30, 2022 and 2021, no amounts have been accrued related to such indemnification provisions.

From time to time, the Company may be exposed to litigation in connection with its operations. The Company's policy is to assess the likelihood of any adverse judgments or outcomes related to legal matters, as well as ranges of probable losses.

MIT Licensing Agreement

In December 2007, the Company entered into a license agreement with MIT pursuant to which the Company acquired an exclusive world-wide license to develop and commercialize technology related to self-assembling peptide compositions, and methods of making and using such compositions in medical and non-medical applications, including claims that cover the Company's proposed products and methods of use thereof. The license also provides non-exclusive rights to additional intellectual property in the fields that cover the Company's proposed products and methods of use thereof, in order to provide freedom to operate. The license provides the Company a right to sublicense the exclusively licensed intellectual property. The Company has not sublicensed the exclusively licensed intellectual property to any party for any field.

In exchange for the licenses granted in the agreement, the Company has paid MIT license maintenance fees and patent prosecution costs. The Company paid license maintenance fees of \$50,000 to MIT in the fiscal years ended September 30, 2022 and 2021. For the years ended September 30, 2022 and 2021, the annual MIT license maintenance fees of \$50,000 are included in accrued expenses and other liabilities on the Consolidated Balance Sheets. The license maintenance fees and patent prosecution costs cover the contract year beginning January 1 through December 31. Annual license maintenance obligations extend through the life of the patents. In addition, MIT is entitled to royalties on applicable future product sales, if any. The annual payments may be applied towards royalties payable to MIT for that year for product sales.

The Company is obligated to indemnify MIT and related parties from losses arising from claims relating to the exercise of any rights granted to the Company under the license, with certain exceptions. The maximum potential amount of future payments the Company could be required to make under this provision is unlimited. The Company considers there to be a low performance risk as of September 30, 2022.

The agreement expires upon the expiration or abandonment of all patents that are issued and licensed to the Company by MIT under such agreement. The Company expects that patents will be issued from presently pending U.S. and foreign patent applications. Any such patent will have a term of 20 years from the filing date of the underlying application. MIT may terminate the agreement immediately, if the Company ceases to carry on its business, if any nonpayment by the Company is not cured or the Company commits a material breach that is not cured. The Company may terminate the agreement for any reason upon six months' notice to MIT.

Leases

The Company's corporate offices are located in Framingham, MA. During July 2017, we entered into a three-year operating lease commencing October 1, 2017 and ending on September 30, 2020 at our current location, pursuant to which we are obliged to pay annual rent of \$38,400 during the first year, \$39,600 during the second year and \$42,000 during the third year. During August 2020, we extended the lease through September 30, 2021 at our current location pursuant to which we are obligated to pay annual rent of \$42,000. During October 2021 we extended the lease for six months through March 31, 2022 at our current location pursuant to which we are obligated to pay \$21,000. As of April 1, 2022 we have converted our current lease to a monthly rental and are obligated to pay \$500 per month. As of September 30, 2022 and 2021, there was no ROU asset or liability. We believe our present offices are suitable for our current and planned near-term operations.

16. RISKS AND UNCERTAINTIES - COVID-19 AND GEOPOLITICAL CONFLICTS

The Company sources its materials and services for its products and product candidates from facilities in areas impacted or which may be impacted by the outbreak of the COVID-19 or geopolitical conflicts. The Company's ability to obtain future inventory may be impacted, therefore potentially affecting the Company's future revenue stream. In addition, the Company has historically and principally funded its operations through debt borrowings, the issuance of convertible debt, and the issuance of units consisting of Common Stock and warrants which may also be impacted by economic conditions beyond the Company's control as well as uncertainties resulting from geopolitical conflicts, including the recent war in Ukraine. The extent to which the COVID-19 and recent events in Ukraine will impact the global economy and the Company is uncertain and cannot be reasonably measured.

Arch Therapeutics, Inc. and Subsidiary

Consolidated Balance Sheets

As of June 30, 2023 (Unaudited) and September 30, 2022

	June 30, 2023	September 30, 2022
ASSETS		
Current assets:		
Cash	\$ 86,542	\$ 746,940
Inventory	1,382,938	1,414,848
Prepaid expenses and other current assets	90,538	436,407
Total current assets	1,560,018	2,598,195
Long-term assets:		
Property and equipment, net	728	2,044
Other assets	3,500	3,500
Total long-term assets	4,228	5,544
Total assets	\$ 1,564,246	\$ 2,603,739
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 2,471,162	\$ 1,328,000
Shareholder advances	50,000	-
Shareholder and Third-Party Advances related to Bridge Financing	690,015	-
Accrued expenses and other liabilities	200,522	318,505
Insurance premium financing	-	247,933
Current Portion of Series 2 convertible note	550,000	550,000
Current Portion of Series 1 convertible note	450,000	-
Current Portion of Unsecured convertible notes	1,401,618	-
Current Portion of 2022 Notes	2,945,448	-
Current Portion of Accrued Interest	820,509	127,781
Current portion of derivative liability	-	748,275
Total current liabilities	9,579,274	3,320,494
Long-term liabilities:		
Unsecured convertible notes	-	699,781
Series 2 convertible notes	-	450,000
2022 Notes	-	1,662,492
Accrued interest	-	204,575
Derivative liability	-	459,200
Total long-term liabilities	-	3,476,048
Total liabilities	9,579,274	6,796,542
Commitments and contingencies		
Stockholders' deficit:		
Common stock, \$0.001 par value, 12,000,000 and 4,000,000 shares authorized as of June 30, 2023 and September 30, 2022, 1,285,213 and 1,252,734 shares issued as of June 30, 2023 and September 30, 2022 and 1,285,213 and 1,249,432 shares outstanding as of June 30, 2023 and September 30, 2022, each respectively	1,285	1,252
Additional paid-in capital	51,582,100	50,878,718
Accumulated deficit	(59,598,413)	(55,072,773)
Total stockholders' deficit	(8,015,028)	(4,192,803)
Total liabilities and stockholders' deficit	\$ 1,564,246	\$ 2,603,739

The accompanying notes are an integral part of these consolidated financial statements.

Arch Therapeutics, Inc. and Subsidiary

Consolidated Statements of Operations (Unaudited)

For the Three and Nine Months Ended June 30, 2023 and 2022

	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Nine Months Ended June 30, 2023	Nine Months Ended June 30, 2022
Revenue	\$ 13,293	\$ 6,261	\$ 36,207	\$ 14,086
Operating expenses:				
Cost of revenues	18,529	17,140	54,882	51,363
Selling, general and administrative expenses	870,053	836,215	3,225,753	3,308,227
Research and development expenses	139,048	159,846	471,135	922,120
Total costs and expenses	1,027,630	1,013,201	3,751,770	4,281,710
Loss from operations	(1,014,337)	(1,006,940)	(3,715,563)	(4,267,624)
Other income (expense):				
Interest expense	(808,770)	(39,890)	(1,968,274)	(119,671)
Gain on extinguishment of derivative liabilities	-	-	1,158,197	-
Expiration of derivative liability/Series F warrant	-	-	-	1,000,000
Total other income (expense)	(808,770)	(39,890)	(810,077)	880,329
Net loss	<u>\$ (1,823,107)</u>	<u>\$ (1,046,830)</u>	<u>\$ (4,525,640)</u>	<u>\$ (3,387,295)</u>
Loss per share - basic and diluted				
Net loss per common share - basic and diluted	\$ (1.42)	\$ (0.88)	\$ (3.58)	\$ (2.86)
Weighted common shares - basic and diluted	1,279,967	1,184,738	1,265,340	1,184,266

The accompanying notes are an integral part of these consolidated financial statements.

Arch Therapeutics, Inc. and Subsidiary

Consolidated Statements of Changes in Stockholders' Deficit (Unaudited)
For the Three and Nine Months Ended June 30, 2023 and 2022

Three Months Ended June 30, 2023	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balance at March 31, 2023	1,274,605	\$ 1,275	\$ 51,387,943	\$ (57,775,306)	(6,386,088)
Net loss	-	-	-	(1,823,107)	(1,823,107)
Stock-based compensation expense	-	-	41,259	-	41,259
Issuance of common stock and warrants, net of financing costs	10,608	10	152,898	-	152,908
Exchange of warrants into common stock	-	-	-	-	-
Balance at June 30, 2023	<u>1,285,213</u>	<u>\$ 1,285</u>	<u>\$ 51,582,100</u>	<u>\$ (59,598,413)</u>	<u>\$ (8,015,028)</u>
Nine Months Ended June 30, 2023	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balance at September 30, 2022	1,252,734	\$ 1,252	\$ 50,878,718	\$ (55,072,773)	(4,192,803)
Net loss	-	-	-	(4,525,640)	(4,525,640)
Vesting of restricted stock	250	-	-	-	-
Stock-based compensation expense	-	-	213,809	-	213,809
Issuance of common stock and warrants, net of financing costs	20,210	20	440,308	-	440,328
Exchange of warrants into common stock	12,019	13	49,265	-	49,278
Balance at June 30, 2023	<u>1,285,213</u>	<u>\$ 1,285</u>	<u>\$ 51,582,100</u>	<u>\$ (59,598,413)</u>	<u>\$ (8,015,028)</u>
Three Months Ended June 30, 2022	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance at March 31, 2022	1,184,599	\$ 1,185	\$ 49,076,775	\$ (52,137,384)	\$ (3,059,424)
Net loss	-	-	-	(1,046,830)	(1,046,830)
Vesting of restricted stock	375	-	-	-	-
Stock-based compensation expense	-	-	90,755	-	90,755
Balance at June 30, 2022	<u>1,184,974</u>	<u>\$ 1,185</u>	<u>\$ 49,167,530</u>	<u>\$ (53,184,214)</u>	<u>\$ (4,015,499)</u>
Nine Months Ended June 30, 2022	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balance at September 30, 2021	1,183,599	\$ 1,184	\$ 48,770,061	\$ (49,796,919)	\$ (1,025,674)
Net loss	-	-	-	(3,387,295)	(3,387,295)
Vesting of restricted stock	1,375	1	(1)	-	-
Stock-based compensation expense	-	-	397,470	-	397,470
Balance at June 30, 2022	<u>1,184,974</u>	<u>\$ 1,185</u>	<u>\$ 49,167,530</u>	<u>\$ (53,184,214)</u>	<u>\$ (4,015,499)</u>

The accompanying notes are an integral part of these consolidated financial statements.

Arch Therapeutics, Inc. and Subsidiary

Consolidated Statements of Cash Flows (Unaudited)
For the Nine Months Ended June 30, 2023 and 2022

	Nine Months Ended June 30, 2023	Nine Months Ended June 30, 2022
Cash flows from operating activities:		
Net loss	\$ (4,525,640)	\$ (3,387,295)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	1,316	2,397
Stock-based compensation	213,809	397,470
Decrease to fair value of derivative	-	(1,000,000)
Gain on extinguishment of derivative liabilities	(1,158,197)	-
Accretion of discount and debt issuance costs on 2022 Notes and Unsecured convertible notes	1,480,121	-
Inventory obsolescence charge	-	248,073
Changes in operating assets and liabilities:		
(Increase) decrease in:		
Inventory	31,910	(582,572)
Prepaid expenses and other current assets	345,869	223,854
Increase (decrease) in:		
Accounts payable	1,143,162	1,288,130
Accrued interest	488,153	119,671
Accrued expenses and other current liabilities	(167,983)	(96,370)
Net cash used in operating activities	(2,147,480)	(2,786,642)
Cash flows from financing activities:		
Repayment of insurance premium financing	(247,933)	-
Proceeds from shareholder advances	1,228,015	575,000
Proceeds from Unsecured convertible notes	507,000	-
Net cash provided by financing activities	1,487,082	575,000
Net decrease in cash	(660,398)	(2,211,642)
Cash, beginning of year	746,940	2,266,639
Cash, end of period	\$ 86,542	\$ 54,997
Non-cash financing activities:		
Exchange of Series G and Series H warrants for common stock	\$ 49,278	\$ -
Issuance of restricted stock	\$ 3,019	\$ 29,831
Fair value of warrants issued - second close	\$ 256,439	\$ -
Fair value of inducement shares issued - second close	\$ 25,840	\$ -
Fair value of placement agent warrants - second close	\$ 28,093	\$ -
Fair value of warrants issued - third close	\$ 137,252	\$ -
Fair value of inducement shares issued - third close	\$ 15,656	\$ -
Conversion of shareholder advance into unsecured convertible note	\$ 488,000	\$ -

The accompanying notes are an integral part of these consolidated financial statements.

ARCH THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. BASIS OF PRESENTATION AND DESCRIPTION OF BUSINESS

Organization and Description of Business

Arch Therapeutics, Inc. (together with its subsidiary, the “Company” or “Arch”) was incorporated under the laws of the State of Nevada on September 16, 2009, under the name “Almah, Inc.”. Effective June 26, 2013, the Company completed a merger (the “Merger”) with Arch Biosurgery, Inc. (formerly known as Arch Therapeutics, Inc.), a Massachusetts corporation (“ABS”), and Arch Acquisition Corporation (“Merger Sub”), the Company’s wholly owned subsidiary formed for the purpose of the transaction, pursuant to which Merger Sub merged with and into ABS and ABS thereby became the wholly owned subsidiary of the Company. As a result of the acquisition of ABS, the Company abandoned its prior business plan and changed its operations to the business of a biotechnology company. The Company’s principal offices are located in Framingham, Massachusetts.

ABS was incorporated under the laws of the Commonwealth of Massachusetts on March 6, 2006, as Clear Nano Solutions, Inc. On April 7, 2008, ABS changed its name from Clear Nano Solutions, Inc. to Arch Therapeutics, Inc. Effective upon the closing of the Merger, ABS changed its name from Arch Therapeutics, Inc. to Arch Biosurgery, Inc.

In the first quarter of 2021, the Company commenced commercial sales of our first product, AC5® Advanced Wound System, and has devoted substantially all of the Company’s operational effort to the research, development and regulatory programs necessary to turn the Company’s core technology into commercial products. To date, the Company has principally raised capital through the issuance of convertible debt, and the issuance of units consisting of its common stock, \$0.001 par value per share (“Common Stock”) and warrants to purchase Common Stock (“warrants”).

The Company expects to incur substantial expenses for the foreseeable future relating to research, development and commercialization of its potential future products. However, there can be no assurance that the Company will be successful in securing additional resources when needed, on terms acceptable to the Company, if at all. Therefore, there exists substantial doubt about the Company’s ability to continue as a going concern. The consolidated financial statements do not include any adjustments related to the recoverability of assets that might be necessary despite this uncertainty.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accompanying unaudited interim consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America (“US GAAP”). The interim consolidated financial statements included herein are unaudited; however, they contain all normal recurring accruals and adjustments that, in the opinion of management, are necessary to present fairly the Company’s results of operations and financial position for the interim periods.

Although the Company believes that the disclosures in these unaudited interim consolidated financial statements are adequate to make the information presented not misleading, certain information normally included in the footnotes prepared in accordance with US GAAP has been omitted as permitted by the rules and regulations of the Securities and Exchange Commission (“SEC”). These unaudited interim consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the fiscal year ended September 30, 2022, filed with the SEC on December 28, 2022 (the “Annual Report”).

For a complete summary of the Company’s significant accounting policies, please refer to Note 2 included in Item 8 of the Company’s Annual Report. There have been no material changes to the Company’s significant accounting policies during the nine months ended June 30, 2023.

Basis of Presentation

The consolidated financial statements include the accounts of Arch Therapeutics, Inc. and its wholly owned subsidiary, Arch Biosurgery, Inc., a biotechnology company. All intercompany accounts and transactions have been eliminated in consolidation.

On January 6, 2023, the directors of the Company authorized a reverse share split of the issued and outstanding Common Shares in a ratio of 1:200, effective January 17, 2023 (the “Reverse Share Split”). All information included in these consolidated financial statements has been adjusted, on a retrospective basis, to reflect the Reverse Share Split, unless otherwise stated. All outstanding securities entitling their holders to purchase shares of Common Stock or acquire shares of Common Stock, including stock options, restricted stock units, and warrants, were adjusted as a result of the Reverse Stock Split, as required by the terms of those securities.

Use of Estimates

Management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenue and expense during the reporting periods. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. The Company had no cash equivalents as of June 30, 2023 and September 30, 2022.

Inventories

Inventories are stated at the lower of cost or net realizable value. The cost of inventories comprises expenditures incurred in acquiring the inventories, the cost of conversion and other costs incurred in bringing them to their existing location and condition. The cost of raw materials, goods-in-process and finished goods are determined on a First in First out (FIFO) basis. When determining net realizable value, appropriate consideration is given to obsolescence, excessive levels, deterioration, and other factors.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist primarily of cash. The Company maintains its cash in bank deposits accounts, which, at times, may exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk on cash.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful life of the related asset. Upon sale or retirement, the cost and accumulated depreciation are eliminated from their respective accounts, and the resulting gain or loss is included in income or loss for the period. Repair and maintenance expenditures are charged to expense as incurred.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment when circumstances indicate the carrying value of an asset may not be recoverable in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 360, *Property, Plant and Equipment*. For assets that are to be held and used, impairment is recognized when the estimated undiscounted cash flows associated with the asset or group of assets is less than their carrying value. If impairment exists, an adjustment is made to write the asset down to its fair value, and a loss is recorded as the difference between the carrying value and fair value. Fair values are determined based on quoted market values, discounted cash flows or internal and external appraisals, as applicable. Assets to be disposed of are carried at the lower of carrying value or estimated net realizable value. For the nine months ended June 30, 2023 and 2022 there has not been any impairment of long-lived assets.

Leases

The Company determines if an arrangement is a lease at its inception. Operating lease right-of-use assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. The Company's lease does not provide an implicit interest rate, the Company used an incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Income Taxes

In accordance with FASB ASC Topic 740, *Income Taxes*, the Company recognizes deferred tax assets and liabilities for the expected future tax consequences or events that have been included in the Company's consolidated financial statements and/or tax returns. Deferred tax assets and liabilities are based upon the differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities and for loss and credit carryforwards using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

The Company provides reserves for potential payments of tax to various tax authorities related to uncertain tax positions when management determines that it is more likely than not that a loss will be incurred related to these matters and the amount of the loss is reasonably determinable.

Revenue

In accordance with FASB ASC Topic 606, *Revenue Recognition*, the Company recognizes revenue through a five-step process: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) a performance obligation is satisfied.

The Company's source of revenue is product sales. Contracts with customers contain a single performance obligation and the Company recognizes revenue from product sales when the Company has satisfied our performance obligation by transferring control of the product to the customers. Control of the product transfers to the customer upon shipment from the Company's third-party warehouse. In circumstances where the transaction price is not able to be determined at the time of shipment, the Company does not recognize revenue or any receivable amount until such time that the final transaction price is established.

Cost of Revenue

Cost of revenue includes product costs, warehousing, overhead allocation and royalty expense.

Research and Development

The Company expenses internal and external research and development costs, including costs of funded research and development arrangements, in the period incurred.

Accounting for Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with the guidance of FASB ASC Topic 718, *Compensation-Stock Compensation* (“ASC 718”), which requires all share-based payments be recognized in the consolidated financial statements based on their fair values. In accordance with ASC 718, the Company has elected to use the Black-Scholes Option Pricing Model (the “*Black-Scholes Model*”) to determine the fair value of options granted and recognizes the compensation cost of share-based awards on a straight-line basis over the vesting period of the award.

The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by the fair value of the Common Stock and a number of other assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. The expected life for awards uses the simplified method for all “plain vanilla” options, as defined in ASC 718-10-S99, and the contractual term for all other employee and non-employee awards. The risk-free interest rate assumption is based on observed interest rates appropriate for the terms of the Company’s awards. The dividend yield assumption is based on history and the expectation of paying no dividends. Stock-based compensation expense, when recognized in the consolidated financial statements, is based on awards that are ultimately expected to vest.

Fair Value Measurements

The Company measures both financial and nonfinancial assets and liabilities in accordance with FASB ASC Topic 820, *Fair Value Measurements and Disclosures*, including those that are recognized or disclosed in the consolidated financial statements at fair value on a recurring basis. The standard created a fair value hierarchy which prioritizes the inputs to valuation techniques used to measure fair value into three broad levels as follows: Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities; Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and Level 3 inputs are unobservable inputs that reflect the Company’s own views about the assumptions market participants would use in pricing the asset or liability.

At June 30, 2023 and September 30, 2022, the carrying amounts of cash, accounts payables and accrued expense and other liabilities approximate fair value because of their short-term nature. The carrying amounts for the Series Convertible Notes (See Note 12), 2022 Notes (see Note 11), and Second Notes (see Note 11), and Third Notes (see Note 11) approximate fair value because borrowing rates and terms are similar to comparable market participants.

Derivative Liabilities

The Company accounts for its warrants and other derivative financial instruments as either equity or liabilities based upon the characteristics and provisions of each instrument, in accordance with FASB ASC Topic 815, *Derivatives and Hedging* (“ASC 815”). Warrants classified as equity are recorded at fair value as of the date of issuance on the Company’s consolidated balance sheets and no further adjustments to their valuation are made. Warrants classified as derivative liabilities and other derivative financial instruments that require separate accounting as liabilities are recorded on the Company’s consolidated balance sheets at their fair value on the date of issuance and will be revalued on each subsequent balance sheet date until such instruments are exercised or expire, with any changes in the fair value between reporting periods recorded as other income or expense. Management estimates the fair value of these liabilities using option pricing models and assumptions that are based on the individual characteristics of the warrants or instruments on the valuation date, as well as assumptions for future financings, expected volatility, expected life, yield, and risk-free interest rate. During the nine months ended June 30, 2023, \$1,158,197 was recorded to gain on extinguishment of derivative liability for the exchange of the Series G warrants and Series H warrants and \$49,278 was recorded as part of shareholder's deficit.

Complex Financial Instruments

The Company does not use derivative instruments to hedge exposures to cash flow, market, or foreign currency risks. The Company evaluates its financial instruments, including warrants, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. The Company values its derivatives using the Black-Scholes option-pricing model or other acceptable valuation models, including Monte-Carlo simulations. Derivative instruments are valued at inception, upon events such as an exercise of the underlying financial instrument, and at subsequent reporting periods. The classification of derivative instruments, including whether such instruments should be recorded as liabilities, is re-assessed at the end of each reporting period.

The Company reviews the terms of debt instruments, equity instruments, and other financing arrangements to determine whether there are embedded derivative features, including embedded conversion options that are required to be bifurcated and accounted for separately as a derivative financial instrument. Additionally, in connection with the issuance of financing instruments, the Company may issue freestanding options and warrants, including options or warrants to non-employees in exchange for consulting or other services performed.

The Company accounts for its common stock warrants in accordance with Accounting Standards Codification (“ASC”) 815, *Derivatives and Hedging* (“ASC 815”). Based upon the provisions of ASC 815, the Company accounts for common stock warrants as liabilities if the warrant requires net cash settlement or gives the holder the option of net cash settlement, or it fails the equity classification criteria. The Company accounts for common stock warrants as equity if the contract requires physical settlement or net physical settlement or if the Company has the option of physical settlement or net physical settlement and the warrants meet the requirements to be classified as equity. Common stock warrants classified as liabilities are initially recorded at fair value on the grant date and remeasured at fair value each balance sheet date with the offset adjustments recorded in change in fair value of warrant liability within the consolidated statements of operations. Common stock warrants classified as equity are initially measured at fair value on the grant date and are not subsequently remeasured.

Financial Statement Reclassification

Certain balances in the prior year consolidated financial statements have been reclassified for comparison purposes to conform to the presentation in the current period consolidated financial statements. During the nine-month period ended June 30, 2023, the Company reclassified the carrying amount of Exchanged Notes of \$699,781 (see Note 12) that were previously included in the 2022 Notes payable to Unsecured convertible notes.

Subsequent Events

The Company evaluated all events or transactions through August 11, 2023, the date which these consolidated financial statements were issued. See note 15 for matters deemed to be subsequent events.

Going Concern Basis of Accounting

As reflected in the consolidated financial statements, the Company has an accumulated deficit as of June 30, 2023, has suffered significant net losses and negative cash flows from operations, only recently commenced generating limited operating revenues, and has limited working capital. The continuation of the Company’s business as a going concern is dependent upon raising additional capital, the ability to successfully market and sell its product and eventually attaining and maintaining profitable operations. In particular, as of June 30, 2023, the Company will be required to raise additional capital, obtain alternative means of financial support, or both, in order to continue to fund operations, and therefore there is substantial doubt about the Company’s ability to continue as a going concern. The Company expects to incur substantial expenses into the foreseeable future for the research, development and commercialization of its current and potential products. In addition, the Company will require additional financing in order to seek to license or acquire new assets, research and develop any potential patents and the related compounds, and obtain any further intellectual property that the Company may seek to acquire. Finally, some of our product candidates or the materials contained therein (such as the Active Pharmaceutical Ingredients for our AC5® product line), are manufactured from facilities in areas impacted by the outbreak of the COVID-19, which could result in shortages due to ongoing efforts to address the outbreak. Historically, the Company has principally funded operations through debt borrowings, the issuance of convertible debt, and the issuance of units consisting of common stock and warrants. Provisions in the Securities Purchase Agreements that the Company entered into on July 6, 2022 (“2022 SPA”), and July 7, 2023 (the “2023 SPA”) restrict the Company’s ability to effect or enter into an agreement to effect any issuance by the Company or its subsidiary of Common Stock or securities convertible, exercisable or exchangeable for Common Stock (or a combination of units thereof) with respect to (i) any variable rate debt transactions (as defined in the 2022 SPA), for a period of six months after the date of the 2022 SPA, involving any transaction where the conversion or exercise of the security issued by the Company varies based on the market price of the Common Stock that does not contain a floor price that is more than 50% of the closing price of the Common Stock on the trading day immediately prior to the date of the 2022 SPA, and (ii) any Variable Rate Transaction (as defined in the 2023 SPA) including, but not limited to, an equity line of credit or “At-the-Market” financing facility until twelve (12) months after the closing date of the 2023 SPA. Furthermore, initially, under the 2022 SPA, we were required to complete an uplist to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American by February 15, 2023. This deadline has been subsequently extended on numerous occasions. Most recently, on July 31, 2023, the Company secured waivers from the required holders of the 2022 Notes, Second Notes and Third Notes to extend the deadline to complete an Uplisting Transaction to August 31, 2023. See Note 11 for more information regarding the 2022 Convertible Note Offering including the terms of the 2022 Warrants and 2022 Placement Agent Warrants, as well as for more information regarding the Amendment No. 1 to the 2022 SPA, and Amendment No. 2 to the 2022 SPA.

The 2023 SPA contains certain restrictions on our ability to conduct subsequent sales of any future securities (See Note 15). The continued spread of COVID-19 and uncertain market conditions may also limit the Company’s ability to access capital. If the Company is unable to obtain adequate capital, the Company may be required to reduce the scope, delay, or eliminate some or all of its planned activities. These conditions, in the aggregate, raise substantial doubt as to the Company’s ability to continue as a going concern.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The consolidated financial statements do not include any adjustments that might result from this uncertainty.

3. PROPERTY AND EQUIPMENT

At June 30, 2023 and September 30, 2022, property and equipment consisted of:

	Estimated Useful Life (in years)	June 30, 2023	September 30, 2022
Furniture and fixtures	5	\$ 9,357	\$ 9,357
Leasehold improvements	Life of Lease	8,983	8,983
Computer equipment	3	14,416	14,416
Lab equipment	5	1,000	1,000
		33,756	33,756
Less – accumulated depreciation		33,028	31,712
Property and equipment, net		<u>\$ 728</u>	<u>\$ 2,044</u>

For the three months ended June 30, 2023 and 2022, depreciation expense recorded was \$73 and \$799, respectively. For the nine months ended June 30, 2023 and 2022, depreciation expense recorded was \$1,316 and \$2,397, respectively.

4. INVENTORIES

Inventories consist of the following:

	June 30, 2023	September 30, 2022
Finished Goods	\$ 56,828	\$ 9,063
Goods-in-process	1,326,110	1,405,785
Total	<u>\$ 1,382,938</u>	<u>\$ 1,414,848</u>

The Company capitalizes inventory that has been produced for commercial sale and has been determined to have a probable future economic benefit. The determination of whether or not the inventory has a future economic benefit requires estimates by management. To the extent that inventory is expected to expire prior to being sold or used for research and development or used for samples, the Company will write down the value of inventory. In evaluating the net realizable value of the inventory, appropriate consideration is given to obsolescence, excessive levels, deterioration, and other factors.

5. INSURANCE PREMIUM FINANCING

In July 2022, the Company entered into a finance agreement with First Insurance Funding in order to fund a portion of its insurance policies. The amount financed was approximately \$354,000 and incurred interest at a rate of 2.99%. The Company made monthly payments of approximately \$35,000 through April 2023. The outstanding balance as of June 30, 2023 and September 30, 2022 was approximately \$0 and \$248,000, respectively. As of June 30, 2023, the Company had not entered into a new finance agreement with First Insurance Funding, or any other similar provider.

6. STOCK-BASED COMPENSATION

2013 Stock Incentive Plan

On June 18, 2013, the Company established the 2013 Stock Incentive Plan (the “2013 Plan”). Under the 2013 Plan, as of September 30, 2022, a maximum number of 170,571 shares of the Company’s authorized and available common stock could be issued in the form of options, stock appreciation rights, sales or bonuses of restricted stock, restricted stock units or dividend equivalent rights, and an award may consist of one such security or benefit, or two or more of them in any combination or alternative. The 2013 Plan provides that on the first business day of each fiscal year commencing with fiscal year 2014, the number of shares of our common stock reserved for issuance under the 2013 Plan for all awards except for incentive stock option awards will be subject to increase by an amount equal to the lesser of (A) 15,000 Shares, (B) four (4) percent of the number of shares outstanding on the last day of the immediately preceding fiscal year of the Company, or (C) such lesser number of shares as determined by the Company’s Board of Directors (the “Board”). The exercise price of each option shall be the fair value as determined in good faith by the Board at the time each option is granted. On October 1, 2022, the aggregate number of authorized shares under the Plan was further increased by 15,000 shares to a total of 185,571 shares. On June 18, 2023, the 2013 Stock Incentive Plan expired.

The exercise price of each option is equal to the closing price of a share of the Company’s Common Stock on the date of grant.

Share-Based Awards

During the nine months ended June 30, 2023, the Company awarded 20,875 options to employees and directors and 3,625 options to consultants to purchase shares of Common Stock under the 2013 Plan.

Share-based compensation expense for awards granted during the nine months ended June 30, 2023 was based on the grant date fair value estimated using the Black-Scholes Model.

Common Stock Options

Stock compensation activity under the 2013 Plan for the nine months ended June 30, 2023 follows:

	Option Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at September 30, 2022	98,626	\$ 52.00	1.36	\$ 16,900
Awarded	24,500	\$ 8.00		
Forfeited/Cancelled	(19,101)	\$ 70.00		
Outstanding at June 30, 2023	104,025	\$ 39.00	5.72	—
Vested at June 30, 2023	79,409	\$ 48.00	4.85	—
Vested and expected to vest at June 30, 2023	104,325	\$ 39.00	5.72	—

On June 18, 2023, the 2013 Stock Incentive Plan expired. Therefore no shares are available for future grants under the 2013 Plan as of June 30, 2023.

Share-based compensation expense recorded in the Company's Consolidated Statements of Operations for the three months ended June 30, 2023 and 2022 resulting from options awarded to the Company's employees, directors and consultants was approximately \$41,000 and \$81,000, respectively. Of this amount, during the three months ended June 30, 2023 and 2022, \$7,000 and \$29,000, respectively, were recorded as research and development expense, and \$34,000 and \$52,000, respectively were recorded as general and administrative expense in the Company's Consolidated Statements of Operations. Share-based compensation expense recorded in the Company's Consolidated Statements of Operations for the nine months ended June 30, 2023 and 2022 resulting from options awarded to the Company's employees, directors and consultants was approximately \$211,000 and \$367,000, respectively. Of this amount, during the nine months ended June 30, 2023 and 2022, \$55,000 and \$123,000, respectively, were recorded as research and development expense, and \$156,000 and \$245,000, respectively were recorded as general and administrative expense in the Company's Consolidated Statements of Operations.

During the nine months ended June 30, 2023 and 2022, no options awarded were exercised.

As of June 30, 2023, there is approximately \$200,000 of unrecognized compensation expense related to unvested stock-based compensation arrangements granted under the 2013 Plan. That cost is expected to be recognized over a weighted average period of 2.11 years.

Restricted Stock

Restricted stock activity under the 2013 Plan for the three months ended June 30, 2023 and 2022, in shares, follows:

	Three months Ended	
	June 30, 2023	June 30, 2022
Non Vested at March 31, 2023 and 2022	—	1,250
Vested	—	(375)
Non Vested at June 30, 2023 and 2022	—	875

The weighted grant date fair value average of the restricted stock for the three months ended June 30, 2023 and 2022 follows:

	Three months Ended	
	June 30, 2023	June 30, 2022
Non Vested at March 31, 2023 and 2022	\$ —	\$ 20.00
Vested	—	(20.00)
Non Vested at June 30, 2023 and 2022	\$ —	\$ 20.00

Restricted stock activity under the 2013 Plan for the nine months ended June 30, 2023 and 2022, in shares, follows:

	Nine months Ended	
	June 30, 2023	June 30, 2022
Non Vested at September 30, 2022 and 2021	250	2,250
Vested	(250)	(1,375)
Non Vested at June 30, 2023 and 2022	—	875

The weighted grant date fair value average of the restricted stock for the nine months ended June 30, 2023 and 2022 follows:

	Nine months Ended	
	June 30, 2023	June 30, 2022
Non Vested at September 30, 2022 and 2021	\$ 18.00	\$ 20.00
Vested	(18.00)	(20.00)
Non Vested at June 30, 2023 and 2022	\$ —	\$ 20.00

For the three months ended June 30, 2023 and 2022, compensation expense recorded for the restricted stock awards was approximately \$0 and \$10,000, respectively. For the nine months ended June 30, 2023 and 2022, compensation expense recorded for the restricted stock awards was approximately \$3,000 and \$30,000, respectively.

7. REGISTERED DIRECT OFFERINGS

On September 30, 2016, the Company filed a registration statement with the SEC utilizing a “shelf” registration process, which was subsequently declared effective by the SEC on October 20, 2016 (such registration statement, the “*Shelf Registration Statement*”). Under the Shelf Registration Statement, the Company may offer and sell any combination of its Common Stock, warrants, debt securities, subscription rights, and/or units comprised of the foregoing to raise up to \$50,000,000 in gross proceeds.

On February 20, 2017, the Company entered into a Securities Purchase Agreement (the “*2017 SPA*”) with six accredited investors (collectively, the “*2017 Investors*”) providing for the issuance and sale by the Company to the 2017 Investors of an aggregate of 50,833 units at a purchase price of \$120.00 per unit in a registered offering (the “*2017 Financing*”). The securities comprising the units sold in the 2017 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant equal to 55% of the shares of Common Stock at an exercise price of \$150.00 per share (“*Series F Warrant*”) at any time prior to the fifth anniversary of the issuance date of the Series F Warrant subject to certain restrictions on exercise (the “*2017 Warrants*”) and the shares issuable upon exercise of the 2017 Warrants (the “*2017 Warrant Shares*”).

On June 28, 2018, the Company entered into a Securities Purchase Agreement (“*2018 SPA*”) with eight accredited investors (collectively, the “*2018 Investors*”) providing for the issuance and sale by the Company to the 2018 Investors of an aggregate of 45,350 units at a purchase price of \$100.00 per unit in a registered offering (“*2018 Financing*”). The securities comprising the units sold in the 2018 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant to purchase up to a number of shares of the Company’s Common Stock equal to 75% of the shares of Common Stock at an exercise price of \$140.00 per share (“*Series G Warrant*”) at any time prior to the fifth anniversary of the issuance date of the Series G Warrant subject to certain restrictions on exercise (the “*2018 Warrants*”) and the shares issuable upon exercise of the 2018 Warrants (the “*2018 Warrant Shares*”).

On May 12, 2019, the Company entered into a Securities Purchase Agreement (“*2019 SPA*”) with five accredited investors (collectively, the “*2019 Investors*”) providing for the issuance and sale by the Company to the 2019 Investors of an aggregate of 43,077 units at a purchase price of \$65.00 per unit in a registered offering (“*2019 Financing*”). The securities comprising the units sold in the 2019 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant to purchase one share of Common Stock at an exercise price of \$80.00 per share (“*Series H Warrant*”) at any time prior to the fifth anniversary of the issuance date of the Series H Warrant subject to certain restrictions on exercise (the “*2019 Warrants*”) and the shares issuable upon exercise of the 2019 Warrants (the “*2019 Warrant Shares*”).

On March 10, 2023, the Company entered into exchange agreements (the “*Exchange Agreements*”) with each holder (the “*Warrantholders*”) of the Company’s outstanding Series G Warrants to purchase shares of the Company’s common stock, par value \$ 0.001 per share (the “*Common Stock*”) at an exercise price of \$140.00 per share (the “*Series G Warrants*”) and the Company’s outstanding Series H Warrants to purchase shares of Common Stock at an exercise price of \$ 80.00 per share (the “*Series H Warrants*”) and, together with the Series G Warrants, the “*Warrants*”). Pursuant to the Exchange Agreements, the Warrantholders exchanged 34,013 Series G Warrants for 3,402 shares of Common Stock and 43,077 Series H Warrants for 8,617 shares of Common Stock. All 27,958 remaining Series F Warrants expired during the fiscal year ended September 30, 2022.

8. Derivative Liabilities

The Company accounted for the Series F Warrants, Series G Warrants and the Series H Warrants in accordance with ASC 815-10. Since the Company was required to purchase its Series F Warrants, Series G Warrants and Series H Warrants for an amount of cash equal to \$ 36.00, \$22.00 and \$10.66, respectively, for each share of Common Stock (the “*Minimum Value*”) they are recorded as liabilities at the greater of the Minimum Value or fair value. They are marked to market each reporting period through the Consolidated Statement of Operations.

On the respective closing dates of June 28, 2018 and May 12, 2019, respectively, the derivative liabilities related to the Series G Warrants and Series H Warrants were recorded at an aggregate fair value of \$1,628,113. Given that the fair value of the derivative liabilities was less than the net proceeds, the remaining proceeds were allocated to Common Stock and additional paid-in-capital.

On March 10, 2023, Arch Therapeutics, Inc. entered into exchange agreements (the “*Exchange Agreements*”) with each holder (the “*Warrantholders*”) of the Company’s outstanding Series G Warrants to purchase shares of the Company’s common stock, par value \$ 0.001 per share at an exercise price of \$140.00 per share and the Company’s outstanding Series H Warrants to purchase shares of Common Stock at an exercise price of \$80.00 per share. Pursuant to the Exchange Agreements, the Warrantholders exchanged 34,013 Series G Warrants for 3,402 shares of Common Stock and 43,077 Series H Warrants for 8,617 shares of Common Stock.

During the three and nine months ended June 30, 2023, \$0 and \$1,158,197, respectively was recorded to gain on extinguishment of derivative liability for the exchange of the Series G warrants and Series H warrants and \$49,278 was recorded as part of shareholder’s deficit. During the three and nine months ended June 30, 2022, \$0 and \$1,000,000, respectively was recorded to decrease the fair value of derivative liability related to the expired Series F warrants.

Fair Value Measurements Using Significant Unobservable Inputs – Nine Months Ended June 30, 2023 (Level 3)

	Series G	Series H
Beginning balance at September 30, 2022	\$ 748,275	\$ 459,200
Exchange of warrants into common stock	(13,948)	(35,330)
Extinguishment of derivative liabilities	(734,327)	(423,870)
Ending balance at June 30, 2023	<u>\$ —</u>	<u>\$ —</u>

Fair Value Measurements Using Significant Unobservable Inputs - Nine Months Ended June 30, 2022 (Level 3)

	Series F	Series G	Series H
Beginning balance at September 30, 2021	\$ 1,000,000	\$ 748,275	\$ 459,200
Issuances	—	—	—
Adjustments to estimated fair value	—	—	—
Expiration of derivative liability	(1,000,000)	—	—
Ending balance at June 30, 2022	<u>\$ —</u>	<u>\$ 748,275</u>	<u>\$ 459,200</u>

As of March 10, 2023 and September 30, 2022, the derivative liabilities were valued at the greater of their minimum value or by using the Black Scholes Model with the following assumptions.

As of March 10, 2023, the derivative liabilities are recorded at their minimum value.

	Series G	Series H
Closing price per share of Common Stock	\$ 4.10	\$ 4.10
Exercise price per share	\$ 140.00	\$ 80.00
Expected volatility	179.41%	141.03%
Risk-free interest rate	4.91%	4.75%
Dividend yield	—	—
Remaining expected term of underlying securities (years)	0.24	1.31

As of September 30, 2022, the derivative liabilities are recorded at their minimum value.

	Series G	Series H
Closing price per share of Common Stock	\$ 3.84	\$ 3.84
Exercise price per share	\$ 140.00	\$ 80.00
Expected volatility	132.97%	122.50%
Risk-free interest rate	4.05%	4.14%
Dividend yield	—	—
Remaining expected term of underlying securities (years)	0.69	1.57

9. OCTOBER 2019 REGISTERED DIRECT OFFERING

On October 16, 2019, the Company entered into a Securities Purchase Agreement (the “October 2019 SPA”) with seven accredited investors (collectively, the “October 2019 Investors”) providing for the issuance and sale by the Company to the 2019 Investors of an aggregate of 71,429 units at a purchase price of \$35.00 per unit in a registered offering (“October 2019 Financing”). The securities comprising the units sold in the October 2019 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant to purchase one share of Common Stock at an exercise price of \$44.00 per share (“Series I Warrant”) at any time prior to the fifth anniversary of the issuance date of the Series I Warrant subject to certain restrictions on exercise and the shares issuable upon exercise of the Series I Warrants (collectively, the “October 2019 Warrant Shares”). As of October 18, 2019, the Company recorded the 71,429 shares as Common Stock. Pursuant to the Engagement Agreement (as defined below), the Company also agreed to issue to the Placement Agent, or its designees, warrants to purchase up to 5,358 shares (the “Placement Agent Warrants”). The 2019 Placement Agent Warrants have substantially the same terms as the Series I Warrants, except that the exercise price of the Placement Agent Warrants is \$43.75 per share and the term of the Placement Agent Warrants is five years.

The gross proceeds to the Company from the October 2019 Financing, which were received as of October 18, 2019, were approximately \$2.5 million before deducting financing costs of approximately \$333,000 which includes approximately \$158,000 of placement fees. The number of shares of the Company’s Common Stock into which each of the Series I Warrants is exercisable and the exercise price therefore are subject to adjustment, as set forth in the Series I Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise).

The Company engaged H.C. Wainwright as its exclusive institutional investor placement agent (the “Placement Agent”) in connection with the October 2019 SPA pursuant to an engagement agreement dated as of October 10, 2019 (the “2019 Engagement Agreement”). In consideration for the services provided by the Placement Agent, the Placement Agent was entitled to receive cash fees ranging from 6.0% to 8.2% of the gross proceeds received by the Company, as well as reimbursement for all reasonable expenses incurred by it in connection with its engagement. The Company received gross proceeds of approximately \$2.5 million in the aggregate, resulting in a fee of approximately \$158,000.

During the three and nine months ended June 30, 2023 and 2022, no Series I Warrants or Placement Agent Warrants were exercised. As of June 30, 2023, up to 71,429 and 5,358 shares may be acquired upon the exercise of the Series I Warrants and Placement Agent Warrants, respectively.

Equity Value of Warrants

The Company accounted for the Series I Warrants and the Placement Agent Warrants relating to the aforementioned October 2019 Financing in accordance with ASC 815-40. Because the Series I Warrants and the Placement Agent Warrants are indexed to the Company's Common Stock, they are classified within stockholders' deficit in the accompanying consolidated financial statements.

10. 2021 REGISTERED DIRECT OFFERING

On February 11, 2021, the Company entered into a Securities Purchase Agreement (the "*2021 SPA*") with certain institutional and accredited investors (collectively, "*2021 Investors*") providing for the issuance and sale by the Company to the 2021 Investors of an aggregate of 215,625 shares (the "*Shares*") of the Company's Common Stock, and warrants (the "*Series K Warrants*") to purchase an aggregate of 161,719 shares (the "*Warrant Shares*") of Common Stock, at a combined offering price of \$32.00 per share (the "*2021 Financing*"). The Series K Warrants have an exercise price of \$34.00 per share and are exercisable for a period of 5.5 years. The aggregate gross proceeds for the sale of the Shares and Series K Warrants were approximately \$6.9 million, before deducting the Placement Agent's fees and expenses and other offering expenses payable by the Company, of approximately \$700,000. Pursuant to an engagement agreement dated as of February 8, 2021 (the "*2021 Engagement Agreement*"), by and between the Company and the Placement Agent, the Company agreed to pay the Placement Agent cash fees equal to (i) 7.5% of the gross proceeds received by the Company from certain investors in the 2021 Financing, and (ii) 6.0% of the gross proceeds received by the Company from certain investors that had pre-existing relationships with the Company. In addition, the Placement Agent received a one-time non-accountable expense fee of \$10,000, up to \$50,000 for fees and expenses of legal counsel and other out-of-pocket expenses and \$10,000 for clearing expenses. Pursuant to the 2021 Engagement Agreement, the Company also agreed to issue to the Placement Agent, or its designees, warrants to purchase up to 7.5% of the aggregate number of Shares sold to the 2021 Investors, or warrants to purchase up to 16,172 shares (the "*2021 Placement Agent Warrants*") of the Company's Common Stock. The 2021 Placement Agent 2 Warrants have substantially the same terms as the Series K Warrants, except that the exercise price of the 2021 Placement Agent Warrants is \$40.00 per share. The 2021 Engagement Agreement contained indemnity and other customary provisions for transactions of this nature.

The 2021 SPA contained certain restrictions on the Company's ability to conduct subsequent sales of the Company's equity securities. In particular, we were prohibited from entering into or effecting a Variable Rate Transaction (as defined in the 2021 SPA) until February 11, 2022; provided, however, the Company may enter into and effect an at-the-market offering facility with the Placement Agent.

The number of shares of the Company's Common Stock into which each of the Series K Warrants is exercisable and the exercise price therefore are subject to adjustment, as set forth in the Series K Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise).

During the three and nine months ended June 30, 2023, no Series K Warrants or Placement Agent 2 Warrants were exercised. As of June 30, 2023, up to 161,719 and 16,172 shares may be acquired upon the exercise of the Series K Warrants and Placement Agent Warrants, respectively.

Common Stock

On February 17, 2021, the Closing Date of the 2021 Financing, the Company issued 215,625 shares of Common Stock.

Equity Value of Warrants

The Company accounted for the Series K Warrants and the Placement Agent 2 Warrants relating to the aforementioned February 2021 Registered Direct Offering in accordance with ASC 815-40, *Derivatives and Hedging*. Because the Series K Warrants and the Placement Agent 2 Warrants are indexed to the Company's stock, they are classified within stockholders' deficit in the accompanying consolidated financial statements.

11. 2022 CONVERTIBLE NOTE OFFERING, SECOND NOTES OFFERING, AND THIRD NOTES OFFERING

On July 7, 2022, the Company announced that it had entered into a Securities Purchase Agreement (the “2022 SPA”) with certain institutional and accredited individual investors (collectively, the “2022 Investors”) providing for the issuance and sale by the Company to the 2022 Investors of (i) Senior Secured Convertible Promissory Notes (each a “2022 Note” and collectively, the “2022 Notes”) in the aggregate principal amount of \$4.23 million, which includes an aggregate \$0.705 million original issue discount in respect of the 2022 Notes; (ii) warrants (the “2022 Warrants”), to purchase an aggregate of 425,554 shares (the “2022 Warrant Shares”) of Common Stock; and (iii) 63,833 shares of Common Stock (the “2022 Inducement Shares”) equal to 15% of the principal amount of the 2022 Notes divided by the closing price of the Common Stock immediately prior to the Closing Date (as defined below). The 2022 Notes, 2022 Warrants and 2022 Inducement Shares were issued as part of a convertible note offering authorized by the Company’s board of directors (the “2022 Convertible Note Offering”). The aggregate gross proceeds for the sale of the 2022 Notes, 2022 Warrants and 2022 Inducement Shares was approximately \$3.5 million, before deducting debt issuance costs of \$775,000 consisting of fair value of the placement agent’s warrants of approximately \$220,000 and other estimated fees and offering expenses payable by the Company of approximately \$555,000. The closing of the sales of these securities under the 2022 SPA occurred on July 6, 2022 (the “2022 Closing Date”).

On January 18, 2023, the Company entered into Amendment No. 1 to the 2022 SPA (the “Amendment” and, together with the 2022 SPA, the “Amended 2022 SPA”), with certain Investors in connection with the Second Closing of the 2022 Convertible Note Offering for the issuance and sale by the Company to such Investors of an aggregate of (i) Unsecured Convertible Promissory Notes (each a “Second Note” and collectively, the “Second Notes”) in the aggregate principal amount of \$636,000, which includes an aggregate \$106,000 original issue discount in respect of the Second Notes; (ii) warrants (the “Second Warrants”) to purchase an aggregate of 127,968 shares (the “Second Warrant Shares”) of Common Stock; and (iii) 9,598 shares of Common Stock (the “Second Inducement Shares”). The aggregate gross proceeds for the sale of the Second Notes, Second Warrants and Second Inducement Shares was approximately \$530,000, before deducting the placement agent’s fees and other estimated fees and offering expenses payable by the Company of approximately \$15,000. The second closing of the sales of these securities under the Amended 2022 SPA occurred on January 18, 2023 (the “Second Closing Date”).

On May 15, 2023, the Company entered into Amendment No. 2 to the 2022 SPA related to the 2022 Convertible Note Offering (the “Second Amendment” and, together with the Amendment and the 2022 SPA, the “Second Amended 2022 SPA”), with an Investor in connection with the third closing of the 2022 Convertible Note Offering for the issuance and sale by the Company to an Investor of an aggregate of (i) Unsecured Convertible Promissory Notes (each a “Third Note” and collectively, the “Third Notes”) in the aggregate principal amount of \$702,720, which includes an aggregate \$214,720 original issue discount in respect of the Third Notes; (ii) warrants (the “Third Warrants”) to purchase an aggregate of 141,396 shares (the “Third Warrant Shares”) of Common Stock; and (iii) 10,608 shares of Common Stock (the “Third Inducement Shares”). The aggregate gross proceeds for the sale of the Third Notes, Third Warrants and Third Inducement Shares was approximately \$488,000, before deducting any estimated fees and offering expenses payable by the Company. The Company did not engage a placement agent in connection with the issuance of the Third Notes, Third Warrants, and Third Inducement Shares. The third closing of the sales of these securities under the Amended SPA occurred on May 15, 2023 (the “Third Closing Date”). The 2022 Notes, the Second Notes and the Third Notes bear interest on the unpaid principal balance at a rate equal to ten percent (10%) (computed on the basis of the actual number of days elapsed in a 360-day year) per annum accruing from the Closing Date until the 2022 Notes, Second Notes and Third Notes become due and payable at maturity or upon their conversion, acceleration or by prepayment, and may become due and payable upon the occurrence of an event of default under the 2022 Notes, Second Notes and Third Notes. Any amount of principal or interest on the 2022 Notes, the Second Notes and Third Notes which is not paid when due shall bear interest at the rate of the lesser of (i) eighteen percent (18%) per annum or (ii) the maximum amount allowed by law from the due date thereof until payment in full.

The 2022 Notes, the Second Notes and the Third Notes are convertible into shares of Common Stock at the option of each holder of the 2022 Notes, the Second Notes, and the Third Notes from the date of issuance at \$9.14 (the “Conversion Price”) through the later of (i) January 6, 2024 (the “Maturity Date”) or (ii) the date of payment of the Default Amount (as defined in the 2022 Notes); provided, however, certain 2022 Notes, Second Notes and Third Notes include a provision preventing such conversion if, as a result, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than 4.99% or 9.99% of the Common Stock (as applicable, the “Ownership Limitation”) immediately after giving effect to the Conversion; and provided further, the holder, upon notice to us, may increase or decrease the Ownership Limitation; (i) the Ownership Limitation may only be increased to a maximum of 9.99% of the Common Stock; and (ii) any increase in the Ownership Limitation will not become effective until the 61st day after delivery of such waiver notice. The Conversion Price is subject to adjustment as set forth in the 2022 Notes, Second Notes, and Third Notes.

The 2022 Notes, Second Notes and Third Notes contain customary events of default, which include, among other things, (i) the Company’s failure to pay when due any principal or interest payment under the 2022 Notes, Second Notes, and Third Notes; (ii) our insolvency; (iii) delisting of the Company’s Common Stock; (iv) the Company’s breach of any material covenant or other material term or condition under the 2022 Notes, Second Notes and/or Third Notes; and (v) the Company’s breach of any representations or warranties under the 2022 Notes, Second Notes and Third Notes which cannot be cured within five (5) days. Further, events of default under the 2022 Notes, Second Notes and Third Notes also include (i) the unavailability of Rule 144 on or after January 6, 2023; (ii) our failure to deliver the shares of Common Stock to the 2022 Notes, Second Notes, and/or Third Notes holder upon exercise by such holder of its conversion rights under the 2022 Notes, Second Notes, and/or Third Notes; (iii) our loss of the “bid” price for its Common Stock and/or a market and such loss is not cured during the specified cure periods; and (iv) our failure to complete an uplisting of our Common Stock to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American by August 31, 2023 (as amended) (an “Uplist Transaction”).

The 2022 Warrants, Second Warrants and Third Warrants (i) have an exercise price of \$9.94 per share; (ii) have a term of exercise equal to 5 years after their issuance date; (iii) became exercisable immediately after their issuance; and (iv) have a provision preventing the exercisability of such 2022 Warrants, the Second Warrants and the Third Warrants if, as a result of the exercise of the 2022 Warrants, Second Warrants, and/or Third Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of our Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than the Ownership Limitation. The holder, upon notice to us, may increase or decrease the Ownership Limitation; provided that (i) the Ownership Limitation may only be increased to a maximum of 9.99% of our Common Stock; and (ii) any increase in the Ownership Limitation will not become effective until the 61st day after delivery of such waiver notice. The number of shares of Common Stock into which each of the 2022 Warrants, Second Warrants, and Third Warrants is exercisable and the exercise price therefor are subject to adjustment as set forth in the 2022 Warrants, Second Warrants, and Third Warrants, including standard antidilution provisions, and adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise). In the event of a Fundamental Transaction (as defined in the 2022 Warrants, Second Warrants, and Third Warrants) holders of the 2022 Warrants, Second Warrants, and Third Warrants would be entitled to receive alternate consideration in connection with such Fundamental Transaction, but only to the extent that holders of our Common Stock were entitled to receive the same. Moreover, as long as the 2022 Notes, Second Notes, and Third Notes, and 2022 Warrants, Second Warrants, and Third Warrants remaining outstanding, upon the issuance of any security in connection with any potential future financing activity on terms more favorable than the existing terms, the Company has an obligation to notify the holders of the 2022 Notes, Second Notes, and Third Notes, and the 2022 Warrants, Second Warrants, and Third Warrants of such more favorable terms, and to use best efforts to effect such terms in the 2022 Notes, Second Notes, and Third Notes, and the 2022 Warrants, Second Warrants, and Third Warrants. Finally, because of the Company’s net loss position, the shares underlying the 2022 Notes, Second Notes, and Third Notes on an as converted basis are excluded from the calculation of basic and fully diluted earnings per share. Similarly, because of the Company’s net loss position, there was no impact on the calculation of basic and fully diluted earnings per share related to the classification of the 2022 Warrants, Second Warrants, and Third Warrants as participating securities.

The Company retained a placement agent in connection with the private placement of \$2.4 million of the 2022 Notes to the institutional investors. The Company paid the 2022 Placement Agent 10% of the gross proceeds received from certain institutional investors, or \$240,000 and we also reimbursed the 2022 Placement Agent approximately \$58,000 for non-accountable banking fees, legal fees and other expenses. In addition, we issued 2022 Placement Agent Warrants to purchase an aggregate of 31,510 shares of Common Stock. An additional \$1.1 million was raised in connection with the placement of the private placement notes, which included certain accredited investors some of which were Board members and executive officers of the Company. Board member, Laurence Hicks, and executive officers, Terrence W. Norchi and Michael S. Abrams, invested in the 2022 Notes. The investment made in the 2022 Notes made by the Board member and executive officers totaled \$80,000.

The Company's agreement with the 2022 Placement Agent was still effective at the time of the private placement of \$0.5 million of the Second Notes to certain institutional investors. Per the terms of a termination agreement dated February 21, 2023 by and between the Company and the 2022 Placement Agent (the "Placement Agent Termination Agreement"), the Company owes the 2022 Placement Agent 10% of the gross proceeds received from certain institutional investors, or \$50,000, and, such amount was deferred until the Company completes an additional financing with gross proceeds of at least \$1 million. In addition, per the Placement Agent Termination Agreement, we agreed to issue 2022 Placement Agent Warrants to purchase an aggregate of 6,565 shares of Common Stock.

In addition, as a part of the 2022 Convertible Note Offering, certain holders of the Company's 10% Series 2 Convertible Notes agreed to exchange their Series 2 Notes for promissory notes of the Company on substantially similar terms to those of the 2022 Notes (the "Exchanged Notes"). The Exchanged Notes are convertible into 76,563 shares of Common Stock at a conversion price of \$9.14. The holders of the Exchanged Notes did not receive warrants or inducement shares. In connection with the issuance of the Exchanged Notes, the holders of the Series 2 Notes that participated in the exchange, entered into a subordination agreement on July 6, 2022 (the "Closing Date") to subordinate their rights in respect of the Exchanged Notes to the rights of the Investors in respect of the 2022 Notes. As of July 7, 2022, approximately \$600,000 of the Series 2 Notes and accrued interest of approximately \$100,000 were included in the exchange.

Further, in connection with the 2022 Convertible Note Offering, we initially were required to complete an Uplist Transaction by February 15, 2023 under the terms of the 2022 Notes. If we are unable to complete or secure an extension to the Uplist Transaction deadline, then the 2022 Notes, Second Notes, and Third Notes will become immediately due and payable and we will be obligated to pay to each holder of the 2022 Notes, Second Notes, and Third Notes an amount equal to 125%, multiplied by the sum of the outstanding principal amount of the 2022 Notes, Second Notes, and Third Notes plus any accrued and unpaid interest on the unpaid principal amount of the 2022 Notes, Second Notes, and Third Notes to the date of payment, plus any default interest and any other amounts owed to the holder, payable in cash or shares of Common Stock. The Company has secured waivers from all required holders of the 2022 Notes, Second Notes, and Third Notes to extend the deadline to complete an uplist from (i) February 15, 2023 to March 15, 2023, (ii) March 15, 2023 to April 15, 2023, (iii) April 15, 2023 to May 15, 2023, (iv) May 15, 2023 to June 15, 2023, (v) June 15, 2023 to July 1, 2023, (vi) July 1, 2023 to July 31, 2023 and (vii) July 31, 2023 to August 31, 2023. No consideration was paid by the Company in connection with any of the Uplist Transaction deadline extensions.

On March 10, 2023, the Company entered into an amendment ("Amendment No. 2 to the First Notes") with the required holders of the Company's outstanding 2022 Notes issued in connection with a private placement financing the Company completed on July 6, 2022 (the "First Closing"). On March 10, 2023, the Company also entered into an amendment ("Amendment No. 2 to the Second Notes" and, together with Amendment No. 2 to the First Notes, "Amendment No. 2 to the 2022 Notes") with each of the required holders of Company's outstanding Second Notes issued in connection with a private placement financing the Company completed on January 18, 2023.

Under Amendment No. 2 to the 2022 Notes, the following amendments to the 2022 Notes, and Second Notes will be effective at the moment in time immediately preceding the consummation of the offering in connection with the uplist of the Common Stock to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (the "Uplist Transaction"). If a holder of the 2022 Notes and/or the Second Notes elects to participate in the Uplist Transaction (each, a "Participating Holder") for an amount equal to no less than 50% of the Participating Holder's original investment amount in the 2022 Convertible Note Offering, such holder will be entitled to repayment of the principal amount of their 2022 Notes and/or Second Notes upon closing of the Uplist Transaction. In addition, the Company will issue to each Participating Holder a new convertible promissory note equal to the product of 2.4 and the sum of any prepayment premiums and total interest payable on such Participating Holder's 2022 Notes and/or Second Notes (the "2023 Notes"). The 2023 Notes will have a maturity date of July 6, 2024 and will be on substantially the same terms as the Second Notes. For non-Participating Holders (each, a "Non-Participating Holder"), the maturity date of the 2022 Notes and/or Second Notes held by such Non-Participating Holder will be extended to July 6, 2024. Further, each Non-Participating Holder will waive their right to demand repayment of any portion of the outstanding balance of such holder's 2022 Notes and Second Notes upon an Uplist Transaction. Notwithstanding the foregoing, if the registration statement filed in connection with the Uplist Transaction is not declared effective by 11:59 P.M. (EST) on June 15, 2023 (the "Amendment No. 2 Termination Date"), Amendment No. 2 to the 2022 Notes will automatically terminate and shall be of no further force or effect without any further action by the Company or the Requisite Holders, provided, that the Amendment No. 2 Termination Date may be extended by the written approval of the Company and required holders of the 2022 Notes, Second Notes and Third Notes which purchased at least 50% plus \$1.00 of the 2022 Notes, Second Notes, and Third Notes based on the initial principal amounts thereunder (the "Requisite Holders"). Amendment No. 2 to the 2022 Notes was superseded by Amendment No. 8 to the 2022 Notes, Amendment No. 8 to the Second Notes and Amendment No. 3 to the Third Notes, and therefore, it is of no further force or effect.

During the three months ended June 30, 2023, the Company recorded interest expense on the 2022 Notes, the Second Notes, and the Third Notes of approximately \$74,000 consisting of accrued interest of approximately \$150,000 and accretion of original issue debt discount and issuance costs of approximately \$634,000. During the nine months ended June 30, 2023, the Company recorded interest expense on the 2022 Notes, the Second Notes, and the Third Notes of approximately \$1,893,000 consisting of accrued interest of approximately \$413,000 and accretion of original issue debt discount and issuance costs of approximately \$1,480,000.

Allocation of Proceeds

The Company accounted for the 2022 Notes, Second Notes, and Third Notes, and the 2022 Warrants, the Second Warrants, and the Third Warrants, and the 2022 Inducement Shares, Second Inducement Shares and the Third Inducement Shares in accordance with ASC 470-20-25-2 “Debt” which states that the allocation of the proceeds from the financing shall be based on the relative fair values of the securities issued at the time of the issuance. The 2022 Inducement Shares, the Second Inducement Shares, and the Third Inducement Shares and the 2022 Warrants, the Second Warrants, and the Third Warrants which are indexed to the Company’s stock, are classified within stockholders’ deficit in the accompanying consolidated financial statements. The allocated value of the 2022 Inducement Shares and the 2022 Warrants are \$314,523 and \$1,470,133, respectively. The allocated value of the Second Inducement Shares and the Second Warrants are \$25,840 and \$256,439, respectively. The allocated value of the Third Inducement Shares and the Third Warrants are \$18,394 and \$164,136, respectively. The allocated value of the 2022 Notes of \$1,740,344 are allocated as short-term liabilities in the accompanying consolidated financial statements. The allocated value of the Second Notes of \$247,721 are allocated as short-term liabilities in the accompanying consolidated financial statements. The allocated value of the Third Notes of \$305,470 is allocated as short-term liabilities in the accompanying consolidated financial statements. The fair value of the 2022 Placement Agent Warrants and the Second Placement Agent Warrants of \$ 219,894 and \$28,093, respectively, are being accounted for as debt issuance costs and are classified within stockholders’ deficit in the accompanying consolidated financial statements. As of June 30, 2023 and September 30, 2022, the net carrying amount of the 2022 Notes was \$2,945,448 and \$1,662,492, respectively, with unamortized debt discount and issuance costs of \$1,284,552 and \$2,567,507, respectively. Effective September 30, 2022, the Company reclassified the carrying amount of the Exchanged Notes of \$699,781 (see Note 12) that were previously included in 2022 Notes payable to Unsecured convertible notes. After the reclassification, the Unsecured convertible notes included both the Second Notes and the Exchanged Notes. As of June 30, 2023, the net carrying amount of the Second Notes was \$345,845 with unamortized debt discount and issuance costs of \$290,155, all of which is included in Unsecured convertible notes. In addition, as of June 30, 2023, the net carrying amount of the Third Notes was \$55,992 with unamortized debt discount and issuance costs of \$346,728, all of which is included in Unsecured convertible notes.

The 2022 Warrants and the 2022 Placement Agent Warrants were valued as of July 6, 2022 using the Black Scholes Model with the following assumptions:

	2022 Warrants	2022 Placement Agent Warrants
Closing price per share of Common Stock	\$ 9.98	\$ 9.98
Exercise price per share	\$ 9.94	\$ 10.06
Expected volatility	88.44%	88.44%
Risk-free interest rate	2.96%	2.96%
Dividend yield	—	—
Remaining expected term of underlying securities (years)	5.0	5.0

The Second Warrants and the Second Placement Agent Warrants were valued as of January 18, 2023 using the Black Scholes Model with the following assumptions:

	Second Warrants	Second Placement Agent Warrants
Closing price per share of Common Stock	\$ 5.76	\$ 5.76
Exercise price per share	\$ 9.94	\$ 10.06
Expected volatility	111.31%	111.31%
Risk-free interest rate	3.43%	3.43%
Dividend yield	—	—
Remaining expected term of underlying securities (years)	5.0	5.0

The Third Warrants were valued as of May 15, 2023 using the Black Scholes Model with the following assumptions:

	Third Warrants
Closing price per share of Common Stock	\$ 2.77
Exercise price per share	\$ 9.94
Expected volatility	114.33%
Risk-free interest rate	3.46%
Dividend yield	—
Remaining expected term of underlying securities (years)	5.0

12. SERIES CONVERTIBLE NOTES

On June 4, 2020 and November 6, 2020, the Company issued unsecured 10% Series 1 Convertible Notes (“Series 1 Notes”) and Series 2 Convertible Notes (“Series 2 Notes”, and collectively with the Series 1 Notes, the “Series Convertible Notes”) in the aggregate principal amount of \$550,000 and \$1,050,000, respectively. The maturity dates of the Series 1 Notes and Series 2 Notes are June 30, 2023 and November 30, 2023, respectively. On July 12, 2023, the Company secured countersigned notices of conversion from all remaining holders of the Series 1 Convertible Notes and provided instructions to its transfer agent to issue a total of 59,912 shares of Common Stock in full satisfaction of all previously outstanding Series 1 Convertible Notes. The Series Convertible Notes provide, among other things, for (i) a term of approximately three years; (ii) the Company’s ability to prepay the Series Convertible Notes, in whole or in part, at any time; (iii) the automatic conversion of the Series Convertible Notes upon a Change of Control (all capitalized terms not otherwise defined to have the meaning ascribed to such terms of the Series Convertible Notes) into shares of the Company’s Common Stock, at a per share price of \$54.00 and \$50.00 (the “Conversion Price”) for the Series 1 Notes and Series 2 Notes, respectively; (iv) the ability of the holders of the Series Convertible Notes (each a “Holder”, and together, the “Holders”) to convert the principal of the Series Convertible Notes, along with accrued interest, in whole or in part, into shares of Common Stock at the respective Conversion Price; (v) the Company’s ability to convert all Note Obligations outstanding upon a Qualified Equity Financing into shares of Common Stock at the respective Conversion Price; (vi) the Company’s ability to convert the principal of the Series Convertible Notes, along with accrued interest, in whole or in part, into shares of Common Stock at the respective Conversion Price in the event the volume weighted average price (“VWAP”) of the Common Stock equals or exceeds \$64.00 per share for at least fifteen consecutive Trading Days; (vii) the Company’s ability to convert all outstanding Note Obligations into shares of Common Stock at the respective Conversion Price (an “In Kind Note Repayment”) in lieu of repaying the Note Obligations outstanding on the Maturity Date, provided, however, that in the case of an In-Kind Note Repayment, the outstanding Note Obligations will be calculated by increasing by thirty-five percent the aggregate sum of the unpaid Principal Amount held by each Holder and the accrued interest at a rate of ten percent per annum, subject to, with respect to any portion of the Principal Amount that is converted or prepaid before the twelve month anniversary of the Issuance Date, a minimum interest payment equal to ten percent of the amount that is converted or prepaid. As consideration for agreeing to subordinate to the 2022 Notes, the premium applicable in connection with an In-Kind Note Repayment at maturity was increased from thirty-five percent to sixty percent. As consideration for agreeing to provide for an In-Kind Note Repayment upon the earlier of i) maturity or ii) the completion of an Uplist Transaction, the premium applicable in connection with an In-Kind Note Repayment at either maturity or simultaneous with an Uplist Transaction was further increased from sixty percent to three hundred and fifty percent.

As described in Note 11 above, as a part of the 2022 Convertible Note Offering, certain holders of the Series 2 Notes agreed to exchange their Series 2 Notes with an aggregate principal amount of \$600,000 and accrued interest of approximately \$100,000 for promissory notes of the Company on substantially similar terms to those of the 2022 Notes (the “Exchanged Notes”). As of July 6, 2022, \$699,781 of principal and accrued interest of the Series 2 notes was exchanged for the Exchanged Notes.

On March 10, 2023, the Company entered into an amendment (the “Series 2 Note Amendment” and, together with the Series 1 Amendment, the “Series Note Amendments”) with each of the holders of the Company’s outstanding Series 2 Convertible Notes (as amended, the “Series 2 Notes” and, together with the Series 1 Notes, the “Series Convertible Notes”). Pursuant to the Series Note Amendments, the Company can elect to convert the principal and accrued interest under the Series Convertible Notes (the “Series Note Obligations”) at or after the effective time of the Uplisting Transaction, or the maturity date. In the event the Company exercises such option, the Series Note Obligations will be deemed to equal the product of 4.5 (which was previously 1.6 prior to the Series Note Amendments) and the outstanding Series Note Obligations. Notwithstanding the foregoing, if the registration statement filed in connection with the Uplist Transaction is not declared effective by 11:59 P.M. (EST) on or before the Uplisting Transaction deadline under the 2022 Notes and Second Notes, which was originally February 15, 2023, or such later extended date as provided for therein (the “Series Note Amendments Termination Date”), the Series Note Amendments will automatically terminate without any further action by the Company or the holders of the Series Convertible Notes. The Series Note Amendments Termination Date will be automatically extended upon any extension of the Uplisting Transaction deadline under the 2022 Notes, Second Notes, and Third Notes. As previously discussed herein, the deadline to complete the Uplist Transaction was extended on multiple previous occasions. As of July 31, 2023 the Uplist Transaction deadline under the 2022 Notes, Second Notes, and Third Notes is August 31, 2023. No consideration was paid by the Company in connection with any of the extensions of the Uplisting Transaction deadline under the 2022 Notes, Second Notes, and/or Third Notes.

During the three months ended June 30, 2023 and 2022, the Company recorded interest expense on the Series Convertible Notes of approximately \$5,000 and \$40,000, respectively. During the nine months ended June 30, 2023 and 2022, the Company recorded interest expense on the Series Convertible Notes of approximately \$75,000 and \$120,000, respectively.

13. RISKS AND UNCERTAINTIES – COVID-19 AND GEOPOLITICAL CONFLICTS

The Company sources its materials and services for its products and product candidates from facilities in areas impacted or which may be impacted by the outbreak of the COVID-19 or geopolitical conflicts. The Company's ability to obtain future inventory may be impacted, therefore potentially affecting the Company's future revenue stream. In addition, the Company has historically and principally funded its operations through debt borrowings, the issuance of convertible debt, and the issuance of units consisting of Common Stock and warrants which may also be impacted by economic conditions beyond the Company's control as well as uncertainties resulting from geopolitical conflicts, including the recent war in Ukraine. The extent to which the COVID-19 and recent events in Ukraine will impact the global economy and the Company is uncertain and cannot be reasonably measured.

14. SHAREHOLDER ADVANCES AND PREFUNDINGS RELATED TO THE ANTICIPATED BRIDGE FINANCING

Through May 12, 2023, the Company raised \$538,000 in the form of shareholder advances from two different investors to support operations in advance of the Company's prospective Uplisting Transaction. On May 15, 2023, \$488,000 of these shareholder advances, which were contributed by a single investor, were converted to an Unsecured convertible note (the "Third Note") in connection with the Third Closing of the 2022 Convertible Note Offering (see Notes 11 and 15). The remaining \$50,000 that was raised by the Company in the form of shareholder advances was repaid per the agreed terms on July 7, 2023 for \$60,000.

On May 18, 2023 and May 31, 2023, the Company raised \$340,000 and \$350,015 from a shareholder and a third-party investor, respectively, to support operations in advance of the Company's anticipated closing of the Bridge Offering (as defined below, see Note 15). On July 7, 2023, the amount prefunded by the current shareholder was included in the first closing of the Bridge Offering. The amount prefunded by the third party investor is expected to be included in a subsequent closing of the Bridge Offering.

15. SUBSEQUENT EVENTS

On July 1, 2023, the "Company" entered into an amendment ("Amendment No. 7 to the First Notes") with the holders of the Company's outstanding 2022 Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, and June 15, 2023, issued in connection with a private placement financing the Company completed on July 6, 2022 (the "First Closing"). On July 1, 2023, the Company also entered into an amendment ("Amendment No. 7 to the Second Notes") with the holders of the Company's outstanding Second Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, and June 15, 2023, issued in connection with a private placement financing the Company completed on January 18, 2023 (the "Second Closing"). On July 1, 2023, the Company also entered into an amendment ("Amendment No. 2 to the Third Notes and, together with Amendment No. 7 to the First Notes and Amendment No. 7 to the Second Notes, the "Amendments to the 2022 Notes") with the holders of the Company's outstanding Third Notes, as amended on June 15, 2023, issued in connection with a private placement financing the Company completed on May 15, 2023 (the "Third Closing").

Under the Amendments to the 2022 Notes, the 2022 Notes, Second Notes, and Third Notes were amended to extend the date of the completion of an uplist to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (such transaction, an "Uplist Transaction") from July 31, 2023 to August 31, 2023.

As a result of the entry into the Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Exchanged Notes, the Exchanged Notes were automatically amended to extend the date of completion of an Uplist Transaction from July 31, 2023 to August 31, 2023. Also, as a result of the entry into the Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Series 1 Unsecured Convertible Promissory Notes and Series 2 Unsecured Convertible Promissory Notes, each as amended on March 10, 2023, the Series Note Amendments Termination Date set forth under Amendment No. 1 to the Series 1 Unsecured Convertible Promissory Notes and Amendment No. 1 to the Series 2 Unsecured Convertible Promissory Notes was automatically amended to extend from July 31, 2023 to August 31, 2023. Additional information related to such matters can be found in the Form 8-K filed by the Company with Securities and Exchange Commission on July 7, 2023.

On July 7, 2023, the Company announced that it had entered into a Securities Purchase Agreement (the "2023 SPA") with certain institutional and accredited individual investors (collectively, the "Investors") providing for the issuance and sale by the Company to the Investors of an aggregate of (i) 1,749,245 shares (the "Shares") of common stock, par value \$0.001, of the Company (the "Common Stock") at a purchase price of \$0.275 per share; (ii) 4,996,199 warrants (the "Pre-Funded Warrants") at a purchase price of \$0.274 per Pre-Funded Warrant, to purchase an aggregate of 4,996,199 shares of Common Stock (the "Pre-Funded Warrant Shares"); and (iii) 13,490,888 warrants (the "Common Warrants") to purchase an aggregate 13,490,888 shares of Common Stock (the "Common Stock Warrants Shares"). The Shares, Pre-Funded Warrants, and Common Warrants were issued as part of a private placement offering authorized by the Company's board of directors (the "Bridge Offering"). The Company engaged an investment bank in connection with Bridge Offering. Per the terms of that agreement, the Company is obligated to pay the placement agent a fee of 8% of gross proceeds received and issue placement agent warrants to purchase that number of securities equal to 5% of the aggregate number of securities sold in the offering.

Pursuant to the lock-up agreement provided for by the SPA, the Investors agreed that they would either (A) purchase securities, for cash, in an offering conducted in conjunction with an uplist of the Common Stock to any of, and in compliance with the rules of, the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (the "Uplist Transaction") with an aggregate purchase price equal to at least 4.3 multiplied by the aggregate purchase price paid by the Investor for the Shares, Pre-Funded Warrants and Common Warrants under the SPA or (B) be subject to a lock-up provision not to sell or otherwise transfer any of the Shares, Pre-Funded Warrant Shares or Common Warrant Shares acquired by them in the Bridge Offering until the one-year anniversary of the Closing Date. The aggregate gross proceeds for the sale of the Shares, Pre-Funded Warrants, and Common Warrants will be approximately \$1.85 million, before deducting the placement agent's fees and other estimated fees and offering expenses payable by the Company. The closing of the sales of these securities under the SPA occurred on July 7, 2023 (the "Closing Date").

The 2023 SPA also provides additional provisions including: i) certain adjustments that would require the Company to issue additional securities to the Investors if the effective offering price to the public of Common Stock in connection with the next underwritten public offering is less than \$4.00 per share; ii) a requirement to register the Shares, Pre-Funded Warrant Shares, and Common Stock Warrant Shares on a subsequent registration statement or statements; and, iii) certain restrictions on the Company's ability to conduct subsequent sales of its equity securities and certain business activities. Additional information related to such matters can be found in the Form 8-K filed by the Company with Securities and Exchange Commission on July 13, 2023.

On July 7, 2023, the Company entered into an amendment (“Amendment No. 8 to the First Notes”) with the holders of the Company’s outstanding 2022 Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, and July 1, 2023, issued in connection with a private placement financing the Company completed on July 6, 2022 (the “First Closing”). On July 1, 2023, the Company also entered into an amendment (“Amendment No. 8 to the Second Notes”) with the holders of the Company’s outstanding Second Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, and July 1, 2023, issued in connection with a private placement financing the Company completed on January 18, 2023 (the “Second Closing”). On July 1, 2023, the Company also entered into an amendment (“Amendment No. 3 to the Third Notes”, and, together with Amendment No. 8 to the First Notes and Amendment No. 8 to the Second Notes, the “Amendments to the 2022 Notes”) with the holders of the Company’s outstanding Third Notes, as amended on June 15, 2023, and as subsequently amended on July 1, 2023, issued in connection with a private placement financing the Company completed on May 15, 2023 (the “Third Closing”).

Under the Amendments to the 2022 Notes, the following amendments to the 2022 Notes, Second Notes, and Third Notes will be simultaneously effective upon the closing of an offering conducted in conjunction with an uplist of the Common Stock to any of, and in compliance with the rules of, the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (the “Uplist Transaction”). The Specified Percentage (as defined below) of the then outstanding principal amount of the 2022 Notes, Second Notes, and Third Notes shall automatically convert (the “Automatic Conversion”) into shares of Common Stock, with the conversion price for purposes of such Automatic Conversion being equal to the lower of (i) the per unit price at which any units (each unit being comprised of one share or share equivalent and accompanying warrants, if any) are sold in the Uplist Transaction or (ii) the price at which warrants issued in the Uplist Transaction are exercisable (but in no event increased above the conversion price in effect immediately prior to the pricing of the Uplist Transaction).

In addition, if the Holder (as defined below) (i) participates in the Uplist Transaction and in the Bridge Offering for a combined (taking into account the Holder’s aggregate investment in the Uplist Transaction and the Bridge Offering) amount equal to no less than fifty percent (50%) of the Holder’s original purchase price under the 2022 Notes, Second Notes, and Third Notes, and (ii) the Holder’s amount of participation in the Uplist Transaction is at least 4.3 times the Holder’s amount of participation in the Bridge Offering, then the Holder shall receive a pre-funded warrant (the “Participating Pre-Funded Warrant”) to purchase a number of shares of Common Stock equal to the Specified Number (as defined below) times the dollar amount under the 2022 Notes that was converted in the Automatic Conversion. The Participating Pre-Funded Warrant (i) shall have an exercise price of \$0.001 per share, (ii) may be exercised on a cashless basis, (iii) shall be exercisable by the Holder at any time commencing on the 90th day after issuance, (iv) may be redeemed by the Company for cash at a redemption price of \$0.82 per share underlying the Participating Pre-Funded Warrant with any such redemption made pro rata to all holders of the Participating Pre-Funded Warrants, (v) and shall contain a customary beneficial ownership limitation provision. Additionally, the holder of the Participating Pre-Funded Warrants will agree that, until January 6, 2024, it shall not offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of, or announce the intention to otherwise dispose of, the Participating Pre-Funded Warrant.

“Specified Percentage” means the greater of: (i) the percentage specified by the Company by notice to the 2022 Note holders (the “Holders”, and each a “Holder”) at least five business days prior to the closing of the Uplist Transaction, which percentage shall be the percentage necessary to ensure the applicable Nasdaq requirements regarding the Uplist Transaction are satisfied, and (ii) the percentage specified by the Holder by notice to the Company at least three business days prior to the closing of the Uplist Transaction (which percentage may be different for each 2022 Note, Second Note, and/or Third Note as determined by each Holder thereof); provided, that in no event shall the Specified Percentage for the 2022 Notes, Second Notes, and/or Third Notes (A) exceed twenty five percent (25%) unless otherwise agreed in writing by the Holder, or (B) exceed fifty percent (50%) unless otherwise agreed in writing by the Company.

“Specified Number” means, if the Specified Percentage is 50%, 2.4, which number shall be increased by 1.6% for each percentage point decrease in the Specified Percentage, such increase being compounded iteratively for each percentage point decrease in the Specified Percentage, with the result rounded to two decimal places. Additional information related to such matters can be found in the Form 8-K filed by the Company with Securities and Exchange Commission on July 13, 2023.

Additionally, on July 7, 2023, the Company entered into an amendment (the “Omnibus Amendment to Notes and Warrants”) with the Holders of the 2022 Notes, Second Notes, and Third Notes amending the 2022 Notes, Second Notes, and Third Notes and related warrants issued at each of the First Closing, Second Closing, and Third Closing (the “First Warrants”, “Second Warrants” and “Third Warrants”, respectively, and collectively, the “2022 Warrants”). Under the Omnibus Amendment to Notes and Warrants, the 2022 Notes, Second Notes, Third Notes, and related warrants were amended (i) to modify the Most Favored Nation provisions therein to exclude the Bridge Offering, and (ii) to prohibit the Company from engaging in any capital raising transactions, subject to certain exceptions, until the earlier of (A) July 7, 2027, and (B) the first date on which all Holders hold less than 20% of the original amount of the Participating Pre-Funded Warrants received by each Holder, respectively, in connection with the Automatic Conversion. Additional information related to such matters can be found in the Form 8-K filed by the Company with Securities and Exchange Commission on July 13, 2023.

On July 7, 2023 the Company paid \$60,000 to a shareholder that had previously advanced the Company \$50,000 to support operations. The payment satisfied all remaining obligations in connection with the \$538,000 of shareholder advances received by the Company through May 12, 2023. The additional \$488,000 was issued as a Third Note (see Note 11).

On July 11, 2023, the Company entered into a finance agreement with First Insurance Funding in order to fund a portion of its insurance policies. The amount financed is approximately \$310,000 and incurs interest at a rate of 7.49%. Per the terms of its agreement with First Insurance Funding, the Company is required to make monthly payments of approximately \$32,000 through April 2024.

On July 12, 2023, the Company secured countersigned notices of conversion from all remaining holders of the Series 1 Convertible Notes, and provided instructions to its transfer agent to issue a total of 59,912 shares of Common Stock in full satisfaction of all previously outstanding Series 1 Convertible Notes. Pursuant to the Series 1 Convertible Notes, the Company can elect to convert the principal and accrued interest under the Series Convertible Notes obligation (the “Series Note Obligations”) upon the earlier of the effective time of the Uplisting Transaction, or the maturity date. In the case of an In-Kind Note Repayment, the outstanding Note Obligations will be calculated by increasing by thirty-five percent the aggregate sum of the unpaid Principal Amount held by each Holder and the accrued interest at a rate of ten percent per annum, subject to, with respect to any portion of the Principal Amount that is converted or prepaid before the twelve month anniversary of the Issuance Date, a minimum interest payment equal to ten percent of the amount that is converted or prepaid. As consideration for agreeing to subordinate to the 2022 Notes, the premium applicable in connection with an In-Kind Note Repayment at maturity was increased from thirty-five percent to sixty percent. In the event the Company exercises such option, the Series Note Obligations will be deemed to equal the product of 4.5 (which was previously 1.6 prior to the Series Note Amendments) and the outstanding Series Note Obligations.

On July 18, 2023, the Board of the Directors of the Company executed a unanimous written consent that, among other things, approved, subject to the approval of a majority of the stockholders of the Company, the following: 1) amend the Amended and Restated Articles of Incorporation (the “Articles”) to a) increase the number of authorized shares of common stock, par value \$0.001 (the “Common Stock”) from 12 million to 350 million, b) create 5,000,000 shares of “blank check” preferred stock, and c) approve a reverse split at a ratio of between 1.5-for-1 and 20-for-1 without any proportionate decrease in the number of authorized shares; 2) amend the Bylaws of the Company to a) allow action by written consent of stockholders representing more than 50% of the total number of shares of Common Stock currently issued and outstanding, and b) establish that holders of thirty-three and one-third (33.3333%) of the total number of shares of Common Stock currently issued and outstanding shall constitute a quorum at any meeting of stockholders for the transaction of business, except as otherwise provided by the NRS or by the Articles; and, 3) approve the 2023 Omnibus Equity Incentive Plan with an initial reservation of 455,169 shares, options or other such grants. Additional information related to such matters can be found in the Form 8-K filed by the Company with Securities and Exchange Commission on July 24, 2023.

On July 31, 2023, Arch Therapeutics, Inc. (the “Company”) entered into an amendment (“Amendment No. 9 to the First Notes”) with the holders of the Company’s outstanding 2022 Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023 and July 7, 2023 issued in connection with a private placement financing the Company completed on July 6, 2022 (the “First Closing”). On July 31, 2023, the Company also entered into an amendment (“Amendment No. 9 to the Second Notes”) with the holders of the Company’s outstanding Second Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, and July 7, 2023 issued in connection with a private placement financing the Company completed on January 18, 2023 (the “Second Closing”). On July 31, 2023, the Company also entered into an amendment (“Amendment No. 4 to the Third Notes and, together with Amendment No. 9 to the First Notes and Amendment No. 9 to the Second Notes, the “Amendments to the 2022 Notes”) with the holders of the Company’s outstanding Third Notes, as amended on June 15, 2023, and as subsequently amended on July 1, 2023 and July 7, 2023 issued in connection with a private placement financing the Company completed on May 15, 2023 (the “Third Closing”).

Under the Amendments to the 2022 Notes, the 2022 Notes, Second Notes, and Third Notes were amended to extend the date of the completion of an uplist to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (such transaction, an “Uplist Transaction”) from July 31, 2023 to August 31, 2023.

As a result of the entry into the Amendments to the 2022 Notes, and pursuant to the terms of the Company’s outstanding Exchanged Notes, the Exchanged Notes were automatically amended to extend the date of completion of an Uplist Transaction from July 31, 2023 to August 31, 2023. Additional information related to such matters can be found in the Form 8-K filed by the Company with Securities and Exchange Commission on August 4, 2023.

6,750,000 Units (consisting of 6,750,000 Shares of Common Stock and Investor Warrants to Purchase up to 6,750,000 Shares of Common Stock)
Up to 6,750,000 Pre-Funded Units (consisting of Pre-Funded Warrants to Purchase up to 6,750,000 Shares of Common Stock and Investor Warrants to Purchase up to 6,750,000 Shares of Common Stock)
Up to 6,750,000 Shares of Common Stock Underlying the Pre-Funded Warrants and
Up to 6,750,000 Shares of Common Stock Underlying the Investor Warrants

ARCH THERAPEUTICS, INC.

PRELIMINARY PROSPECTUS

Sole Book-Running Manager

Dawson James Securities, Inc.

, 2023

Until , 2023 (25 days after the date of this prospectus), all dealers that buy, sell or trade our securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

The information in this prospectus is not complete and may be changed. The selling stockholders named herein may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED October 5, 2023

PRELIMINARY PROSPECTUS

ARCH THERAPEUTICS, INC.

3,364,527 Shares of Common Stock

Up to 146,473 Shares of Common Stock underlying the Second Notes and Third Notes

Up to 783,564 Shares of Common Stock underlying the 2022 Notes upon Automatic Conversion

Up to 275,930 Shares of Common Stock underlying the 2022 Warrants and

2022 Placement Agent Warrants

Up to 81,690,984 Shares of Common Stock underlying the Common Warrants, Bridge Pre-Funded Warrants, Exchange Investor Warrants, and Bridge Placement Agent Warrants

Up to 8,305,767 Shares of Common Stock underlying the Participating Pre-Funded Warrants and 2022 Note Conversion Pre-Funded Warrants

This prospectus relates to the offer and sale of up to 94,567,245 shares of our common stock, par value \$0.001 per share (**Common Stock**), by the selling stockholders identified in this prospectus. The shares of Common Stock being offered include:

- 20,206 shares of Common Stock (the **“Inducement Shares”**) issued to selling stockholders in the second and third closing of our private placement that we completed on January 18, 2022, and May 15, 2023, respectively (the **“2022 Private Placement Financing”**) and 3,344,321 shares of Common Stock (the **“Bridge Shares”**) issued in our private placement that we completed on July 6, 2023 (the **2023 Bridge Financing**);
 - Up to 146,473 shares of Common Stock (the **“Conversion Shares”**) issuable to selling stockholders upon conversion of our convertible notes issued in the second and third closing of our 2022 Private Placement Financing at a conversion price of \$9.14 per share;
 - Up to 783,564 shares of Common Stock (the **“Automatic Conversion Shares”**) issuable to selling stockholders upon conversion of our convertible notes issued in the 2022 Private Placement Financing upon the Automatic Conversion (as defined in this prospectus);
 - Up to 269,365 shares of Common Stock (the **“2022 Warrant Shares”**) issuable to selling stockholders upon exercise, at an exercise price of \$ 9.94 per share, of our warrants (the **“2022 Warrants”**) issued in the second and third closing of our 2022 Private Placement Financing;
 - Up to 783,564 shares of Common Stock (**“2022 Note Conversion Pre-Funded Warrant Shares”**) issuable to the selling stockholders upon exercise, at an exercise price of \$0.001 per share, of our pre-funded warrants (the **“2022 Note Conversion Pre-Funded Warrants”**) issuable upon the Automatic Conversion;
 - Up to 6,565 shares of Common Stock (the **“2022 Placement Agent Warrant Shares”**) issuable to the selling stockholders upon exercise, at an exercise price of \$10.06 per share, of placement agent warrants issued in the 2022 Private Placement Financing (the **“2022 Placement Agent Warrants”**);
 - Up to 18,798,526 shares of Common Stock (the **“Common Warrant Shares”**) issuable to selling stockholders upon exercise, at an exercise price of \$1.00 per share, of our warrants (the **“Common Warrants”**) issued in the 2023 Bridge Financing;
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- Up to 6,054,942 shares of Common Stock (“**Bridge Pre-Funded Warrant Shares**” and together with the Common Warrant Shares, the “**Bridge Warrant Shares**”) issuable to the selling stockholders upon exercise, at an exercise price of \$0.001 per share, of pre-funded warrants issued in the 2023 Bridge Financing (the “**Bridge Pre-Funded Warrants**” and together with the Common Warrants, the “**Bridge Warrants**”);
- Up to 56,395,578 shares of Common Stock (the “**Exchange Investor Warrant Shares**”) issuable to selling stockholders upon exercise, at an exercise price per share equal to the exercise price per share of the warrants sold in an Uplist Transaction (as defined below), of our warrants (the “**Exchange Investor Warrants**”) issuable in exchange for the Common Warrants upon the closing of an Uplist Transaction;
- Up to 441,938 shares of Common Stock (the “**Bridge Placement Agent Warrant Shares**”) issuable to selling stockholders upon exercise, at an exercise price of \$0.275 per share, of our warrants (the “**Bridge Placement Agent Warrants**”) issued in the 2023 Bridge Financing; and up to 441,938 shares of Common Stock (the “**Bridge Placement Agent Warrant Shares**”) issuable to selling stockholders upon exercise, at an exercise price of \$0.275 per share, of our warrants (the “**Bridge Placement Agent Warrants**”) issued in the 2023 Bridge Financing; and
- Up to 7,522,203 shares of Common Stock (“**Conversion Warrant Shares**”) issuable to the selling stockholders upon exercise, at an exercise price of \$0.001 per share, of our pre-funded warrants (“**Participating Pre-Funded Warrants**”) issuable upon the closing of an Uplist Transaction.

The selling stockholders may sell the shares of Common Stock to be registered hereby from time to time on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale, in the over-the-counter market, in one or more transactions otherwise than on these exchanges or systems or in the over-the-counter market, such as privately negotiated transactions, or using a combination of these methods, and at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. See the disclosure under the heading “**Plan of Distribution**” beginning on page 44 of this prospectus for more information.

We will not receive any proceeds from the resale of Common Stock by the selling stockholders.

Our Common Stock is traded on the QB tier of the OTC Marketplace (“**OTCQB**”) under the symbol “ARTH”. On October 3, 2023, the closing price of our Common Stock was \$1.20 per share.

We originally offered and sold the securities issued or issuable in connection with the 2022 Private Placement Financing and the Bridge Offering under an exemption from the registration requirements of the Securities Act of 1933, as amended (the “**Securities Act**”), pursuant to Section 4(a)(2) thereof and Rule 506 of Regulation D promulgated thereunder.

We are a “smaller reporting company” as defined under the federal securities laws and, as such, are eligible for reduced public company reporting requirements. See “Prospectus Summary — Implications of Being a Smaller Reporting Company”.

Investing in our Common Stock involves a high degree of risk. Before making any investment in our Common Stock, you should read and carefully consider the risks described in this prospectus under the heading “**Risk Factors**” beginning on page 13 of this prospectus.

You should rely only on the information contained in this prospectus or any prospectus supplement or amendment thereto. We have not authorized anyone to provide you with different information.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

This prospectus is dated , 2023

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ABOUT THIS PROSPECTUS

This prospectus relates to the offering by the selling stockholders identified in this prospectus of shares of our Common Stock that were issued in the 2022 Private Placement Financing, are issuable upon the exercise of 2022 Warrants or 2022 Placement Agent Warrants issued in the 2022 Private Placement Financing, or are issuable upon the conversion of 2022 Notes issued in the 2022 Private Placement Financing as well as shares of our Common Stock that were issued in the Bridge Offering, are issuable upon exercise of Bridge Warrants or Bridge Placement Agent Warrants issued in the Bridge Offering, or are issuable upon exercise of Exchange Investor Warrants, Participating Pre-Funded Warrants, and 2022 Note Conversion Pre-Funded Warrants issuable upon the closing of an Uplist Transaction (as defined below).

You should rely only on the information that we have provided or incorporated by reference in this prospectus, any applicable prospectus supplement and any related free writing prospectus that we may authorize to be provided to you. We have not authorized anyone to provide you with different information. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus, any applicable prospectus supplement or any related free writing prospectus that we may authorize to be provided to you. You must not rely on any unauthorized information or representation. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information in this prospectus, any applicable prospectus supplement or any related free writing prospectus is accurate only as of the date on the front of the document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus, any applicable prospectus supplement or any related free writing prospectus, or any sale of a security registered under the Registration Statement of which this prospectus forms a part.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to this Registration Statement of which this prospectus forms a part, and you may obtain copies of those documents as described below under the heading **“WHERE YOU CAN FIND MORE INFORMATION”** beginning on page 103 of this prospectus.

As used in this prospectus, unless the context indicates or otherwise requires, the **“Company”**, **“we”**, **“us”**, **“our”** and **“Arch”** refer to Arch Therapeutics, Inc., a Nevada corporation, and its consolidated subsidiary, and the term **“ABS”** refers to Arch Biosurgery, Inc., a private Massachusetts corporation that, through a reverse merger acquisition completed on June 26, 2013, has become our wholly owned subsidiary.

AC5, AC5-G, AC5-V, AC5-P, Crystal Clear Surgery, NanoDrape and NanoBioBarrier and associated logos are trademarks and/or registered trademarks of Arch Therapeutics, Inc. and subsidiary. All other trademarks, trade names and service marks included in this prospectus are the property of their respective owners.

This prospectus and the information incorporated by reference into this prospectus contain references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus and the information incorporated by reference into this prospectus, including logos, artwork, and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other company.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve risks, uncertainties and assumptions. In some cases, you can identify forward-looking statements by terminology such as “if,” “shall,” “may,” “might,” “will likely result,” “should,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “project,” “intend,” “goal,” “objective,” “predict,” “potential” or “continue,” or the negative of these terms or other comparable terminology. All statements made in this prospectus other than statements of historical fact are statements that could be deemed forward-looking statements, including without limitation statements about our business plan, our plan of operations and our need to obtain future financing. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks in the section entitled “**Risk Factors**” beginning on page 13 of this prospectus, and the risks set out below, any of which may cause our or our industry’s actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. These risks include, by way of example and not in limitation, risks related to:

- Our ability to continue as a going concern;
- Our ability to obtain financing necessary to operate our business;
- Our limited operating history;
- Our ability to comply with the terms and covenants of our existing agreements and outstanding convertible notes, including the First Notes (as defined below) which are secured by security interests in substantially all of our assets;
- The dilutive effect of our outstanding warrants and convertible notes;
- The results of our research and development activities, including uncertainties relating to the preclinical and clinical testing of our product candidates;
- The commercialization of our primary product candidate;
- Our ability to develop, obtain required approvals for and commercialize our product candidates;
- Our ability to recruit and retain qualified key executives, and medical and science personnel;
- Our ability to develop and maintain an effective sales force to market our approved product candidates;
- Our ability to manage any future growth we may experience;
- Our ability to obtain and maintain protection of our intellectual property;
- Our dependence on third party manufacturers, suppliers, research organizations, academic institutions, testing laboratories and other potential collaborators;
- The size and growth of the potential markets for any of our approved product candidates, and the rate and degree of market acceptance of any of our approved product candidates;
- Our ability to successfully complete potential acquisitions and collaborative arrangements;
- Competition in our industry;
- The impact of the COVID-19 pandemic, and related responses of businesses and governments to the pandemic, on our operations and personnel, on commercial activity in the markets in which we operate and on our results of operations;
- General economic and business conditions; and
- Other factors discussed under the section entitled “**Risk Factors**.”

New risks emerge in our rapidly-changing industry from time to time. As a result, it is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business. If any such risks or uncertainties materialize or such assumptions prove incorrect, our results could differ materially from those expressed or implied by such forward-looking statements and assumptions. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity or performance. These forward-looking statements speak only as of the date of this prospectus. Except as required by applicable law, we do not intend to update any of these forward-looking statements.

PROSPECTUS SUMMARY

Our Company

We are a biotechnology company marketing a number of products based on our innovative AC5® self-assembling technology platform. We believe these products are important advances in the field of stasis and barrier applications, which includes managing wounds created during surgery, trauma, interventional care or disease; stopping bleeding (hemostasis); controlling leaking (sealant). We have recently devoted substantially all of our operational effort to the market adoption and commercial sales of AC5® Advanced Wound System, our first product. Our goal is to make care faster and safer for patients with products for use on external wounds, which we refer to as Dermal Sciences applications, and products for use inside the body, which we refer to as BioSurgery applications.

Our flagship products and product candidates are derived from our AC5® self-assembling peptide (“SAP”) technology platform and are sometimes referred to as AC5 or the “AC5 Devices.” These include AC5 Advanced Wound System and AC5® Topical Hemostat, which have received marketing authorization as medical devices in the United States and Europe, respectively, and which are intended for skin applications, such as management of complicated chronic wounds or acute surgical wounds. Marketing for AC5 Topical Hemostat in Europe has not initiated. Other products are in development for use in minimally invasive or open surgical procedures and include, for example, AC5-G™ for gastrointestinal endoscopic procedures and AC5-V™ and AC5® Surgical Hemostat for hemostasis inside the body, all of which are currently investigational devices limited by law to investigational use.

Products based on the AC5 platform contain a proprietary biocompatible peptide that is synthesized from proteogenic, naturally occurring L-amino acids. Unlike products that contain traditional peptide sequences, when applied to a wound, AC5-based products intercalate into the interstices of the tissue and self-assemble (i.e., self-build) into a protective physical-mechanical nanoscale structure that can provide a barrier to leaking substances, such as blood, while also acting as a biodegradable scaffold that enables healing. Self-assembly is a central component of the mechanism of action of our technology. Individual AC5 peptide units readily build themselves, or self-assemble, into an ordered network of nanofibrils when in aqueous solution by the following process:

- Peptide strands line up with neighboring peptide strands, interacting via hydrogen bonds (non-covalent bonds) to form a ribbon-like structure called a beta sheet.
- This process continues such that hundreds of strands organize with charged and polar side chains oriented on one face and non-polar side chains oriented on the opposite face of the beta sheets.
- Interactions of the resulting structure with water molecules and ions results in formation nanofibrils, which extend in length and can join together to form larger nanofibers.
- This network of AC5 peptide nanofibers forms the semi-solid physical-mechanical barrier that interacts with the extracellular matrix, is responsible for sealant, hemostatic and/or other properties that may be observed even in the presence of antithrombotic agents (i.e., blood thinners), and which subsequently becomes the scaffold that supports the repair and regeneration of damaged tissue.

Based on the intended application, we believe that the underlying AC5 SAP technology can impart important features and benefits to our products that may include, for instance, stopping bleeding (hemostasis), mitigating contamination, modulating inflammation, donating moisture, and enabling an appropriate wound microenvironment conducive to healing. Furthermore, we believe that AC5 SAP technology permits cell and tissue growth and is self-healing, in that it can dynamically self-repair around migrating cells. For instance, AC5 Advanced Wound System, which is indicated for the management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds, is shipped and stored at room temperature, is applied directly as a liquid, can conform to irregular wound geometry, self-assembles into a wound care matrix that can provide clinicians with multi-modal support, and does not possess sticky or glue-like handling characteristics. We believe these properties enhance its utility in several settings and contribute to its user-friendly profile.

We believe that our technology lends itself to a range of potential applications for wounds inside or on the body including those for which a hemostatic agent or sealant is needed. For instance, the results of certain preclinical and clinical investigations that either we have conducted, or others have conducted on our behalf, have shown quick and effective hemostasis with the use of AC5 SAP technology, and that time to hemostasis (“TTH”) is comparable among test subjects regardless of whether such test subject had or had not been treated with therapeutic doses of anticoagulant or antiplatelet medications, commonly called “blood thinners.” Furthermore, the transparency and physical properties of certain AC5 Devices may enable a surgeon to operate through it in order to maintain a clearer field of vision and prophylactically stop or lessen bleeding as surgery starts, a concept that we call Crystal Clear Surgery™. An example of a product that contains related features and benefits is AC5 Topical Hemostat, which is indicated for use as a dressing and to control mild to moderate bleeding, each during the management of injured skin and the micro-environment of an acute surgical wound. AC5 Topical Hemostat has not yet been marketed in Europe but has received marketing authorization.

Sales and marketing efforts for our AC5 Advanced Wound System, which has received 510(k) marketing clearance from the FDA, address the demand for improved solutions to treat challenging chronic and acute surgical wounds, with a particular early focus on diabetic foot ulcers, venous leg ulcers and pressure ulcers. Chronic wounds are typically defined as wounds that have not healed after four weeks of standard care. Approximately 4 million to 6.5 million new onset chronic wounds are estimated to occur in the U.S. annually, including approximately 700,000 to 2 million diabetic foot ulcers, 2.5 million pressure ulcers, and 1.2 million venous leg ulcers. If untreated, improperly treated or unresponsive to treatment, these wounds can ultimately lead to amputation. The 5-year mortality rate among patients with chronic wounds, especially after an amputation, is significant.

Published data on AC5 Advanced Wound System shows encouraging outcomes, including limb salvage (avoided limb loss), among patients with multiple co-morbidities and challenging chronic wounds that failed to heal despite treatment with either traditional or other advanced wound care modalities over prolonged periods of time.

We currently maintain an internal commercial team focused on driving awareness and adoption of AC5 Advanced Wound System in several targeted channels with a particular focus on physician offices and government channels, such as Veterans Affairs (“VA”) hospitals and military treatment facilities (“MTFs”). We anticipate that material growth in the physician office setting will require product reimbursement. To that end, we submitted an application to the Centers for Medicare and Medicaid Services (“CMS”) in July 2022 for a unique product reimbursement code. Our application was subsequently approved with a go-live date of April 1, 2023. We have launched a temporary reimbursement support program in line with CMS guidance to support commercial use and adoption of AC5 Advanced Wound System both before and after the go-live date of our unique product code (A2020). In support of the VA and MTF market, we partnered with Lovell Government Services (“LGS”), a service-disabled veteran-owned small business, as its distributor in the government channel. As a direct result of its relationship with LGS, AC5 Advanced Wound System is listed on the four major government supply schedules (ECAT, DAPA, FSS and GSA) in order to allow doctors in any VA or MTF to order AC5 Advanced Wound System. We have also established and will continue to seek partnerships with reputable, value-added independent sales distributors on a case-by-case basis to expand the overall reach and footprint of its total sales organization. Presently, our commercialization efforts and resources remain dedicated to the U.S. market for advanced wound care.

Much of our operational efforts to date, which we often perform in collaboration with partners, have included selecting compositions and formulations for our initial products; conducting preclinical studies, including safety and other tests; conducting a human trial for safety and performance of AC5; developing and conducting a human safety study to assess for irritation and sensitization potential; securing marketing authorization for our first product in the United States and in Europe; supporting surgeons performing clinical case studies; obtaining post-marketing clinical data; developing, optimizing, and validating manufacturing methods and formulations, which are particularly important components of self-assembling peptide development; developing methods for manufacturing scale-up, reproducibility, and validation; engaging with regulatory authorities to seek early regulatory guidance as well as marketing authorization for our products; sourcing and evaluating commercial partnering opportunities in the United States and abroad; and developing and protecting the intellectual property rights underlying our technology platform.

Our long-term business plan includes the following goals:

- Continue to build recent commercial momentum and grow revenues by driving awareness, adoption and payment policies for AC5 Advanced Wound System with the now-effective CMS Level II Healthcare Common Procedure Coding System (“**HCPCS**”) code dedicated to the “AC5”;
- conducting biocompatibility, pre-clinical, and clinical studies on our products and product candidates;
- obtaining additional marketing authorization for products in the United States, Europe, and other jurisdictions as we may determine;
- continuing to develop third party relationships to manufacture, distribute, market and otherwise commercialize our products;
- continuing to develop academic, scientific and institutional relationships to collaborate on product research and development;
- expanding and maintaining protection of our intellectual property portfolio; and
- developing additional product candidates in Dermal Sciences, BioSurgery, and other areas.

In furtherance of our long-term business goals, we expect to continue to focus on the following activities during the next twelve months:

- seek additional funding as required to support the milestones described previously and our operations generally;
- work with our manufacturing partners to scale up production of product compliant with current good manufacturing practices (“**cGMP**”), which activities will be ongoing and tied to our development and commercialization needs;
- further clinical development of our product platform;
- assess our technology platform in order to identify and select product candidates for potential advancement into development;
- seek regulatory input to guide activities related to expanded and new product marketing authorizations;
- continue to expand and enhance our financial and operational reporting and controls;
- pursue commercial partnerships; and
- expand and enhance our intellectual property portfolio by filing new patent applications, obtaining allowances on currently filed patent applications, and/or adding to our trade secrets in self-assembly, manufacturing, analytical methods and formulation, which activities will be ongoing as we seek to expand our product candidate portfolio.

We believe that our current cash on hand as of September 15, 2023 is sufficient to meet our anticipated cash requirements into the first fiscal quarter of 2024, and we must obtain additional financing in order to continue to operate our business. Even if the Primary Offering (as defined below) is successful, depending upon additional input from EU and US regulatory authorities, however, we do not expect to generate sufficient revenues from operations before we need to raise additional capital. Further, our estimates regarding our use of cash could change if we encounter unanticipated difficulties or other issues arise, including without limitation those set forth in this prospectus under the heading “**Risk Factors**” beginning on page 13, in which case our current funds may not be sufficient to operate our business for the period we expect.

Additionally, we are bound by certain contractual terms and obligations that may limit or otherwise impact our ability to raise additional funding in the near-term including, but not limited to, provisions in the Bridge SPA (as defined below) and securities purchase agreement dated July 6, 2022, as amended (the “**2022 Notes SPA**”), associated with the sale of the 2022 Notes (the “**2022 Notes Financing**”), in each case as described in greater detail in the risk factor entitled *‘The terms of the Bridge Offering and 2022 Notes Financing could impose additional challenges on our ability to raise funding in the future’* under the heading “**Risk Factors**” in this prospectus.

We have an aggregate of \$6,268,501 in principal outstanding as of September 15, 2023 under the 2022 Notes (as defined below) and an aggregate of \$587,959 in principal and accrued interest outstanding as of September 15, 2023 (calculated through maturity) under the Series 2 Notes (as defined below). The holders of the First Notes (as defined below) have been granted a security interest in substantially all of our assets pursuant to the terms of the security agreement dated July 6, 2022 (the “**Security Agreement**”), pursuant to which we provided a security interest in, and a lien on, substantially all of our assets as collateral for the repayment of the First Notes. If we fail to make payments on the First Notes when due or otherwise comply with the covenants contained in the First Notes, the First Note holders could declare us in default, in which event such holders would have the right to exercise their rights as a secured creditor with respect to our assets that secure the indebtedness, which would force us to suspend operations.

Proposed Listing on the Nasdaq Capital Market or an Alternate Exchange

Our Common Stock is presently quoted on the OTCQB under the trading symbol “ARTH.” In connection with the offering pursuant to the Company Prospectus (the “**Primary Offering**”), we have applied to list our Common Stock and Investor Warrants (as defined in the Company Prospectus) on the Nasdaq Capital Market under the symbols “ARTH” and “ARTHW,” respectively. Although we have applied to list the Investor Warrants, there is no established public trading market for the Investor Warrants and without an active trading market, the liquidity of the Investor Warrants will be limited. No assurance can be given that our listing application for our Common Stock and Investor Warrants will be approved by the Nasdaq Capital Market or an Alternate Exchange. If our listing application is approved, our Common Stock will cease to be traded on the OTCQB. The Primary Offering will occur only if the Nasdaq Capital Market or an Alternate Exchange approves the listing of our Common Stock by October 31, 2023. The Nasdaq Capital Market and Alternate Exchange listing requirements include, among other things, a stock price threshold. As a result, prior to effectiveness, we will need to take the necessary steps to meet Nasdaq Capital Market listing requirements or the listing requirements of an Alternate Exchange, including but not limited to a reverse split of our outstanding shares of Common Stock.

Implications of Being a Smaller Reporting Company

We are a “smaller reporting company,” meaning that the market value of our Common Stock held by non-affiliates is less than \$700 million and our annual revenue is less than \$100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after the Primary Offering if either (i) the market value of our stock held by non-affiliates is less than \$250 million as of the last business day of our second fiscal quarter or (ii) our annual revenue is less than \$100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700 million. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Corporate Information

Arch Therapeutics, Inc. (together with its subsidiary, the “**Company**” or “**Arch**”) arose from the June 26, 2013 merger (the “**Merger**”) of three entities previously known as Arch Biosurgery, Inc., Almah, Inc., and Arch Acquisition Corporation, respectively.

Arch Biosurgery, Inc. (“**ABS**”) is a biotechnology company that was incorporated under the laws of the Commonwealth of Massachusetts on March 6, 2006 as Clear Nano Solutions, Inc., changed its name from Clear Nano Solutions, Inc. to Arch Therapeutics, Inc. on April 7, 2008, and, as part of the Merger transaction, changed its name from Arch Therapeutics, Inc. to Arch Biosurgery.

Almah, Inc., was incorporated under the laws of the State of Nevada on September 16, 2009 and, as part of the Merger transaction, changed its name to Arch Therapeutics, Inc. and abandoned both its prior business plan and operations in order to adopt those of ABS.

Arch Acquisition Corporation, or Merger Sub, was a wholly owned subsidiary of Almah, Inc., formed for the purpose of the Merger transaction, pursuant to which Merger Sub merged with and into ABS, and ABS thereafter became the wholly owned subsidiary of the Company.

Prior to the completion of the Merger, we were a “shell company” under applicable rules of the SEC, and had no or nominal assets or operations.

Our principal executive offices are located at 235 Walnut St., Suite 6, Framingham, Massachusetts 01702. The telephone number of our principal executive offices is (617) 431-2313. Our website address is <http://www.archtherapeutics.com>. We have not incorporated by reference into this prospectus the information on, or that can be accessed through, our website, and you should not consider it to be a part of this document. You should not rely on any information on that website in making your decision to purchase shares of our Common Stock.

The Transactions

The shares of our Common Stock being offered for resale by selling stockholders named herein pursuant to this prospectus were issued or are issuable in connection with (i) the 2022 Private Placement Financing and (ii) the Bridge Offering.

Bridge Offering

Between July 7, 2023 and September 11, 2023, pursuant to a Securities Purchase Agreement dated July 7, 2023, as subsequently amended on August 30, 2023 (as amended, the “**Bridge SPA**”), among the Company and certain institutional and accredited individual investors (collectively, the “**Bridge Investors**”) the Company issued and sold to the Bridge Investors an aggregate of (i) 3,344,321 shares (the “**Bridge Shares**”) of Common Stock; (ii) 6,054,942 warrants (the “**Bridge Pre-Funded Warrants**”) to purchase an aggregate of 6,054,942 shares of Common Stock (the “**Bridge Pre-Funded Warrant Shares**”); and (iii) 18,798,526 warrants (the “**Common Warrants**” and together with the **Bridge Pre-Funded Warrants**, the “**Bridge Warrants**”) to purchase an aggregate 18,798,526 shares of Common Stock (the “**Common Warrant Shares**” and together with the Bridge Pre-Funded Warrant Shares, the “**Bridge Warrant Shares**”), at a purchase price of \$0.275 per Bridge Share and accompanying Common Warrant to purchase two shares of Common Stock, and \$0.274 per Bridge Pre-Funded Warrant to purchase one share of Common Stock and accompanying Common Warrant to purchase two shares of Common Stock. The Bridge Shares, Bridge Pre-Funded Warrants, and Common Warrants were issued as part of a private placement offering authorized by the Company’s board of directors (the “**Bridge Offering**”).

Pursuant to the lock-up agreement provided for by the Bridge SPA, the Bridge Investors agreed that they would either (A) purchase securities, for cash, in an offering conducted in conjunction with an uplist of the Common Stock to any of, and in compliance with the rules of, the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (the “**Uplist Transaction**”), which the Primary Offering is intended to be, with an aggregate purchase price equal to at least 4.3 multiplied by the aggregate purchase price paid by the Bridge Investor for the Bridge Shares and Bridge Warrants under the Bridge SPA or (B) be subject to a lock-up provision not to sell or otherwise transfer any of the Bridge Shares or Bridge Warrant Shares acquired by them in the Bridge Offering until the one-year anniversary of the Bridge Closing Date (as defined below). The aggregate gross proceeds for the sale of the Bridge Shares, Bridge Pre-Funded Warrants, and Common Warrants was approximately \$2.6 million, before deducting the placement agent’s fees and other estimated fees and offering expenses payable by the Company. The first closing of the sales of these securities under the Bridge SPA occurred on July 7, 2023 (the “**Bridge Closing Date**”).

Under the Bridge SPA, the Company also agreed that upon the closing of the next underwritten public offering of Common Stock (a “**Qualifying Offering**”), if the effective offering price to the public per share of Common Stock (the “**Qualifying Offering Price**”) is lower than the \$4.00 per share, then the Company shall issue additional Bridge Pre-Funded Warrants in an amount reflecting a reduction in the purchase price paid for the Bridge Shares and Bridge Pre-Funded Warrants that equals the proportion by which the Qualifying Offering Price is less than the \$4.00.

The Company retained Dawson James Securities, Inc. (“DJ”) as placement agent in connection with the Bridge Offering. Pursuant to an engagement agreement the Company entered with DJ, the Company paid DJ a cash fee equal to 8.0% of the aggregate gross proceeds of the Bridge Offering and reimbursement of expenses of \$50,000. Additionally, on September 7, 2023, the Company issued to DJ, or its designees, warrants (the “**Bridge Placement Agent Warrants**”) to purchase an aggregate of 441,938 shares of Common Stock (the “**Bridge Placement Agent Warrant Shares**”). The Bridge Placement Agent Warrants are exercisable at any time and from time to time, in whole or in part, during the five-year period commencing March 7, 2024, at a price per share equal to \$0.275.

Bridge Pre-Funded Warrants

The Bridge Pre-Funded Warrants (i) have a nominal exercise price of \$0.001 per share; (ii) are exercisable after the earlier of (A) the six-month anniversary after the date of issuance, (B) 120 days after the closing date of an Uplist Transaction, and (C) the date that a registration statement registering the Bridge Pre-Funded Warrant Shares is declared effective; (iii) are exercisable until all of the Bridge Pre-Funded Warrants are exercised in full; and (iv) have a provision preventing the exercisability of such Bridge Pre-Funded Warrants if, as a result of the exercise of the Bridge Pre-Funded Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than either 4.99% or 9.99% of the Common Stock (the “**Ownership Limitation**”) immediately after giving effect to the exercise of the Bridge Pre-Funded Warrants.

Common Warrants

The Common Warrants (i) have an exercise price of \$1.00 per share; (ii) have a term of exercise equal to 5 years after their issuance date; (iii) are exercisable after the earlier of (A) the six-month anniversary after the date of issuance and (B) the date that a registration statement registering the Common Warrant Shares is declared effective; (iv) have a provision permitting voluntary adjustments to the exercise price by the Company, subject to the prior written consent of the Common Warrant holder; (v) are automatically exchanged upon the closing of an Uplist Transaction for a new warrant that is identical to the warrants (other than any pre-funded warrants), if any, being issued to investors in such Uplist Transaction, with the number of shares underlying such new warrant being equal to the number of Common Warrant Shares then underlying the Common Warrant multiplied by three and (vi) have a provision preventing the exercisability of such Common Warrants if, as a result of the exercise of the Common Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Company Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than the Ownership Limitation immediately after giving effect to the exercise of the Common Warrants. Accordingly, at the closing of the Primary Offering, the Common Warrants will be canceled and exchanged for newly issued warrants identical to the Investor Warrants (the “**Exchange Investor Warrants**”) to purchase an aggregate of 56,395,578 shares of Common Stock at an exercise price per share equal to the exercise price per share of the Investor Warrants (the “**Exchange Investor Warrant Shares**”).

Registration Rights Agreement

The Company also entered into a registration rights agreement with the Bridge Investors dated July 7, 2023, as subsequently amended on August 30, 2023 (as amended, the “**Bridge Registration Rights Agreement**”), pursuant to which the Company is obligated, subject to certain conditions, to file with the Securities and Exchange Commission within the earlier of (i) 30 days following the closing date of the Uplist Transaction and (ii) October 31, 2023, one or more registration statements (any such registration statement, a “**Resale Registration Statement**”) to register the Bridge Shares, the Bridge Warrant Shares, the shares of Common Stock issuable upon exercise in full of the Exchange Investor Warrants (the “**Exchange Investor Warrant Shares**”) and the shares of Common Stock issuable upon exercise in full of the Participating Pre-Funded Warrant (as defined below) (the “**Conversion Warrant Shares**”) for resale under the Securities Act. The Company’s failure to satisfy certain filing and effectiveness deadlines with respect to a Resale Registration Statement and certain other requirements set forth in the Bridge Registration Rights Agreement may subject the Company to payment of monetary penalties.

We are registering for resale by the selling shareholders named herein (i) the 3,344,321 Bridge Shares; (ii) up to 24,853,468 Bridge Warrant Shares; (iii) up to 56,395,578 Exchange Investor Warrant Shares; (iv) up to 7,522,203 Conversion Warrant Shares; and (v) up to 441,938 Bridge Placement Agent Warrant Shares.

2022 Private Placement Financing

On July 7, 2022, the Company announced that it had entered into a Securities Purchase Agreement (the “**2022 SPA**”) with certain institutional and accredited individual investors (collectively, the “**2022 Investors**”) providing for the issuance and sale by the Company to the 2022 Investors of (i) Senior Secured Convertible Promissory Notes (the “**First Notes**”); (ii) warrants (the “**First Warrants**”) to purchase shares of Common Stock (the “**First Warrant Shares**”); and (iii) shares of Common Stock (the “**First Inducement Shares**”) equal to 15% of the principal amount of the Senior Secured Convertible Promissory Notes divided by the closing price of the Common Stock immediately prior to the First Closing Date (as defined below). The securities were issued as part of a convertible note offering authorized by the Company’s board of directors (the “**2022 Private Placement Financing**”). The first closing of the sales of these securities under the 2022 SPA (the “**First Closing**”) occurred on July 6, 2022 (the “**First Closing Date**”). The Company retained Maxim Group LLC (“**Maxim**”) as placement agent in connection with the First Closing. Pursuant to an engagement agreement the Company entered into with Maxim (the “**2022 Engagement Letter**”), that we entered into with Maxim, we agreed, among other things, to (i) pay Maxim 10% of the gross proceeds in the First Closing from certain institutional investors, or \$240,000, and (ii) issue Maxim, or its designees, warrants (“**First Placement Agent Warrants**”) to purchase up to 10% of the aggregate number of shares sold to the institutional investors in the First Closing, or warrants to purchase up to 31,510 shares of Common Stock.

On January 18, 2023, the Company entered into Amendment No. 1 to the 2022 SPA (the “**Amendment**”), with certain Investors in connection with the second closing of the 2022 Private Placement Financing (the “**Second Closing**”) for the issuance and sale by the Company to such Investors of an aggregate of (i) Unsecured Convertible Promissory Notes (each a “**Second Note**” and collectively, the “**Second Notes**”) in the aggregate principal amount of \$636,000, which includes an aggregate \$106,000 original issue discount in respect of the Second Notes; (ii) warrants (the “**Second Warrants**”) to purchase an aggregate of 127,968 shares of Common Stock at an exercise price of \$9.94 per share (the “**Second Warrant Shares**”); and (iii) 9,598 shares of Common Stock (the “**Second Inducement Shares**”). The aggregate gross proceeds for the sale of the Second Notes, Second Warrants, and Second Inducement Shares was approximately \$530,000, before deducting the placement agent’s fees and other estimated fees and offering expenses payable by the Company of approximately \$15,000. The Second Closing of the sales of these securities under the 2022 SPA, as amended, occurred on January 18, 2023 (the “**Second Closing Date**”). The Company retained Maxim as placement agent in connection with the private placement of \$500,000 of the Second Notes to the institutional investors. Pursuant to the 2022 Engagement Letter, the Company agreed, among other things, to (i) pay Maxim 10% of the gross proceeds in the Second Closing of the 2022 Private Placement Financing from the institutional investors, or \$50,000, and (ii) issue to Maxim, or its designees, warrants (the “**2022 Placement Agent Warrants**”) to purchase up to 10% of the aggregate number of shares sold to the institutional investors in the Second Closing of the Convertible Notes Offering, or warrants to purchase up to 6,565 shares of Common Stock at a price per share equal to \$10.06 (the “**2022 Placement Agent Warrant Shares**”).

On May 15, 2023, the Company entered into Amendment No. 2 to the 2022 SPA related to the 2022 Private Placement Financing (the “**Second Amendment**”) with an Investor in connection with the third closing of the 2022 Private Placement Financing (the “**Third Closing**”) for the issuance and sale by the Company to an Investor of an aggregate of (i) Unsecured Convertible Promissory Notes (each a “**Third Note**” and collectively, the “**Third Notes**”) in the aggregate principal amount of \$702,720, which includes an aggregate \$214,720 original issue discount in respect of the Third Notes; (ii) warrants (the “**Third Warrants**”) to purchase an aggregate of 141,396 shares of Common Stock at an exercise price of \$9.94 per share (the “**Third Warrant Shares**” and together with the Second Warrant Shares, the “**2022 Warrant Shares**”); and (iii) 10,608 shares of Common Stock (the “**Third Inducement Shares**” and together with the Second Inducement Shares, the “**2022 Inducement Shares**”). The aggregate gross proceeds for the sale of the Third Notes, Third Warrants, and Third Inducement Shares was approximately \$488,000, before deducting any estimated fees and offering expenses payable by the Company. The Company did not engage a placement agent in connection with the issuance of the Third Notes, Third Warrants, and Third Inducement Shares. The Third Closing of the sales of these securities under the 2022 SPA, as amended, occurred on May 15, 2023 (the “**Third Closing Date**”).

2022 Notes

The First Notes, Second Notes, and Third Notes (collectively, the “**2022 Notes**”) bear interest on the unpaid principal balance at a rate equal to ten percent (10%) (computed on the basis of the actual number of days elapsed in a 360-day year) per annum accruing from the issuance date until the 2022 Notes become due and payable at maturity or upon their conversion, acceleration or by prepayment, and may become due and payable upon the occurrence of an event of default under the 2022 Notes. The 2022 Notes mature on January 6, 2024. Any amount of principal or interest on the 2022 Notes that is not paid when due shall bear interest at the rate of the lesser of (i) eighteen percent (18%) per annum or (ii) the maximum amount allowed by law from the due date thereof until payment in full.

The 2022 Notes are convertible into shares of Common Stock at the option of each Holder from the date of issuance at \$9.14 (the “**Conversion Price**”), subject to adjustment, through the later of (i) January 6, 2024 (the “**Maturity Date**”) or (ii) the date of payment of the Default Amount (as defined in the 2022 Notes).

The 2022 Notes contain events of default, which include, among other things, (i) the Company's failure to pay when due any principal or interest payment under the 2022 Notes; and (ii) our failure to complete an Uplist Transaction by October 31, 2023.

The First Warrants, Second Warrants, and Third Warrants (collectively, the "**2022 Warrants**") (i) have an exercise price of \$9.94 per share; (ii) have a term of exercise equal to 5 years after their issuance date; (iii) became exercisable immediately after their issuance; and (iv) have a provision preventing the exercisability of such 2022 Warrants if, as a result of the exercise of the 2022 Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of our Common Stock would be aggregated with the holder's, would be deemed to beneficially own more than the Ownership Limitation. As long as the 2022 Notes and 2022 Warrants remain outstanding, upon the issuance of any security in connection with any potential future financing activity on terms more favorable than the existing terms, the Company has an obligation to notify the holders of the 2022 Notes and 2022 Warrants of such more favorable terms, and to use best efforts to effect such terms in the 2022 Notes and 2022 Warrants.

Note Modification Agreements

On July 7, 2023, the Company entered into an amendment ("**Amendment No. 8 to the First Notes**") with the holders of the Company's outstanding First Notes, as separately amended on February 14, 2023, March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 31, 2023, August 30, 2023 and September 30, 2023, issued in connection with the First Closing. On July 7, 2023, the Company also entered into an amendment ("**Amendment No. 8 to the Second Notes**") with the holders of the Company's outstanding Second Notes, as separately amended on February 14, 2023, March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 31, 2023, August 30, 2023 and September 30, 2023, issued in connection with the Second Closing. On July 7, 2023, the Company also entered into an amendment ("**Amendment No. 3 to the Third Notes**") and, together with Amendment No. 8 to the First Notes and Amendment No. 8 to the Second Notes, the "**Amendments to the 2022 Notes**") with the holders of the Company's outstanding Third Notes, as separately amended on June 15, 2023, July 1, 2023, July 31, 2023, August 30, 2023 and September 30, 2023, issued in connection the Third Closing.

Under the Amendments to the 2022 Notes, the following amendments to the 2022 Notes will be simultaneously effective upon the closing of the Uplist Transaction. The Specified Percentage (as defined below) of the then outstanding principal amount of the 2022 Notes shall automatically convert (the "**Automatic Conversion**") into shares of Common Stock (the "**Automatic Conversion Shares**"), with the conversion price for purposes of such Automatic Conversion being equal to the lower of (i) the per unit price at which any units (each unit being comprised of one share or share equivalent and accompanying warrants, if any) are sold in the Uplist Transaction or (ii) the price at which warrants issued in the Uplist Transaction are exercisable (but in no event increased above the conversion price in effect immediately prior to the pricing of the Uplist Transaction).

In addition, if the Holder (as defined below) (i) participates in the Uplist Transaction and in the Bridge Offering for a combined (taking into account the Holder's aggregate investment in the Uplist Transaction and the Bridge Offering) amount equal to no less than fifty percent (50%) of the Holder's original purchase price under the 2022 Notes and (ii) the Holder's amount of participation in the Uplist Transaction is at least 4.3 times the Holder's amount of participation in the Bridge Offering (such criteria in clauses (i) and (ii) above, the "**Participation Criteria**"), then the Holder shall receive a pre-funded warrant (the "**Participating Pre-Funded Warrants**") to purchase a number Conversion Warrant Shares equal to the Specified Number (as defined below) times the dollar amount under the 2022 Notes that was converted in the Automatic Conversion. The Participating Pre-Funded Warrant (i) shall have an exercise price of \$0.001 per share, (ii) may be exercised on a cashless basis, (iii) shall be exercisable by the Holder at any time commencing on the 90th day after issuance, (iv) may be redeemed by the Company for cash at a redemption price of \$0.82 per share underlying the Participating Pre-Funded Warrant, with any such redemption made pro rata to all holders of the Participating Pre-Funded Warrants, (v) and shall contain a customary beneficial ownership limitation provision. Additionally, the holder of the Participating Pre-funded Warrants will agree that, until January 6, 2024, it shall not offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of, or announce the intention to otherwise dispose of, the Participating Pre-Funded Warrant.

"Specified Percentage" means the greater of: (i) the percentage specified by the Company by notice to the 2022 Note holders (the "**Holders**" and each a "**Holder**") at least five business days prior to the closing of the Uplist Transaction, which percentage shall be the percentage necessary to ensure the applicable Nasdaq requirements regarding the Uplist Transaction are satisfied, and (ii) the percentage specified by the Holder by notice to the Company at least three business days prior to the closing of the Uplist Transaction (which percentage may be different for each 2022 Note as determined by each Holder thereof); provided, that in no event shall the Specified Percentage for the 2022 Notes (A) exceed twenty five percent (25%) unless otherwise agreed in writing by the Holder, or (B) exceed fifty percent (50%) unless otherwise agreed in writing by the Company.

“Specified Number” means, if the Specified Percentage is 50%, 2.4, which number shall be increased by 1.6% for each percentage point decrease in the Specified Percentage, such increase being compounded iteratively for each percentage point decrease in the Specified Percentage, with the result rounded to two decimal places.

Additionally, on September 30, 2023, the Company entered into an amendment (“**Amendment No. 11 to the First Notes**”) to the First Notes, an amendment (“**Amendment No. 11 to the Second Notes**”) to the Second Notes and an amendment (“**Amendment No. 6 to the Third Notes**” and, together with Amendment No. 11 to the First Notes and Amendment No. 11 to the Second Notes, the “**September Amendments to the 2022 Notes**”) to the Third Notes. The September Amendments to the 2022 Notes extend the deadline by which the Company must close the Uplist Transaction to October 31, 2023 and provide that upon the Automatic Conversion and to the extent that a Holder’s beneficial ownership would increase over the applicable Ownership Limitation, the Holder will receive pre-funded warrants (the “**2022 Note Conversion Pre-Funded Warrants**”) in lieu of shares of Common Stock otherwise issuable to the Holder in connection with the Automatic Conversion, which 2022 Note Conversion Pre-Funded Warrants shall have an exercise price of \$0.001 per share, may be exercised on a cashless basis, shall be exercisable immediately upon issuance and shall contain a customary beneficial ownership limitation provision (such Common Stock issuable upon exercise of the 2022 Note Conversion Pre-Funded Warrants, the “**2022 Note Conversion Pre-Funded Warrant Shares**”).

Accordingly, it is currently anticipated that the Specified Percentage will be 50%, and thus this prospectus registers: (i) an aggregate of up to 783,564 Automatic Conversion Shares that may be issued upon the Automatic Conversion of an aggregate of \$3,134,250 of principal amount under the 2022 Notes, representing 50% of the \$6,268,501 in principal amount currently outstanding under the 2022 Notes, based on an assumed minimum per unit price at which any units (each unit being comprised of one share or share equivalent and accompanying warrants, if any) are sold in the Uplist Transaction of \$4.00; (ii) an aggregate of up to 783,564 shares of Common Stock that may be issuable upon the exercise of 2022 Note Conversion Pre-Funded Warrants, in the event that the maximum amount of 2022 Note Conversion Pre-Funded Warrants are issued upon the Automatic Conversion of \$3,134,250 of principal amount under the 2022 Notes, representing 50% of the \$6,268,501 in principal amount currently outstanding under the 2022 Notes, based on an assumed minimum per unit price at which any units (each unit being comprised of one share or share equivalent and accompanying warrants, if any) are sold in the Uplist Transaction of \$4.00; and (iii) an aggregate of 7,522,203 shares of Common Stock issuable upon exercise of the Participating Pre-Funded Warrants to be issued upon the Automatic Conversion, assuming that all Holders fulfill the Participation Criteria, based on a Specified Number of 2.4 multiplied by the \$3,134,250 of principal amount converted in the Automatic Conversion.

On July 7, 2023, the Company entered into an amendment (the “**Omnibus Amendment to Notes and Warrants**”) with the Holders of the 2022 Notes, amending the 2022 Notes and the 2022 Warrants issued at each of the First Closing, Second Closing, and Third Closing. Under the Omnibus Amendment to Notes and Warrants, the 2022 Notes and 2022 Warrants were amended (i) to modify the Most Favored Nation provisions therein to exclude the Bridge Offering and (ii) to prohibit the Company from engaging in any capital raising transactions, subject to certain exceptions, until the earlier of (A) July 7, 2027, and (B) the first date on which all Holders hold less than 20% of the original amount of the Participating Pre-Funded Warrants received by each Holder, respectively, in connection with the Automatic Conversion.

Under the registration rights agreement, dated as of May 15, 2023, as amended, (as amended, the **“Second Amended and Restated Registration Rights Agreement”**) the Company is required to file a registration statement registering the securities issued in the Second Closing and Third Closing, including the applicable 2022 Notes and 2022 Warrants, no later than 45 days following the closing of the Uplist Transaction.

We are registering for resale by the selling shareholders named herein (i) up to 146,473 Conversion Shares, (ii) up to 783,564 Automatic Conversion Shares; (iii) the 20,206 2022 Inducement Shares; (iv) up to 269,364 2022 Warrant Shares; (v) up to 783,564 2022 Note Conversion Pre-Funded Warrant Shares; and (vi) up to 6,565 2022 Placement Agent Warrant Shares.

Recent Developments

Bylaw Amendments

On July 18, 2023, the Board approved an amendment to the Amended and Restated Bylaws of the Company (the **“Bylaw Amendment”**), effective immediately. The Bylaw Amendment amended the Amended and Restated Bylaws (i) to allow stockholders of the Company to take action by written consent without a meeting with not less than the minimum number of votes that would be necessary to take such action if the matter was presented at a meeting of stockholders at which all shares entitled to vote thereon were present and voted, subject to certain limitations and (ii) to provide that in the absence of a quorum, the chairman of a stockholder meeting can adjourn the meeting, respectively.

Equity Incentive Plan

Effective August 13, 2023, the Board adopted and approved the Amended and Restated 2023 Equity Incentive Plan (the **“2023 Plan”**) and reserved 455,169 shares of Common Stock for issuance thereunder to employees, officers, directors and consultants of the Company. The stockholders of the Company approved the plan on August 22, 2023. The Plan has a term of 6 years and is intended to replace the Company’s 2013 Stock Incentive Plan, which expired on June 18, 2023.

The general purpose of the 2023 Plan is to provide a means whereby eligible employees, officers, non-employee directors, consultants, advisors, and other individual service providers may develop a sense of proprietorship and personal involvement in the Company’s development and financial success, and to encourage them to devote their best efforts to the Company, thereby advancing the Company’s interests and the interests of stockholders of the Company. The 2023 Plan permits the Company to grant a variety of forms of awards, including stock options, stock appreciation rights, restricted stock, restricted stock units, and dividend equivalent rights, to allow the Company to adapt its incentive compensation program to meet its needs.

In addition, the number of shares of Common Stock available for issuance under the 2023 Plan will automatically increase on October 1st of each fiscal year of the Company commencing with October 1, 2023, and on each October 1 thereafter until the 6th anniversary of the date of the 2023 Plan’s initial adoption by the Board, in an amount equal to five percent (5%) of the total number of shares of Common Stock outstanding on September 30th of the preceding fiscal year. Furthermore, effective at the close of business on the date of the closing (the **“Uplist Date”**) of the public offering in connection with which the Common Stock becomes tradeable on a national exchange and on the first day of each fiscal quarter of the Company thereafter until the earlier of (i) the five-year anniversary of the Uplist Date and (ii) October 31, 2028, the number of shares of Common Stock available for issuance under the 2023 Plan shall automatically increase by an amount equal to fifteen percent (15%) of the incremental number of shares of Common Stock, if any, issued by the Company (x) with respect to the “Bridge Offering,” including without limitation “Pre-Funded Warrant Shares” and “Common Warrant Shares,” the “Uplist Transaction” and/or a “Qualifying Offering” (as such terms are defined in the 2023 Plan), (y) with respect to the Uplist Date, since the date on which the stockholders ratified the 2023 Plan, and (z) with respect to each fiscal quarter thereafter, during the previous fiscal quarter (excluding in each case shares of Common Stock issued pursuant to awards under the 2023 Plan); provided, however, that shares of Common Stock issued in connection with any such Qualifying Offering shall not be taken into account except to the extent, if any, that such shares are issued with respect to shares of Common Stock issued in connection with the Bridge Offering and/or the Uplist Transaction.

The Offering

Common Stock being offered	Up to 94,567,245 shares of Common Stock, including (i) 20,206 Inducement Shares; (ii) up to 146,473 Conversion Shares; (iii) up to 783,564 Automatic Conversion Shares; (iv) up to 269,365 2022 Warrant Shares; (v) up to 783,564 2022 Note Conversion Pre-Funded Warrant Shares; (vi) up to 6,565 2022 Placement Agent Warrant Shares; (vii) 3,344,321 Bridge Shares; (viii) up to 24,853,526 Bridge Warrant Shares; (ix) 56,395,578 Exchange Investor Warrant Shares; (x) up to 441,938 Bridge Placement Agent Warrants; and (xi) up to 7,522,203 Conversion Warrant Shares.
Common Stock outstanding prior to the offering	4,689,446 (as of September 15, 2023)
Common Stock to be outstanding after the offering ⁽¹⁾ :	76,236,837
Use of proceeds	We will not receive any of the proceeds from the sale or other disposition of shares of our Common Stock by the selling stockholders. We may receive proceeds upon exercise for cash of the 2022 Warrants, 2022 Note Conversion Pre-Funded Warrants, 2022 Placement Agent Warrants, Bridge Warrants, Exchange Investor Warrants, Bridge Placement Agent Warrants, and Participating Pre-Funded Warrants in which case such proceeds will be used for general working capital purposes. However, each of the aforementioned warrants contains a cashless exercise provision.
Market for common stock:	Our Common Stock is traded on the QB tier of the OTC Marketplace (“ OTCQB ”) under the symbol “ARTH”. On October 3, 2023, the closing price of our Common Stock was \$1.20 per share.
Risk Factors	See “ Risk Factors ” beginning on page 13 and other information in this prospectus for a discussion of the factors you should consider before you decide to invest in our Common Stock.

- (1) Assumes (a) the full exercise of the 2022 Warrants, 2022 Placement Agent Warrants, Bridge Pre-Funded Warrants, Exchange Investor Warrants, Bridge Placement Agent Warrants and Participating Pre-Funded Warrants; (b) the Automatic Conversion of 50% of the face amount of the 2022 Notes into the maximum amount of Automatic Conversion Shares at the assumed minimum conversion price of \$4.00, and no issuance of any 2022 Note Conversion Pre-Funded Warrants; (c) the issuance of the Exchange Investor Warrants and cancellation of the Common Warrants at the closing of the Uplist Transaction; and (d) the conversion of the remaining 50% of the outstanding amount of the 2022 Notes into 73,236 Conversion Shares at the conversion price of \$9.14 per share. Common Stock outstanding as of September 15, 2023 excludes: (i) options granted to employees, directors and consultants under our 2013 Stock Incentive Plan (the “**2013 Plan**”) to purchase up to an aggregate of 100,900 shares of Common Stock at exercise prices ranging from \$4.00 to \$130.00 per share and with a weighted average exercise price of \$37.57 per share; (ii) 26,283,816 shares of Common Stock issuable upon the exercise of outstanding warrants, having a weighted average exercise price of \$1.36 per share (which includes 18,798,526 Common Warrants that will automatically be cancelled and exchanged for 56,395,578 Exchange Investor Warrants at the closing of an Uplist Transaction); (iii) Series 2 Convertible Notes convertible into 52,917 shares of Common Stock at a conversion price of \$50.00 per share; (iv) 685,846 shares of Common Stock issuable upon conversion of the 2022 Notes at the exercise price of \$9.14 per share; (v) 7,522,203 shares of Common Stock to be issuable upon exercise of the Participating Pre-Funded Warrants expected to be issued at the closing of an Uplist Transaction; (vi) 56,395,578 shares of Common Stock to be issuable upon exercise of the Exchange Investor Warrants expected to be issued at the closing of an Uplist Transaction; and (vii) 455,169 shares of Common Stock reserved for future issuance under the 2023 Plan.

RISK FACTORS

Investment in our securities involves a high degree of risk. You should carefully consider the risks that are summarized below and discussed in greater detail in the following pages, together with the other information contained in this prospectus, including our financial statements and the related notes appearing at the end of this prospectus, before making an investment decision. If any of the following risks and uncertainties actually occur, our business, financial condition, and results of operations could be negatively impacted, and you could lose all or part of your investment.

Risk Factor Summary

- There is substantial doubt about our ability to continue as a going concern, and we believe that our current cash on hand as of September 15, 2023 is not sufficient to meet our anticipated cash requirements through the end of the first quarter of fiscal 2024, and we must obtain additional financing in order to continue to operate the business.
- We have incurred significant losses since inception, we expect to continue to incur losses for the foreseeable future, and we may not generate sufficient revenue to achieve or maintain profitability.
- We will need to raise additional capital, which may not be available to us on acceptable terms, or at all. In addition, the terms of our previous financings could impose additional challenges on our ability to raise funding in the future.
- Our obligations under the First Notes, including our obligation to repay the outstanding balance under the First Notes upon such holder's demand for repayment upon the completion of an Uplist Transaction, are secured by security interests in substantially all of our assets and our failure to comply with the terms and covenants of the First Notes could result in our loss of substantially all of our assets.
- The holders of our 2022 Notes have certain additional rights upon an event of default under such notes, which could harm our business, financial condition, and results of operations and could require us to reduce or cease our operations.
- If we issue additional shares in the future, including issuances of shares upon exercise of our outstanding warrants or conversion of our outstanding convertible notes, our existing stockholders will be significantly diluted and our stock price may be negatively affected.
- If we do not successfully market our products, we will continue to incur losses and will never be profitable.
- Our business may be materially adversely affected by the coronavirus (COVID-19) pandemic. Should the pandemic or its aftereffects continue, our business operations could and will likely be delayed or interrupted.
- Our flagship product is novel without any history of use in the clinical fields in which it is marketed requiring education and training regarding its application to gain and maintain market acceptance by patients, physicians, healthcare payors or others in the medical community.
- Applications for regulatory marketing authorization for commercialization of our additional products or elements of our supply chain may not be accepted, or if accepted, may be voluntarily withdrawn or eventually rejected, and the future success of our business is significantly dependent on the success of our being able to obtain regulatory marketing authorization for our development stage candidates.
- Our additional product candidates are inherently risky because they are based on novel technologies and thus create significant challenges with respect to product development and optimization, engineering, manufacturing, scale-up, quality systems, pre-clinical in vitro and in vivo testing, government regulation and approval, third-party reimbursement and market acceptance.

- Any changes in our supply chain, including to the third-party contract manufacturers, service providers, or other vendors, or in the processes that they employ, could adversely affect us.
- If the FDA or similar foreign agencies or intermediaries impose requirements more onerous than we anticipate, our business could be adversely affected.
- We are subject to extensive and dynamic medical device regulations outside of the United States, which may impede or hinder the approval, marketing authorization or sale of our products and, in some cases, may ultimately result in an inability to obtain approval of certain products or may result in the recall or seizure of previously approved or authorized products.
- Any clinical trials that are planned or are conducted on our flagship product or additional product candidates may not start or may fail. Clinical trials are lengthy, complex and extremely expensive processes with uncertain expenditures and results and frequent failures.
- We cannot market and sell any additional product candidate in the United States or in any other country or region if we fail to obtain the necessary marketing authorization, clearances or certifications from applicable government agencies.
- The flagship product for which we obtained required regulatory marketing authorization is subject to post-approval regulation, and we may be subject to penalties if we fail to comply with such post-approval requirements.
- Use of third parties to manufacture our product and our additional product candidates may increase the risk that preclinical development, clinical development and potential commercialization of our product candidates could be delayed, prevented or impaired.
- We face competition from companies that have greater resources than we do, and we may not be able to effectively compete against these companies.
- If others claim we and/or the parties from whom we license some of our intellectual property are infringing on their intellectual property rights, we may be subject to costly and time-consuming litigation.
- There is not now, and there may not ever be, an active market for our Common Stock, which trades in the over-the-counter market in low volumes and at volatile prices. Although we have applied to list our Common Stock on the Nasdaq Capital Market there is no assurance that our application will be approved.
- Even if the Primary Offering is successful and our application to list our Common Stock and Investor Warrants on the Nasdaq Capital Market or an Alternate Exchange is approved, no assurance can be given that an active trading market for our Common Stock or Investor Warrants will develop or be maintained.

AC5, AC5-G, AC5-V, AC5-P, Crystal Clear Surgery, NanoDrape and NanoBioBarrier and associated logos are trademarks and/or registered trademarks of Arch Therapeutics, Inc. and subsidiary. For purposes herein, references to regulatory approval and marketing authorization may be used interchangeably.

Risks Related to our Business, Financial Position and Capital Requirements

There is substantial doubt about our ability to continue as a going concern. Even if the Primary Offering is successful, we will need additional funding to continue our operations and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts and could cause our business to fail.

We have only recently commenced commercial sales of our first product, AC5 Advanced Wound System, and we have incurred substantial net losses as a result. We believe that our current cash on hand as of September 15, 2023 is sufficient to meet our anticipated cash requirements into the first fiscal quarter of 2024, and we must obtain additional financing in order to continue to operate our business. Even if the Primary Offering is successful, we will need to secure additional resources to support our continued operations.

We have obtained additional cash from debt and equity financings during the last several fiscal quarters to continue operations and fund our planned future operations, which include research and development of our product candidates, steps related to seeking regulatory marketing authorization for our initial product candidates, and planning for their commercialization in the U.S. and Europe. Even with the additional funds received from these financings, there exists substantial doubt about our ability to continue as a going concern. In addition, our plans may change and/or we may use our capital resources more rapidly than we currently anticipate. We presently expect that our expenses will increase in connection with our ongoing activities to support our business operations, inclusive of regulatory submissions, marketing authorization, and commercialization of our product candidates and products, and, therefore, we will require additional funding.

Our future capital requirements will depend on many factors, including:

- the success of our marketing efforts;
- the success of our additional commercialization efforts;
- the scope, progress and results of our research and development collaborations;
- the extent of potential direct or indirect grant funding for our research and development activities;
- the scope, progress, results, costs, timing and outcomes of any regulatory process and clinical trials conducted for any of our product candidates;
- the timing of entering into, and the terms of, any collaboration agreements with third parties relating to any of our product candidates;
- the timing of and the costs involved in obtaining regulatory marketing authorization for our product candidates;
- the costs of operating, expanding and enhancing our operations to support our clinical activities and, if our product candidates are approved, commercialization activities;
- the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities;
- the costs associated with maintaining and expanding our product pipeline;
- the costs associated with expanding our geographic focus;
- operating revenues, if any, received from sales of our product candidates, if any are approved by the FDA or other applicable regulatory agencies;
- the cost associated with being a public company, including obligations to regulatory agencies, and increased investor relations and corporate communications expenses; and
- the costs of additional general and administrative personnel, including accounting and finance, legal and human resources employees.

We intend to obtain additional financing for our business through public or private securities offerings, the incurrence of additional indebtedness, or some combination of those sources. We may also seek funding through collaborative arrangements with strategic partners if we determine them to be necessary or appropriate, although these arrangements could require us to relinquish rights to our technology or product candidates and could result in our receipt of only a portion of any revenues associated with the partnered product. We cannot provide any assurance that additional financing from these sources will be available on favorable terms, if at all.

In addition, we are bound by certain contractual terms and obligations that may limit or otherwise impact our ability to raise additional funding in the near-term including, but not limited to, provisions in the Bridge SPA and the 2022 Notes SPA, associated with the 2022 Notes Financing, in each case as described in greater detail in the risk factor entitled “***The terms of the Bridge Offering and 2022 Notes Financing could impose additional challenges on our ability to raise funding in the future***” below.

These restrictions and provisions could make it more challenging for us to raise capital through the incurrence of additional debt or through future equity issuances. Further, if we do raise capital through the sale of equity, or securities convertible into equity, the ownership of our then existing stockholders would be diluted, which dilution could be significant depending on the price at which we may be able to sell our securities. Also, if we raise additional capital through the incurrence of indebtedness, we may become subject to covenants restricting our business activities, and the holders of debt instruments may have rights and privileges senior to those of our equity investors. Finally, servicing the interest and principal repayment obligations under any debt facilities that we may enter into in the future could divert funds that would otherwise be available to support research and development, clinical or commercialization activities.

If we are unable to obtain adequate financing on a timely basis or on acceptable terms in the future, we would likely be required to delay, reduce or eliminate one or more of our product development activities, which could cause our business to fail.

We have incurred significant losses since inception. We expect to continue to incur losses for the foreseeable future, and we may never increase revenue or achieve or maintain profitability.

As noted above under the risk factor entitled “***There is substantial doubt about our ability to continue as a going concern,***” we have only recently commenced commercial sales of our first product, AC5 Advanced Wound System, and we have incurred substantial net losses as a result. Consequently, we have incurred losses in each year since our inception and we expect that losses will continue to be incurred in the foreseeable future in the operation of our business. To date, we have financed our operations primarily through equity and debt investments by founders, other investors and third parties, and we expect to continue to rely on these sources of funding, to the extent available in the foreseeable future. Losses from operations have resulted principally from costs incurred in research and development programs and from general and administrative expenses, including significant costs associated with establishing and maintaining intellectual property rights, significant legal and accounting costs incurred in connection with both the closing of the Merger and complying with public company reporting and control obligations, and personnel expenses. In addition, we expect to continue to incur additional general and administrative expenses due to the costs associated with being a public company, including obligations to regulatory agencies, and increased investor relations and corporate communications expenses. We have devoted much of our operational effort to date to the research and development of our core technology, including selecting our initial product composition, conducting safety and other related tests, conducting a human trial for safety and performance, developing methods for manufacturing scale-up, reproducibility and validation, and developing and protecting the intellectual property rights underlying our technology platform. We have recently devoted substantially all of our operational effort to continue the ongoing commercialization and market adoption of AC5 Advanced Wound System, our first product.

We expect to continue to incur significant expenses and anticipate that those expenses and losses may increase in the foreseeable future as we:

- commercialize AC5 Advanced Wound System;
- develop our additional product candidates, and the underlying technology, including advancing applications and conducting biocompatibility and other preclinical studies and clinical studies;
- raise capital needed to fund our operations;
- enhance investor relations and corporate communications capabilities;
- conduct clinical trials on products and product candidates;
- attempt to obtain regulatory marketing authorizations for product candidates;
- build relationships with additional contract manufacturing partners, and invest in product and process development through such partners;
- maintain, expand and protect our intellectual property portfolio;
- advance additional product candidates and technologies through our research and development pipeline;
- seek to market selected product candidates, which may require regulatory marketing authorization; and
- hire additional regulatory, clinical, quality control, scientific, financial, and management, consultants and advisors.

To become and remain profitable, we must successfully market AC5 Advanced Wound System and succeed in developing and eventually commercializing other product candidates with significant market potential. This will require us to be successful in a number of challenging activities, including successfully completing preclinical testing and clinical trials of product candidates, obtaining regulatory marketing authorization for our product candidates and manufacturing, marketing and selling any products for which we have or may obtain marketing authorization. We are only in the preliminary stages of many of those activities. We may never succeed in those activities and may never generate sufficient operating revenues to achieve profitability. Even if we do generate operating revenues sufficient to achieve profitability, we may not be able to sustain or increase profitability. Our failure to generate sufficient operating revenues to become and remain profitable would impair our ability to raise capital, expand our business or continue our operations, all of which would depress the price of our Common Stock. A further decline or lack of increase in the price of our Common Stock could cause our stockholders to lose all or a part of their investment in the Company.

The terms of the Bridge Offering and 2022 Notes Financing could impose additional challenges on our ability to raise funding in the future.

The Bridge SPA contains certain restrictions on the Company's ability to conduct subsequent sales of its equity securities and certain business activities. In particular, until July 7, 2024, the Company will be prohibited from effecting or entering into agreements to effect any issuance by the Company, or any of its subsidiaries, of Common Stock or Common Stock equivalents (or a combination of units thereof) involving a variable rate transaction.

The 2022 Notes SPA contains certain restrictions on our ability to conduct subsequent sales of our equity securities and certain business activities. In particular, until the 2022 Notes are paid in full and/or converted in full and the 2022 Warrants are exercised in full, we are prohibited from (i) changing the nature of business, (ii) selling, divesting, acquiring, or changing the structure of any material assets other than in the ordinary course of business; or (iii) negotiating or entering into certain variable rate debt transactions; in each instance without each applicable 2022 Note holder's prior written consent, which shall not be unreasonably withheld. In addition, the 2022 Notes, as amended, prohibit the Company from engaging in any capital raising transactions, subject to certain exceptions, until the earlier of (A) July 7, 2027, and (B) the first date on which all Holders hold less than 20% of the original amount of the Participating Pre-Funded Warrants received by each Holder, respectively, in connection with the Automatic Conversion.

Our obligations under the First Notes are secured by security interests in substantially all of our assets and our failure to comply with the terms and covenants of the First Notes could result in our loss of substantially all of our assets.

Our obligations under the First Notes and the related transaction documents are secured by a security interest in substantially all of our assets. As a result, if we default on our obligations under such First Notes, the First Note holders could foreclose on the security interests and liquidate some or all of our assets, which would harm our business, financial condition and results of operations and could require us to reduce or cease operations.

In connection with the First Closing, the First Note holders were granted a security interest in substantially all of our assets pursuant to the terms of the Security Agreement. If we fail to make payments on the First Notes when due or otherwise comply with the covenants contained in the First Notes, the First Note holders could declare us in default, in which event such holders would have the right to exercise their rights as a secured creditor with respect to our assets that secure the indebtedness, which would force us to suspend operations.

In addition, the 2022 Notes contain customary events of default, which include, among other things, (i) our failure to pay when due any principal or interest payment under the 2022 Notes; (ii) our insolvency; (iii) delisting of our Common Stock; (iv) our breach of any material covenant or other material term or condition under the 2022 Notes; and (v) our breach of any representations or warranties under the 2022 Notes which cannot be cured within five (5) days. Further, events of default under the 2022 Notes also include (i) the unavailability of Rule 144 at certain times; (ii) our failure to deliver the shares of Common Stock to the 2022 Note holder upon exercise by such holder of its conversion rights under the 2022 Notes; (iii) our loss of the "bid" price for our Common Stock and/or a market and such loss is not cured during the specified cure periods; and (iv) our failure to complete an Uplist Transaction by October 31, 2023.

The 2022 Note holders have certain additional rights upon an event of default under such notes, which could harm our business, financial condition, and results of operations and could require us to reduce or cease our operations.

Under the 2022 Notes, the holders have certain rights upon an event of default. Such rights include that, upon an event of default, the 2022 Notes will become immediately due and payable and we will be obligated to pay to each such note holder an amount equal to the Default Premium multiplied by the sum of the outstanding principal amount of such notes plus any accrued and unpaid interest on the unpaid principal amount of such notes to the date of payment, plus any Default Interest and any other amounts owed to the holder under the SPA, or the Default Amount; *provided that*, upon any subsequent event of default not in connection with the first event of default, such holder shall be entitled to an additional 5% to the Default Premium for each subsequent event of default. At the election of each 2022 Note holder, the Default Amount may be paid in cash or shares of Common Stock equal to the Default Amount divided by the \$9.14 (subject to adjustment as more specifically set forth in the 2022 Notes) at the time of payment.

In addition, the 2022 Notes are subject to prepayment penalties, subject to adjustment as a result of certain time-based prepayment premiums set forth in such notes; provided, that, the written consent of the lead investor is not required in connection with a prepayment made from the proceeds of an Uplist Transaction. The 2022 Notes bear interest on the unpaid principal balance at a rate equal to ten percent (10%) (computed on the basis of the actual number of days elapsed in a 360-day year) per annum accruing from July 6, 2022 until such notes become due and payable on the Maturity Date or upon their conversion, acceleration or by prepayment. Any amount of principal or interest on the 2022 Notes which is not paid when due will bear interest at the rate of the lesser of (i) eighteen percent (18%) per annum or (ii) the Default Interest.

We may not have sufficient funds to pay the Default Amount and, as described above, this could trigger rights under the security interest granted to the holders and result in the foreclosure of their security interests and liquidation of some or all of our assets. The exercise of any of these rights upon an event of default could substantially harm our financial condition, substantially dilute our other stockholders and force us to reduce or cease operations and cause our stockholders to lose all or a part of their investment in the Company.

General economic factors may adversely affect our financial performance.

General economic conditions may adversely affect our financial performance. In the United States, changes in interest rates, changes in fuel and other energy costs, weakness in the housing market, inflation or deflation or expectations of either inflation or deflation, higher levels of unemployment, decreases in discretionary consumer spending or consumer demand, unavailability or limitations of consumer credit, higher consumer debt levels or efforts by consumers to reduce debt levels, higher tax rates and other changes in tax laws, overall economic slowdown, changes in consumer desires affecting demand for the products we sell and other economic factors could adversely affect consumer demand for the products we sell, change the mix of products we sell to a mix with a lower average gross margin and result in slower inventory turnover. Higher interest rates, transportation costs, inflation, higher costs of labor, insurance and healthcare, foreign exchange rates fluctuations, higher tax rates and other changes in tax laws, changes in other laws and regulations and other economic factors in the United States or internationally can increase our cost of sales and operating, selling, general and administrative expenses, decrease sales, and otherwise adversely affect our operations and operating results. These factors affect not only our operations, but also the operations of suppliers from whom we purchase goods and services, a condition that can result in an increase in the cost to us of the goods we sell to customers.

The COVID-19 pandemic could continue to affect our suppliers and employees, and cause disruptions in current and future plans for operations and expansion.

The COVID-19 pandemic may continue to directly and indirectly adversely impact our business, financial condition and operating results. The extent to which this will continue will depend on numerous evolving factors that are highly uncertain, rapidly changing and cannot be predicted with precision or certainty at this time.

Our business may continue to be disrupted due to the costs incurred as a result of additional necessary actions and preparedness plans to help ensure the health and safety of our employees and continued operations, including enhanced cleaning processes, protocols designed to implement appropriate social distancing practices, and/or adoption of additional wage and benefit programs to assist employees. We also cannot predict the effect of the COVID-19 pandemic on our supply chain's reliability and costs.

In addition, our business and operations, and the operations of our suppliers, may continue to be adversely affected by the COVID-19 pandemic. The pandemic, including the related response, could cause disruptions due to potential suspension or slowdown of activities at our third-party suppliers, manufacturing delays, or increased prices implemented by our suppliers. The COVID-19 pandemic has disrupted nearly every aspect of the global supply chain, including the manufacturing or delivery of some of the key supplies used in our tests. We currently utilize third parties to, among other things, manufacture raw materials. If any third party involved in the production of our products, product candidates, or raw materials is adversely impacted by restrictions resulting from the coronavirus outbreak, our supply chain may be disrupted, limiting our ability to manufacture products for research and development operations, clinical trials and, in the case of AC5 Advanced Wound System) and AC5 Topical Hemostat, commercialization.

Finally, while we believe that we currently have sufficient supply of our products to continue commercialization efforts, our products and product candidates or the materials contained therein (such as the Active Pharmaceutical Ingredients ("APIs") for our AC5 product line) are manufactured from facilities in areas impacted by the coronavirus, which could result in shortages due to ongoing efforts to address the outbreak. If any of the foregoing were to occur, it could materially adversely affect our future revenues, financial condition, profitability, and cash flows.

Unfavorable global political or economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The global credit and financial markets have experienced severe volatility and disruptions in the past several years. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services.

Geopolitical conflicts could potentially affect our sales and disrupt our operations and could have a material adverse impact on the Company.

Geopolitical conflicts, including the recent war in Ukraine, could adversely impact our operations or those of our customers. The extent to which these events impact our operations and those of our customers will depend on future developments, which are highly uncertain and cannot be predicted with confidence. If the uncertainty surrounding geopolitical conflicts and in the global marketplace continues, or if we, or any of our customers encounter any disruptions to our or their respective operations or facilities, then we or they may be prevented or delayed from effectively operating our or their business, respectively, and the marketing and sale of our products and our financial results could be adversely affected.

Russia's invasion and military attacks on Ukraine have triggered significant sanctions from North American and European leaders. These events are currently escalating and creating increasingly volatile global economic conditions. Related sanctions, export controls or other actions have been or may in the future be initiated by nations including the United States, the European Union or Russia (e.g., potential cyberattacks, disruption of energy flows, etc.), which could adversely affect our business and/or our supply chain and other third parties with whom we conduct business. Furthermore, the current military conflict between Russia and Ukraine could disrupt or otherwise adversely impact our operations and those of third parties upon which we rely. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our operating history may hinder our ability to successfully meet our objectives.

We are transitioning from being strictly a development stage company subject to the risks, uncertainties and difficulties frequently encountered by early-stage companies in evolving markets to a combination commercial stage and development stage company. Our operations to date have been primarily limited to organizing and staffing, developing and securing our technology and undertaking funding preclinical studies of our lead product candidates, and funding one clinical trial. We have not demonstrated our ability to successfully complete large-scale, pivotal clinical trials, reliably obtain regulatory marketing authorizations, manufacture a commercial scale product or arrange for a third-party to do so on our behalf, and we have only recently begun to generate revenue from commercial sales of our first product, AC5 Advanced Wound System, and there can be no assurance that we will be successful in generating increased revenue.

Because of our limited operating history, we have limited insight into trends that may emerge and affect our business, and errors may be made in developing an approach to address those trends and the other challenges faced by development stage companies. Failure to adequately respond to such trends and challenges could cause our business, results of operations and financial condition to suffer or fail. Further, our limited operating history may make it difficult for our stockholders to make any predictions about our likelihood of future success or viability.

If we are not able to attract and retain qualified management and scientific personnel, we may fail to develop our technologies and product candidates.

Our future success depends to a significant degree on the skills, experience and efforts of the principal members of our scientific and management personnel. These members include Terrence Norchi, MD, our President and Chief Executive Officer. The loss of Dr. Norchi or any of our other key personnel could harm our business and might significantly delay or prevent the achievement of research, development or business objectives. Further, our operation as a public company will require that we attract additional personnel to support the establishment of appropriate financial reporting and internal controls systems. Competition for personnel is intense. We may not be able to attract, retain and/or successfully integrate qualified scientific, financial and other management personnel, which could materially harm our business.

If we fail to properly manage any growth we may experience, our business could be adversely affected.

We anticipate increasing the scale of our operations as we seek to develop our product candidates, including hiring and training additional personnel and establishing appropriate systems for a company with larger operations. The management of any growth we may experience will depend, among other things, upon our ability to develop and improve our operational, financial and management controls, reporting systems and procedures. If we are unable to manage any growth effectively, our operations and financial condition could be adversely affected.

We have identified material weaknesses in our internal control over financial reporting. These material weaknesses could continue to adversely affect our ability to report our results of operations and financial condition accurately and in a timely manner. If we fail to enhance appropriate internal controls in the future, we may not be able to report our financial results accurately, which may adversely affect our stock price and our business

Our management is responsible for establishing and maintaining adequate internal control over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with the generally accepted accounting principles generally accepted in the United States of America (“GAAP”). As a public company, we are required, on a quarterly basis, to evaluate the effectiveness of our internal controls and to disclose any changes and material weaknesses identified through such evaluation in those internal controls. Our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and the related regulations regarding our required assessment of our internal controls over financial reporting requires the commitment of significant financial and managerial resources. Internal control over financial reporting has inherent limitations, including human error, the possibility that controls could be circumvented or become inadequate because of changed conditions, and fraud.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Our management identified material weaknesses in our internal control over financial reporting relating to a lack of sufficient resources with an understanding of the technical guidance under GAAP related to accounting for complex financial instruments within the 2022 Notes and certain accounting practices relating to the recording of the insurance premium advanced by a third party. As a result of these material weaknesses, our management concluded that our internal control over financial reporting was not effective as of September 30, 2022.

We are working to remediate the material weaknesses as efficiently and effectively as possible. Accordingly, the Audit Committee in consultation with management has determined that these matters may be best addressed by: (i) reviewing accounting literature and other technical materials to ensure that the appropriate personnel have a full awareness and understanding of the applicable accounting pronouncements and how they are to be implemented; (ii) additional education on new and existing accounting pronouncements and their application and (iii) requiring senior accounting staff and outside consultants with technical accounting experience to review complex transactions to evaluate and approve the accounting treatment of such transactions. Accordingly, the Board has recommended to management and management has agreed that the Company’s accounting staff, including its Chief Financial Officer, undertake additional training on an accelerated basis and that such training, in view of the complexity of certain generally accepted accounting principles and other matters be ongoing and engage third party specialists on an as-needed basis to help supplement the Company’s internal resources.

If we are unable to enhance effective internal controls, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations as a publicly traded company or comply with the requirements of the SEC or the Sarbanes-Oxley Act of 2002. This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our stock, or investigation by regulatory authorities, all of which is exacerbated by the recent determination of a material weakness related to our internal controls over financial reporting as disclosed herein. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our stock and our business.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

We maintain sensitive data pertaining to our Company on our computer networks, including information about our research and development activities, our intellectual property and other proprietary business information. Our internal computer systems and those of third parties with which we contract may be vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures, despite the implementation of security measures. System failures, accidents or security breaches could cause interruptions to our operations, including material disruption of our research and development activities, result in significant data losses or theft of our intellectual property or proprietary business information, and could require substantial expenditures to remedy. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability and our research and development programs could be delayed, any of which would harm our business and operations.

Legal, political and economic uncertainty surrounding the exit of the United Kingdom from the European Union is a source of instability and uncertainty.

Legal, political and economic uncertainty surrounding the exit of the United Kingdom from the European Union (“**Brexit**”) is a source of instability and uncertainty.

The uncertainty concerning the U.K.’s legal, political and economic relationship with the E.U. after the transition period may be a source of instability in the international markets, create significant currency fluctuations, and/or otherwise adversely affect trading agreements or similar cross-border co-operation arrangements (whether economic, tax, fiscal, legal, regulatory or otherwise).

These developments, or the perception that any of them could occur, have had, and may continue to have, a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and limit the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the U.K. financial and banking markets, as well as on the regulatory process in Europe. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility.

If the U.K. and the E.U. are unable to negotiate acceptable trading and customs terms or if other E.U. Member States pursue withdrawal, barrier-free access between the U.K. and other E.U. Member States or among the European Economic Area (“**E.E.A.**”) overall could be diminished or eliminated. The long-term effects of Brexit will depend on any agreements (or lack thereof) between the U.K. and the E.U. and, in particular, any arrangements for the U.K. to retain access to E.U. markets after the transition period. Such a withdrawal from the E.U. is unprecedented, and it is unclear how the U.K. access to the European single market for goods, capital, services and labor within the E.U., or single market, and the wider commercial, legal and regulatory environment, will impact our U.K. operations.

We may also face new regulatory costs and challenges that could have an adverse effect on our operations and development programs. For example, the U.K. could lose the benefits of global trade agreements negotiated by the E.U. on behalf of its members, which may result in increased trade barriers that could make our doing business in the E.U. and the E.E.A. more difficult. There may continue to be economic uncertainty surrounding the consequences of Brexit, which could adversely affect our financial condition, results of operations, cash flows and market price of our Common Stock.

Risks Related to the Development and Commercialization of our Product Candidates

The commercial success of AC5 Advanced Wound System will depend upon the degree of its market acceptance by patients, physicians, healthcare payors and others in the medical community. If AC5 Advanced Wound System does not achieve an adequate level of market acceptance, we may not generate sufficient revenues to achieve or maintain profitability.

AC5 Advanced Wound System is a novel use in the clinical fields in which it is marketed and may not gain or maintain market acceptance by patients, physicians, healthcare payors or others in the medical community. Additionally, we believe that we will need to educate physicians and other healthcare providers about AC5 Advanced Wound System in order for these providers to administer AC5 Advanced Wound System. If we are unsuccessful in educating these practitioners about AC5 Advanced Wound System, we do not expect to achieve an appropriate level of market acceptance for AC5 Advanced Wound System. We could incur substantial and unanticipated additional expense in an effort to increase market acceptance, which would increase the cost of commercializing AC5 Advanced Wound System and could limit its commercial success and result in lower-than-expected revenues. We believe the degree of market acceptance of AC5 Advanced Wound System will depend on a number of factors, including:

- its efficacy and potential advantages over other treatments,
- the extent to which physicians are successful in treating patients with other products or treatments,
- the extent to which physicians and patients experience similar or improved clinical results to that reported on the approved product labeling,
- market acceptance of the cost at which we sell AC5 Advanced Wound System,
- the timing of the release of competitive products or treatments,
- our marketing and sales resources, the quantity of our supplies of AC5 Advanced Wound System and our ability to establish a distribution infrastructure for AC5 Advanced Wound System, and
- whether third-party and government payors cover or reimburse for AC5 Advanced Wound System, and if so, to what extent and in what amount.

If market acceptance of AC5 Advanced Wound System is adversely affected by any of these or other factors, then sales of AC5 Advanced Wound System may be reduced and our business will be materially harmed.

We are seeking reimbursement arrangements with privately managed care organizations and government payors and additional third-party payors. If we are unable to obtain adequate reimbursement from third-party payors, or acceptable prices, for AC5 Advanced Wound System, our revenues and prospects for profitability will suffer.

Our future revenues and ability to become profitable will depend heavily upon the availability of adequate reimbursement for the use of AC5 Advanced Wound System from government-funded and private third-party payors. Reimbursement by a third-party payor depends on a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan,
- safe, effective and medically necessary,
- appropriate for the specific patient,
- cost effective, and
- neither experimental nor investigational.

Obtaining reimbursement approval for AC5 Advanced Wound System from each government-funded and private third-party payor is a time-consuming and costly process, which in some cases requires us to provide to the payor supporting scientific, clinical and cost-effectiveness data for AC5 Advanced Wound System's use. We may not be able to provide data sufficient to gain acceptance with respect to reimbursement.

Even when a third-party payor determines that a product is generally eligible for reimbursement, third-party payors may impose coverage limitations that preclude payment for some product uses that are approved by the FDA or similar authorities or impose patient co-insurance or co-pay amounts that may result in lower market acceptance and which would lower our revenues. Some payors establish prior authorization programs and procedures requiring physicians to document several different parameters, which may impede patient access to therapy. Moreover, eligibility for coverage does not necessarily mean that AC5 Advanced Wound System will be reimbursed in all cases or at a rate that allows us to sell AC5 Advanced Wound System at an acceptable price adequate to make a profit or even cover our costs. If we are not able to obtain coverage and adequate reimbursement promptly from third-party payors for AC5 Advanced Wound System, our ability to generate revenues and become profitable will be compromised.

The scope of coverage and payment policies varies among private third-party payors, including indemnity insurers, employer group health insurance programs and managed care plans. These third-party payors may base their coverage and reimbursement on the coverage and reimbursement rate paid by carriers for Medicare beneficiaries, which are traditionally at a substantially discounted rate. Furthermore, many such payors are investigating or implementing methods for reducing healthcare costs, such as the establishment of capitated or prospective payment systems. Cost containment pressures have led to an increased emphasis on the use of cost-effective products by healthcare providers. If third-party payors do not provide adequate coverage or reimbursement for AC5 Advanced Wound System, it could have a negative effect on our revenues, results of operations and liquidity.

Applications for regulatory marketing authorization for commercialization of our additional product candidates or elements of our supply chain may not be accepted, or if accepted, may be voluntarily withdrawn or eventually rejected, and the future success of our business is significantly dependent on the success of our being able to obtain regulatory marketing authorization for our development stage candidates.

For example, on July 17, 2017, we filed a 510(k) notification with the FDA for AC5 Topical Gel. As previously announced on December 18, 2017, we voluntarily withdrew the submission after receiving a communication from the FDA near the end of the agency's 90-day review period for a final decision on 510(k) notifications. The communication contained questions for which a comprehensive response could not be provided in the limited review time remaining on the submission. Given that it was not possible to respond in the time available, the Company made the decision to withdraw the 510(k) notification but noted at the time that it remained committed to continued collaboration with the FDA to appropriately address the outstanding questions and planned to submit a new 510(k) notification as soon as possible following further discussion with the agency. On March 12, 2018, we announced that we were utilizing the FDA's pre-submission process to submit a proposed development strategy to the FDA to address the agency's comments on our 510(k) notification. As indicated in that March 12, 2018, announcement, we determined that providing additional data to the FDA would be the most expeditious path forward for addressing the FDA's comments, subject to any further comments that we may receive from the FDA.

On May 8, 2018, we announced that the Company would initiate the previously disclosed study designed to address FDA comments on Arch's previous 510(k) notification for our AC5 Topical Gel. The agency provided feedback via the pre-submission process and indicated that the proposed study design was acceptable to support our future marketing application. On June 15, 2018, we further announced that we completed enrollment for our human skin sensitization study and that applications of our AC5 Topical Gel were underway for all subjects.

On October 1, 2018, we announced that the Company submitted a 510(k) notification to the FDA for our AC5 Topical Gel (AC5) and received acknowledgment from the FDA that the submission has been received. On December 17, 2018, we announced that the 510(k) premarket notification for AC5 Topical Gel has been reviewed and cleared by the FDA.

Our business plan is dependent on the success of our development stage product candidates.

Our business is currently focused almost entirely on the development and commercialization of our initial product candidates and products ("AC5 Devices"). Our reliance on AC5 Devices means that, if we are not able to obtain both regulatory marketing authorization and market acceptance of those product candidates, our chances for success will be significantly reduced. We are also less likely to withstand competitive pressures if any of our competitors develop and obtain regulatory marketing authorization for similar products or for products that may be more attractive to the market. Our current dependence on AC5 Devices increases the risk that our business will fail if our development efforts for those products experience delays or other obstacles or are otherwise not successful.

The Chemistry, Manufacturing and Control ("CMC") process for our commercial product and product candidates may be challenging.

Because of the complexity of our lead product candidates, the CMC process, including but not limited to product scale-up activities and cGMP manufacturing for human use, may be difficult to complete successfully within the parameters required by the FDA or its foreign counterparts. Peptide formulation optimization is particularly challenging, and any delays could negatively impact our ability to conduct clinical trials and our subsequent commercialization timeline. Furthermore, we have, and the third parties with whom we may establish relationships may also have, limited experience with attempting to commercialize a self-assembling peptide as a medical device, which increases the risks associated with completing the CMC process successfully, on time, or within the projected budget. Failure to complete the CMC process successfully would impact our ability to complete product development activities, such as conducting clinical trials and submitting applications for regulatory approval, which could affect the long-term viability of our business.

Our AC5 Devices are inherently risky because they are based on novel technologies.

We are subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of AC5 Devices creates significant challenges with respect to product development and optimization, engineering, manufacturing, scale-up, quality systems, pre-clinical in vitro and in vivo testing, government regulation and approval, third-party reimbursement and market acceptance. Our failure to overcome any one of those challenges could harm our operations, commercialization efforts, ability to complete additional clinical trials, and overall chances for success.

Any changes in our supply chain, including to the third-party contract manufacturers, service providers, or other vendors, or in the processes that they employ could adversely affect us.

We are dependent on third parties in our supply chain, including manufacturers, service providers, and other vendors, and the processes that they employ to make major and minor components of our products, and this dependence exposes us to risks associated with regulatory requirements, delivery schedules, manufacturing capability, quality control, quality assurance and costs. We make periodic changes within our supply chain, for example, as our business needs evolve; and/or if a third party does not perform as agreed or desired; and/or if we decide to add an additional manufacturer, service provider, or vendor where we were previously single sourced; and/or if processes are altered to meet evolving scale requirements. For instance, the Company harmonized its U.S. and European product supply chains by adding a supplier and additional manufacturing processes to the list of approved suppliers and processes for the production of AC5 Advanced Wound System that is commercially available in the United States. The Company filed documentation with the FDA related to these supply chain changes and announced on March 23, 2020, that the FDA provided the required clearance to market with the supply chain and manufacturing process changes. We cannot yet provide assurance that the changes or resulting product will prove acceptable to us.

The manufacturing, production, and sterilization methods that we intend to be utilized are detailed and complex and are a difficult process to manage.

We intend to utilize third-party manufacturers to manufacture and sterilize our products. We believe that our proposed manufacturing methods make our choice of manufacturer and sterilizer critical, as they must possess sufficient expertise in synthetic organic chemistry and device manufacturing. If such manufacturers are unable to properly manufacture to product specifications or sterilize our products adequately, that could severely limit our ability to market our products.

Compliance with governmental regulations regarding the treatment of animals used in research could increase our operating costs, which would adversely affect the commercialization of our technology.

The Animal Welfare Act ("AWA") is the federal law that covers the treatment of certain animals used in research. Currently, the AWA imposes a wide variety of specific regulations that govern the humane handling, care, treatment and transportation of certain animals by producers and users of research animals, most notably relating to personnel, facilities, sanitation, cage size, and feeding, watering and shipping conditions. Third parties with whom we contract are subject to registration, inspections and reporting requirements under the AWA. Furthermore, some states have their own regulations, including general anti-cruelty legislation, which establish certain standards in handling animals. Comparable rules, regulations, and/or obligations exist in many foreign jurisdictions. If our contractors or we fail to comply with regulations concerning the treatment of animals used in research, we may be subject to fines and penalties and adverse publicity, and our operations could be adversely affected.

If the FDA or similar foreign agencies or intermediaries impose requirements more onerous than we anticipate, our business could be adversely affected.

The FDA and other regulatory authorities or related bodies separately determine the classification of our products and product candidates. The development plan for our lead product candidates is based on our anticipation of pursuing the medical device regulatory pathway, and in February 2015 we received confirmation from The British Standards Institution (“BSI”), a European notified body (which is a private commercial entity designated by the national government of a European Union (“EU”) member state as being competent to make independent judgments about whether a medical device complies with applicable regulatory requirements), confirmed that AC5 Topical Hemostat fulfills the definition of a medical device within the EU, and it was classified as such in consideration of the CE mark, receipt of which was announced by the Company on April 13, 2020. The FDA also determined AC5 Topical Gel, which was later renamed AC5 Advanced Wound System, to be a medical device. If the FDA or similar foreign agencies or intermediaries deem our products to be a member of a category other than a medical device, such as a drug or biologic, or impose additional requirements on our pre-clinical and clinical development than we presently anticipate, financing needs would increase, the timeline for product approval would lengthen, the program complexity and resource requirements would increase, and the probability of successfully commercializing a product would decrease. Any or all of those circumstances would materially adversely affect our business.

We are subject to extensive and dynamic medical device regulations outside of the United States, which may impede or hinder the approval, or sale of our products and, in some cases, may ultimately result in an inability to obtain approval of certain products or may result in the recall or seizure of products that were previously approved.

In the European Union, we are required to comply with applicable medical device directives, including the Medical Devices Directive, and obtain CE mark in order to market medical device products. The CE mark is applied following approval from an independent notified body or declaration of conformity. As is the case in the United States, the process of obtaining marketing approval or clearance from comparable agencies in foreign countries for new products, or with respect to enhancements or modifications to existing products, could:

- take a significant period of time;
- require the expenditure of substantial resources;
- involve rigorous pre-clinical and clinical testing;
- require extensive post-marketing surveillance;
- require changes to products; and
- result in limitations on the indicated uses of products.

In addition, exported devices are subject to the regulatory requirements of each country to which the device is exported. Most foreign countries possess medical devices regulations and require that they be applied to medical devices before they can be commercialized.

There can be no assurance that we will receive the required approvals for our products on a timely basis or that any approval will not be subsequently withdrawn or conditioned upon extensive post-market study requirements.

Our global regulatory environment is becoming increasingly stringent and unpredictable, which could increase the time, cost and complexity of obtaining marketing authorization for our products, as well as the clinical and regulatory costs of supporting those approvals. Several countries that did not have regulatory requirements for medical devices have established such requirements in recent years and other countries have expanded existing regulations. Certain regulators are exhibiting less flexibility by requiring, for example, the collection of local preclinical and/or clinical data prior to approval. While harmonization of global regulations has been pursued, requirements continue to differ significantly among countries. We expect the global regulatory environment to continue to evolve, which could impact our ability to obtain future approvals for our products and increase the cost and time to obtain such approvals. By way of example, the European Union regulatory bodies recently implemented a new Medical Device Regulation (“MDR”). The MDR changes several aspects of the existing regulatory framework, such as clinical data requirements, and introduces new ones, such as Unique Device Identification (“UDI”). We, and the Notified Bodies who will oversee compliance to the new MDR, face uncertainties in the upcoming years as the MDR is rolled out and enforced, creating risks in several areas, including the CE mark process, data transparency and application review timetables.

If we are not able to secure and maintain relationships with third parties that are capable of conducting clinical trials on our product candidates and support our regulatory submissions, our product development efforts, and subsequent marketing authorization could be adversely impacted.

Our management has limited experience in conducting preclinical development activities and clinical trials. As a result, we have relied and will need to continue to rely on third-party research institutions, organizations and clinical investigators to conduct our preclinical and clinical trials and support our regulatory submissions. If we are unable to reach agreement with qualified research institutions, organizations and clinical investigators on acceptable terms, or if any resulting agreement is terminated prior to the completion of our clinical trials, then our product development efforts could be materially delayed or otherwise harmed. Further, our reliance on third parties to conduct our clinical trials and support our regulatory submissions will provide us with less control over the timing and cost of those trials, the ability to recruit suitable subjects to participate in the trials, and the timing, cost, and probability of success for the regulatory submissions. Moreover, the FDA and other regulatory authorities require that we comply with standards, commonly referred to as good clinical practices (“GCP”), for conducting, recording and reporting the results of our preclinical development activities and our clinical trials, to assure that data and reported results are credible and accurate and that the rights, safety and confidentiality of trial participants are protected. Additionally, both we and any third-party contractor performing preclinical and clinical studies are subject to regulations governing the treatment of human and animal subjects in performing those studies. Our reliance on third parties that we do not control does not relieve us of those responsibilities and requirements. If those third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical development activities or clinical trials in accordance with regulatory requirements or stated protocols, we may not be able to obtain, or may be delayed in obtaining, marketing authorization for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. Any of those circumstances would materially harm our business and prospects.

Any clinical trials that are planned or are conducted on our flagship product and additional product candidates may not start or may fail.

Clinical trials are lengthy, complex and extremely expensive processes with uncertain expenditures and results and frequent failures. While we have completed our first clinical trial in Western Europe, clinical trials that are planned or which have or shall commence for any of our product candidates could be delayed or fail for a number of reasons, including if:

- FDA or other regulatory authorities, or other relevant decision-making bodies do not grant permission to proceed or place a trial on clinical hold due to safety concerns or other reasons;
- sufficient suitable subjects do not enroll, enroll more slowly than anticipated or remain in our trials;
- we fail to produce necessary amounts of the product or product candidate;
- subjects experience an unacceptable rate of efficacy of the product or product candidate;
- subjects experience an unacceptable rate or severity of adverse side effects, demonstrating a lack of safety of the product or product candidate;
- any portion of the trial or related studies produces negative or inconclusive results or other adverse events;
- reports from preclinical or clinical testing on similar technologies and products raise safety and/or efficacy concerns;
- third-party clinical investigators lose their licenses or permits necessary to perform our clinical trials, do not perform their clinical trials on the anticipated schedule or consistent with the clinical trial protocol, GCP or regulatory requirements, or other third parties do not perform data collection and analysis in a timely or accurate manner;
- inspections of clinical trial sites by the FDA or an institutional review board (“IRB”) or other applicable regulatory authorities find violations that require us to undertake corrective action, suspend or terminate one or more testing sites, or

- prohibit us from using some or all of the resulting data in support of our marketing applications with the FDA or other applicable agencies;
- manufacturing facilities of our third-party manufacturers are ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of cGMP or other applicable requirements;
- third-party contractors become debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements;
- the FDA or other regulatory authorities impose requirements on the design, structure or other features of the clinical trials for our product candidates that we and/or our third-party contractors are unable to satisfy;
- one or more IRB refuses to approve, suspends or terminates a trial at an investigational site, precludes enrollment of additional subjects, or withdraws its approval of the trial;
- the FDA or other regulatory authorities seek the advice of an advisory committee of physician and patient representatives that may view the risks of our product candidates as outweighing the benefits;
- the FDA or other regulatory authorities require us to expand the size and scope of the clinical trials, which we may not be able to do; or
- the FDA or other regulatory authorities impose prohibitive post-marketing restrictions on any of our product candidates that attain marketing authorization.

Any delay or failure of one or more of our clinical trials may occur at any stage of testing. Any such delay could cause our development costs to materially increase, and any such failure could significantly impair our business plans, which would materially harm our financial condition and operations.

We cannot market and sell any additional product candidate in the U.S. or in any other country or region if we fail to obtain the necessary marketing authorization, clearances or certifications from applicable government agencies.

We cannot sell our additional product candidates in any country until regulatory agencies grant marketing approval, clearance or other required certification(s). The process of obtaining such approval is lengthy, expensive and uncertain. If we are able to obtain such approvals for our lead product candidate or additional product candidates we may pursue, which we may never be able to do, it would likely be a process that takes many years to achieve.

To obtain marketing approvals in the U.S. for our product candidates, we believe that we must, among other requirements, complete carefully controlled and well-designed clinical trials sufficient to demonstrate to the FDA that the product candidate is safe and effective for each indication for which we seek approval. As described above, many factors could cause those trials to be delayed or to fail.

We believe that the pathway to marketing approval in the U.S. for our lead product candidate for internal use will likely be classified as a Class III medical device and require the process of FDA Premarket Approval (“**PMA**”). This approval pathway can be lengthy and expensive and is estimated to take from one to three years or longer from the time the PMA application is submitted to the FDA until approval is obtained, if approval can be obtained at all.

Similarly, to obtain approval to market our product candidates outside of the U.S., we will need to submit clinical data concerning our product candidates to and receive marketing approval or other required certifications from governmental or other agencies in those countries, which in certain countries includes approval of the price we intend to charge for a product. For instance, in order to obtain the certification needed to market our lead product candidate in the EU, we believe that we will need to obtain a CE mark for the product, which entails scrutiny by applicable regulatory agencies and bears some similarity to the PMA process, including completion of one or more successful clinical trials.

We may encounter delays or rejections if changes occur in regulatory agency policies, if difficulties arise within regulatory or related agencies such as, for instance, any delays in their review time, or if reports from preclinical and clinical testing on similar technology or products raise safety and/or efficacy concerns during the period in which we develop a product candidate or during the period required for review of any application for marketing approval or certification.

Any difficulties we encounter during the approval or certification process for any of our product candidates would have a substantial adverse impact on our operations and financial condition and could cause our business to fail.

We cannot guarantee that we will be able to effectively market our product candidates.

A significant part of our success depends on the various marketing strategies we plan to implement. Our business model has historically focused solely on product development, and we have never attempted to market any product. There can be no assurance as to the success of any such marketing strategy that we develop or that we will be able to build a successful sales and marketing organization. If we cannot effectively market those products we seek to market directly, such products' prospects will be harmed.

AC5 Advanced Wound System and any other product for which we obtain required regulatory marketing authorization are subject to post-approval regulation, and we may be subject to penalties if we fail to comply with such post-approval requirements.

AC5 Advanced Wound System and any other product for which we are able to obtain marketing approval or other required certifications, and for which we are able to obtain approval of the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and comparable foreign regulatory authorities, including through periodic inspections. These requirements include, without limitation, submissions of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents. Maintaining compliance with any such regulations that may be applicable to us or our product candidates in the future would require significant time, attention and expense. Even if marketing approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or other conditions of approval or may contain requirements for costly and time-consuming post-marketing approval testing and surveillance to monitor the safety or efficacy of the product. Discovery after approval of previously unknown problems with any approved product candidate or related manufacturing processes, or failure to comply with regulatory requirements, may result in consequences to us such as:

- restrictions on the marketing or distribution of a product, including refusals to permit the import or export of the product;
- the requirement to include warning labels on the products;
- withdrawal or recall of the products from the market;
- refusal by the FDA or other regulatory agencies to approve pending applications or supplements to approved applications that we may submit;
- suspension of any ongoing clinical trials;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals or certifications; or
- civil or criminal penalties.

If any of our product candidates achieve required regulatory marketing approvals or certifications in the future, the subsequent occurrence of any such post-approval consequences would materially adversely affect our business and operations.

Current or future legislation may make it more difficult and costly for us to obtain marketing approval or other certifications of our product candidates.

In 2007, the Food and Drug Administration Amendments Act of 2007 ("FDAAA") was adopted. This legislation grants significant powers to the FDA, many of which are aimed at assuring the safety of medical products after approval. For example, the FDAAA grants the FDA authority to impose post-approval clinical study requirements, require safety-related changes to product labeling and require the adoption of complex risk management plans. Pursuant to the FDAAA, the FDA may require that a new product be used only by physicians with specialized training, only in specified health care settings, or only in conjunction with special patient testing and monitoring. The legislation also includes requirements for disclosing clinical study results to the public through a clinical study registry, and renewed requirements for conducting clinical studies to generate information on the use of products in pediatric patients. Under the FDAAA, companies that violate these laws are subject to substantial civil monetary penalties. The requirements and changes imposed by the FDAAA, or any other new legislation, regulations or policies that grant the FDA or other regulatory agencies additional authority that further complicates the process for obtaining marketing approval and/or further restricts or regulates post-marketing approval activities, could make it more difficult and more costly for us to obtain and maintain approval of any of our product candidates.

Public perception of ethical and social issues may limit or discourage the type of research we conduct.

Our clinical trials involve human subjects, and third parties with whom we contract also conduct research involving animal subjects. Governmental authorities could, for public health or other purposes, limit the use of human or animal research or prohibit the practice of our technology. Further, ethical and other concerns about our or our third-party contractors' methods, particularly the use of human subjects in clinical trials or the use of animal testing, could delay our research and preclinical and clinical trials, which would adversely affect our business and financial condition.

Use of third parties to manufacture our additional product candidates may increase the risk that preclinical development, clinical development and potential commercialization of our product candidates could be delayed, prevented or impaired.

We have limited personnel with experience in medical device development and manufacturing, do not own or operate manufacturing facilities, and generally lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We currently outsource all or most of the clinical and commercial manufacturing and packaging of our product candidates to third parties. However, we have not established long-term agreements with any third-party manufacturers for the supply of any of our product candidates. There are a limited number of manufacturers that operate under cGMP regulations and that are capable of and willing to manufacture our lead product candidates utilizing the manufacturing methods that are required to produce our product candidates, and our product candidates will compete with other product candidates for access to qualified manufacturing facilities. If we have difficulty locating third-party manufacturers to develop our product candidates for preclinical and clinical work, then our product development programs will experience delays and otherwise suffer. We may also be unable to enter into agreements for the commercial supply of products with third-party manufacturers in the future or may be unable to do so when needed or on acceptable terms. Any such events could materially harm our business.

Reliance on third-party manufacturers entails risks to our business, including without limitation:

- the failure of the third-party to maintain regulatory compliance, quality assurance, and general expertise in advanced manufacturing techniques and processes that may be necessary for the manufacture of our product candidates;
- limitations on supply availability resulting from capacity and scheduling constraints of the third parties;
- failure of the third-party manufacturers to meet the demand for the product candidate, either from future customers or for preclinical or clinical trial needs;
- the possible breach of the manufacturing agreement by the third-party; and
- the possible termination or non-renewal of the agreement by the third-party at a time that is costly or inconvenient for us.

The failure of any of our contract manufacturers to maintain high manufacturing standards could result in harm to clinical trial participants or patients using the products. Such failure could also result in product liability claims, product recalls, product seizures or withdrawals, delays or failures in testing or delivery, cost overruns or other problems that could seriously harm our business or profitability. Further, our contract manufacturers will be required to adhere to FDA and other applicable regulations relating to manufacturing practices. Those regulations cover all aspects of the manufacturing, testing, quality control and recordkeeping relating to our product candidates and any products that we may commercialize in the future. The failure of our third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval or other required certifications of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business, financial condition and operations.

Materials necessary to manufacture our product candidates may not be available on time, on commercially reasonable terms, or at all, which may delay or otherwise hinder the development and commercialization of those products and product candidates.

We rely on the manufacturers of our product and product candidates to purchase from third-party suppliers the materials necessary to produce the compounds for preclinical and clinical studies and may continue to rely on those suppliers for commercial distribution if we obtain marketing approval or other required certifications for any of our product candidates. The materials to produce our products may not be available when needed or on commercially reasonable terms, and the prices for such materials may be susceptible to fluctuations. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently do not have any agreements relating to the commercial production of any of these materials. If these materials cannot be obtained for our preclinical and clinical studies, product testing and potential regulatory marketing authorization of our product candidates will be delayed, which would significantly impact our ability to develop our product candidates and materially adversely affect our ability to meet our objectives and obtain operations success.

We may not be successful in maintaining or establishing collaborations, which could adversely affect our ability to develop and, if required regulatory authorizations are obtained, commercialize our product candidates.

If required regulatory authorizations are obtained to market any of our product candidates, then we may consider entering into additional collaboration arrangements with medical technology, pharmaceutical or biotechnology companies and/or seek to establish strategic relationships with marketing partners for the development, sale, marketing and/or distribution of our products within or outside of the U.S. If we elect to expand our current relationships or seek additional collaborators in the future but are unable to reach agreements with such other collaborators, as applicable, then we may fail to meet our business objectives for the affected product or program. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement, and we may not be successful in our efforts, if any, to establish and implement additional collaborations or other alternative arrangements. The terms of any collaboration or other arrangements that we establish may not be favorable to us, and the success of any such collaboration will depend heavily on the efforts and activities of our collaborators. Any failure to engage successful collaborators could cause delays in our product development and/or commercialization efforts, which could harm our financial condition and operational results.

We compete with other pharmaceutical and medical device companies, including companies that may develop products that make our product and product candidates less attractive or obsolete.

The medical device, pharmaceutical and biotechnology industries are highly competitive. If our product candidates become available for commercial sale, we will compete in that competitive marketplace. There are several products on the market or in development that could be competitors with our lead product candidates. Further, most of our competitors have greater resources or capabilities and greater experience in the development, approval and commercialization of medical devices or other products than we do. We may not be able to compete successfully against them. We also compete for funding with other companies in our industry that are focused on discovering and developing novel improvements in surgical bleeding prevention.

We anticipate that competition in our industry will increase. In addition, the healthcare industry is characterized by rapid technological change, resulting in new product introductions and other technological advancements. Our competitors may develop and market products that render our lead product candidate or any future product candidate we may seek to develop non-competitive or otherwise obsolete. Any such circumstances could cause our operations to suffer.

If we fail to generate market acceptance of our product and product candidates and establish programs to educate and train surgeons as to the distinctive characteristics of our product and product candidates, we will not be able to generate revenues on our product candidates.

Acceptance in the marketplace of AC5 Advanced Wound System and our lead product candidates depends in part on our and our third-party contractors' ability to establish programs for the training of surgeons in the proper usage of those product candidates, which will require significant expenditure of resources. Convincing surgeons to dedicate the time and energy necessary to properly train to use new products and techniques is challenging, and we may not be successful in those efforts. If surgeons are not properly trained, they may ineffectively use our product candidates. Such misuse could result in unsatisfactory patient outcomes, patient injury, negative publicity or lawsuits against us. Accordingly, even if our product candidates are superior to alternative treatments, our success will depend on our ability to gain and maintain market acceptance for those product candidates among certain select groups of the population and develop programs to effectively train them to use those products. If we fail to do so, we will not be able to generate revenue from product sales and our business, financial condition and results of operations will be adversely affected.

The use of our product and product candidates in human subjects may expose us to product liability claims, and we may not be able to obtain adequate insurance or otherwise defend against any such claims.

We face an inherent risk of product liability claims and currently have product liability and clinical trial liability coverage. If claims against us exceed any applicable insurance coverage we may obtain, then our business could be adversely impacted. Regardless of whether we would be ultimately successful in any product liability litigation, such litigation could consume substantial amounts of our financial and managerial resources, which could significantly harm our business.

Risks Related to our Intellectual Property

If we are unable to obtain and maintain protection for intellectual property rights that we own, seek, or have licensed from other parties, the value of our technology and products will be adversely affected.

Our success will depend in large part on our ability to obtain and maintain protection in the U.S. and other countries for the intellectual property rights covering or incorporated into our technology and products. The ability to obtain patents covering technology in the field of medical devices generally is highly uncertain and involves complex legal, technical, scientific and factual questions. We may not be able to obtain and maintain patent protection relating to our technology or products. Many of our owned or licensed patent applications are pending. Even if issued, patents issued or licensed to us may be challenged, narrowed, invalidated, held to be unenforceable or circumvented, or determined not to cover our product candidates or our competitors' products, which could limit our ability to stop competitors from marketing identical or similar products. Because our patent portfolio includes certain patents and applications that are in-licensed on a non-exclusive basis, other parties may be able to develop, manufacture, market and sell products with similar features covered by the same patent rights and technologies, which in turn could significantly undercut the value of any of our product candidates and adversely affect our business. Our licensed MIT European patent No. 1879606 was opposed; however, this patent was maintained in amended form following an administrative hearing. Both parties appealed this decision. MIT granted European patent EP1879606, to which Arch Therapeutics has an exclusive license, was the subject of a hearing at the European Patent Office Board of Appeal (the "**Board of Appeal**") on November 26, 2021 as a result of an appeal by MIT to obtain broader claim scope than was upheld by the European Patent Opposition Division in 2016 and appeals by opponents for the upheld scope to be denied to MIT. At the oral proceedings, in light of concerns expressed by the Board of Appeal, MIT withdrew its appeal and the affected claims, resulting in a formal revocation of the European patent. There is a pending divisional patent application in which the concerns that the Board of Appeal expressed can be addressed. MIT can file further divisional patent applications to seek additional claim scope. There is no guarantee that any divisional patent application will result in a granted patent or that any granted patent will not be opposed and revoked. The Board of Appeal's decision is in relation to the granted European patent EP1879606 and the various national patents that are derived therefrom, and it has no legal significance outside of Europe except in Hong Kong. Further, we cannot be certain that we were the first to make the inventions claimed in the patents we own or license, or that protection of the inventions set forth in those patents was the first to be filed in the U.S. Third parties that have filed patents or patent applications covering similar technologies or processes may challenge our claim of sole right to use the intellectual property covered by the patents we own or exclusively license. Moreover, changes in applicable intellectual property laws or interpretations thereof in the U.S. and other countries may diminish the value of our intellectual property rights or narrow the scope of our patent protection. Any failure to obtain or maintain adequate protection for our intellectual property would materially harm our business, product development programs and prospects. In addition, our proprietary information, trade secrets and know-how are important components of our intellectual property rights. We seek to protect our proprietary information, trade secrets, know-how and confidential information, in part, with confidentiality agreements with our employees, corporate partners, outside scientific collaborators, sponsored researchers, consultants and other advisors. We also have invention or patent assignment agreements with our employees and certain consultants and advisors. If our employees or consultants breach those agreements, we may not have adequate remedies for any of those breaches. In addition, our proprietary information, trade secrets and know-how may otherwise become known to or be independently developed by others. Enforcing a claim that a party illegally obtained and/or for which a party is using our proprietary information, trade secrets and/or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek to defend, enforce and/or determine the scope of our intellectual property rights, and failure to obtain or maintain protection thereof could adversely affect our competitive business position and results of operations.

Many of our owned patent applications are pending, and our patent portfolio includes certain patents and applications that are in-licensed on a non-exclusive basis.

As of September 15, 2023, we either own or license from others a number of U.S. patents, U.S. patent applications, foreign patents and foreign patent applications.

We have also entered into a license agreement with MIT pursuant to which we have been granted exclusive rights under two portfolios of patents and non-exclusive rights under another three portfolios of patents.

The two portfolios exclusively licensed from MIT include approximately 30 patents and pending applications drawn to self-assembling peptides, formulations and methods of use thereof and self-assembling peptidomimetics and methods of use thereof in a total of nine jurisdictions. The portfolios include five issued U.S. patents (US 9,511,113; US 9,084,837; US 10,137,166; US 9,327,010; and US 9,364,513) that expire between 2026 and 2027 (absent any potential patent term extension), as well as additional patents that have been either allowed, issued or granted in foreign jurisdictions.

The portfolios non-exclusively licensed from MIT include a number of US and foreign applications, including three issued U.S. patents (US 7,846,891; US 7,713,923; and US 8,901,084) that expire between 2024 and 2026 (absent any potential patent term extension), as well as additional patents that have been either allowed, issued or granted in foreign jurisdictions.

If we lose certain intellectual property rights owned by third parties and licensed to us, our business could be materially harmed.

We have entered into certain in-license agreements with MIT and with certain other third parties and may seek to enter into additional in-license agreements relating to other intellectual property rights in the future. To the extent we and our product candidates rely heavily on any such in-licensed intellectual property, we are subject to our and the counterparty's compliance with the terms of such agreements in order to maintain those rights. Presently, we, our lead product candidates and our business plans are dependent on the patent and other intellectual property rights that are licensed to us under our license agreement with MIT. Although that agreement has a durational term through the life of the licensed patents, it also imposes or imposed certain diligence, capital raising, and other obligations on us, our breach of which could permit MIT to terminate the agreement. Further, we are responsible for all patent prosecution and maintenance fees under that agreement, and a failure to pay such fees on a timely basis could also entitle MIT to terminate the agreement. Any failure by us to satisfy our obligations under our license agreement with MIT or any other dispute or other issue relating to that agreement could cause us to lose some or all of our rights to use certain intellectual property that is material to our business and our lead product candidates, which would materially harm our product development efforts and could cause our business to fail.

If we infringe or are alleged to infringe the intellectual property rights of third parties, our business and financial condition could suffer.

Our research, development and commercialization activities, as well as any product candidates or products resulting from those activities, may infringe or be accused of infringing a patent or other intellectual property under which we do not hold a license or other rights. Third parties may own or control those patents or other rights in the U.S. or abroad and could bring claims against us that would cause us to incur substantial time, expense, and diversion of management attention. If a patent or other intellectual property infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales, if any, of the applicable product or product candidate that is the subject of the suit. In order to avoid or settle potential claims with respect to any of the patent or other intellectual property rights of third parties, we may choose or be required to seek a license from a third-party and be required to pay license fees or royalties or both. Any such license may not be available on acceptable terms, or at all. Even if we or our future collaborators were able to obtain a license, the rights granted to us or them could be non-exclusive, which could result in our competitors gaining access to the same intellectual property rights and materially negatively affecting the commercialization potential of our planned products. Ultimately, we could be prevented from commercializing one or more product candidates, or be forced to cease some aspects of our business operations, if, as a result of actual or threatened infringement claims, we are unable to enter into licenses on acceptable terms or at all or otherwise settle such claims. Further, if any such claims were successful against us, we could be forced to pay substantial damages. Any of those results could significantly harm our business, prospects and operations.

Risks Related to Ownership of our Common Stock and Investor Warrants

We have pursued an Uplist Transaction by filing an application to list our Common Stock to trade on the Nasdaq Capital Market. We may not satisfy the listing requirements and thereby consummate an Uplist Transaction, including the requirement to have sufficient capital to satisfy our working capital requirements for at least one year, and the minimum bid price requirement to list on the Nasdaq Capital Market. In the event we fail to consummate an Uplist Transaction and list our Common Stock on the Nasdaq Capital Market, such failure may inhibit or preclude our ability to raise additional financing.

We have committed to pursue an Uplist Transaction. Accordingly, we have filed an application to list our Common Stock on the Nasdaq Capital Market. To successfully list our Common Stock, we are required to satisfy certain Nasdaq listing requirements, including having sufficient capital to satisfy our working capital requirements for at least one year, achieving a minimum bid price for our Common Stock, among other requirements relating to stockholder equity, market value of listed securities and number of market makers and stockholders. If we fail to meet any of those requirements, our application to list our Common Stock on the Nasdaq Capital Market will be denied. No assurances can be given that we will satisfy the listing requirements. If our application is not successful, our Board will weigh the available alternatives to successfully consummate an Uplist Transaction and list our Common Stock on the Nasdaq Capital Market. However, there can be no assurance that we will be able to successfully meet such listing requirements. If, for any reason, our listing application is not approved by Nasdaq and we are unable to otherwise consummate an Uplist Transaction on another national securities exchange or take action to successfully list our Common Stock on the Nasdaq Capital Market, our ability to raise additional capital may be adversely affected.

There is not now, and there may not ever be, an active market for our Common Stock, which trades in the over-the-counter market in low volumes and at volatile prices. Even if the Primary Offering is successful and our application to list our Common Stock on the Nasdaq Capital Market or an Alternate Exchange is approved, no assurance can be given that an active trading market for our Common Stock will develop or be maintained.

There currently is a limited market for our Common Stock. Although our Common Stock is quoted on the OTCQB, an over-the-counter quotation system, trading of our Common Stock is extremely limited and sporadic and generally at very low volumes. Further, the price at which our Common Stock may trade is volatile and we expect that it will continue to fluctuate significantly in response to various factors, many of which are beyond our control. The stock market in general, and securities of small-cap companies driven by novel technologies in particular, has experienced extreme price and volume fluctuations in recent years. Continued market fluctuations could result in further volatility in the price at which our Common Stock may trade, which could cause its value to decline. To the extent we seek to raise capital in the future through the issuance of equity, those efforts could be limited or hindered by low and/or volatile market prices for our Common Stock.

We have applied to list our Common Stock on the Nasdaq Capital Market under the symbol “ARTH.” No assurance can be given that our application will be approved or that, if approved, an active trading market for our securities will develop or be maintained. If our Common Stock is not approved for listing on the Nasdaq Capital Market or an Alternate Exchange, we will not complete the Primary Offering. Even if our Common Stock is approved for listing on the Nasdaq Capital Market or an Alternate Exchange, an active trading market for our Common Stock may not develop or be sustained. In the absence of an active trading market for our Common Stock, the ability of our stockholders to sell their securities could be limited. As a result, investors must bear the economic risk of holding their shares of our Common Stock for an indefinite period of time.

Under the 2022 Notes, we are obligated to complete an Uplist Transaction by October 31, 2023 to the Nasdaq Capital Market or an Alternate Exchange. In the event we are unable to uplist our Common Stock, we anticipate that our Common Stock will continue to be quoted on the OTCQB or another over-the-counter quotation system. In those venues, our stockholders may find it difficult to obtain accurate quotations as to the market value of their shares of our Common Stock and may find few buyers to purchase their stock and few market makers to support its price. There is no assurance that our Common Stock will ever be listed on a national securities exchange, that we will be able to comply with or continue to meet such applicable listing standards.

There is not now and may not be an active liquid trading market for our Investor Warrants.

There is no established public trading market for our Investor Warrants. Although we plan to apply to have the Investor Warrants listed on the Nasdaq Capital Market or Alternate Exchange under the symbol “ARTHW,” there is no assurance our application will be approved, or even if it is approved, that a public trading market will develop or if one develops that it will be maintained. Without a public market, the liquidity of the Investor Warrants will remain limited.

Even if our planned Reverse Split achieves the requisite increase in the market price of our Common Stock, there can be no assurance that we will be approved for listing on the Nasdaq Capital Market or an Alternate Exchange or be able to comply with other continued listing standards of the Nasdaq Capital Market or an Alternate Exchange.

On August 22, 2023, the stockholders approved a reverse stock split between 1.5-for-1 to 20-for-1, with the exact ratio to be determined by the Board within 1 year following the date of such approval, and without correspondingly decreasing the number of authorized shares of Common Stock (the “Reverse Split”). Even if our planned Reverse Split increases the market price of our Common Stock sufficiently so that we comply with the minimum market price requirement, no assurance can be given that we will be able to comply with the other standards that we are required to meet in order to be approved for listing on the Nasdaq Capital Market or an Alternate Exchange or maintain a listing of our Common Stock on such exchange. Our failure to meet these requirements prior to listing will result in the Primary Offering not occurring and our failure to meet these requirements following listing may result in our Common Stock being delisted from the Nasdaq Capital Market or an Alternate Exchange.

The Reverse Split may decrease the liquidity of the shares of our Common Stock.

The liquidity of the shares of our Common Stock may be affected adversely by the Reverse Split given the reduced number of shares that will be outstanding following the Reverse Split. In addition, the Reverse Split may increase the number of stockholders who own odd lots (less than 100 shares) of our Common Stock, creating the potential for such stockholders to experience an increase in the cost of selling their shares and greater difficulty affecting such sales.

We intend to pursue an Uplist Transaction and have submitted an application to list our Common Stock to trade on the Nasdaq Capital Market. We may not satisfy the listing requirements including the requirement to have sufficient capital to satisfy our working capital requirements for at least one year, the market value of listed securities requirement and the minimum bid price requirement to list on the Nasdaq Capital Market and therefore may not consummate an Uplist Transaction. In the event we fail to consummate an Uplist Transaction and list our Common Stock on the Nasdaq Capital Market, such failure may inhibit or preclude our ability to raise additional financing.

We have committed to pursue an Uplist Transaction. Accordingly, we have submitted an application to list our Common Stock on the Nasdaq Capital Markets. To successfully list our Common Stock, we are required to satisfy certain Nasdaq listing requirements, including having sufficient capital to satisfy our working capital requirements for at least one year, achieving a minimum bid price for our Common Stock, among other requirements relating to stockholder equity, market value of listed securities and number of market makers and stockholders. If we fail to meet any of those requirements, our application to list our Common Stock on the Nasdaq Capital Market will be denied. No assurances can be given that we will satisfy the listing requirements. If our application is not successful, our Board of Directors will weigh the available alternatives to successfully consummate an Uplist Transaction and list our Common Stock on the Nasdaq Capital Market. However, there can be no assurance that we will be able to successfully meet such listing requirements. If, for any reason, our listing application is not approved by Nasdaq and we are unable to otherwise consummate an Uplist Transaction on another national securities exchange or take action to successfully list our Common Stock on the Nasdaq Capital Market, our ability to raise additional capital may be adversely affected.

If the Primary Offering is successful, we will be subject to the continued listing requirements of the Nasdaq Capital Market or an Alternate Exchange. If we are unable to comply with such requirements, our Common Stock and Investor Warrants would be delisted from the Nasdaq Capital Market or such Alternate Exchange, which would limit investors' ability to effect transactions in our Common Stock and Investor Warrants and subject us to additional trading restrictions.

Even if the Primary Offering is successful and our application to list our Common Stock and Investor Warrants on the Nasdaq Capital Market or an Alternate Exchange is approved, if we fail to meet the Nasdaq Capital Market or such Alternate Exchange continued listing requirements, including stockholder equity requirements, our Common Stock and Investor Warrants could be subject to delisting by the Nasdaq Capital Market or such Alternate Exchange, which could reduce the liquidity of our Common Stock and Investor Warrants materially and result in a corresponding material reduction in the price of our Common Stock and Investor Warrants. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and business development opportunities. Such a delisting likely would impair your ability to sell or purchase our Common Stock and Investor Warrants when you wish to do so. Further, if we were to be delisted from the Nasdaq Capital Market or an Alternate Exchange, our Common Stock and Investor Warrants would no longer be recognized as a "covered security" and we would be subject to regulation in each state in which we offer our securities. Thus, delisting from the Nasdaq Capital Market or an Alternate Exchange could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly impact the ability of investors to trade our securities and would negatively impact the value and liquidity of our Common Stock and Investor Warrants.

Our Common Stock may experience extreme stock price volatility unrelated to our actual or expected operating performance, financial condition or prospects, making it difficult for prospective investors to assess the rapidly changing value of our Common Stock.

Recently, there have been instances of extreme stock price run-ups followed by rapid price declines and strong stock price volatility with a number of recent initial public offerings, especially among companies with relatively smaller public floats. As a relatively small-capitalization company with relatively small public float, we may experience greater stock price volatility, extreme price run-ups, lower trading volume and less liquidity than large-capitalization companies. In particular, our Common Stock may be subject to rapid and substantial price volatility, low volumes of trades and large spreads in bid and ask prices. Such volatility, including any stock-run up, may be unrelated to our actual or expected operating performance, financial condition or prospects, making it difficult for prospective investors to assess the rapidly changing value of our Common Stock.

In addition, if the trading volumes of our Common Stock are low, persons buying or selling in relatively small quantities may easily influence prices of our Common Stock. This low volume of trades could also cause the price of our Common Stock to fluctuate greatly, with large percentage changes in price occurring in any trading day session. Holders of our Common Stock may also not be able to readily liquidate their investment or may be forced to sell at depressed prices due to low volume trading. If high spreads between the bid and ask prices of our Common Stock exist at the time of a purchase, the stock would have to appreciate substantially on a relative percentage basis for an investor to recoup their investment. Broad market fluctuations and general economic and political conditions may also adversely affect the market price of our Common Stock.

As a result of this volatility, investors may experience losses on their investment in our Common Stock. A volatile market price of our Common Stock also could adversely affect our ability to issue additional shares of Common Stock or other securities and our ability to obtain additional financing in the future.

Substantial future sales of our shares of Common Stock or rights to purchase shares of our Common Stock, or the perception that such sales could occur, could cause the market price of our Common Stock to decline, even if our business is doing well.

As noted above under the risk factor entitled, ***“There is substantial doubt about our ability to continue as a going concern. Even if the Primary Offering is successful, we will need additional funding to continue our operations and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts and could cause our business to fail.”*** Sales of substantial amounts of our Common Stock in the public market or the perception that such sales could occur, could adversely affect the trading price of our Common Stock, and may make it more difficult for you to sell your Common Stock at a time and price that you deem appropriate. We are unable to predict the effect that such sales may have on the prevailing price of our Common Stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

We, our directors and executive officers have entered into or will enter into lock-up agreements with the underwriter of the Primary Offering pursuant to which they and we have agreed, or will agree, that, subject to certain exceptions, we will not issue or offer, and they will not sell, contract to sell, encumber, grant any option for the sale of, or otherwise dispose of any shares or any securities convertible into or exchangeable for shares of our Common Stock for a period of 6 months after the offering is completed. Sales of a substantial number of such shares upon expiration of, or the perception that such sales may occur, or early release of the securities subject to, the lock-up agreements, could cause our stock price to fall or make it more difficult for you to sell your Common Stock at a time and price that you deem appropriate. A decline in the price of our Common Stock might impede our ability to raise capital through the issuance of additional Common Stock or other equity securities.

In addition, in the future, we may issue additional shares of Common Stock, warrants or other equity or debt securities convertible into Common Stock in one or more transactions, at prices and in a manner we determine from time to time, in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our Common Stock or warrants to decline.

If we issue additional shares in the future, including issuances of shares upon exercise of our outstanding warrants and convertible notes, our existing stockholders will be significantly diluted.

As of September 21, 2023, our articles of incorporation authorize the issuance of up to 350,000,000 shares of Common Stock. The issuance of shares of our Common Stock upon the exercise of our outstanding warrants or conversion of outstanding convertible notes, summarized below, could result in substantial dilution to our stockholders, which may have a negative effect on the price of our Common Stock.

As of September 15, 2023, there were issued and outstanding: (i) options granted to employees, directors and consultants under our 2013 Plan to purchase up to an aggregate of 100,900 shares of Common Stock at exercise prices ranging from \$4.00 to \$130.00 per share and with a weighted average exercise price of \$37.57 per share; (ii) 26,283,816 shares of Common Stock issuable upon the exercise of outstanding warrants, having a weighted average exercise price of \$1.36 per share (which includes 18,798,526 Common Warrants that will automatically be cancelled and exchanged for 56,395,578 Exchange Investor Warrants at the closing of an Uplist Transaction); (iii) Series 2 Convertible Notes convertible into 52,917 shares of Common Stock at a conversion price of \$50.00 per share; (iv) 685,846 shares of Common Stock issuable upon conversion of the 2022 Notes at the exercise price of \$9.14 per share; (v) 7,522,203 shares of Common Stock to be issuable upon exercise of the Participating Pre-Funded Warrants expected to be issued at the closing of an Uplist Transaction; (vi) 56,395,578 shares of Common Stock to be issuable upon exercise of the Exchange Investor Warrants expected to be issued at the closing of an Uplist Transaction; and (vii) 455,169 shares of Common Stock reserved for future issuance under the 2023 Plan.

Additionally, the numbers issuable under the 2023 Plan will increase by specific amounts, as described above under **“Prospectus Summary—Recent Developments—Equity Incentive Plan.”** Any future grants of options, warrants or other securities exercisable or convertible into our Common Stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our Common Stock.

In addition to capital raising activities, other possible business and financial uses for our authorized Common Stock include, without limitation, future stock splits, acquiring other companies, businesses or products in exchange for shares of Common Stock, issuing shares of our Common Stock to partners in connection with strategic alliances, attracting and retaining employees by the issuance of additional securities under our various equity compensation plans, compensating consultants by issuing shares or options to purchase shares of our Common Stock, or other transactions and corporate purposes that our Board deems are in the Company's best interest. Additionally, shares of Common Stock could be used for anti-takeover purposes or to delay or prevent changes in control or management of the Company. We cannot provide assurances that any issuances of Common Stock will be consummated on favorable terms or at all, that they will enhance stockholder value, or that they will not adversely affect our business or the trading price of our Common Stock. The issuance of any such shares will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our Common Stock. If we issue any such additional shares, such issuance will reduce the proportionate ownership and voting power of all current stockholders. Further, such issuance may result in a change of control of our Company.

We are a smaller reporting company, and we cannot be certain if the reduced disclosure requirements applicable to smaller reporting companies will make our Common Stock less attractive to investors.

We are currently a “smaller reporting company”, meaning that we are not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent company that is not a smaller reporting company and we either have a public float of less than \$250 million as of the last business day of our second fiscal quarter or annual revenues of less than \$100 million during our most recently completed fiscal year and a public float of less than \$700 million. Smaller reporting companies are able to provide simplified executive compensation disclosures in their filings; are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting; and have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports and in a registration statement under the Exchange Act on Form 10. Decreased disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects.

Financial Industry Regulatory Authority (“FINRA”) sales practice requirements may limit a stockholder’s ability to buy and sell our stock.

In addition to the “penny stock” rules described above, FINRA has adopted rules that require that, in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA has indicated its belief that there is a high probability that speculative low-priced securities will not be suitable for at least some customers. These FINRA requirements make it more difficult for broker-dealers to recommend that at least some of their customers buy our Common Stock, which may limit the ability of our stockholders to buy and sell our Common Stock and could have an adverse effect on the market for our shares.

There may be additional risks because we completed a reverse merger transaction in June 2013.

Additional risks may exist because we completed a “reverse merger” transaction in June 2013. Securities analysts of major brokerage firms may not provide coverage of the Company because there may be little incentive to brokerage firms to recommend the purchase of our Common Stock. There may also be increased scrutiny by the SEC and other government agencies and holders of our securities due to the nature of the transaction, as there has been increased focus on transactions such as the Merger in recent years. Further, since the Company existed as a “shell company” under applicable rules of the SEC up until the closing of the Merger on June 26, 2013, there will be certain restrictions and limitations on the Company going forward relating to any potential future issuances of additional securities to raise funding and compliance with applicable SEC rules and regulations.

The elimination of monetary liability against our directors and officers under Nevada law and the existence of indemnification rights held by our directors, officers and employees may result in substantial expenditures by us and may discourage lawsuits against our directors, officers and employees.

Our articles of incorporation eliminate the personal liability of our directors and officers to our Company and our stockholders for damages for breach of fiduciary duty as a director or officer to the extent permissible under Nevada law. Further, our amended and restated bylaws provide that we are obligated to indemnify any of our directors or officers to the fullest extent authorized by Nevada law and, subject to certain conditions, advance the expenses incurred by any director or officer in defending any action, suit or proceeding prior to its final disposition.

Those indemnification obligations could result in our Company incurring substantial expenditures to cover the cost of settlement or damage awards against our directors or officers, which we may be unable to recoup. These provisions and resultant costs may also discourage us from bringing a lawsuit against any of our current or former directors or officers for breaches of their fiduciary duties and may similarly discourage the filing of derivative litigation by our stockholders against our directors and officers even if such actions, if successful, might otherwise benefit us or our stockholders.

We are subject to the reporting requirements of federal securities laws, compliance with which involves significant time, expense and expertise.

We are a public reporting company in the U.S., and, accordingly, are subject to the information and reporting requirements of the Exchange Act and other federal securities laws, including the obligations imposed by the Sarbanes-Oxley Act. The costs associated with preparing and filing annual, quarterly and current reports, proxy statements and other information with the SEC in the ordinary course, as well as preparing and filing audited financial statements, has caused, and could continue to cause, our operational expenses to remain at higher levels or continue to increase.

Shares of our Common Stock that have not been registered under federal securities laws are subject to resale restrictions imposed by Rule 144. In addition, any shares of our Common Stock that are held by affiliates, including any that are registered, will be subject to the resale restrictions of Rule 144.

Rule 144 imposes requirements on us and our stockholders that must be met in order to effect a sale thereunder. As a result, it will be more difficult for us to raise funding to support our operations through the sale of debt or equity securities unless we agree to register such securities under the Securities Act, which could cause us to expend significant additional time and cash resources and which we presently have no intention to pursue. Further, it may be more difficult for us to compensate our employees and consultants with our securities instead of cash. We were a shell company prior to the closing of the Merger, and such status could also limit our use of our securities to pay for any acquisitions we may seek to pursue in the future (although none are currently planned) and could cause the value of our securities to decline. In addition, any shares held by affiliates, including shares received in any registered offering, will be subject to certain additional requirements in order to effect a sale of such shares under Rule 144.

We do not intend to pay cash dividends on our Common Stock in the foreseeable future.

We have never declared or paid any dividends on our shares and do not anticipate paying any such dividends in the foreseeable future. Any future payment of cash dividends would depend on our financial condition, contractual restrictions, solvency tests imposed by applicable corporate laws, results of operations, anticipated cash requirements and other factors and will be at the discretion of our Board.

The market price of our Common Stock may be volatile which could subject us to securities class action litigation.

The market price for our Common Stock has been and may continue to be volatile and subject to wide fluctuations in response to factors including the following:

- sales or potential sales of substantial amounts of our Common Stock;
- delay or failure in initiating or completing preclinical or clinical trials or unsatisfactory results of these trials;
- announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions;
- developments concerning our product manufacturers;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- conditions in the pharmaceutical or biotechnology industries;
- governmental regulation and legislation;
- variations in our anticipated or actual operating results;
- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations; foreign currency values and fluctuations; and
- overall economic conditions.

In the past, securities class action litigation has been brought against companies following periods of volatility of its securities in the marketplace. The stock markets in general, and the market for pharmaceutical and biotechnology companies in particular, have historically experienced extreme price and volume fluctuations. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors could reduce the market price of our Common Stock, regardless of our actual operating performance. Due to the volatility of our stock price, we could be the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources.

SELLING STOCKHOLDERS

The Common Stock being offered by the selling stockholders are the Inducement Shares, Bridge Shares, and those issuable to the selling stockholders, upon conversion of the 2022 Notes and exercise of the 2022 Warrants, 2022 Note Conversion Pre-Funded Warrants, 2022 Placement Agent Warrants, Bridge Warrants, Exchange Investor Warrants, Bridge Placement Agent Warrants, and Participating Pre-Funded Warrants. For additional information regarding the issuances of Inducement Shares, Bridge Shares, 2022 Notes, 2022 Warrants, 2022 Note Conversion Pre-Funded Warrants, 2022 Placement Agent Warrants, Bridge Warrants, Exchange Investor Warrants, Bridge Placement Agent Warrants, and Participating Pre-Funded Warrants, see “**The Transactions**” above. We are registering the shares of Common Stock in order to permit the selling stockholders to offer the shares for resale from time to time. Except for Terrence Norchi, our Chief Executive Officer; Michael Abrams, our Chief Financial Officer; Laurence Hicks, a member of our Board and holder of an ownership interest in Drake Partners LLC, Maxim Group LLC and Dawson James Securities, Inc. and its designees, the selling stockholders have not had any material relationship with us within the past three years.

The table below lists the selling stockholders and other information regarding the beneficial ownership of the shares of Common Stock by each of the selling stockholders. The second column lists the number of shares of Common Stock beneficially owned by each selling stockholder, based on its ownership of the shares of Common Stock and warrants, as of September 15, 2023, assuming exercise of the warrants and conversion of convertible notes held by the selling stockholders on that date, without regard to any limitations on exercises. The third column lists the shares of Common Stock being offered by this prospectus by the selling stockholders.

In accordance with the terms of (i) Second Amended and Restated Registration Rights Agreement with certain of the selling stockholders or (ii) the terms of the 2022 Notes, 2022 Warrants and 2022 Placement Agent Warrants held by certain of the selling stockholders, this prospectus generally covers the resale of the sum of (A) the maximum number of shares of Common Stock issuable upon conversion of the 2022 Notes issued to the selling stockholders in the 2022 Private Placement Financing; and (B) the maximum number of shares of Common Stock issuable upon exercise of the 2022 Warrants and 2022 Placement Agent Warrant, determined as if the outstanding 2022 Notes were converted and the 2022 Warrants and 2022 Placement Agent Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the Second Amended and Restated Registration Rights Agreement, 2022 Note, 2022 Warrant or 2022 Placement Agent Warrant, as applicable, without regard to any limitations on the conversion of the 2022 Notes or the exercise of the 2022 Warrants and 2022 Placement Agent Warrants.

In accordance with the terms of (i) Bridge Registration Rights Agreement with certain of the selling stockholders or (ii) the terms of the Bridge Warrants, Exchange Investor Warrants, and Bridge Placement Agent Warrants held by certain of the selling stockholders, this prospectus generally covers the resale of the sum of the maximum number of shares of Common Stock issuable upon exercise of the Bridge Warrants, Exchange Investor Warrants, and Bridge Placement Agent Warrants determined as if the outstanding Bridge Warrants, Exchange Investor Warrants, and Bridge Placement Agent Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the Bridge Registration Rights Agreement, Bridge Warrants, Exchange Investor Warrants, and Bridge Placement Agent Warrants, as applicable, without regard to any limitations on the exercise of the Bridge Warrants, Exchange Investor Warrants, and Bridge Placement Agent Warrants.

Additionally, this prospectus generally covers the resale of the sum of the maximum number of shares of Common Stock issuable upon exercise of the Participating Pre-Funded Warrants and 2022 Note Conversion Pre-Funded Warrants determined as if the outstanding Participating Pre-Funded Warrants and 2022 Note Conversion Pre-Funded Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the Participating Pre-Funded Warrants and 2022 Note Conversion Pre-Funded Warrants, as applicable, without regard to any limitations on the exercise of Participating Pre-Funded Warrants and 2022 Note Conversion Pre-Funded Warrants. The fourth column assumes the sale of all of the shares offered by the selling stockholders pursuant to this prospectus.

Under the terms of the 2022 Notes, 2022 Warrants, 2022 Placement Agent Warrants, Bridge Warrants, Exchange Investor Warrants, Bridge Placement Agent Warrants, Participating Pre-Funded Warrants and 2022 Note Conversion Pre-Funded Warrants a selling stockholder may not convert the notes or exercise the warrants to the extent such exercise would cause such selling stockholder, together with its affiliates and attribution parties, to beneficially own a number of shares of Common Stock which would exceed 4.99% (or 9.99% if elected and as applicable) of our then outstanding Common Stock following such exercise, excluding for purposes of such determination shares of Common Stock issuable upon conversion of the 2022 Notes and exercise of the 2022 Warrants, 2022 Placement Agent Warrants, Bridge Warrants, Exchange Investor Warrants, Bridge Placement Agent Warrants, Participating Pre-Funded Warrants and 2022 Note Conversion Pre-Funded Warrants which have not been exercised. The number of shares in the second column does not reflect this limitation. The selling stockholders may sell all, some or none of their shares in this offering. See “**Plan of Distribution**” on page 46.

Name of Selling Shareholder	Number of shares of Common Stock Owned Prior to Offering	Maximum Number of shares of Common Stock to be Sold Pursuant to this Prospectus	Number of shares of Common Stock Owned After Offering
Oasis Capital, LLC (1)	847,954	14,919,209	266,504
District 2 Capital Fund LP (2)	314,322	6,835,440	130,432
Bigger Capital Fund, LP (3)	315,352	6,835,422	130,947
Cavalry Fund I LP (4)	431,869	12,360,361	108,052
Sanibel Island Associates LLC (Anestis) (5)	38,003	293,583	13,508
Michael & Ana Parker (6)	451,849	3,845,144	259,571
ProActive Capital Partners, L.P. (7)	108,386	960,614	39,775
Michael Abrams (8)	23,195	144,828	12,903
Jason Adelman (9)	36,793	289,656	16,209
Centurion Therapeutics, Inc. (10)	20,261	130,500	20,261
Drake Partners LLC (11)	21,902	144,828	11,610
Terrence Norchi (12)	113,194	96,558	106,332
Michael Tuttle (13)	27,014	174,000	27,014
Trina Whitridge GST Trust (14)	123,065	1,064,989	39,775
Mark Woolfson (15)	45,990	362,061	20,261
Steve Woolfson (16)	52,122	410,340	22,962
Walleye Opportunities Master Fund Ltd (17)	300,000	11,486,502	-
Sixth Borough Capital Fund, LP (18)	300,000	3,274,821	-
Brandt Wilson and Mona Wilson (19)	300,000	11,486,502	-
Andrew Stahl (20)	300,000	11,486,502	-
John Robert Baleno (21)	72,727	654,543	-
Roxanne Rosetto (22)	36,364	327,276	-
Robert Forster (23)	181,818	1,636,362	-
Thomas Pilgrim (24)	72,727	654,543	-
Rajiv P Dewan (25)	40,000	360,000	-
David L McClain (26)	20,000	180,000	-
Norman McClain (27)	40,000	360,000	-
Ronald Nash (28)	36,364	327,276	-
Richard Molinsky (29)	54,545	490,905	-
George Benashvili (30)	10,300	92,700	-
Dan Armstrong (31)	72,727	654,543	-
CNP Consulting (32)	14,000	126,000	-
Ivan Chi Vei Tong (33)	20,000	180,000	-
Genmark Holdings (34)	72,727	654,543	-
Stephen Ross (35)	18,182	163,638	-
Efrat Investments (36)	36,364	327,276	-
Daniel Shalhoub (37)	18,182	163,638	-
Jeffrey and Shiela Negus (38)	18,182	163,638	-
Maxim Group LLC (39)	38,075	6,565	31,510
Dawson James Securities, Inc. (40)	-	260,040	-
Robert D. Keyser, Jr. (41)	-	97,971	-
James Hopkins (42)	-	83,927	-
Total	5,044,555	94,567,245	1,257,626

1. Assuming exercise or conversion of the warrants or convertible notes held by Oasis Capital, LLC (“**Oasis**”) or its affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Oasis may be deemed to have beneficial ownership of 14,919,209 shares of Common Stock, which consists of the following: (i) 14,381 Inducement Shares; (ii) 271,132 Bridge Shares; (iii) 104,239 Conversion Shares; (iv) 269,090 Automatic Conversion Shares; (v) 191,698 2022 Warrant Shares; (vi) 269,090 2022 Note Conversion Pre-Funded Warrant Shares; (vii) 2,552,766 Common Warrant Shares; (viii) 1,005,251 Bridge Pre-Funded Warrant Shares; (ix) 7,658,298 Exchange Investor Warrant Shares; and (x) 2,583,264 Conversion Warrant Shares.
2. Assuming exercise or conversion of the warrants or convertible notes held by District 2 Capital Fund LP (“**District 2**”) or its affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, District 2 may be deemed to have beneficial ownership of 6,835,440 shares of Common Stock, which consists of the following: (i) 1,886 Inducement Shares; (ii) 143,176 Bridge Shares; (iii) 13,677 Conversion Shares; (iv) 90,625 Automatic Conversion Shares; (v) 25,151 2022 Warrant Shares; (vi) 90,625 2022 Note Conversion Pre-Funded Warrant Shares; (vii) 1,276,328 Common Warrant Shares; (viii) 494,988 Bridge Pre-Funded Warrant Shares; (ix) 3,828,984 Exchange Investor Warrant Shares; and (x) 870,000 Conversion Warrant Shares.
3. Assuming exercise or conversion of the warrants or convertible notes held by Bigger Capital Fund, LP (“**Bigger Capital**”) or its affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Bigger Capital may be deemed to have beneficial ownership of 6,835,422 shares of Common Stock, which consists of the following: (i) 1,886 Inducement Shares; (ii) 143,691 Bridge Shares; (iii) 13,677 Conversion Shares; (iv) 90,625 Automatic Conversion Shares; (v) 25,151 2022 Warrant Shares; (vi) 90,625 2022 Note Conversion Pre-Funded Warrant Shares; (vii) 1,276,324 Common Warrant Shares; (viii) 494,471 Bridge Pre-Funded Warrant Shares; (ix) 3,828,972 Exchange Investor Warrant Shares; and (x) 870,000 Conversion Warrant Shares.
4. Assuming exercise or conversion of the warrants or convertible notes held by Cavalry Fund I, LP (“**Cavalry**”) or its affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Cavalry may be deemed to have beneficial ownership of 12,360,361 shares of Common Stock, which consists of the following: (i) 1,509 Inducement Shares; (ii) 291,246 Bridge Shares; (iii) 10,941 Conversion Shares; (iv) 72,500 Automatic Conversion Shares; (v) 20,121 2022 Warrant Shares; (vi) 72,500 2022 Note Conversion Pre-Funded Warrant Shares; (vii) 2,552,620 Common Warrant Shares; (viii) 985,064 Bridge Pre-Funded Warrant Shares; (ix) 7,657,860 Exchange Investor Warrant Shares; and (x) 696,000 Conversion Warrant Shares.
5. Assuming exercise or conversion of the warrants or convertible notes held by Sanibel Island Associates LLC (Anestis) (“**Sanibel**”) or its affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Sanibel may be deemed to have beneficial ownership of 293,583 shares of Common Stock, which consists of the following: (i) 181 Inducement Shares; (ii) 20,586 Bridge Shares; (iii) 1,313 Conversion Shares; (iv) 9,000 Automatic Conversion Shares; (v) 2,415 2022 Warrant Shares; (vi) 9,000 2022 Note Conversion Pre-Funded Warrant Shares; (vii) 41,172 Common Warrant Shares; (viii) 123,516 Exchange Investor Warrant Shares; and (ix) 86,400 Conversion Warrant Shares.

6. Assuming exercise or conversion of the warrants or convertible notes held by Ana Parker or her affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Ms. Parker may be deemed to have beneficial ownership of 3,845,144 shares of Common Stock, which consists of the following: (i) 192,278 Bridge Shares; (ii) 118,316 Automatic Conversion Shares; (iii) 118,316 2022 Note Conversion Pre-Funded Warrant Shares; (iv) 549,486 Common Warrant Shares; (v) 82,465 Bridge Pre-Funded Warrant Shares; (vi) 1,648,458 Exchange Investor Warrant Shares; and (vii) 1,135,825 Conversion Warrant Shares.
7. Assuming exercise of the warrants held by ProActive Capital Partners, L.P. (“**ProActive**”) as of September 15, 2023 and disregarding any limitations on exercise applicable to such warrants, ProActive may be deemed to have beneficial ownership of 960,614 shares of Common Stock, which consists of the following: (i) 68,611 Bridge Shares; (ii) 29,579 Automatic Conversion Shares; (iii) 29,579 2022 Note Conversion Pre-Funded Warrant Shares; (iv) 137,222 Common Warrant Shares; (v) 411,666 Exchange Investor Warrant Shares; and (vi) 283,957 Conversion Warrant Shares.
8. Assuming exercise or conversion of the warrants or convertible notes held by Michael Abrams or his affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Abrams may be deemed to have beneficial ownership of 144,828 shares of Common Stock, which consists of the following: (i) 10,292 Bridge Shares; (ii) 4,500 Automatic Conversion Shares; (iii) 4,500 2022 Note Conversion Pre-Funded Warrant Shares; (iv) 20,584 Common Warrant Shares; (v) 61,752 Exchange Investor Warrant Shares; and (vi) 43,200 Conversion Warrant Shares.
9. Assuming exercise or conversion of the warrants or convertible notes held by Jason Adelman or his affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Adelman may be deemed to have beneficial ownership of 289,656 shares of Common Stock, which consists of the following: (i) 20,584 Bridge Shares; (ii) 9,000 Automatic Conversion Shares; (iii) 9,000 2022 Note Conversion Pre-Funded Warrant Shares; (iv) 41,168 Common Warrant Shares; (v) 123,504 Exchange Investor Warrant Shares; and (vi) 86,400 Conversion Warrant Shares.
10. Assuming exercise or conversion of the warrants or convertible notes held by Centurion Therapeutics, Inc. (“Centurion”) or its affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Centurion may be deemed to have beneficial ownership of 130,500 shares of Common Stock, which consists of the following: (i) 11,250 Automatic Conversion Shares; (ii) 11,250 2022 Note Conversion Pre-Funded Warrant Shares; and (iii) 108,000 Conversion Warrant Shares.
11. Assuming exercise or conversion of the warrants or convertible notes held by Drake Partners LLC (“**Drake Partners**”) or its affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Drake Partners may be deemed to have beneficial ownership of 144,828 shares of Common Stock, which consists of the following: (i) 10,292 Bridge Shares; (ii) 4,500 Automatic Conversion Shares; (iii) 4,500 2022 Note Conversion Pre-Funded Warrant Shares; (iv) 20,584 Common Warrant Shares; (v) 61,752 Exchange Investor Warrant Shares; and (vi) 43,200 Conversion Warrant Shares.

12. Assuming exercise or conversion of the warrants or convertible notes held by Terrence Norchi or his affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Norchi may be deemed to have beneficial ownership of 96,558 shares of Common Stock, which consists of the following: (i) 6,862 Bridge Shares; (ii) 3,000 Automatic Conversion Shares; (iii) 3,000 2022 Note Conversion Pre-Funded Warrant Shares; (iv) 13,724 Common Warrant Shares; (v) 41,172 Exchange Investor Warrant Shares; and (vi) 28,800 Conversion Warrant Shares.
13. Assuming exercise or conversion of the warrants or convertible notes held by Michael Tuttle or his affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Tuttle Norchi may be deemed to have beneficial ownership of 174,000 shares of Common Stock, which consists of the following: (i) 15,000 Automatic Conversion Shares; (ii) 15,000 2022 Note Conversion Pre-Funded Warrant Shares; and (iii) 144,000 Conversion Warrant Shares.
14. Assuming exercise or conversion of the warrants or convertible notes held by Trina Whitridge GST Trust (“**Whitridge**”) or its affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Whitridge may be deemed to have beneficial ownership of 1,064,989 shares of Common Stock, which consists of the following: (i) 362 Inducement Shares; (ii) 75,473 Bridge Shares; (iii) 2,626 Conversion Shares; (iv) 32,579 Automatic Conversion Shares; (v) 4,829 2022 Warrant Shares; (vi) 32,579 2022 Note Conversion Pre-Funded Warrant Shares; (vii) 150,946 Common Warrant Shares; (viii) 452,838 Exchange Investor Warrant Shares; and (ix) 312,757 Conversion Warrant Shares.
15. Assuming exercise or conversion of the warrants or convertible notes held by Mark Woolfson or his affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Woolfson may be deemed to have beneficial ownership of 362,061 shares of Common Stock, which consists of the following: (i) 25,729 Bridge Shares; (ii) 11,250 Automatic Conversion Shares; (iii) 11,250 2022 Note Conversion Pre-Funded Warrant Shares; (iv) 51,458 Common Warrant Shares; (v) 154,374 Exchange Investor Warrant Shares; and (vi) 108,000 Conversion Warrant Shares.
16. Assuming exercise or conversion of the warrants or convertible notes held by Steve Woolfson or his affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Woolfson be deemed to have beneficial ownership of 410,340 shares of Common Stock, which consists of the following: (i) 29,160 Bridge Shares; (ii) 12,750 Automatic Conversion Shares; (iii) 12,750 2022 Note Conversion Pre-Funded Warrant Shares; (iv) 58,320 Common Warrant Shares; (v) 174,960 Exchange Investor Warrant Shares; and (vi) 122,400 Conversion Warrant Shares.
17. Assuming exercise or conversion of the warrants held by Walleye Opportunities Master Fund Ltd (“**Walleye**”) or its affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Walleye may be deemed to have beneficial ownership of 11,486,502 shares of Common Stock, which consists of the following: (i) 300,000 Bridge Shares; (ii) 2,552,556 Common Warrant Shares; (iii) 976,278 Bridge Pre-Funded Warrant Shares; and (iv) 7,657,668 Exchange Investor Warrant Shares.
18. Assuming exercise or conversion of the warrants held by Sixth Borough Capital Fund, LP (“**Sixth Borough**”) or its affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Sixth Borough may be deemed to have beneficial ownership of 3,274,821 shares of Common Stock, which consists of the following: (i) 300,000 Bridge Shares; (ii) 727,738 Common Warrant Shares; (iii) 63,869 Bridge Pre-Funded Warrant Shares; and (iv) 2,183,214 Exchange Investor Warrant Shares.
19. Assuming exercise or conversion of the warrants held by Brandt Wilson and Mona Wilson or their affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Wilson and Mrs. Wilson may be deemed to have beneficial ownership of 11,486,502 shares of Common Stock, which consists of the following: (i) 300,000 Bridge Shares; (ii) 2,552,556 Common Warrant Shares; (iii) 976,278 Bridge Pre-Funded Warrant Shares; and (iv) 7,657,668 Exchange Investor Warrant Shares.
20. Assuming exercise or conversion of the warrants held by Andrew Stahl or his affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Stahl may be deemed to have beneficial ownership of 11,486,502 shares of Common Stock, which consists of the following: (i) 300,000 Bridge Shares; (ii) 2,552,556 Common Warrant Shares; (iii) 976,278 Bridge Pre-Funded Warrant Shares; and (iv) 7,657,668 Exchange Investor Warrant Shares.

21. Assuming exercise or conversion of the warrants held by John Robert Baleno or his affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Baleno may be deemed to have beneficial ownership of 654,543 shares of Common Stock, which consists of the following: (i) 72,727 Bridge Shares; (ii) 145,454 Common Warrant Shares; and (iii) 436,362 Exchange Investor Warrant Shares.
22. Assuming exercise or conversion of the warrants held by Roxanne Rosetto or her affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Ms. Rosetto may be deemed to have beneficial ownership of 327,276 shares of Common Stock, which consists of the following: (i) 36,364 Bridge Shares; (ii) 72,728 Common Warrant Shares; and (iii) 218,184 Exchange Investor Warrant Shares.
23. Assuming exercise or conversion of the warrants held by Robert Forster or his affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Forster may be deemed to have beneficial ownership of 1,636,362 shares of Common Stock, which consists of the following: (i) 181,818 Bridge Shares; (ii) 363,636 Common Warrant Shares; and (iii) 1,090,908 Exchange Investor Warrant Shares.
24. Assuming exercise or conversion of the warrants held by Thomas Pilgrim or his affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Pilgrim may be deemed to have beneficial ownership of 654,543 shares of Common Stock, which consists of the following: (i) 72,727 Bridge Shares; (ii) 145,454 Common Warrant Shares; and (iii) 436,362 Exchange Investor Warrant Shares.
25. Assuming exercise or conversion of the warrants held by Rajiv P. Dewan or his affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Dewan may be deemed to have beneficial ownership of 360,000 shares of Common Stock, which consists of the following: (i) 40,000 Bridge Shares; (ii) 80,000 Common Warrant Shares; and (iii) 240,000 Exchange Investor Warrant Shares.
26. Assuming exercise or conversion of the warrants held by David L. McClain or his affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. McClain may be deemed to have beneficial ownership of 180,000 shares of Common Stock, which consists of the following: (i) 20,000 Bridge Shares; (ii) 40,000 Common Warrant Shares; and (iii) 120,000 Exchange Investor Warrant Shares.
27. Assuming exercise or conversion of the warrants held by Norman McClain or his affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. McClain may be deemed to have beneficial ownership of 360,000 shares of Common Stock, which consists of the following: (i) 40,000 Bridge Shares; (ii) 80,000 Common Warrant Shares; and (iii) 240,000 Exchange Investor Warrant Shares.
28. Assuming exercise or conversion of the warrants held by Ronald Nash or his affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Nash may be deemed to have beneficial ownership of 327,276 shares of Common Stock, which consists of the following: (i) 36,364 Bridge Shares; (ii) 72,728 Common Warrant Shares; and (iii) 218,184 Exchange Investor Warrant Shares.
29. Assuming exercise or conversion of the warrants held by Richard Molinsky or his affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Molinsky may be deemed to have beneficial ownership of 490,905 shares of Common Stock, which consists of the following: (i) 54,545 Bridge Shares; (ii) 109,090 Common Warrant Shares; and (iii) 327,270 Exchange Investor Warrant Shares.
30. Assuming exercise or conversion of the warrants held by George Benashvili or his affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Benashvili may be deemed to have beneficial ownership of 92,700 shares of Common Stock, which consists of the following: (i) 10,300 Bridge Shares; (ii) 20,600 Common Warrant Shares; and (iii) 61,800 Exchange Investor Warrant Shares.
31. Assuming exercise or conversion of the warrants held by Dan Armstrong or his affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Armstrong may be deemed to have beneficial ownership of 654,543 shares of Common Stock, which consists of the following: (i) 72,727 Bridge Shares; (ii) 145,454 Common Warrant Shares; and (iii) 436,362 Exchange Investor Warrant Shares.
32. Assuming exercise or conversion of the warrants held by CNP Consulting or its affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, CNP Consulting may be deemed to have beneficial ownership of 126,000 shares of Common Stock, which consists of the following: (i) 14,000 Bridge Shares; (ii) 28,000 Common Warrant Shares; and (iii) 84,000 Exchange Investor Warrant Shares.
33. Assuming exercise or conversion of the warrants held by Ivan Chi Vei Tong or his affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Tong may be deemed to have beneficial ownership of 180,000 shares of Common Stock, which consists of the following: (i) 20,000 Bridge Shares; (ii) 40,000 Common Warrant Shares; and (iii) 120,000 Exchange Investor Warrant Shares.

34. Assuming exercise or conversion of the warrants held by Genmark Holdings or its affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Genmark Holdings may be deemed to have beneficial ownership of 654,543 shares of Common Stock, which consists of the following: (i) 72,727 Bridge Shares; (ii) 145,454 Common Warrant Shares; and (iii) 436,362 Exchange Investor Warrant Shares.
35. Assuming exercise or conversion of the warrants held by Stephen Ross or his affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Ross may be deemed to have beneficial ownership of 163,638 shares of Common Stock, which consists of the following: (i) 18,182 Bridge Shares; (ii) 36,364 Common Warrant Shares; and (iii) 109,092 Exchange Investor Warrant Shares.
36. Assuming exercise or conversion of the warrants held by Efrat Investments or its affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Efrat Investments may be deemed to have beneficial ownership of 327,276 shares of Common Stock, which consists of the following: (i) 36,364 Bridge Shares; (ii) 72,728 Common Warrant Shares; and (iii) 218,184 Exchange Investor Warrant Shares.
37. Assuming exercise or conversion of the warrants held by Daniel Shalhoub or his affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Shalhoub may be deemed to have beneficial ownership of 163,638 shares of Common Stock, which consists of the following: (i) 18,182 Bridge Shares; (ii) 36,364 Common Warrant Shares; and (iii) 109,092 Exchange Investor Warrant Shares.
38. Assuming exercise or conversion of the warrants held by Jeffrey and Shiela Negus or their affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Negus and Mrs. Negus may be deemed to have beneficial ownership of 163,638 shares of Common Stock, which consists of the following: (i) 18,182 Bridge Shares; (ii) 36,364 Common Warrant Shares; and (iii) 109,092 Exchange Investor Warrant Shares.
39. Assuming exercise or conversion of the warrants held by Maxim or its affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Maxim may be deemed to have beneficial ownership of 163,638 shares of Common Stock, which consists of the following: (i) 6,565 2022 Placement Agent Warrant Shares.
40. Assuming exercise or conversion of the warrants held by DJ or its affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, DJ may be deemed to have beneficial ownership of 260,040 shares of Common Stock, which consists of the following: (i) 260,040 Bridge Placement Agent Warrant Shares.
41. Assuming exercise or conversion of the warrants held by Robert D. Keyser, Jr. or his affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Keyser may be deemed to have beneficial ownership of 97,971 shares of Common Stock, which consists of the following: (i) 97,971 Bridge Placement Agent Warrant Shares.
42. Assuming exercise or conversion of the warrants held by James Hopkins or his affiliates as of September 15, 2023 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Hopkins may be deemed to have beneficial ownership of 83,927 shares of Common Stock, which consists of the following: (i) 83,927 Bridge Placement Agent Warrant Shares.

PLAN OF DISTRIBUTION

Each selling stockholder of the securities and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their securities covered hereby on the principal Trading Market or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling stockholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker dealer solicits purchasers;
- block trades in which the broker dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker dealer as principal and resale by the broker dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- in transactions through broker dealers that agree with the selling stockholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell securities under Rule 144 or any other exemption from registration under the Securities Act, if available, rather than under this prospectus.

Broker dealers engaged by the selling stockholders may arrange for other brokers dealers to participate in sales. Broker dealers may receive commissions or discounts from the selling stockholders (or, if any broker dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

In connection with the sale of the securities or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The selling stockholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling stockholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling stockholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the securities. The Company has agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the securities may be resold by the selling stockholders without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, without the requirement for the Company to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect or (ii) all of the securities have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the common stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

USE OF PROCEEDS

We will not receive proceeds from the sale of Common Stock under this prospectus. We may, however, receive proceeds upon exercise for cash of the 2022 Warrants, 2022 Note Conversion Pre-Funded Warrants, 2022 Placement Agent Warrants, Bridge Warrants, Exchange Investor Warrants, Bridge Placement Agent Warrants, and Participating Pre-Funded Warrants in which case such proceeds will be used for general working capital purposes. However, each of the aforementioned warrants contains a cashless exercise provision.

The selling stockholders may (i) convert their 2022 Notes at any time at their own discretion, if at all, subject to conversion, prepayment, and acceleration under the terms of the 2022 Notes, (ii) exercise their 2022 Warrants, 2022 Note Conversion Pre-Funded Warrants, Bridge Warrants, Exchange Investor Warrants, and Participating Pre-Funded Warrants at any time at their own discretion, if at all, and (iii) exercise their 2022 Placement Agent Warrants and Bridge Placement Agent Warrants 6 months from the date of issuance, if at all; in each instance in accordance with the terms thereof until their expiration.

For further information, see the descriptions under **“Prospectus Summary—The Transactions”** beginning at page 6 of this prospectus and **“Description of Securities”** beginning at page 46 of this prospectus. Additionally, if there is no effective registration statement registering the resale of the shares of Common Stock underlying the 2022 Warrants, 2022 Note Conversion Pre-Funded Warrants, Bridge Warrants, Exchange Investor Warrants, Participating Pre-Funded Warrants, 2022 Placement Agent Warrants, and Bridge Placement Agent Warrants as of certain time periods, then the selling stockholders may choose to exercise the 2022 Warrants, 2022 Note Conversion Pre-Funded Warrants, Bridge Warrants, Exchange Investor Warrants, Participating Pre-Funded Warrants, 2022 Placement Agent Warrants, and Bridge Placement Agent Warrants on a “cashless exercise” or “net exercise” basis. If they do so, we will not receive any proceeds from the exercise of the 2022 Warrants, 2022 Note Conversion Pre-Funded Warrants, Bridge Warrants, Exchange Investor Warrants, Participating Pre-Funded Warrants, 2022 Placement Agent Warrants, and Bridge Placement Agent Warrants. As a result, we cannot plan on receiving any proceeds from the exercise of any of 2022 Warrants, 2022 Note Conversion Pre-Funded Warrants, Bridge Warrants, Exchange Investor Warrants, Participating Pre-Funded Warrants, 2022 Placement Agent Warrants, and Bridge Placement Agent Warrants, nor can we plan on any specific uses of any proceeds we may receive beyond the purposes described herein. We have agreed to bear the expenses (other than any underwriting discounts or commissions or agent’s commissions) in connection with the registration of the Common Stock being offered hereby by the selling stockholders.

DESCRIPTION OF SECURITIES

Authorized Capital Stock

Pursuant to our amended and restated articles of incorporation, as amended, as of September 21, 2023, our authorized capital stock consists of 350,000,000 shares of Common Stock. The following description summarizes the material terms of our capital stock. Because it is only a summary, it may not contain all the information that is important to you. In connection with the Primary Offering, we intend to effect a reverse stock split of our Common Stock at a ratio of between 1.5-for-1 and 20-for-1, with the exact ratio to be determined by our Board of Directors prior to effecting the reverse stock split.

Preferred Stock

We are authorized to issue up to 5,000,000 shares of preferred stock, par value \$0.001 per share, from time to time in one or more series. As of the date of this prospectus, there are no shares of our preferred stock outstanding.

The shares of preferred stock may be issued in series, and each such series shall have such voting powers, full or limited, or no voting powers, and such designations, preferences and relative participating, optional or other special rights, and qualifications, limitations or restrictions thereof, as shall be stated and expressed in the certificate of designation relating to such series, as approved by the board of directors and filed with the Nevada Secretary of State. Pursuant to our articles of incorporation, our Board of Directors is expressly vested with the authority, without further action by the stockholders, to determine and fix in the resolution or resolutions providing for the issuances of preferred stock the voting powers, designations, preferences and rights, and the qualifications, limitations or restrictions thereof, of each such series to the full extent now or hereafter permitted by the laws of the State of Nevada.

Prior to the issuance of any series of preferred stock, we will further amend our articles of incorporation, as amended, by way of a certificate of designation designating such series and its terms. We will file a copy of the certificate of designation that contains the terms of each such series of preferred stock with the Nevada Secretary of State and the SEC each time we issue a new series of preferred stock. Each certificate of designation will establish the number of shares included in a designated series and fix the designation, powers, privileges, preferences and rights of the shares of each series as well as any applicable qualifications, limitations or restrictions, including, as applicable:

- the designation, stated value and liquidation preference of the series;
- the number of shares authorized within the series;
- the offering price;
- the dividend rate or rates (or method of calculation), the date or dates from which dividends shall accrue, and whether such dividends shall be cumulative or noncumulative and, if cumulative, the dates from which dividends shall commence to cumulate;
- any redemption or sinking fund provisions;
- the amount that shares of the series shall be entitled to receive in the event of our liquidation, dissolution or winding-up;
- the terms and conditions, if any, on which shares of the series shall be convertible or exchangeable for shares of our stock of any other class or classes, or other series of the same class;
- the voting rights, if any, of shares of the series; the status as to reissuance or sale of shares of the series redeemed, purchased or otherwise reacquired, or surrendered to us on conversion or exchange;
- the conditions and restrictions, if any, on the payment of dividends or on the making of other distributions on, or the purchase, redemption or other acquisition by us or any subsidiary, of the common stock or of any other class of our shares ranking junior to the shares of the series as to dividends or upon liquidation;
- the conditions and restrictions, if any, on the creation of indebtedness by us or by any subsidiary, or on the issuance of any additional stock ranking on a parity with or prior to the shares of the series as to dividends or upon liquidation; and
- any additional dividend, liquidation, redemption, sinking or retirement fund and other rights, preferences, privileges, limitations and restrictions of the series.

The issuance of any preferred stock could adversely affect the rights of the holders of common stock and, therefore, reduce the value of the common stock. The ability of our Board of Directors to issue preferred stock could discourage, delay or prevent a takeover or other corporate action.

Common Stock Issued and Outstanding; Common Stock Registered Hereby

As of September 15, 2023, there were issued and outstanding 4,689,446 shares of Common Stock.

Transfer Agent

The transfer agent for our Common Stock is Empire Stock Transfer. Our transfer agent's address is 1859 Whitney Mesa Drive, Henderson, Nevada 89014.

Anti-Takeover Provisions of Nevada State Law

Some features of the Nevada Revised Statutes ("NRS"), which are further described below, may have the effect of deterring third parties from making takeover bids for control of us or may be used to hinder or delay a takeover bid. This would decrease the chance that our stockholders would realize a premium over market price for their shares of Common Stock as a result of a takeover bid.

Acquisition of Controlling Interest

The NRS contain provisions governing acquisition of a controlling interest of a Nevada corporation. These provisions provide generally that any person or entity that acquires a certain percentage of the outstanding voting shares of a Nevada corporation may be denied voting rights with respect to the acquired shares, unless certain criteria are satisfied. Our amended and restated bylaws provide that these provisions will not apply to us or to any existing or future stockholder or stockholders.

Combination with Interested Stockholder

The NRS contain provisions governing combinations of a Nevada corporation that has 200 or more stockholders of record with an “interested stockholder.” These provisions only apply to a Nevada corporation that, at the time the potential acquirer became an interested stockholder, has a class or series of voting shares listed on a national securities exchange, or has a class or series of voting shares traded in an “organized market” and satisfies certain specified public float and stockholder levels. As we do not now meet those requirements, we do not believe that these provisions are currently applicable to us. However, to the extent they become applicable to us in the future, they may have the effect of delaying or making it more difficult to affect a change in control of the Company in the future.

A corporation affected by these provisions may not engage in a combination within two years after the interested stockholder acquires his, her or its shares unless the combination or purchase is approved by the board of directors before the interested stockholder acquired such shares. Generally, if approval is not obtained, then after the expiration of the two-year period, the business combination may be consummated with the approval of the board of directors before the person became an interested stockholder or a majority of the voting power held by disinterested stockholders, or if the consideration to be received per share by disinterested stockholders is at least equal to the highest of:

- the highest price per share paid by the interested stockholder within the three years immediately preceding the date of the announcement of the combination or within three years immediately before, or in, the transaction in which he, she or it became an interested stockholder, whichever is higher;
- the market value per share on the date of announcement of the combination or the date the person became an interested stockholder, whichever is higher; or
- if higher for the holders of preferred stock, the highest liquidation value of the preferred stock, if any.

Generally, these provisions define an interested stockholder as a person who is the beneficial owner, directly or indirectly of 10% or more of the voting power of the outstanding voting shares of a corporation, and define combination to include any merger or consolidation with an interested stockholder, or any sale, lease, exchange, mortgage, pledge, transfer or other disposition, in one transaction or a series of transactions with an interested stockholder of assets of the corporation:

- having an aggregate market value equal to 5% or more of the aggregate market value of the assets of the corporation;
- having an aggregate market value equal to 5% or more of the aggregate market value of all outstanding shares of the corporation; or
- representing 10% or more of the earning power or net income of the corporation.

MARKET PRICE OF AND DIVIDENDS ON COMMON STOCK AND RELATED MATTERS

Market Information

Our Common Stock is currently quoted on the OTCQB over-the-counter quotation system under the stock symbol “ARTH”. Our Common Stock began quotation on the OTCBB and the OTCQB on June 27, 2013 and since that date has been primarily traded on the OTCQB. There was no trading of our Common Stock on the OTCBB, OTCQB or any other over-the-counter market prior to January 2, 2013. Although our Common Stock is currently quoted on the OTCQB, there is a limited trading market for our Common Stock and there have been few trades in our Common Stock to date. Because our Common Stock is thinly traded on the OTCQB, (i) any reported sale prices may not be a true market-based valuation of our Common Stock; and (ii) such over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

Dividends

We have never declared or paid any cash dividends or distributions on our capital stock. We currently intend to retain our future earnings, if any, to support operations and to finance expansion and therefore we do not anticipate paying any cash dividends on our Common Stock in the foreseeable future.

Holders

As of September 15, 2023, there were approximately 131 holders of record of our Common Stock.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the other sections of this prospectus, including our audited annual consolidated financial statements and related notes beginning on page F-1 of this prospectus. This discussion and analysis contains forward-looking statements, including information about possible or assumed results of our financial condition, operations, plans, objectives and performance that involve risks, uncertainties and assumptions. See “Cautionary Note Regarding Forward-Looking Statements” beginning on page 2 of this prospectus. Our actual results may differ materially from those anticipated or suggested in any forward-looking statements.

Corporate Overview

Arch Therapeutics, Inc. (together with its subsidiary, the “**Company**” or “**Arch**”) arose from the June 26, 2013 merger (the “**Merger**”) of three entities previously known as Arch Biosurgery, Inc., Almah, Inc., and Arch Acquisition Corporation, respectively.

Arch Biosurgery, Inc. (“**ABS**”) is a biotechnology company that was incorporated under the laws of the Commonwealth of Massachusetts on March 6, 2006 as Clear Nano Solutions, Inc., changed its name from Clear Nano Solutions, Inc. to Arch Therapeutics, Inc. on April 7, 2008, and, as part of the Merger transaction, changed its name from Arch Therapeutics, Inc. to Arch Biosurgery.

Almah, Inc., was incorporated under the laws of the State of Nevada on September 16, 2009 and, as part of the Merger transaction, changed its name to Arch Therapeutics, Inc. and abandoned both its prior business plan and operations in order to adopt those of ABS.

Arch Acquisition Corporation, or Merger Sub, was a wholly owned subsidiary of Almah, Inc., formed for the purpose of the Merger transaction, pursuant to which Merger Sub merged with and into ABS, and ABS thereafter became the wholly owned subsidiary of the Company.

The Company's principal offices are located in Framingham, Massachusetts.

The Company has recently devoted substantially all of its operational effort to the market adoption and commercial sales of AC5® Advanced Wound System, its first product. To date, the Company has principally raised capital through debt borrowings, the issuance of convertible debt, and the issuance of units consisting of shares of the Company's common stock, \$0.001 par value per share (“**Common Stock**”), and warrants.

The Company expects to incur substantial expenses for the foreseeable future relating to research, development and commercialization of current and potential products. However, there can be no assurance that the Company will be successful in securing additional capital when needed, on terms acceptable to the Company, if at all. Therefore, there exists substantial doubt about the Company's ability to continue as a going concern for one year past the issuance of the financial statements. The consolidated financial statements do not include any adjustments related to the recoverability of assets that might be necessary despite this uncertainty.

Liquidity

We devote a significant amount of our efforts on fundraising, planning and conducting clinical trials, activities in connection with obtaining regulatory approval, and product research. We have principally raised capital through borrowings, the issuance of convertible debt, and units consisting of Common Stock and warrants to fund our operations. For the year ended September 30, 2022, we had a net loss of \$5,275,854 versus a net loss of \$6,240,482 in the prior year. The losses for each of the years ended September 30, 2022 and 2021 can be attributable to research and development expense, including regulatory approval and product research, and general and administrative costs, primarily relating to legal costs associated with intellectual property and patent application, general corporate legal expense all of which were partially offset by adjustments to the derivative liabilities and, for the fiscal year ended September 30, 2021, a gain on the forgiveness of the loan issued by First Republic Bank under the Paycheck Protection Program, established under the Coronavirus Aid, Relief, and Economic Security Act. For the nine months ended June 30, 2023, we had a net loss of \$4,525,640 versus a net loss of \$3,387,295 in the same period in fiscal year 2022. Cash used in operating activities decreased \$1,502,553 during the year ended September 30, 2022 to \$4,456,075, compared to \$5,958,628 for the year ended September 30, 2021. Cash used in operating activities during the nine months ended June 30, 2023 was \$2,147,480, compared to \$2,786,642 for the same period in fiscal year 2022.

Business Overview

We are a biotechnology company marketing and developing a number of products based on our innovative AC5® self-assembling technology platform. We believe these products can be important advances in the field of stasis and barrier applications, which includes managing wounds created during surgery, trauma, interventional care or disease; stopping bleeding (hemostasis); and controlling leaking (sealant). We have recently devoted substantially all of our operational effort to the market adoption and commercial sales of AC5 Advanced Wound System, our first product. Our goal is to make care faster and safer for patients with products for use on external wounds, which we refer to as Dermal Sciences applications, and products for use inside the body, which we refer to as BioSurgery applications.

Core Technology

Our flagship products and product candidates are derived from our AC5® self-assembling peptide (SAP) technology platform and are sometimes referred to as AC5 or the “AC5 Devices.” These include AC5 Advanced Wound System and AC5® Topical Hemostat, which have received marketing authorization as medical devices in the United States and Europe, respectively, and which are intended for skin applications, such as the management of complicated chronic wounds and acute surgical wounds. Marketing for AC5 Topical Hemostat in Europe has not initiated. Other products are in development for use in minimally invasive or open surgical procedures and include, for example, AC5-G™ for gastrointestinal endoscopic procedures and AC5-V® and AC5® Surgical Hemostat for hemostasis inside the body, all of which are currently investigational devices limited by law to investigational use.

Products based on the AC5 platform contain a proprietary biocompatible peptide that is synthesized from proteogenic, naturally occurring L-amino acids. Unlike products that contain traditional peptide sequences, when applied to a wound, AC5-based products intercalate into the interstices of the tissue and self-assemble (i.e., self-build) into a protective physical-mechanical nanoscale structure that can provide a barrier to leaking substances, such as blood, while also acting as a biodegradable scaffold that enables healing. Self-assembly is a central component of the mechanism of action of our technology. Individual AC5 peptide units readily build themselves, or self-assemble, into an ordered network of nanofibrils when in aqueous solution by the following process:

- Peptide strands line up with neighboring peptide strands, interacting via hydrogen bonds (non-covalent bonds) to form a ribbon-like structure called a beta sheet.
- This process continues such that hundreds of strands organize with charged and polar side chains oriented on one face and non-polar side chains oriented on the opposite face of the beta sheets.
- Interactions of the resulting structure with water molecules and ions results in formation nanofibrils, which extend in length and can join together to form larger nanofibers.
- This network of AC5 peptide nanofibers forms the semi-solid physical-mechanical barrier that interacts with the extracellular matrix, is responsible for sealant, hemostatic and/or other properties that may be observed even in the presence of antithrombotic agents (i.e., blood thinners), and which subsequently becomes the scaffold that supports the repair and regeneration of damaged tissue.

Based on the intended application, we believe that the underlying AC5 SAP technology can impart important features and benefits to our products that may include, for instance, stopping bleeding (hemostasis), mitigating contamination, modulating inflammation, donating moisture, and enabling an appropriate wound microenvironment conducive to healing. Furthermore, we believe that AC5 SAP technology permits cell and tissue growth and is self-healing, in that it can dynamically self-repair around migrating cells. For instance, AC5 Advanced Wound System, which is indicated for the management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds, is shipped and stored at room temperature, is applied directly as a liquid, can conform to irregular wound geometry, self-assembles into a wound care matrix that can provide clinicians with multi-modal support, and does not possess sticky or glue-like handling characteristics. We believe these properties enhance its utility in several settings and contribute to its user-friendly profile.

We believe that our technology lends itself to a range of potential applications for wounds inside or on the body, including those for which a hemostatic agent or sealant is needed. For instance, the results of certain preclinical and clinical investigations that either we have conducted, or others have conducted on our behalf, have shown quick and effective hemostasis with the use of AC5 SAP technology, and that time to hemostasis (“TTH”) is comparable among test subjects regardless of whether such test subject had or had not been treated with therapeutic doses of anticoagulant or antiplatelet medications, commonly called “blood thinners.” Furthermore, the transparency and physical properties of certain AC5 Devices may enable a surgeon to operate through it in order to maintain a clearer field of vision and prophylactically stop or lessen bleeding as surgery starts, a concept that we call Crystal Clear Surgery™. An example of a product that contains related features and benefits is AC5 Topical Hemostat, which is indicated for use as a dressing and to control mild to moderate bleeding, each during the management of injured skin and the micro-environment of an acute surgical wound. AC5 Topical Hemostat has not yet been marketed in Europe but has received marketing authorization.

Marketing

Sales and marketing efforts for our AC5 Advanced Wound System, which has received 510(k) marketing clearance from the FDA, address the demand for improved solutions to treat challenging chronic and acute surgical wounds, with a particular early focus on diabetic foot ulcers, venous leg ulcers and pressure ulcers. Chronic wounds are typically defined as wounds that have not healed after four weeks of standard care. Approximately 4 million to 6.5 million new onset chronic wounds are estimated to occur in the U.S. annually, including approximately 700,000 to 2 million diabetic foot ulcers, 2.5 million pressure ulcers, and 1.2 million venous leg ulcers. If untreated, improperly treated or unresponsive to treatment, these wounds can ultimately lead to amputation. The 5-year mortality rate among patients with chronic wounds, especially after an amputation, is significant.

Published data on AC5 Advanced Wound System shows encouraging outcomes, including limb salvage (avoided limb loss), among patients with multiple co-morbidities and challenging chronic wounds that failed to heal despite treatment with either traditional or other advanced wound care modalities over prolonged periods of time.

We currently maintain an internal commercial team focused on driving awareness and adoption of AC5 Advanced Wound System in several targeted channels with a particular focus on physician offices and government channels, such as Veterans Health Administration hospitals (“**VA Hospitals**”) and military treatment facilities (“**MTFs**”). We anticipate that material growth in the physician office setting will require product reimbursement. To that end, we submitted an application to the Centers for Medicare and Medicaid Services (“**CMS**”) in July 2022 for a unique product reimbursement code. Our application was subsequently approved with a go-live date of April 1, 2023. We have launched a temporary reimbursement support program in line with CMS guidance to support commercial use and adoption of AC5 Advanced Wound System both before and after the go-live date of our unique product code (A2020). In support of the VA and MTF market, we partnered with Lovell Government Services (“**LGS**”), a Service-Disabled Veteran-Owned Small Business, as its distributor in the government channel. As a direct result of its relationship with LGS, AC5 Advanced Wound System is listed on the four major government supply schedules (ECAT, DAPA, FSS and GSA) in order to allow doctors in any VA or MTF to order AC5 Advanced Wound System. We have also established and will continue to seek partnerships with reputable, value-added independent sales distributors on a case-by-case basis to expand the overall reach and footprint of its total sales organization. Presently, our commercialization efforts and resources remain dedicated to the U.S. market for advanced wound care.

Operations

Much of our operational efforts to date, which we often perform in collaboration with partners, have included selecting compositions and formulations for our initial products; conducting preclinical studies, including safety and other tests; conducting a human trial for safety and performance of AC5; developing and conducting a human safety study to assess for irritation and sensitization potential; securing marketing authorization for our first product in the United States and in Europe; supporting surgeons performing clinical case studies; obtaining post-marketing clinical data; developing, optimizing, and validating manufacturing methods and formulations, which are particularly important components of self-assembling peptide development; developing methods for manufacturing scale-up, reproducibility, and validation; engaging with regulatory authorities to seek early regulatory guidance as well as marketing authorization for our products; sourcing and evaluating commercial partnering opportunities in the United States and abroad; and developing and protecting the intellectual property rights underlying our technology platform.

Our long-term business plan includes the following goals:

- Continue to build recent commercial momentum and grow revenues by driving awareness, adoption and payment policies for AC5 Advanced Wound System with the now-effective CMS Level II Healthcare Common Procedure Coding System (“**HCPCS**”) code dedicated to the “AC5”;
- conducting biocompatibility, pre-clinical, and clinical studies on our products and product candidates;
- obtaining additional marketing authorization for products in the United States, Europe, and other jurisdictions as we may determine;
- continuing to develop third party relationships to manufacture, distribute, market and otherwise commercialize our products;
- continuing to develop academic, scientific and institutional relationships to collaborate on product research and development;
- expanding and maintaining protection of our intellectual property portfolio; and
- developing additional product candidates in Dermal Sciences, BioSurgery, and other areas.

In furtherance of our long-term business goals, we expect to continue to focus on the following activities during the next twelve months:

- seek additional funding as required to support the previously described milestones necessary to support our operations;

- work with our manufacturing partners to scale up production of product compliant with cGMP, which activities will be ongoing and tied to our development and commercialization needs;
- further clinical development of our product platform;
- assess our technology platform in order to identify and select product candidates for potential advancement into development;
- seek regulatory input to guide activities related to expanded and new product marketing authorizations;
- continue to expand and enhance our financial and operational reporting and controls;
- pursue commercial partnerships; and
- expand and enhance our intellectual property portfolio by filing new patent applications, obtaining allowances on currently filed patent applications, and/or adding to our trade secrets in self-assembly, manufacturing, analytical methods and formulation, which activities will be ongoing as we seek to expand our product candidate portfolio.

In addition to capital required for operating expenses, depending upon input from regulatory authorities, authorized representatives, patent and trademark offices, or other agencies in the US, EU or elsewhere, as well as for potential additional regulatory filings and approvals during the approximately next two years, additional capital will be required.

We have no commitments for any future capital. We will require significant additional financing to fund our planned operations, including further research and development relating to AC5, seeking regulatory approval of any product we may choose to develop, commercializing any product for which we are able to obtain regulatory approval or certification, seeking to license or acquire new assets or business, and maintaining our intellectual property rights, pursuing new technologies and for financing the investor relations and incremental administrative costs associated with being a public corporation. In addition, we are bound by certain contractual terms and obligations that may limit or otherwise impact our ability to raise additional funding in the near-term including, but not limited to, provisions in the Bridge SPA (as defined below) and securities purchase agreement dated July 6, 2022, as amended (the “**2022 Notes SPA**”), associated with the sale of the 2022 Notes (the “**2022 Notes Financing**”), in each case as described in greater detail in the risk factor entitled “*The terms of the Bridge Offering and 2022 Notes Financing could impose additional challenges on our ability to raise funding in the future*” under the heading “Risk Factors” in this prospectus.

The estimated capital requirements potentially could increase significantly if a number of risks relating to conducting these activities were to occur, including without limitation those set forth under the heading “**Risk Factors**” in this prospectus. We anticipate that our operating and other expenses will continue to increase as we continue to implement our business plan and pursue and achieve these goals. After giving effect to the funds received in past equity and debt financings and assuming our use of that funding at the rate we presently anticipate, as of September 15, 2023, we believe that our current cash on hand is sufficient to meet our anticipated cash requirements into the first fiscal quarter of 2024, and we must obtain additional financing in order to continue to operate our business. Even if the Primary Offering is successful, we could spend our financial resources much faster than we expect, in which case we would need to raise additional capital as our current funds may not be sufficient to operate our business for the entire duration of that period.

Preclinical Testing

We have engaged and continue to engage third parties in the United States and abroad to advise on and perform certain preclinical bench-top and animal research and development studies, typically with assistance from our team. These third parties can include contract research organizations, academic institutions, consultants, advisors, scientists, clinicians, and/or other collaborators.

We completed the biocompatibility studies required to receive marketing authorizations for AC5 Advanced Wound System in the United States and AC5 Topical Hemostat in Europe, and such test results support that the products are biocompatible. We will perform further biocompatibility testing that we deem necessary for additional indications, classifications, jurisdictions, and/or as required by regulatory authorities.

Acute and survival animal studies assessing the safety and performance of our technology have also demonstrated favorable outcomes in Dermal Sciences and BioSurgical applications.

Clinical Testing

We have engaged and continue to engage third parties in the United States and abroad to advise on and perform certain clinical studies and related activities, typically with assistance from our team. These third parties can include contract research organizations, academic institutions, consultants, advisors, scientists, clinicians, and/or other collaborators.

We completed two clinical studies. The first study, which met its primary and secondary endpoints, assessed the safety and performance of our product candidate in 46 patients with bleeding skin wounds that resulted from excision of skin lesions and followed for 30 days. The second study assessed our product candidate on skin, determining that it was neither an irritant nor a sensitizer, and no immunogenic response or serious or other adverse events attributable to our product were reported in any of the approximately 50 enrolled volunteers. The product candidate in these studies subsequently received marketing authorization and is presently known as AC5 Advanced Wound System in the United States and AC5 Topical Hemostat in Europe.

Post marketing clinical case reports have been published demonstrating both efficacy and safety in a range of challenging acute surgical or chronic wounds on patients.

Commercialization

Our commercialization efforts are currently focused on Dermal Sciences. Our BioSurgery products for internal use will require additional preclinical and clinical testing before we seek marketing authorization to commercialize them.

Our Dermal Sciences products are AC5 Advanced Wound System in the United States and AC5 Topical Hemostat in Europe, and the indication for use, or purpose, for each product follows, respectively:

- Under the supervision of a health care professional, AC5 Advanced Wound System is a topical dressing used for the management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds.
- AC5 Topical Hemostat is intended for use locally as a dressing and to control mild to moderate bleeding, each during the management of injured skin and the micro-environment of an acute surgical wound.

In practice, we envision that both products will be used in comparable wounds, including, in particular, acute or chronic wounds that require surgical intervention. Examples include, surgical excision of dead, contaminated, or damaged tissue, otherwise known as debridement, in chronic wounds; complicated wounds created during an acute surgical procedure; failed acute surgical wounds; wounds requiring wound bed preparation in advance of other procedures; wounds in need of an advanced dressing that incorporates an initial protective barrier function followed by a scaffolding or lattice function that enables healing.

We announced receipt of 510(k) premarket notification clearances for AC5 Advanced Wound System on December 17, 2018, providing marketing authorization, and on March 23, 2020, clearing use of an additional supplier and additional manufacturing processes. We announced receipt of the CE mark for AC5 Topical Hemostat on April 13, 2020.

The COVID-19 pandemic environment introduced new challenges related to product launch, marketing and sales, as clinicians and facilities are increasingly focused on managing resources, the disease, or its potential spread. We believe that these challenges have also highlighted some potential opportunities for our new technology to address certain poorly met needs. For instance, wound interventions are too often considered to be elective procedures instead of being treated essentially or emergently as National Pressure Ulcer Advisory Panel guidelines and others recommend, resulting in a projected increased risk to limb and life while elective procedures are delayed and not prioritized. Furthermore, the implications of these delays are a growing backlog of chronic wounds awaiting care and a worsening of such wounds, leading to greater morbidity, such as infection, necrosis, and amputation, and potentially mortality.

We expect our Dermal Sciences product commercialization to be gradual, initially, and moderately accelerate into new market channels. In addition to identifying and encouraging product use by key opinion leaders and early adopters, we will prioritize our focus on private and government facilities. VA Hospitals, for example, tend to have many patients whose needs we believe we can help address. We prioritized the launch of AC5 Advanced Wound System in the United States over that of AC5 Topical Hemostat in Europe to maximize operational efficiencies in light of the COVID-19 pandemic and have not yet determined when we will launch the product in Europe.

On December 13, 2021, we announced that in partnership with Lovell Government Services, our AC5 Advanced Wound System has been added to the Federal Supply Schedule and General Services Administration contracts and is approved for purchase by all federal government agencies, including the Department of VA, Indian Health Services, and Department of Defense Medical Treatment Facilities effective December 15, 2021.

On March 14, 2022, we announced the Company had entered into a distribution agreement with Centurion Therapeutics Inc. (**Centurion**), an exclusive strategic partner to the world's largest tissue bank, to expand sales opportunities for AC5 Advanced Wound System. Centurion distributes a comprehensive portfolio of aseptically processed human tissues to support surgeons in a broad array of specialties through over a hundred contracted wound care distributors nationwide. AC5 Advanced Wound System will be added to their advanced wound care product line as part of this distribution agreement.

We have engaged and continue to engage third parties in the United States and abroad to advise on and perform certain sales and marketing activities, typically with assistance from our team. These third parties can include contract organizations, consultants, advisors, scientists, clinicians, and/or other collaborators.

The COVID-19 Pandemic Impact on Commercialization

The COVID-19 pandemic environment introduced significant challenges related to product launch, marketing and sales, as clinicians and facilities became overburdened and increasingly focused on managing resources, the disease, and the virus spread. While the overall environment has improved, many negative effects linger. We have observed the following effects at different times, and anticipate that they will variously wax and wane over time:

- the volume of elective surgical procedures has been constrained periodically, with many institutions indefinitely suspending or eliminating such procedures at times;
- healthcare facilities often have been required to ration staff and resources, including ventilators, personal protective equipment (**PPE**), and operating rooms, thereby negatively impacting the focus on wound care;
- clinicians often have been required to divert their time and resources to urgent COVID-19 needs;
- clinicians often have been required to quarantine due to exposure to a COVID-19 positive individual or isolate because of contracting symptomatic or asymptomatic COVID-19 disease;
- some institutions have been periodically designated "COVID Hospitals";
- access to surgeons, potential strategic partners, and facilities outside of the United States has become curtailed;
- administrators who may be required to facilitate or approve new product intake are constrained by new and other pressing priorities; and
- both clinicians and patients often try to minimize possible COVID-19 exposure, resulting in reduced access to healthcare system and essential care treatments and services.

We believe that these challenges have also highlighted some potential opportunities for our new technology to address certain poorly met needs. For instance, wound interventions are too often considered to be elective procedures instead of being treated essentially or emergently as National Pressure Ulcer Advisory Panel guidelines and others recommend, resulting in a projected increased risk to limb and life while elective procedures are delayed and not prioritized. Furthermore, the implications of these delays are a growing backlog of chronic wounds awaiting care and a worsening of such wounds, leading to greater morbidity, such as infection, necrosis, and amputation, and potentially mortality.

While highlighted by the COVID-19 pandemic, we also believe that these challenges reveal an underlying problem in the healthcare system-clinicians and other providers are being asked to accomplish more in less time with fewer resources. These resources may include higher acuity settings, such as operating rooms; expensive wound care products that may not work as well as desired; nursing time to change wound dressings; and surgeon time for managing wounds during debridement; repeat patient visits over months and often years, and others. Our COVID-19 related discussions with surgeons, economic stakeholders and other decision-making personnel often include whether AC5 Advanced Wound System may enable them to accomplish more for their patients while deploying overall fewer resources and achieving desired outcomes.

Manufacturing

We work with contract manufacturing and related organizations, including those operating under cGMP, as is required by applicable regulatory agencies for production of product that can be used for preclinical and human testing as well as for commercial use. We also have engaged and continue to engage other third parties in the United States and abroad to advise on and perform certain manufacturing and related activities, typically with assistance from our team. These third parties include academic institutions, consultants, advisors, scientists, and/or other collaborators. The activities include development of our primary product candidates, as well as generation of appropriate analytical methods, scale-up, and other procedures for use by manufacturers and/or other members of our supply chain to produce or process our products at current and/or larger scale quantities for preclinical and clinical testing and ultimately, as required marketing authorizations are obtained, commercialization.

Our products are regulated as medical devices, and as such, many of our activities have focused on optimizing traditional parameters to target specifications, biocompatibility, physical appearance, stability, and handling characteristics, among other metrics, in order to achieve the desired product. We and our partners intend to continue to monitor manufacturing processes and formulation methods closely, as success or failure in establishing and maintaining appropriate specifications may directly impact our ability to conduct additional preclinical and clinical trials and/or deliver commercial product.

Merger with ABS and Related Activities

On June 26, 2013, the Company completed the Merger with ABS, pursuant to which ABS became a wholly owned subsidiary of the Company. In contemplation of the Merger, effective May 24, 2013, the Company increased its authorized shares of Common Stock from 375,000 shares to 1,500,000 shares and effected a forward stock split, by way of a stock dividend, of its issued and outstanding shares of Common Stock at a ratio of 11 shares to each one issued and outstanding share. Also, in contemplation of the Merger, effective June 5, 2013, the Company changed its name from Almah, Inc. to Arch Therapeutics, Inc. and changed the ticker symbol under which our Common Stock trades on the OTC Bulletin Board from “AACH” to “ARTH”.

Recent Events

On July 18, 2023, the board of directors of the Company (the “**Board**”) adopted resolutions by unanimous written consent, pursuant to which the Board determined that it is advisable and in the best interests of the Company to amend the Certificate of Incorporation of the Company (the “**Amendment**”) to (i) increase the total number of authorized shares of Common Stock from 12,000,000 to 350,000,000 (the “**Authorized Share Increase**”), (ii) authorize 5,000,000 shares of “blank check” preferred stock of the Company, thereby giving the Board the authority to designate from time to time one or more series of preferred stock (the “**Blank Check Preferred**”), and (iii) provide for a reverse stock split of the outstanding Common Stock, at a ratio within a range of 1.5-for-1 to 20-for-1, with the exact ratio to be determined by the Board subsequent to the applicable approval by the Company’s stockholders, within 1 year following the date of such approval, and without correspondingly decreasing the number of authorized shares of Common Stock (the “**Reverse Split**” and, together with the Authorized Share Increase and the Blank Check Preferred, the “**Charter Amendments**”). On August 22, 2023, stockholders representing a majority of the voting power of the then outstanding shares of voting stock of the Company (the “**Majority Stockholders**”) executed a written consent approving the Charter Amendments and the Company filed a preliminary Information Statement with the SEC with respect to the transactions contemplated hereby. The Company filed a definitive Information Statement with the SEC and mailed the definitive Information Statement to the Company’s stockholders notifying them of the action taken by written consent on September 1, 2023. Accordingly, the Company filed the Amendment with respect to the Authorized Share Increase and the Blank Check Preferred with the Secretary of State of Nevada on September 21, 2023. The Company intends to effect the Reverse Split prior to the pricing of the Primary Offering.

Reverse Stock Split

On January 17, 2023, the Company effected a prior reserve stock split (the “**Prior Reverse Stock Split**”) of the Common Stock at a ratio of 1-for-200. As a result of the Prior Reverse Stock Split, every two hundred (200) shares of Common Stock issued and outstanding were combined into one (1) share of Common Stock, with a proportionate 1:200 reduction in the Company’s authorized Common Stock. The Prior Reverse Stock Split affected all stockholders uniformly and did not alter any stockholder’s percentage interest in the Company’s equity, except to the extent that the Prior Reverse Stock Split would have resulted in some stockholders owning a fractional share. No fractional shares were issued in connection with the Prior Reverse Stock Split. Any fractional shares of Common Stock resulting from the Prior Reverse Stock Split were rounded up to the nearest whole post-Prior Reverse Stock Split share and no stockholders received cash in lieu of fractional shares. The Prior Reverse Stock Split did not change the par value of the Common Stock. All outstanding securities entitling their holders to purchase shares of Common Stock or acquire shares of Common Stock, including stock options, restricted stock units, and warrants, were adjusted as a result of the Prior Reverse Stock Split, as required by the terms of those securities. The Prior Reserve Stock Split was approved by the Company’s stockholders on September 29, 2022.

On January 13, 2023, the Company filed a Certificate of Amendment (the “**Certificate of Amendment**”) to the Company’s Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Nevada to increase the number of authorized shares of Common stock from 4,000,000 shares to 12,000,000 shares. The increase in the number of authorized shares was approved by the Company’s stockholders on September 29, 2022.

Bridge Offering

Between July 7, 2023 and September 11, 2023, pursuant to a Securities Purchase Agreement dated July 7, 2023, as subsequently amended (the “**Bridge SPA**”), among the Company and certain institutional and accredited individual investors (collectively, the “**Bridge Investors**”) the Company issued and sold to the Bridge Investors an aggregate of (i) 3,344,321 shares (the “**Bridge Shares**”) of Common Stock; (ii) warrants (the “**Bridge Pre-Funded Warrants**”) to purchase an aggregate of 6,054,942 shares of Common Stock (the “**Bridge Pre-Funded Warrant Shares**”); and (iii) warrants (the “**Common Warrants**”) and together with the Bridge Pre-Funded Warrants, the “**Bridge Warrants**”) to purchase an aggregate 18,798,526 shares of Common Stock (the “**Common Warrant Shares**” and together with the Bridge Pre-Funded Warrant Share, the “**Bridge Warrant Shares**”), at a purchase price of \$0.275 per Bridge Share and accompanying Common Warrant to purchase two shares of Common Stock, and \$0.274 per Bridge Pre-Funded Warrant to purchase one share of Common Stock and accompanying Common Warrant to purchase two shares of Common Stock. The Shares, Bridge Pre-Funded Warrants, and Common Warrants were issued as part of a private placement offering authorized by the Company’s board of directors (the “**Bridge Offering**”).

Pursuant to the lock-up agreement provided for by the Bridge SPA, the Bridge Investors agreed that they would either (A) purchase securities, for cash, in an offering conducted in conjunction with an uplist of the Common Stock to any of, and in compliance with the rules of, the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (the “**Uplist Transaction**”), which the Primary Offering is intended to be, with an aggregate purchase price equal to at least 4.3 multiplied by the aggregate purchase price paid by the Bridge Investor for the Bridge Shares and Bridge Warrants under the Bridge SPA or (B) be subject to a lock-up provision not to sell or otherwise transfer any of the Bridge Shares or Bridge Warrant Shares acquired by them in the Bridge Offering until the one-year anniversary of the Bridge Closing Date (as defined below). The aggregate gross proceeds for the sale of the Bridge Shares, Bridge Pre-Funded Warrants, and Common Warrants was approximately \$2.6 million, before deducting the placement agent’s fees and other estimated fees and offering expenses payable by the Company. The first closing of the sales of these securities under the Bridge SPA occurred on July 7, 2023 (the “**Bridge Closing Date**”).

Under the Bridge SPA, the Company also agreed that upon the closing of the next underwritten public offering of Common Stock (a “**Qualifying Offering**”), if the effective offering price to the public per share of Common Stock (the “**Qualifying Offering Price**”) is lower than the \$4.00 per share, then the Company shall issue additional Bridge Pre-Funded Warrants in an amount reflecting a reduction in the purchase price paid for the Bridge Shares and Bridge Pre-Funded Warrants that equals the proportion by which the Qualifying Offering Price is less than the \$4.00.

The Company retained Dawson James Securities, Inc. (“**DJ**”) as placement agent in connection with the Bridge Offering. The Company paid DJ a cash fee equal to 8.0% of the aggregate gross proceeds of the Bridge Offering and reimbursement of expenses of \$50,000. Additionally, on September 7, 2023 the Company issued to DJ, or its designees, warrants (the “**Placement Agent Warrants**”) to purchase an aggregate of 441,938 shares of Common Stock. The Placement Agent Warrants are exercisable at any time and from time to time, in whole or in part, during the five-year period commencing March 7, 2024, at a price per share equal to \$0.275.

Bridge Pre-Funded Warrants

The Bridge Pre-Funded Warrants (i) have a nominal exercise price of \$0.001 per share; (ii) are exercisable after the earlier of (A) the six-month anniversary after the date of issuance, (B) 120 days after the closing date of an Uplist Transaction, and (C) the date that a registration statement registering the Bridge Pre-Funded Warrant Shares is declared effective; (iii) are exercisable until all of the Bridge Pre-Funded Warrants are exercised in full; and (iv) have a provision preventing the exercisability of such Bridge Pre-Funded Warrants if, as a result of the exercise of the Bridge Pre-Funded Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder's, would be deemed to beneficially own more than either 4.99% or 9.99% of the Common Stock (the "**Ownership Limitation**") immediately after giving effect to the exercise of the Bridge Pre-Funded Warrants.

Common Warrants

The Common Warrants (i) have an exercise price of \$1.00 per share; (ii) have a term of exercise equal to 5 years after their issuance date; (iii) are exercisable after the earlier of (A) the six-month anniversary after the date of issuance and (B) the date that a registration statement registering the Common Warrant Shares is declared effective; (iv) have a provision permitting voluntary adjustments to the exercise price by the Company, subject to the prior written consent of the Common Warrant holder; (v) are automatically exchanged upon the closing of an Uplist Transaction for a new warrant that is identical to the warrants (other than any pre-funded warrants), if any, being issued to investors in such Uplist Transaction, with the number of shares underlying such new warrant being equal to the number of Common Warrant Shares then underlying the Common Warrant multiplied by three and (vi) have a provision preventing the exercisability of such Common Warrants if, as a result of the exercise of the Common Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Company Common Stock would be aggregated with the holder's, would be deemed to beneficially own more than the Ownership Limitation immediately after giving effect to the exercise of the Common Warrants. **Accordingly, at the closing of the Primary Offering, the Common Warrants will be cancelled and exchanged for newly issued warrants identical to the Investor Warrants to purchase an aggregate of 56,395,578 shares of Common Stock at an exercise price per share equal to the exercise price per share of the warrants sold in the Primary Offering (the "Exchange Investor Warrants").**

Registration Rights Agreement

The Company also entered into a registration rights agreement with the Bridge Investors dated July 7, 2023, as subsequently amended (the "**Registration Rights Agreement**"), pursuant to which the Company is obligated, subject to certain conditions, to file with the Securities and Exchange Commission within the earlier of (i) 30 days following the closing date of the Uplist Transaction and (ii) October 31, 2023 one or more registration statements (any such registration statement, a "**Resale Registration Statement**") to register the Shares, the Bridge Warrant Shares, the shares of Common Stock issuable upon exercise in full of the Exchange Investor Warrants (the "**Exchange Investor Warrant Shares**") and the shares of Common Stock issuable upon exercise in full of the Participating Pre-Funded Warrant (as defined below) (the "**Conversion Warrant Shares**") for resale under the Securities Act of 1933, as amended (the "**Securities Act**"). The Company's failure to satisfy certain filing and effectiveness deadlines with respect to a Resale Registration Statement and certain other requirements set forth in the Registration Rights Agreement may subject the Company to payment of monetary penalties.

Note Modification Agreements

On July 7, 2023, the Company entered into an amendment ("**Amendment No. 8 to the First Notes**") with the holders of the Company's outstanding Senior Secured Convertible Promissory Notes, as separately amended on February 14, 2023, March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 31, 2023, August 30, 2023 and September 30, 2023 (as amended, the "**First Notes**"), issued in connection with a private placement financing the Company completed on July 6, 2022 (the "**First Closing**"). On July 7, 2023, the Company also entered into an amendment ("**Amendment No. 8 to the Second Notes**") with the holders of the Company's outstanding Unsecured Convertible Promissory Notes, as separately amended on February 14, 2023, March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 31, 2023, August 30, 2023 and September 30, 2023 (as amended, the "**Second Notes**"), issued in connection with a private placement financing the Company completed on January 18, 2023 (the "**Second Closing**"). On July 7, 2023, the Company also entered into an amendment ("**Amendment No. 3 to the Third Notes**") and, together with Amendment No. 8 to the First Notes and Amendment No. 8 to the Second Notes, the "**Amendments to the 2022 Notes**") with the holders of the Company's outstanding Unsecured Convertible Promissory Notes, as separately amended on June 15, 2023, July 1, 2023, July 31, 2023, August 30, 2023 and September 30, 2023 (as amended, the "**Third Notes**" and, together with the First Notes and Second Notes, the "**2022 Notes**"), issued in connection with a private placement financing the Company completed on May 15, 2023 (the "**Third Closing**").

Under the Amendments to the 2022 Notes, the following amendments to the 2022 Notes will be simultaneously effective upon the closing of the Uplist Transaction. The Specified Percentage (as defined below) of the then outstanding principal amount of the 2022 Notes shall automatically convert (the “**Automatic Conversion**”) into shares of Common Stock, with the conversion price for purposes of such Automatic Conversion being equal to the lower of (i) the per unit price at which any units (each unit being comprised of one share or share equivalent and accompanying warrants, if any) are sold in the Uplist Transaction or (ii) the price at which warrants issued in the Uplist Transaction are exercisable (but in no event increased above the conversion price in effect immediately prior to the pricing of the Uplist Transaction).

In addition, if the Holder (as defined below) (i) participates in the Uplist Transaction and in the Bridge Offering for a combined (taking into account the Holder’s aggregate investment in the Uplist Transaction and the Bridge Offering) amount equal to no less than fifty percent (50%) of the Holder’s original purchase price under the 2022 Notes and (ii) the Holder’s amount of participation in the Uplist Transaction is at least 4.3 times the Holder’s amount of participation in the Bridge Offering (such criteria in clauses (i) and (ii) above, the “**Participation Criteria**”), then the Holder shall receive a pre-funded warrant (the “**Participating Pre-Funded Warrant**”) to purchase a number of shares of Common Stock equal to the Specified Number (as defined below) times the dollar amount under the 2022 Notes that was converted in the Automatic Conversion. The Participating Pre-Funded Warrant (i) shall have an exercise price of \$0.001 per share, (ii) may be exercised on a cashless basis, (iii) shall be exercisable by the Holder at any time commencing on the 90th day after issuance, (iv) may be redeemed by the Company for cash at a redemption price of \$0.82 per share underlying the Participating Pre-Funded Warrant, with any such redemption made pro rata to all holders of the Participating Pre-Funded Warrants, (v) and shall contain a customary beneficial ownership limitation provision. Additionally, the holder of the Participating Pre-funded Warrants will agree that, until January 6, 2024, it shall not offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of, or announce the intention to otherwise dispose of, the Participating Pre-Funded Warrant.

“Specified Percentage” means the greater of: (i) the percentage specified by the Company by notice to the 2022 Note holders (the “**Holders**” and each a “**Holder**”) at least five business days prior to the closing of the Uplist Transaction, which percentage shall be the percentage necessary to ensure the applicable Nasdaq requirements regarding the Uplist Transaction are satisfied, and (ii) the percentage specified by the Holder by notice to the Company at least three business days prior to the closing of the Uplist Transaction (which percentage may be different for each 2022 Note as determined by each Holder thereof); provided, that in no event shall the Specified Percentage for the 2022 Notes (A) exceed twenty five percent (25%) unless otherwise agreed in writing by the Holder, or (B) exceed fifty percent (50%) unless otherwise agreed in writing by the Company.

“Specified Number” means, if the Specified Percentage is 50%, 2.4, which number shall be increased by 1.6% for each percentage point decrease in the Specified Percentage, such increase being compounded iteratively for each percentage point decrease in the Specified Percentage, with the result rounded to two decimal places.

Further, on September 30, 2023, the Company entered into an amendment (“**Amendment No. 11 to the First Notes**”) to the First Notes, an amendment (“**Amendment No. 11 to the Second Notes**”) to the Second Notes and an amendment (“**Amendment No. 6 to the Third Notes**”) and, together with Amendment No. 11 to the First Notes and Amendment No. 11 to the Second Notes, the “**September Amendments to the 2022 Notes**”) to the Third Notes. The September Amendments to the 2022 Notes extend the deadline by which the Company must close the Uplist Transaction to October 31, 2023 and provide that upon the Automatic Conversion and to the extent that a Holder’s beneficial ownership would increase over the applicable Ownership Limitation, the Holder will receive pre-funded warrants (the “**2022 Note Conversion Pre-Funded Warrants**”) in lieu of shares of Common Stock otherwise issuable to the Holder in connection with the Automatic Conversion, which 2022 Note Conversion Pre-Funded Warrants shall have an exercise price of \$0.001 per share, may be exercised on a cashless basis, shall be exercisable immediately upon issuance and shall contain a customary beneficial ownership limitation provision.

Accordingly, it is currently anticipated that the Specified Percentage will be 50%, and thus, at the closing of the Primary Offering : (i) an aggregate of 1,567,127 shares of Common Stock (assuming no issuance of 2022 Note Conversion Pre-Funded Warrants) will be issued upon the Automatic Conversion of an aggregate of \$3,134,250 of principal amount under the 2022 Notes, representing 50% of the \$6,268,501 in principal amount currently outstanding under the 2022 Notes, based on the assumed offering price of \$2.00 per Unit in the Primary Offering; and (ii) assuming that all Holders fulfill the Participation Criteria, the Holders will be issued Participating Pre-Funded Warrants to purchase an aggregate of 7,522,203 shares of Common Stock, based on a Specified Number of 2.4 multiplied by the \$3,134,250 of principal amount converted in the Automatic Conversion.

Additionally, on July 7, 2023, the Company entered into an amendment (the “**Omnibus Amendment to Notes and Warrants**”) with the Holders of the 2022 Notes, amending the 2022 Notes and related warrants issued at each of the First Closing, Second Closing, and Third Closing (the “**First Warrants**”, “**Second Warrants**” and “**Third Warrants**”, respectively, and collectively, the “**2022 Warrants**”). Under the Omnibus Amendment to Notes and Warrants, the 2022 Notes and 2022 Warrants were amended (i) to modify the Most Favored Nation provisions therein to exclude the Bridge Offering and (ii) to prohibit the Company from engaging in any capital raising transactions, subject to certain exceptions, until the earlier of (A) July 7, 2027, and (B) the first date on which all Holders hold less than 20% of the original amount of the Participating Pre-Funded Warrants received by each Holder, respectively, in connection with the Automatic Conversion.

2022 Notes

The 2022 Notes bear interest on the unpaid principal balance at a rate equal to ten percent (10%) (computed on the basis of the actual number of days elapsed in a 360-day year) per annum accruing from the issuance date until the 2022 Notes become due and payable at maturity or upon their conversion, acceleration or by prepayment, and may become due and payable upon the occurrence of an event of default under the 2022 Notes. The 2022 Notes mature January 6, 2024. Any amount of principal or interest on the 2022 Notes which is not paid when due shall bear interest at the rate of the lesser of (i) eighteen percent (18%) per annum or (ii) the maximum amount allowed by law from the due date thereof until payment in full. As of September 15, 2023, the outstanding unpaid principal balance including all accrued interest under the 2022 Notes totaled \$6,935,071.

The 2022 Notes are convertible into shares of Common Stock at the option of each Holder from the date of issuance at \$9.14 (the “**Conversion Price**”), subject to adjustment, through the later of (i) January 6, 2024 (the “**Maturity Date**”) or (ii) the date of payment of the Default Amount (as defined in the 2022 Notes).

The 2022 Notes contain events of default, which include, among other things, (i) the Company’s failure to pay when due any principal or interest payment under the 2022 Notes; and (ii) our failure to complete an Uplist Transaction by October 31, 2023.

The 2022 Warrants (i) have an exercise price of \$9.94 per share; (ii) have a term of exercise equal to 5 years after their issuance date; (iii) became exercisable immediately after their issuance; and (iv) have a provision preventing the exercisability of such 2022 Warrants if, as a result of the exercise of the 2022 Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of our Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than the Ownership Limitation. As long as the 2022 Notes and 2022 Warrants remaining outstanding, upon the issuance of any security in connection with any potential future financing activity on terms more favorable than the existing terms, except for any offering conducted in connection with the Uplist Transaction which the Primary Offering is intended to be, the Company has an obligation to notify the holders of the 2022 Notes and 2022 Warrants of such more favorable terms, and to use best efforts to effect such terms in the 2022 Notes and 2022 Warrants.

Under the Second Amended and Restated Registration Rights Agreement, dated as of May 15, 2023, as amended, the Company is required to file a registration statement registering the securities issued in the Second Closing and Third Closing, including the applicable 2022 Notes and 2022 Warrants, no later than 45 days following the closing of the Uplist Transaction.

As discussed above, it is currently anticipated that 50% of the of the \$6,268,501 unpaid principal balance currently outstanding under the 2022 Notes will convert into 1,567,127 shares of Common Stock (assuming no issuance of 2022 Note Conversion Pre-Funded Warrants) in connection with the Automatic Conversion.

Series 1 and 2 Convertible Notes

On June 4, 2020 and November 6, 2020, the Company issued unsecured 10% Series 1 Convertible Notes (“**Series 1 Notes**”) and Series 2 Convertible Notes, as amended (“**Series 2 Notes**”, and collectively with the Series 1 Notes, the “**Series Convertible Notes**”). The maturity dates of the Series 1 Notes and Series 2 Notes are June 30, 2023 and November 30, 2023, respectively. On July 12, 2023, the Company secured countersigned notices of conversion from all remaining holders of the Series 1 Convertible Notes and provided instructions to its transfer agent to issue a total of 59,912 shares of Common Stock in full satisfaction of all previously outstanding Series 1 Convertible Notes, which had an aggregate of \$718,918 of principal and interest outstanding at the time of conversion.

As of September 15, 2023, there was \$587,959 of principal and accrued interest (through maturity) outstanding under the Series 2 Notes. The Series 2 Notes have a “Conversion Price” of \$50.00 and allow the Company to convert all obligations thereunder upon the Uplist Transaction, or the maturity date, using the Conversion Price and multiplying the obligations then outstanding by 4.5. **Accordingly, it is currently anticipated that an aggregate of 52,917 shares of Common Stock will be issued at the closing of the Primary Offering upon the conversion of the remaining outstanding amount under the Series 2 Notes.**

Insurance Financing

On July 11, 2023, the Company entered into a finance agreement with First Insurance Funding in order to fund a portion of its insurance policies. The amount financed is approximately \$310,000 and incurs interest at a rate of 7.49%. Per the terms of its agreement with First Insurance Funding, the Company is required to make monthly payments of approximately \$32,000 through April 2024.

Warrant Exchange Agreement

On March 10, 2023, the Company entered into exchange agreements (the “**Exchange Agreements**”) with each holder (the “**Warrantholders**”) of the Company’s outstanding Series G Warrants to purchase shares of the Company’s Common Stock at an exercise price of \$140.00 per share and the Company’s outstanding Series H Warrants to purchase shares of Common Stock at an exercise price of \$80.00 per share. Pursuant to the Exchange Agreements, the Warrantholders exchanged 34,013 Series G Warrants for 3,402 shares of Common Stock and 43,077 Series H Warrants for 8,617 shares of Common Stock.

Reimbursements and Support Program

During the month of September 2022, the Company launched and announced a reimbursement support program designed to help drive increased commercial use of the company’s FDA-approved AC5 Advanced Wound System. During the fiscal year ended September 30, 2022, the Company invoiced and shipped a total of 33 units, of which 23 units were shipped in connection with the launch of the Company’s reimbursement support program. Under the terms of the program, the invoice amount may be adjusted through full or partial write-offs based on actual reimbursement amounts paid by CMS for AC5 units applied and billed by doctors. As such, revenue, if any, for the units shipped in connection with the Company’s reimbursement support program will be booked in future periods when all conditions have been satisfied.

Results of Operations

The following discussion of our results of operations should be read together with the consolidated financial statements included in this prospectus and the notes thereto. Our historical results of operations and the period-to-period comparisons of our results of operations that follow are not necessarily indicative of future results.

Nine Months Ended June 30, 2023 Compared to Nine Months Ended June 30, 2022

	June 30, 2023 (\$)	June 30, 2022 (\$)	Increase (Decrease) (\$)
Revenue	36,207	14,086	22,121
Operating Expense:			
Cost of revenues	54,882	51,363	3,519
Selling, general and administrative	3,225,753	3,308,227	(82,474)
Research and development	471,135	922,120	(450,985)
Loss from Operations	(3,715,563)	(4,267,624)	(552,061)
Other (Expense) Income	(810,077)	880,329	1,690,406
Net loss	<u>(4,525,640)</u>	<u>(3,387,295)</u>	<u>(1,138,345)</u>

Revenue

Revenue for the nine months ended June 30, 2023 was \$36,207, an increase of \$22,121 compared to revenue of \$14,086 for the nine months ended June 30, 2022. Revenue for the nine months ended June 30, 2023 and 2022 was primarily the result of transactions into VA Hospitals through our distribution partner, LGS.

Cost of Revenue

Cost of revenue during the nine months ended June 30, 2023 was \$54,882 an increase of \$3,519 compared to cost of revenue of \$51,363 for the nine months ended June 30, 2022. Cost of revenue includes product costs, third party warehousing, overhead allocation, royalty and shipping costs.

Selling, General and Administrative Expense

Selling, general and administrative expense during the nine months ended June 30, 2023 was \$3,225,753, a decrease of \$82,474 compared to \$3,308,227 for the nine months ended June 30, 2022. The decrease in selling, general and administrative expense for the nine months ended June 30, 2023 is primarily attributable to a decrease in compensation costs attributed to a reduction in headcount partially offset by an increase in legal and consulting costs.

Research and Development Expense

Research and development expense during the nine months ended June 30, 2023 was \$471,135 a decrease of \$450,985 compared to \$922,120 for the nine months ended June 30, 2022. The decrease in research and development expense is primarily attributable to a decrease in compensation costs attributed to a reduction in headcount.

Other (Expense) Income

Other expense during the nine months ended June 30, 2023 was \$810,077 an increase of \$1,690,406 compared to other income of \$880,329 for the nine months ended June 30, 2022. The increase in other (expense) income is primarily attributed to an increase in interest expense related to the 2022 Notes, Second Notes and Third Notes offset by a gain for the extinguishment of the Series G warrants and Series H warrants derivative liabilities during the nine months ended June 30, 2023 and the impact of the expiration of the Series F warrants during the nine months ended June 30, 2022.

Year Ended September 30, 2022 Compared to Year Ended September 30, 2021

	September 30, 2022	September 30, 2021	Increase (Decrease)
	(\$)	(\$)	(\$)
Revenue	15,652	11,565	4,087
Operating Expenses			
Cost of revenues	51,489	26,282	25,207
Selling, general and administrative	4,519,636	5,009,323	(489,687)
Research and development	1,153,333	1,353,084	(199,751)
Loss from Operations	(5,708,806)	(6,377,124)	668,318
Other income	432,952	136,642	296,310
Net loss	(5,275,854)	(6,240,482)	964,628

Revenue

Revenue for the year ended September 30, 2022 was \$15,652, an increase of \$4,087 compared to \$11,565 for the year ended September 30, 2021. Revenue for the year ended September 30, 2022 was the result of four transactions into multiple VA Hospitals consisting of ten (10) total units through our distribution partner, LGS. Revenue for the year ended September 30, 2021 was \$11,565, which was the result of a single transaction with an established key opinion leader and a single transaction into the Veterans Administration of one (1) unit through our distribution partner, LGS.

Cost of revenues

Cost of revenues during the year ended September 30, 2022 was \$51,489, an increase of \$25,207 compared to \$26,282 for the year ended September 30, 2021. Cost of revenue includes product costs, third party warehousing, overhead allocation, royalty and shipping costs.

Selling, General and Administrative Expense

General and administrative expense during the year ended September 30, 2022 were \$4,519,636 a decrease of \$489,687 compared to \$5,009,323 for the year ended September 30, 2021. The decrease in selling, general and administrative expense for the year ended September 30, 2022 is primarily attributable to decrease in legal and consulting costs partially offset by an increase in compensation costs attributed to an increase in headcount.

Research and Development Expense

Research and development expense during the year ended September 30, 2022 was \$1,153,333, a decrease of \$199,751 compared to \$1,353,084 for the year ended September 30, 2021. The decrease in research and development expense is primarily attributable to a decrease in compensation costs, partially offset by an inventory obsolescence charge of approximately \$248,000 for shelf-life, research and development and product samples.

Other Income

Other income during the year ended September 30, 2022 was \$432,952, an increase of \$296,310 compared to total other income of \$136,642 for the year ended September 30, 2021. The increase in other income is attributable to a change in fair market value of the derivative liabilities partially offset by an increase in interest expense and the gain on the forgiveness of PPP loan recorded in the year ended September 30, 2021.

Liquidity and Capital Resources

In the first quarter of 2021, the Company commenced commercial sales of our first product, AC5 Advanced Wound System. We devote a significant amount of our efforts on fundraising as well as planning and conducting product research and development and activities in connection with obtaining regulatory marketing authorization. We have principally raised capital through borrowings and the issuance of convertible debt and units consisting of Common Stock and warrants to fund our operations.

Working Capital

At June 30, 2023, we had total current assets of \$1,560,018 (including cash of \$86,542) and working capital deficit of \$8,019,256. Our working capital as of June 30, 2023 and September 30, 2022 are summarized as follows:

	June 30, 2023	September 30, 2022
Total Current Assets	\$ 1,560,018	\$ 2,598,195
Total Current Liabilities	9,579,274	3,320,494
Working Capital deficit	<u>\$ (8,019,256)</u>	<u>\$ (722,299)</u>

Total current assets as of June 30, 2023 were \$1,560,018, a decrease of \$1,038,177 compared to \$2,598,195 as of September 30, 2022. The decrease in current assets is primarily attributable to a decrease in cash and prepaid expenses. Our total current assets as of June 30, 2023 and September 30, 2022 were comprised primarily of cash, inventory and prepaid expenses and other current assets.

Total current liabilities as of June 30, 2023 were \$9,579,274, an increase of \$6,258,780 compared to \$3,320,494 as of September 30, 2022. The increase is primarily due to an increase in accounts payable, the current portion of the Series 2 Convertible Notes, the current portion of the 2022 Notes, current portion of the Unsecured convertible notes, which includes both the Second Notes, the Third Notes and the Exchanged Notes, Shareholder and Third Party advances related to bridge financing and the accrued interest associated with these notes partially offset by a decrease to the amount owed in connection with the financing of certain insurance premiums and the decrease in the fair value of the derivative liability resulting from the exchange of the Series G warrants into Common Stock.

At September 30, 2022, we had total current assets of \$2,598,195 (including cash of \$746,940) and negative working capital of \$722,299. Our working capital as of September 30, 2022 and September 30, 2021 is summarized as follows:

	September 30, 2022	September 30, 2021
Total Current Assets	\$ 2,598,195	\$ 3,667,745
Total Current Liabilities	3,320,494	1,727,547
Working Capital	<u>\$ (722,299)</u>	<u>\$ 1,940,198</u>

Total current assets as of September 30, 2022 were \$2,598,195, a decrease of \$1,069,550 compared to \$3,667,745 as of September 30, 2021. The decrease in current assets is primarily attributable to selling, general and administrative expense and research and development expense incurred in connection with activities to develop our primary product candidate, which was partially offset by our net proceeds from our 2022 Private Placement Financing. Our total current assets as of September, 2022 and 2021 were comprised primarily of cash, inventory and prepaid expense.

Total current liabilities as of September 30, 2022 were \$3,320,494, an increase of \$1,592,947 compared to \$1,727,547 as of September 30, 2021. The increase is primarily due to an increase in accounts payable, current portion of the Series 1 Convertible Notes, current portion of the Series 1 accrued interest and the amount owed in connection with the financing of certain insurance premiums and the current portion of the derivative liability.

Cash Flow for the Nine Months Ended June 30, 2023 Compared to the Nine Months Ended June 30, 2022

	June 30, 2023	June 30, 2022
Cash Used in Operating Activities	\$ (2,147,480)	\$ (2,786,642)
Cash Provided by Financing Activities	1,487,082	575,000
Net decrease in Cash	<u>\$ (660,398)</u>	<u>\$ (2,211,642)</u>

Cash Used in Operating Activities

Cash used in operating activities decreased by \$639,162 to \$2,147,480 during the nine months ended June 30, 2023, compared to \$2,786,642 during the nine months ended June 30, 2022. The decrease in cash used in operating activities is primarily attributable the Company managing expenses and an increase in accounts payable and accrued interest.

Cash Used in Financing Activities

Cash provided by financing activities increased by \$912,082 to \$1,487,082 during the nine months ended June 30, 2023, compared to \$575,000 cash provided by financing activities during the nine months ended June 30, 2022. For the nine months ended June 30, 2023, the cash provided by financing activities was attributable to the Second Closing of the 2022 Convertible Note Offering, the Third Closing of the 2022 Convertible Note Offering and shareholder advances, which was partially offset by payments made in connection with the financing of certain insurance premiums. For the nine months ended June 30, 2022, the cash provided by financing activities resulted from net proceeds of \$575,000 raised from the advances from investors.

Cash Flow for the Year Ended September 30, 2022 Compared to the Year Ended September 30, 2021

	September 30, 2022	September 30, 2021
Cash Used in Operating Activities	\$ (4,456,075)	\$ (5,958,628)
Cash Used in Investing Activities	-	(3,275)
Cash Provided by Financing Activities	2,936,376	7,269,233
Net Increase (decrease) in Cash	\$ (1,519,699)	\$ 1,307,330

Cash Used in Operating Activities

Cash used in operating activities decreased \$1,502,553 to \$4,456,075 during the fiscal year ended September 30, 2022 compared to \$5,958,628 for the fiscal year ended September 30, 2021. The decrease in cash used in operating activities is primarily attributable to an increase in accounts payable, primarily attributable to increased legal fees, product costs and consulting fees, and accrued interest, which was partially offset by an increase in inventory.

Cash Used in Investing Activities

Cash used in investing activities decreased \$3,275 to \$0 during the fiscal year ended September 30, 2022, compared to \$3,275 during the fiscal year ended September 30, 2021. For the fiscal year ended September 30, 2021, cash used in investing activities is attributed to computer hardware purchases.

Cash Provided by Financing Activities

Cash provided by financing activities decreased \$4,332,857, to \$2,936,376 during the fiscal year ended September 30, 2022, compared to \$7,269,233 the fiscal year ended September 30, 2021. For the year ended September 30, 2022, the cash provided by financing activities resulted from net proceeds of \$2,969,586 raised from the issuance of senior secured convertible notes, warrants and inducement shares partially offset by repayment of financed insurance premium. For the year ended September 30, 2021, the cash provided by financing activities resulted from net proceeds of \$6,219,233 raised from issuance of Common Stock and warrants in the 2021 Financing and \$1,050,000 from the issuance of Series 2 Convertible Notes.

Cash Requirements

We anticipate that our operating expenses, interest expense and other expenses will increase significantly as we continue to implement our business plan and pursue our operational goals. Depending upon additional input from EU and US regulatory authorities, however, we do not expect to generate sufficient revenues from operations before we will need to raise additional capital. Further, our estimates regarding our use of cash could change if we encounter unanticipated difficulties or other issues arise, including without limitation those set forth under the heading “**Risk Factors**” in this prospectus in which case our current funds may not be sufficient to operate our business for the period we expect.

In the first quarter of 2021, the Company commenced commercial sales of our first product, AC5 Advanced Wound System. That revenue will not be sufficient to fund our business operations and we will need to obtain additional funding from external sources for the foreseeable future. We do not have any commitments for future capital. Significant additional financing will be required to fund our planned operations in the near term and in future periods, including research and development activities relating to our potential new product candidates, seeking regulatory approval of any other product candidates we may choose to develop, commercializing any product candidates for which we are able to obtain regulatory approval or certification, seeking to license or acquire new assets or businesses, and maintaining our intellectual property rights and pursuing rights to new technologies. We may not be able to obtain additional financing on commercially reasonable or acceptable terms when needed, or at all. If we cannot raise the money that we need in order to continue to develop our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations. If any of these were to occur, there is a substantial risk that our business would fail, and our stockholders could lose all of their investments.

As previously noted, since inception we have funded our operations primarily through equity and debt financings and we expect to continue to seek to do so in the future. If we obtain additional financing by issuing equity securities, our existing stockholders' ownership will be diluted. Additionally, the terms of securities we may issue in future capital-raising transactions may be more favorable for our new investors, and in particular may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have additional dilutive effects. If we obtain additional financing by incurring debt, we may become subject to significant limitations and restrictions on our operations pursuant to the terms of any loan or credit agreement governing the debt. Further, obtaining any loan, assuming a loan would be available when needed on acceptable terms, would increase our liabilities and future cash commitments. We may also seek funding from collaboration or licensing arrangements in the future, which may require that we relinquish potentially valuable rights to our product candidates or proprietary technologies or grant licenses on terms that are not favorable to us. Moreover, regardless of the manner in which we seek to raise capital, we may incur substantial costs in those pursuits, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other related costs. In addition, we are bound by certain contractual terms and obligations that may limit or otherwise impact our ability to raise additional funding in the near-term including, but not limited to, provisions in the Bridge SPA and 2022 Notes SPA, associated with the 2022 Notes Financing, in each case as described in greater detail in the risk factor entitled "***The terms of the Bridge Offering and 2022 Notes Financing could impose additional challenges on our ability to raise funding in the future***" under the heading "**Risk Factors**" in this prospectus.

Going Concern

We have commenced commercial sales of our first product, AC5 Advanced Wound System. From inception, we have had recurring losses from operations. The continuation of our business as a going concern is dependent upon raising additional capital and eventually attaining and maintaining profitable operations. As of June 30, 2023, there is substantial doubt about the Company's ability to continue as a going concern. The financial statements included in this prospectus do not include any adjustments that might be necessary should operations discontinue.

Critical Accounting Policies and Significant Judgments and Estimates

Pursuant to certain disclosure guidance issued by the SEC, the SEC defines "critical accounting policies" as those that require the application of management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. We do not believe the company has any accounts or circumstances that carry a significant level of estimation uncertainty. Our critical accounting policies that we anticipate will require the application of our most difficult, subjective or complex judgments are as follows:

Derivative Liabilities

The Company accounts for its warrants and other derivative financial instruments as either equity or liabilities based upon the characteristics and provisions of each instrument, in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 815, *Derivatives and Hedging*. Warrants classified as equity are recorded at fair value as of the date of issuance on the Company's consolidated balance sheets and no further adjustments to their valuation are made. Warrants classified as derivative liabilities and other derivative financial instruments that require separate accounting as liabilities are recorded on the Company's consolidated balance sheets at their fair value on the date of issuance and will be revalued on each subsequent balance sheet date until such instruments are exercised or expire, with any changes in the fair value between reporting periods recorded as other income or expense. Management estimates the fair value of these liabilities using option pricing models and assumptions that are based on the individual characteristics of the warrants or instruments on the valuation date, as well as assumptions for future financings, expected volatility, expected life, yield, and risk-free interest rate.

Inventories

Inventories are stated at the lower of cost or net realizable value. The cost of inventories comprises expenditures incurred in acquiring the inventories, the cost of conversion and other costs incurred in bringing them to their existing location and condition. The cost of raw materials, work-in-progress and finished goods and other products are determined on a First in First out (FiFo) basis. When determining net realizable value, appropriate consideration is given to obsolescence, excessive levels, deterioration, and other factors in evaluating net realizable value.

Complex Financial Instruments

The Company does not use derivative instruments to hedge exposures to cash flow, market, or foreign currency risks. The Company evaluates its financial instruments, including warrants, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. The Company values its derivatives using the Black-Scholes option-pricing model or other acceptable valuation models, including Monte-Carlo simulations. Derivative instruments are valued at inception, upon events such as an exercise of the underlying financial instrument, and at subsequent reporting periods. The classification of derivative instruments, including whether such instruments should be recorded as liabilities, is re-assessed at the end of each reporting period.

The Company reviews the terms of debt instruments, equity instruments, and other financing arrangements to determine whether there are embedded derivative features, including embedded conversion options that are required to be bifurcated and accounted for separately as a derivative financial instrument. Additionally, in connection with the issuance of financing instruments, the Company may issue freestanding options and warrants, including options or warrants to non-employees in exchange for consulting or other services performed.

The Company accounts for its common stock warrants in accordance with ASC 815, Derivatives and Hedging (**ASC 815**). Based upon the provisions of ASC 815, the Company accounts for common stock warrants as liabilities if the warrant requires net cash settlement or gives the holder the option of net cash settlement, or it fails the equity classification criteria. The Company accounts for common stock warrants as equity if the contract requires physical settlement or net physical settlement or if the Company has the option of physical settlement or net physical settlement and the warrants meet the requirements to be classified as equity. Common stock warrants classified as liabilities are initially recorded at fair value on the grant date and remeasured at fair value each balance sheet date with the offset adjustments recorded in change in fair value of warrant liability within the consolidated statements of operations. Common stock warrants classified as equity are initially measured at fair value on the grant date and are not subsequently remeasured.

Recent Accounting Guidance

In August 2020, the FASB issued ASU 2020-06, *“Debt with Conversion and other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity’s Own Equity (Subtopic 815-40)”* (**ASU 2020-06**). The purpose of ASU 2020-06 is to address issues identified as a result of the complexity associated with applying generally accepted accounting principles (**GAAP**) for certain financial instruments with characteristics of liabilities and equity. The amendments in ASU 2020-06 are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2023. Early adoption is permitted but no earlier than fiscal years beginning after December 15, 2020. The Company adopted ASU 2020-06 during our first quarter of fiscal year 2022, and the impact was considered immaterial on our consolidated financial statements.

Off-Balance Sheet Arrangements

We have no significant off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to stockholders.

OUR BUSINESS

Corporate Overview

Arch Therapeutics, Inc. (together with its subsidiary, the “**Company**” or “**Arch**”) arose from the June 26, 2013 merger (the “**Merger**”) of three entities previously known as Arch Biosurgery, Inc., Almah, Inc., and Arch Acquisition Corporation, respectively.

Arch Biosurgery, Inc. (“**ABS**”) is a biotechnology company that was incorporated under the laws of the Commonwealth of Massachusetts on March 6, 2006 as Clear Nano Solutions, Inc., changed its name from Clear Nano Solutions, Inc. to Arch Therapeutics, Inc. on April 7, 2008, and, as part of the Merger transaction, changed its name from Arch Therapeutics, Inc. to Arch Biosurgery.

Almah, Inc., was incorporated under the laws of the State of Nevada on September 16, 2009 and, as part of the Merger transaction, changed its name to Arch Therapeutics, Inc. and abandoned both its prior business plan and operations in order to adopt those of ABS.

Arch Acquisition Corporation, or Merger Sub, was a wholly owned subsidiary of Almah, Inc., formed for the purpose of the Merger transaction, pursuant to which Merger Sub merged with and into ABS, and ABS thereafter became the wholly owned subsidiary of the Company.

The Company’s principal offices are located in Framingham, Massachusetts.

The Company has recently devoted substantially all of our operational effort to the market adoption and commercial sales of AC5 Advanced Wound System, its first product. To date, the Company has principally raised capital through debt borrowings, the issuance of convertible debt, and the issuance of units consisting of Common Stock and warrants.

The Company expects to incur substantial expenses for the foreseeable future relating to research, development and commercialization of current and potential products. However, there can be no assurance that the Company will be successful in securing additional capital when needed, on terms acceptable to the Company, if at all. Therefore, there exists substantial doubt about the Company’s ability to continue as a going concern for one year past the issuance of the financial statements. The consolidated financial statements do not include any adjustments related to the recoverability of assets that might be necessary despite this uncertainty.

Our Current Business

We are a biotechnology company marketing a number of products based on our innovative AC5 self-assembling technology platform. We believe these products are important advances in the field of stasis and barrier applications, which includes managing wounds created during surgery, trauma, interventional care or disease; stopping bleeding (hemostasis); and controlling leaking (sealant). We have recently devoted substantially all of our operational effort to the market adoption and commercial sales of AC5 Advanced Wound System, our first product. Our goal is to make care faster and safer for patients with products for use on external wounds, which we refer to as Dermal Sciences applications, and products for use inside the body, which we refer to as BioSurgery applications.

To date, the Company has principally raised capital through debt borrowings, the issuance of convertible debt and the issuance of units consisting of its common stock, par value \$0.001 per share (“**Common Stock**”), and warrants. The Company expects to incur substantial expenses for the foreseeable future relating to the research, development, clinical trials, and commercialization of its current and potential products. As of September 15, 2023, we believe that our cash on hand will meet our anticipated cash requirements into the first fiscal quarter of 2024, and we must obtain additional financing in order to continue to operate our business. The Company will be required to raise additional capital, obtain alternative means of financial support, or both, in order to continue to fund operations. There can be no assurance that the Company will be successful in securing additional resources when needed on terms acceptable to the Company, if at all. Therefore, there exists substantial doubt about the Company’s ability to continue as a going concern.

Core Technology

Our flagship products and product candidates are derived from our AC5 self-assembling peptide (“**SAP**”) technology platform and are sometimes referred to as AC5 or the “AC5 Devices.” These include AC5 Advanced Wound System and AC5 Topical Hemostat, which have received marketing authorization as medical devices in the United States and Europe, respectively, and which are intended for skin applications, such as the management of complicated chronic wounds and acute surgical wounds. Marketing for AC5 Topical Hemostat in Europe has not initiated. Other products are in development for use in minimally invasive or open surgical procedures, and include, for example, AC5-GTM for gastrointestinal endoscopic procedures and AC5-V and AC5 Surgical Hemostat for hemostasis inside the body, all of which are currently investigational devices limited by law to investigational use.

Products based on the AC5 platform contain a proprietary biocompatible peptide that is synthesized from proteogenic, naturally occurring L-amino acids. Unlike products that contain traditional peptide sequences, when applied to a wound, AC5-based products intercalate into the interstices of the tissue and self-assemble (i.e., self-build) into a protective physical-mechanical nanoscale structure that can provide a barrier to leaking substances, such as blood, while also acting as a biodegradable scaffold that enables healing. Self-assembly is a central component of the mechanism of action of our technology. Individual AC5 peptide units readily build themselves, or self-assemble, into an ordered network of nanofibrils when in aqueous solution by the following process:

- Peptide strands line up with neighboring peptide strands, interacting via hydrogen bonds (non-covalent bonds) to form a ribbon-like structure called a beta sheet.
- This process continues such that hundreds of strands organize with charged and polar side chains oriented on one face and non-polar side chains oriented on the opposite face of the beta sheets.
- Interactions of the resulting structure with water molecules and ions results in formation nanofibrils, which extend in length and can join together to form larger nanofibers.
- This network of AC5 peptide nanofibers forms the semi-solid physical-mechanical barrier that interacts with the extracellular matrix, is responsible for sealant, hemostatic and/or other properties that may be observed even in the presence of antithrombotic agents (i.e., blood thinners), and which subsequently becomes the scaffold that supports the repair and regeneration of damaged tissue.

Based on the intended application, we believe that the underlying AC5 SAP technology can impart important features and benefits to our products that may include, for instance, stopping bleeding (hemostasis), mitigating contamination, modulating inflammation, donating moisture, and enabling an appropriate wound microenvironment conducive to healing. Furthermore, we believe that AC5 SAP technology permits cell and tissue growth and is self-healing, in that it can dynamically self-repair around migrating cells. For instance, AC5 Advanced Wound System, which is indicated for the management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds, is shipped and stored at room temperature, is applied directly as a liquid, can conform to irregular wound geometry, self-assembles into a wound care matrix that can provide clinicians with multi-modal support, and does not possess sticky or glue-like handling characteristics. We believe these properties enhance its utility in several settings and contribute to its user-friendly profile.

We believe that our technology lends itself to a range of potential applications for wounds inside or on the body, including those for which a hemostatic agent or sealant is needed. For instance, the results of certain preclinical and clinical investigations that either we have conducted, or others have conducted on our behalf, have shown quick and effective hemostasis with the use of AC5 SAP technology, and that time to hemostasis (“TTH”) is comparable among test subjects regardless of whether such test subject had or had not been treated with therapeutic doses of anticoagulant or antiplatelet medications, commonly called “blood thinners.” Furthermore, the transparency and physical properties of certain AC5 Devices may enable a surgeon to operate through it in order to maintain a clearer field of vision and prophylactically stop or lessen bleeding as surgery starts, a concept that we call Crystal Clear Surgery™. An example of a product that contains related features and benefits is AC5 Topical Hemostat, which is indicated for use as a dressing and to control mild to moderate bleeding, each during the management of injured skin and the micro-environment of an acute surgical wound. AC5 Topical Hemostat has not yet been marketed in Europe but has received marketing authorization.

Operations

Much of our operational efforts to date, which we often perform in collaboration with partners, have included selecting compositions and formulations for our initial products; conducting preclinical studies, including safety and other tests; conducting a human trial for safety and performance of AC5; developing and conducting a human safety study to assess for irritation and sensitization potential; securing marketing authorization for our first product in the United States and in Europe; supporting surgeons performing clinical case studies; obtaining post-marketing clinical data; developing, optimizing, and validating manufacturing methods and formulations, which are particularly important components of self-assembling peptide development; developing methods for manufacturing scale-up, reproducibility, and validation; engaging with regulatory authorities to seek early regulatory guidance as well as marketing authorization for our products; sourcing and evaluating commercial partnering opportunities in the United States and abroad; and developing and protecting the intellectual property rights underlying our technology platform.

Our long-term business plan includes the following goals:

- Continue to build recent commercial momentum and grow revenues by driving awareness, adoption and payment policies for AC5 Advanced Wound System with the now-effective Centers for Medicare and Medicaid Services (“CMS”) Level II Healthcare Common Procedure Coding System (“HCPCS”) code dedicated to the “AC5”;
- educating the wound care field and growing commercial sales;
- conducting biocompatibility, pre-clinical, and clinical studies on our products and product candidates;
- obtaining additional marketing authorization for products in the United States, Europe, and other jurisdictions as we may determine;
- continuing to develop third party relationships to manufacture, distribute, market and otherwise commercialize our products;
- continuing to develop academic, scientific and institutional relationships to collaborate on product research and development;
- expanding and maintaining protection of our intellectual property portfolio; and
- developing additional product candidates in Dermal Sciences, BioSurgery, and other areas.

In furtherance of our long-term business goals, we expect to continue to focus on the following activities during the next twelve months:

- seek additional funding as required to support the previously described milestones necessary to support operations;
- work with our manufacturing partners to scale up production of product compliant with cGMP, which activities will be ongoing and tied to our development and commercialization needs;
- further clinical development of our product platform;
- assess our technology platform in order to identify and select product candidates for potential advancement into development;
- seek regulatory input to guide activities related to expanded and new product marketing authorizations;
- continue to expand and enhance our financial and operational reporting and controls;
- pursue commercial partnerships; and
- expand and enhance our intellectual property portfolio by filing new patent applications, obtaining allowances on currently filed patent applications, and/or adding to our trade secrets in self-assembly, manufacturing, analytical methods and formulation, which activities will be ongoing as we seek to expand our product candidate portfolio.

We have no commitments for any future capital. We will require significant additional financing to fund our planned operations, including further research and development relating to AC5, seeking regulatory approval of any product we may choose to develop, commercializing any product for which we are able to obtain regulatory approval or certification, seeking to license or acquire new assets or business, and maintaining our intellectual property rights, pursuing new technologies and for financing the investor relations and incremental administrative costs associated with being a public corporation. We do not presently have, nor do we expect in the near future to have, sufficient revenue to fund our business from operations, and we will need to obtain substantially all of our necessary funding from external sources for the foreseeable future. We may not be able to obtain additional financing on commercially reasonable or acceptable terms when needed, or at all. If we cannot raise the money that we need in order to continue to develop our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations. If any of these were to occur, there is a substantial risk that our business would fail, and our stockholders could lose all of their investment.

Since inception, we have funded our operations primarily through debt borrowings, the issuance of convertible debt and the issuance of units consisting of Common Stock and warrants, and we may continue to seek to do so in the future. If we obtain additional financing by issuing equity securities, our existing stockholders’ ownership will be diluted. The terms of securities we may issue in future capital-raising transactions may be more favorable for our new investors. Further, newly issued securities may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have additional dilutive effects. If we obtain additional financing by incurring debt, we may become subject to significant limitations and restrictions on our operations pursuant to the terms of any loan or credit agreement governing the debt. Further, obtaining any loan, assuming a loan on acceptable terms would be available when needed, would increase our liabilities and future cash commitments. We may also seek funding from additional collaboration or licensing arrangements in the future, which may require that we relinquish potentially valuable rights to our product candidates or proprietary technologies or grant licenses on terms that are not favorable to us. Moreover, regardless of the manner in which we seek to raise capital, we may incur substantial costs in those pursuits, including investment-banking fees, legal fees, accounting fees, printing and distribution expenses and other related costs. In addition, we are bound by certain contractual terms and obligations that may limit or otherwise impact our ability to raise additional funding in the near-term including, but not limited to, provisions in the Bridge SPA and securities purchase agreement dated July 6, 2022, as amended (the “**2022 Notes SPA**”), associated with the sale of the 2022 Notes (the “**2022 Notes Financing**”), in each case as described in greater detail in the risk factor entitled ***The terms of the Bridge Offering and 2022 Notes Financing could impose additional challenges on our ability to raise funding in the future***” under the heading “Risk Factors” in this prospectus.

In addition to the foregoing, our estimated capital requirements potentially could increase significantly if a number of risks relating to conducting these activities were to occur, including without limitation those set forth under the heading “**Risk Factors**” in this prospectus.

Merger with ABS and Related Activities

On June 26, 2013, the Company completed the Merger with ABS, pursuant to which ABS became a wholly owned subsidiary of the Company. In contemplation of the Merger, effective May 24, 2013, the Company increased its authorized Common Stock from 75,000,000 shares to 300,000,000 shares and effected a forward stock split, by way of a stock dividend, of its issued and outstanding shares of Common Stock at a ratio of 11 shares to each one issued and outstanding share. Also, in contemplation of the Merger, effective June 5, 2013, the Company changed its name from Almah, Inc. to Arch Therapeutics, Inc. and changed the ticker symbol under which its Common Stock trades on the OTC Bulletin Board from “AACH” to “ARTH.”

Research and Development

Preclinical and clinical testing of our product candidates is required in order to receive regulatory marketing authorizations and to support products upon commercialization, and we anticipate that such testing will continue as deemed appropriate.

Preclinical Testing

We have engaged and continue to engage third parties in the United States and abroad to advise on and/or perform certain preclinical bench-top and animal research and development studies, typically with assistance from our team. These third parties include contract research organizations, academic institutions, consultants, advisors, scientists, clinicians, and/or other collaborators.

We have conducted and anticipate continuing to conduct in vivo and in vitro research and development studies on our products and product candidates. A co-founding inventor of certain of our technology, Dr. Rutledge Ellis-Behnke, performed a significant portion of the early preclinical animal experiments conducted with our technology. Some of the most significant findings from Dr. Ellis-Behnke's studies have been published. Additionally, through collaborations with the National University of Ireland system and related parties, preclinical bench-top and animal research and development studies were performed in Dublin, Cork and Galway, Ireland over an approximately eight-year period that concluded in the third quarter of fiscal 2018.

Before initiating our clinical trials and submitting marketing applications for a given product in most jurisdictions, we are required to have completed a biocompatibility assessment, which typically consists of a battery of in vitro and in vivo tests. Standard biocompatibility tests, as set forth in ISO 10993 issued by the International Organization for Standardization, may include:

- in vitro cytotoxicity;
- in vitro blood compatibility;
- in vitro Ames assay (mutagenic activity);
- irritation/intracutaneous reactivity;
- sensitization (allergenic reaction);
- implantation (performed on devices that contact the body's interior);
- pyrogenicity (causing fever or inflammation);
- systemic toxicity; and
- in vitro chromosome aberration assay (structural chromosome changes).

We completed the biocompatibility studies required to receive marketing authorizations for AC5 Advanced Wound System in the United States and AC5 Topical Hemostat in Europe, and such test results support that the products are biocompatible. We will perform further biocompatibility testing that we deem necessary for additional indications, classifications, jurisdictions, and/or as required by regulatory authorities.

Acute and survival animal studies assessing safety and performance of our technology have also demonstrated favorable outcomes in Dermal Sciences and BioSurgery applications.

Porcine studies, also known as swine or pig studies, are often selected due to the morphological, physiological, and biochemical similarities between porcine skin and human skin and are very useful to assess the performance of AC5 Advanced Wound System or AC5 Topical Hemostat as a barrier and advanced wound dressing, as well as their safety and effects on healing.

In an assessment versus saline in a porcine partial thickness excision wound model, tissue response to AC5 Advanced Wound System over a 28-day follow-up period was consistent with normal wound healing and included complete re-epithelialization, normal collagen organization, and minimal inflammation and TTH was faster.

In an assessment versus both a market leading skin substitute and saline in a porcine full thickness 10 mm punch biopsy wound model, AC5 Advanced Wound System was solely associated with complete epithelialization by the end of the 11-day study.

In an assessment versus each a market leading antimicrobial burn dressing, a hydrogel, and saline in a porcine second degree burn wound model, AC5 Advanced Wound System was associated with less progression of thermal damage and less inflammation over three days.

Arch Therapeutics' technology has also demonstrated hemostasis in liver and other organs in in vivo surgical models, including rapid hemostasis within 15 seconds. In a range of small and large animal models, our compositions have been shown to stop bleeding, seal leaking, allow for normal healing, and mitigate inflammation while being biocompatible.

AC5 Surgical Hemostat demonstrated rapid average TTH when applied to a range of animal tissues. Certain surgical procedure studies have assessed TTH when using AC5 Surgical Hemostat as well as using an active control, a saline control, a peptide control, and a cautery control. The results of those tests have shown a TTH of approximately 10 - 30 seconds when AC5 Surgical Hemostat was applied, compared to 80 seconds to significantly more than 300 seconds when various control substances were applied, depending on the nature of the control substance and procedure performed. In several studies comparing AC5 Surgical Hemostat to popular commercially available branded hemostatic agents (absorbable cellulose, flowable gelatin with and without thrombin, and fibrin) applied to stop the bleeding from full thickness penetrating wounds surgically created in rat livers, AC5 Surgical Hemostat achieved hemostasis in significantly less than 30 seconds, whereas control products took from over 50% - 400% longer to achieve hemostasis.

AC5 Surgical Hemostat was also demonstrated in preclinical tests to stop surgically induced liver bleeding in animals that had been treated with therapeutic amounts of anticoagulant and antiplatelet medications, collectively known as antithrombotic medications and commonly called "blood thinners." In one preclinical study, an independent third-party research group obtained positive data assessing the use of AC5 Surgical Hemostat in animals that had been treated with therapeutic doses of the antiplatelet medications Plavix® (clopidogrel) and aspirin, alone and in combination. The results of the study were consistent with data obtained from two prior preclinical studies, in which AC5 Surgical Hemostat quickly stopped bleeding from surgical wounds created in rats following treatment with clinically relevant doses of the anticoagulant medication heparin. In these studies, the average TTH after AC5 Surgical Hemostat was applied to bleeding liver wounds in animals that had received anticoagulant medication was comparable to the average TTH as measured in their non-anticoagulated counterparts.

AC5-V was assessed for its ability to provide hemostasis after bleeding was intentionally created at vascular reconstruction sites in preclinical studies. In an acute study in swine that had been premedicated with therapeutic doses of heparin before undergoing end-to-end femoral artery anastomosis and synthetic graft to vessel anastomosis in carotid and femoral arteries, AC5-V promoted effective hemostasis at the vascular anastomotic site and allowed for clear visualization of the surgical site.

In a 14-day survival study in sheep that had been premedicated with therapeutic doses of heparin before undergoing end-to-side anastomosis between synthetic vascular grafts and carotid arteries, AC5-V promoted effective hemostasis at the vascular anastomotic site, the graft remained patent during the study as assessed by angiography and ultrasound, clinical observations were normal during the study, and tissue response as assessed by histopathological examination at the end of the study was consistent with expectations for a biodegrading implant.

AC5-G was studied in swine to assess visualization, submucosal lift generation and durability, and hemostatic and sealant performance when used during endoscopic mucosal resections and endoscopic submucosal dissections as well as hemostatic performance during endoscopic management of gastrointestinal bleeding. AC5-G was easily delivered through a 25G endoscopic injection needle into the tissue and provided a durable submucosal lift in the gastric antrum that lasted beyond 2 hours. When delivered with the visualizing agent prior to tissue dissection, AC5-G allowed for easy visualization with both snare and electrosurgical knives, and no visible bleeding was observed following polyp removal. AC5-G was also shown to provide hemostasis in actively bleeding lesions when applied with or without the visualizing agent either topically to a bleeding site or when injected into the nearby mucosa. AC5-G was found to be useful in conjunction with clips as a potential sealant when applied following application of clips to a post-polypectomy site for the purpose of mitigating leaks and potentially enabling healing.

The AC5 self-assembling peptide was studied in an experimental intraocular inflammation model of injected Lipopolysaccharide (**LPS**), in which an intraocular application of the peptide with LPS was associated with a marked reduction in retinal inflammation. The density of activated retinal microglial cells was significantly lower in the eyes of the study animals with LPS and AC5 than in the eyes of the LPS-only control group. The results suggest that the AC5 self-assembling peptide may reduce inflammation and may represent a new class of devices that act as anti-inflammatory agents to control ocular inflammation.

Clinical Testing

We have engaged and continue to engage third parties in the United States and abroad to advise on and perform certain clinical studies and related activities, typically with assistance from our team. These third parties include contract research organizations, academic institutions, consultants, advisors, scientists, clinicians, and other collaborators.

In order to complete a clinical trial, we are required to enroll a sufficient number of patients to conduct the trial after obtaining each patient's informed consent in a form and substance that complies with FDA and/or other regulatory authority requirements as well as state and federal privacy and human subject protection regulations. Many factors could lead to delays or inefficiencies in conducting clinical trials, some of which are discussed under the heading "**Risk Factors**" in this prospectus. Further, we, the FDA or an institutional review board ("**IRB**") could suspend a clinical trial at any time for various reasons, including a belief that the risks to the subjects of the trial outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA clearance or approval to market the product in the U.S.

We completed two clinical studies. The first study, which met its primary and secondary endpoints, assessed the safety and performance of our product candidate in 46 patients with bleeding skin wounds that resulted from excision of skin lesions and followed for 30 days. The second study assessed our product candidate on skin, determining that it was neither an irritant nor a sensitizer, and no immunogenic response or serious or other adverse events attributable to our product were reported in any of the approximately 50 enrolled volunteers. The product candidate in these studies subsequently received marketing authorization and is presently known as AC5 Advanced Wound System in the United States and AC5 Topical Hemostat in Europe.

Post marketing clinical case reports have been published demonstrating both efficacy and safety in a range of challenging acute surgical or chronic wounds on patients.

Regulatory

We have engaged and continue to engage third parties in the United States ("**U.S.**") and abroad to advise on and/or perform certain regulatory activities, typically with assistance from our team. These third parties can include contract research organizations, academic institutions, consultants, advisors, scientists, clinicians, and other collaborators.

Our research, development and clinical programs, as well as our manufacturing and marketing operations that may be performed by us or third-party service providers on our behalf, are subject to extensive regulation in the United States and other countries. Notably, for example, AC5 Advanced Wound System is subject to regulation as a medical device under the U.S. Food Drug and Cosmetic Act (the "**FDCA**") as implemented and enforced by the FDA and equivalent regulations that are enforced by foreign agencies in any other countries in which we pursue commercialization. The FDA and its foreign counterparts generally govern the following activities that we do or will perform or that will be performed on our behalf, as well as potentially additional activities, to ensure that products we may manufacture, promote and distribute domestically or export internationally are safe and effective for their intended uses:

- product design, preclinical and clinical development and manufacture;
- product premarket clearance and approval;
- product safety, testing, labeling and storage;
- certain supply chain changes;
- record keeping procedures;
- product marketing, sales and distribution; and
- post-marketing surveillance, complaint handling, medical device reporting, reporting of deaths, serious injuries or device malfunctions and repair or recall of products.

Medical Device Classification in the United States and Europe

AC5 Advanced Wound System in the United States and AC5 Topical Hemostat in Europe are classified as medical devices. Generally, a product is a medical device if it requires neither metabolic nor chemical activity to achieve the desired effect. Furthermore, a medical device can achieve its desired effects without requiring a body (animal/human), whereas a drug or a biologic requires a body in order to operate. Self-assembly, which is the desired effect and can occur outside of a body, is accordingly consistent with the medical device definition.

Medical devices in the United States and Europe are classified along a spectrum on the basis of the amount of risk to the patient associated with the medical device and the controls deemed necessary to reasonably ensure their safety and effectiveness. Class III status, which is the higher-level classification for devices compared to Classes II and I, involves additional procedures and regulatory scrutiny of the product candidate to obtain approvals. Class III devices are those that are deemed to pose the greatest risks, such as life-sustaining, life-supporting or implantable devices, or that have a new intended use or that use advanced technology not substantially equivalent to that of a legally marketed device.

As a result of the intended use of and the novel technology on which our products and product candidates are based, in general, we anticipate that they would typically be regulated as either Class II or Class III medical device in these jurisdictions, depending upon the intended use. Specifically, AC5 Advanced Wound System is a Class II medical device in the United States, and AC5 Topical Hemostat is a Class IIb medical device in Europe.

In the United States, the FDA recognizes these classes of medical devices:

- Class I, requiring general controls, including labeling, device listing, reporting and, for some products, adherence to good manufacturing practices through the FDA's quality system regulations and pre-market notification;
- Class II, requiring general controls and special controls, which may include performance standards and post-market surveillance; or
- Class III, requiring general controls and approval of a premarket approval application ("PMA"), which may include post-market approval conditions and post-market surveillance.

European regulatory authorities, likewise, recognize several classes of medical devices. Classification involves rules found in the European Union Medical Device Directive and is driven in part by the device's degree of contact with the patient, invasiveness, active nature, and indications for use. The medical device classes recognized in the EU are:

- Class IIa, which are considered low-medium risk devices and require certification by a notified body;
- Class IIb, which are considered medium-high risk devices and require certification by a notified body; and
- Class III, which are considered high-risk devices and require certification by a notified body.

United States Class III and certain Class II medical device approvals and European Union Class III and certain Class IIa and IIb medical device approvals may require the successful completion of human clinical trials.

U.S. Regulatory Marketing Authorization Process

Products that are regulated as medical devices and that require review by the FDA are subject to either a premarket notification, also known as a 510(k), which must be submitted to the FDA for clearance, or a PMA application, which the FDA must approve prior to marketing in the United States. The FDA ultimately determines the appropriate regulatory path. For purposes herein, references to regulatory approval and marketing authorization may be used interchangeably.

We believe that the additional products we are currently pursuing for internal use will require a PMA approval prior to commercialization. However, we commercialized an initial product for external use that has been cleared through the 510(k) process. To obtain 510(k) marketing clearance for a medical device, an applicant must submit a premarket notification to the FDA demonstrating that the device is "substantially equivalent" to a predicate device or devices, which is typically a legally marketed Class II device in the United States. A device is substantially equivalent to a predicate device if it has the same intended use and (i) the same technological characteristics, or (ii) has different technological characteristics and the information submitted demonstrates that the device is as safe and effective as a legally marketed device and does not raise different questions of safety or effectiveness. In some cases, the submission must include data from human clinical studies. Marketing may commence when the FDA issues a clearance letter finding substantial equivalence. Depending upon a product's underlying technology and intended use, as well as on FDA processes and procedures, seeking and obtaining a 510(k) can be a lengthy process.

A PMA, which is required for most Class III medical devices, must be submitted to the FDA if a device cannot be cleared through another approval process or is not otherwise exempt from the FDA's premarket clearance requirements. The PMA approval process can be lengthy and expensive. A PMA must generally be supported by extensive data, including without limitation technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use. Clinical trials for a Class III medical device typically require an application for an investigational device exemption ("IDE"), which would need to be approved in advance by the FDA for a specified number of patients and study sites. Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements, and must be conducted under the oversight of an institutional review board ("IRB") for the relevant clinical trial sites and comply with applicable FDA regulations, including those relating to good clinical practices ("GCP").

The PMA process is estimated to take from one to three years or longer, from the time the PMA application is submitted to the FDA until an approval is obtained. During the review period, the FDA will typically request additional information or clarification of the information previously provided. Also, experts from outside the FDA may be convened to review and evaluate the PMA and provide recommendations to the FDA as to the approvability of the device, although the FDA may or may not accept any such recommendations. In addition, the FDA will generally conduct a pre-approval inspection of the manufacturing facility or facilities involved with producing the device to ensure compliance with the cGMP regulations. Upon approval of a PMA, the FDA may require that certain conditions of approval, such as conducting a post-market approval clinical trial, be met.

Further, if post-approval modifications are made, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling or design, then new PMAs or PMA supplements would be required. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is typically limited to information needed to support the changes from the device covered by the original PMA and accordingly may not require as extensive clinical and other data.

We have not submitted to the FDA a PMA or commenced the required clinical trials for an internal use product. Even if we conduct successful preclinical and clinical studies and submit a PMA for an approval or premarket application for clearance, the FDA may not permit commercialization of our product candidate for the desired internal use indications, on a timely basis, or at all. Our inability to achieve regulatory approval for AC5 in the United States for an internal use product, a large market for hemostatic products, would materially adversely affect our ability to grow our business.

European Union Marketing Authorization (CE Mark) Process

A notified body is a private commercial entity designated by the national government of an European Union ("EU") member state as being competent to make independent judgments about whether a medical device complies with applicable regulatory requirements in the EU. Our notified body is The British Standards Institution ("BSI").

The EU has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices, and it has further revised its rules and regulations with increasingly stringent requirements. Each EU member state has implemented legislation applying these directives and standards at a national level. Many countries outside of the EU have also voluntarily adopted laws and regulations that mirror those of the EU with respect to medical devices, potentially increasing the time and cost necessary to potentially achieve an approval in different jurisdictions.

Devices that comply with the requirements of the laws of the selected member state applying the applicable EU directive are entitled to bear a CE *Conformité Européenne* mark and can be distributed throughout the member states of the EU, as well as in other countries that have mutual recognition agreements with the EU or have adopted the EU's regulatory standards.

Under applicable European Medical Device Directives (MDD), a CE mark is a symbol placed on a product that declares that the product is compliant with the essential requirements of applicable EU health, safety and environmental protection legislation. In order to receive a CE mark for a product candidate, the company producing the product candidate must select a country in which to apply. Each country in the EU has one competent authority ("CA") that implements the national regulations by interpreting the EU directives. CAs also designate and regulate Notified Bodies. An assessment by a notified body in the selected country within the EU is required in order to commercially distribute the device. In addition, compliance with ISO 13485 issued by the International Organization for Standardization, among other standards, establishes the presumption of conformity with the essential requirements for CE mark. Certification to the ISO 13485 standard demonstrates the presence of a quality management system that can be used by a manufacturer for design and development, production, installation and servicing of medical devices and the design, development and provision of related services.

While there are many similarities between the processes required to obtain marketing authorization in the United States and Europe, there are several key differences between the jurisdictions, as well. Obtaining a CE mark is not equivalent to obtaining FDA clearance or approval. For instance, FDA requirements for products typically vary based on whether the submission is for a premarket notification (510(k)) or a premarket approval (PMA) whereas EU requirements for product submissions are primarily based on class. Furthermore, EU submissions must meet precise essential requirements, although the data demonstrating such compliance can vary by class of device. Additionally, a CE mark affixed to a product serves as a declaration by the responsible party that the product conforms to applicable provisions and that relevant conformity assessment procedures have been completed with respect to the product.

In 2017, the European Union regulatory bodies implemented a new Medical Device Regulation (“MDR”). The MDR changes several aspects of the existing regulatory framework, such as clinical data requirements, and introduces new ones, such as Unique Device Identification (“UDI”). We, and the Notified Bodies who will oversee compliance to the new MDR, face uncertainties in the upcoming years as the MDR is rolled out and enforced, creating risks in several areas, including the CE mark process, data transparency and application review timetables.

Post-Approval Regulation

After a medical device obtains approval from the applicable regulatory agency and is launched in the market, numerous post-approval regulatory requirements would apply. Many of those requirements are similar among the United States and EU member states and include:

- product listing and establishment registration;
- requirements that manufacturers, including third-party manufacturers, follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling and other advertising regulations, including prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- approval of product modifications that affect the safety or effectiveness of any of our devices that may achieve approval;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply, when necessary, to protect the public health or to provide additional safety and effectiveness data for the device;
- the recall authority of the applicable government agency and regulations pertaining to voluntary recalls; and
- reporting requirements, including reports of incidents in which a product may have caused or contributed to a death or serious injury or in which a product malfunctioned, and notices of corrections or removals.

Failure by us, our third-party manufacturers or our other suppliers to comply with applicable regulatory requirements could result in enforcement action by various regulatory authorities, which may result in monetary fines, the imposition of operating restrictions, product recalls, criminal prosecution or other sanctions.

Regulation by Other Foreign Agencies

International sales of medical devices outside the EU may be subject to government regulations in each country in which the device is marketed and sold, which vary substantially from country to country. The time required to obtain approval by a non-EU foreign country may be longer or shorter than that required for FDA or CE mark clearance or approval, and the requirements may substantially differ.

Marketing Authorization (510k) for AC5 Advanced Wound System in the United States

On July 25, 2017, we announced that we had made a 510(k) submission to the FDA for AC5 Topical Gel. On December 18, 2017, we voluntarily withdrew the application after receiving questions from the FDA for which an adequately comprehensive response could not be provided within the FDA’s congressionally-mandated 90-day review period. On October 1, 2018, we announced that we both completed the necessary steps required to file a new 510(k) submission to the FDA for AC5 Topical Gel and filed that 510(k) submission during the third calendar quarter. As previously disclosed, these steps included developing a required study protocol and submitting it to the FDA in a pre-submission letter in the first calendar quarter, completing the pre-submission process, initiating the study in the second calendar quarter of 2018 and completing the study. On December 17, 2018, we announced that the 510(k) premarket notification for AC5 Topical Gel had been reviewed and cleared by the FDA, allowing for the product to be marketed.

In line with plans to better harmonize our United States and European product supply chains by using an additional supplier and additional manufacturing processes in the production of AC5 Topical Gel, Arch filed documentation with the FDA seeking such clearance in the United States for these additions, each of which had been incorporated into the technical documentation for the European CE mark filing. On March 23, 2020, we announced that the 510(k) premarket notification for AC5 Topical Gel had been reviewed and cleared by the FDA, allowing for the product to be marketed in the United States with the aforementioned additions. AC5 Topical Gel was subsequently renamed to AC5 Advanced Wound System in the United States.

Marketing Authorization (CE mark) for AC5 Topical Hemostat in Europe

During November 2018 we submitted the required documents for AC5 Topical Hemostat to its notified body seeking a CE mark. During August 2019, we received and responded to customary written and verbal questions related to the technical file, and that BSI had provided and assessed during the review period were acceptable so far. In that announcement, we further expressed our belief that the delay by the regulatory authority in completing the CE mark technical file review appeared to be due to a backlog of work for EU notified bodies related to both Brexit and the implementation of the new EU Medical Devices Regulation.

During April 2020, we received the CE (*Conformité Européenne*) mark for AC5 Topical Hemostat, allowing for commercialization in Europe as a dressing and to control bleeding in external skin wounds in both outpatient and in-patient settings.

Commercialization

Our commercialization efforts are currently focused on Dermal Sciences. Our BioSurgery products for internal use will require additional preclinical and clinical testing before we seek marketing authorization to commercialize them.

Our Dermal Sciences products are AC5 Advanced Wound System in the United States and AC5 Topical Hemostat in Europe, and the indication for use, or purpose, for each product follows, respectively:

- Under the supervision of a health care professional, AC5 Advanced Wound System is a topical dressing used for the management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds.
- AC5 Topical Hemostat is intended for use locally as a dressing and to control mild to moderate bleeding, each during the management of injured skin and the micro-environment of an acute surgical wound.

We have prioritized the launch of AC5 Advanced Wound System in the United States over that of AC5 Topical Hemostat in Europe, where we have not launched, for the foreseeable future to maximize operational efficiencies considering the COVID-19 pandemic.

We expect the Dermal Sciences product commercialization ramp to be initially gradual and then moderately accelerate as we identify and encourage product use by key opinion leaders and early adopters in developing market channels. We are actively concentrating our marketing and selling efforts on doctor's offices, other ambulatory settings, and government facilities, such as hospitals in the Veterans Health Administration ("**VA Hospitals**") and Medical Treatment Facilities. These settings tend to have many patients whose needs we believe can be addressed by AC5 Advanced Wound System because it is a synthetic self-assembling wound care product that provides clinicians with multi-modal support and utility across all phases of wound healing. Numerous published case studies and accolades highlight the efficacy and safety of AC5 in the treatment of challenging chronic and acute surgical wounds, including limb salvage and healing after other modalities have failed.

Securing reimbursement for AC5 Advanced Wound System in ambulatory settings, such as doctor's offices, is an important part of our commercial strategy. Consequently, we applied to the CMS for a dedicated HCPCS Level II billing code specific to AC5 Advanced Wound System on June 29, 2022, which if granted, would better enable providers to bill third party payors for AC5 that is used in doctors' offices. We believe that there is a growing trend toward the use of synthetic wound care products, including those that have been commonly referred to as synthetic skin substitutes. A dedicated HCPCS code is an important step toward, although not a guarantee of, coverage and reimbursement, and it would enhance our ability to work directly with payors as we expand access in outpatient settings and continue to advocate for clinically appropriate usage of our technology for patients. Our application was subsequently approved with a go-live date of April 1, 2023. We have launched a temporary reimbursement support program in line with CMS guidance to support commercial use and adoption of AC5 Advanced Wound System both before and after the go-live date of our unique product code (A2020).

To support commercialization in government facilities, AC5 Advanced Wound System has been added to the Federal Supply Schedule (FSS), General Services Administration (GSA) schedule and the Defense Logistics Agency's Medical Electronic Catalog Program (ECAT) and Distribution and Pricing Agreement (DAPA), enabling purchase by federal government agencies, including the Department of Veterans Affairs (VA), Indian Health Services (IHS), and Department of Defense (DOD) Medical Treatment Facilities effective December 15, 2021.

We envision hiring additional internal sales representatives to help commercialize the Dermal Sciences products.

We have engaged and continue to engage third parties in the United States and abroad to advise on and perform certain sales and marketing activities, typically with assistance from our team. These third parties can include contract organizations, consultants, advisors, scientists, clinicians, and/or other collaborators.

While our core team oversees initial inventory distribution from the warehouse to the customer, our commercialization plans include entering into collaboration agreements with contract sales partners, including independent sales representatives and distributors, and potentially strategic partners. We anticipate that we will enter and periodically terminate certain agreements based on performance or other business criteria.

We are committed to continuous improvement processes. We collect feedback and data when feasible and appropriate to develop and commercialize products that serve patients and doctors; to develop marketing messages; to learn about product use; to evaluate product performance in different settings; to improve our products; to address reimbursement needs, and to support collaborations that we may have or may establish. Data has been and will continue to be collected by informal feedback, observational case reports and/or clinical trials.

We received the CE mark for AC5 Topical Hemostat in April 2020. We announced receipt of 510(k) premarket notification clearances for AC5 Advanced Wound System in December 2018, providing marketing authorization, and on March 23, 2020, clearing use of an additional supplier and additional manufacturing processes.

The COVID-19 Pandemic Impact on Commercialization

The COVID-19 pandemic environment introduced significant challenges related to product launch, marketing and sales, as clinicians and facilities became overburdened and increasingly focused on managing resources, the disease, and the virus spread. While the overall environment has improved, many negative effects linger. We have observed the following effects at different times, and anticipate that they will variously wax and wane over time:

- the volume of elective surgical procedures has been constrained periodically, with many institutions indefinitely suspending or eliminating such procedures at times;
- healthcare facilities often have been required to ration staff and resources, including ventilators, personal protective equipment ("PPE"), and operating rooms, thereby negatively impacting the focus on wound care;
- clinicians often have been required to divert their time and resources to urgent COVID-19 needs;
- clinicians often have been required to quarantine due to exposure to a COVID-19 positive individual or isolate because of contracting symptomatic or asymptomatic COVID-19 disease;
- some institutions have been periodically designated "COVID Hospitals";
- access to surgeons, potential strategic partners, and facilities outside of the United States has become curtailed;
- administrators who may be required to facilitate or approve new product intake are constrained by new and other pressing priorities; and
- both clinicians and patients often try to minimize possible COVID-19 exposure, resulting in reduced access to healthcare system and essential care treatments and services.

We believe that these challenges have also highlighted some potential opportunities for our new technology to address certain poorly met needs. For instance, wound interventions are too often considered to be elective procedures instead of being treated essentially or emergently as National Pressure Ulcer Advisory Panel guidelines and others recommend, resulting in a projected increased risk to limb and life while elective procedures are delayed and not prioritized. Furthermore, the implications of these delays are a growing backlog of chronic wounds awaiting care and a worsening of such wounds, leading to greater morbidity, such as infection, necrosis, and amputation, and potentially mortality.

While highlighted by the COVID-19 pandemic, we also believe that these challenges reveal an underlying problem in the healthcare system-clinicians and other providers are being asked to accomplish more in less time with fewer resources. These resources may include higher acuity settings, such as operating rooms; expensive wound care products that may not work as well as desired; nursing time to change wound dressings; and surgeon time for managing wounds during debridement; repeat patient visits over months and often years, and others. Our COVID-19- related discussions with surgeons, economic stakeholders and other decision-making personnel often include whether AC5 Advanced Wound System may enable them to accomplish more for their patients while deploying overall fewer resources and achieving desired outcomes.

Manufacturing

We work with contract manufacturing and related organizations, including those operating under current good manufacturing practices (“cGMP”), as is required by applicable regulatory agencies for production of product that can be used for preclinical and human testing as well as for commercial use. We also have engaged and continue to engage other third parties in the United States and abroad to advise on and perform certain manufacturing and related activities, typically with assistance from our team. These third parties include academic institutions, consultants, advisors, scientists, and/or other collaborators. The activities include development of our primary product candidates, as well as generation of appropriate analytical methods, scale-up, and other procedures for use by manufacturers and/or other members of our supply chain to produce or process our products at current and/or larger scale quantities for preclinical and clinical testing and ultimately, as required marketing authorizations are obtained, commercialization.

Our products are regulated as medical devices, and as such, many of our activities have focused on optimizing traditional parameters to target specifications, biocompatibility, physical appearance, stability, and handling characteristics, among other metrics, to achieve the desired product. We and our partners intend to continue to monitor manufacturing processes and formulation methods closely, as success or failure in establishing and maintaining appropriate specifications may directly impact our ability to conduct additional preclinical and clinical trials and/or deliver commercial product.

We believe that the manufacturing methods used for a product, including the type and source of ingredients and the burden of waste byproduct elimination, are important determinants of its opportunity for profitability. Industry participants are keenly aware of the downsides of products that rely on expensive biotechnology techniques and facilities for manufacture, onerous and expensive programs to eliminate complex materials, or ingredients that are sourced from the complicated process of human or other animal plasma separation, since those products typically are expensive, burdensome to produce, and at greater risk for failing regulatory oversight.

The manufacturing methods that we use and intend to use to produce our current products and potential future product candidates rely on detailed, complex and difficult to manage synthetic organic chemistry processes. Although use of those methods requires that we engage manufacturers that possess the expertise, skill and know-how involved with those methods, the required equipment to use those methods is widely available. Furthermore, improvements in relevant synthetic manufacturing techniques over the past two decades have reduced their complexity and cost, while increasing large-scale cGMP capacity. Moreover, our current products and currently planned product candidates will be synthesized from naturally occurring ingredients that are not sourced from humans or other animals but do exist in their natural state in humans. That type of ingredient may be more likely to be categorized as “generally recognized as safe”, or “GRAS”, by the FDA.

Industry and Competition

Arch is developing technology for Dermal Sciences and BioSurgery applications, including wound care, surgical procedures on and in the body, and endoscopic gastrointestinal procedures. We seek to provide a product set with broad utility in external and internal applications. Features of the technology highlight its potential utility in a range of settings, including traditional open procedures and the often more challenging minimally invasive surgeries.

Common features of our current and planned products, as described herein, are driven by the mechanism of action, which itself is derived from the underlying physicochemical properties or our self-assembling peptide technology and our product safety and performance specifications. Those features, which include, among others, that they possess barrier properties and can create an environment permissive to healing, can deliver a benefit in the treatment of external and internal wounds that are open, exposed, bleeding, leaking, and/or at risk for excessive inflammation or contamination.

Dermal Sciences

We have received marketing authorizations for AC5 Advanced Wound System in the United States and AC5 Topical Hemostat in Europe. Compared to most other advanced wound dressings on the market, ours can be used throughout all phases of wound healing (i.e., inflammatory, proliferative, and remodeling).

Wounds can vary widely in terms of degree of bleeding and oozing, chronicity, acuity, complications, anatomic location, biochemistry, microenvironment, bioburden and other factors that may inhibit an ideal response. Patients can also vary widely in terms of co-morbidities, compliance, setting of their care, ability to contribute to their own care, and other risk factors. And the approach by surgeons to clinical practice can vary widely in terms of debridement strategy, timing and/or use of advanced modalities, choice and use of consumables, follow-up, and dressing change frequency, and more. Our products are designed to self-assemble on the wound site in response to locally present stimuli (ions), despite these diverse situations, with the objective of providing greater utility to clinicians and enabling better outcomes for patients.

The incidence and prevalence of both acute surgical and chronic wounds is noteworthy. According to a 2020 report by Steiner et al for The Healthcare Cost and Utilization Project, approximately 17 million hospital visits (inpatient and ambulatory) in 2014 resulted in almost 22 million invasive therapeutic surgeries. While more acute surgical wounds occur per year versus chronic wounds, the nature of chronic wounds provides additional greater challenges due to the prolonged duration of the healing period, the frequency of interventions needed to help the wound heal, and the often-underlying medical problem that placed the patient at risk for the wound in the first place, which is itself a hindrance to the healing process.

Chronic wounds affect approximately 2% of the United States Population, accounting for an estimated 6-7 million people.

Diabetic foot ulcers develop in approximately 2 million Americans each year, according to The Health Innovation Program, University of Wisconsin, while the annual incidence across developed countries is estimated to be 2-4%, according to Woods et al in 2020. Pressure ulcers develop in over 2.5 million Americans each year, according to the United States Agency for Healthcare Research & Quality.

Venous leg ulcers, representing the most common chronic wounds, occur in approximately 2.2% of Americans over age 65 each year, according to Rice et al in 2014, which equates to roughly 1.2 million new wounds per year among just that population, while Qiu et al in 2021 provided an estimated prevalence of 2-4%. The Centers for Disease Control and Prevention estimates that approximately 56 million Americans are over age 65. Additional chronic wounds not accounted for above can include, among others, surgical wounds that become chronic wounds, typically in patients with co-morbidities.

The morbidity and mortality associated with wounds, and particularly chronic wounds, is problematic. A 2017 article by Järbrink et al noted that chronic wounds may not heal for several years or, in some cases, decades, during which time the patient may suffer from severe pain, emotional and physical distress, less mobility and greater social isolation, while the family may suffer from other stresses and challenges. Woods et al in 2020 stated that only 2/3 of diabetic foot ulcers heal within 12 months. Some wounds just do not heal, remaining stagnant or progressing to limb loss or worse. Järbrink et al noted in 2017 that ulcers precede 85% of all amputations.

The Health Innovation Program, University of Washington, cited that of patients with diabetic foot ulcers in the United States, more than 50% will die within five years and 5% will have an amputation (<https://hip.wisc.edu/DiabeticFootUlcers>). A common phrase in medicine, which we often cite, is, "Save a limb, save a life." Even the amputations that are required to save a patient from a non-healing, progressing chronic wound are associated with additional significant morbidity and mortality. In an examination of mortality rates after amputations from a chronic wound, Meshkin et al performed a systematic literature review and found that of the sixty-one studies yielding approximately 36,000 patients who previously received a nontraumatic major lower extremity amputation, approximately 34% died by year one, 55% died by year two, and 64% died by year five. Stern et al in 2017 reported an even higher mortality rate one year after amputation of approximately 48%.

According to the US Market Report for Wound and Tissue Management, 2018 by iData Research, advanced wound dressings account for approximately \$2 billion in annual revenues while the overall wound care market is projected to surpass \$10 billion in the United States, yet this represents a relatively small percentage of the overall cost to care for wounds, including chronic wounds, such as venous leg ulcers, diabetic foot ulcers, and pressure ulcers.

As such, the total expenditure required to treat wounds is an important consideration in assessing market opportunity, product need, industry dynamics, and needs of insurers. Several wound related phenomenon influence the overall cost and challenge of wound care. For instance, many surgeons believe that a chronic wound is essentially a chronic infection, which raises costs and complicates treatment plans, and that healing requires aggressive debridement (surgical removal of damaged, dead, lacerated, devitalized, or contaminated tissue), which narrows the scope of which wound care products can be used at the time of the procedure as a useful tool to support healing.

According to a 2018 report by Nussbaum et al., data from calendar year 2014 estimated that Medicare alone spent between \$28.1 to \$96.8 billion for all wound care types, and that nearly 15% (8.2 million) of Medicare beneficiaries were diagnosed with at least one type of wound or wound-related infection. Furthermore, a 2017 report by Chan et al indicated that the mean one-year cost of care from the perspective of a health-care public payer was \$44,200 for a diabetic foot ulcer, \$15,400 for a pressure ulcer and \$11,000 for a leg ulcer. Woods et al in 2020 estimated that the cost per admission among patients with diabetic foot ulcers was \$8,145 if the wound was not infected and \$11,290 if the wound was infected. Han et al noted in 2017 that lessening a hospital admission by just one day represents an enormous cost savings and is separately beneficial to the patient.

A common wound care topic, which has been further highlighted during the COVID-19 pandemic, is how to provide high quality care in lower acuity settings. It is less expensive, more convenient, and potentially better for the patient if a wound care procedure, such as debridement, can be safely performed in a doctor's office or wound clinic in lieu of a hospital operating room. For example, a report by Rogers et al in 2020 discussed changing sites of service to the lowest acuity setting in which care could be safely delivered. As such, we believe that wound care products should be designed to enable clinicians to "do more with less", such as debride in a clinic or office a wound that otherwise may have required an operating room visit.

While the wound care opportunity is large for safe, efficacious, and novel products, the competitive landscape is also crowded and challenging. For instance, while many of the commercially marketed advanced wound care dressings or other products, may provide utility in certain situations and possess some novel features, surgeons often describe an inability to differentiate one from the other. In addition, many advanced products are expensive when accounting for wound surface area coverage, are not user friendly, and/or may need to rely on the passage of several weeks of time for the wound bed to adequately be prepared before they can be used, which itself adds burden to their use.

We believe that the aforementioned elevated wound incidence and prevalence, consequential morbidity and mortality, prolonged healing times and exorbitant cost of overall care underscores the potential opportunity for the overall market and for our products. We believe that the addressable market opportunity for advanced wound care products in the US alone can exceed \$20 billion if improvements enable the best products to increase penetration at the expense of less effective wound care products and categories, lessen expensive non-product-related treatment costs for insurers (e.g., skin grafts, dressing changes, etc.), and deliver improved outcomes more quickly and in lower acuity settings.

We believe that AC5 Advanced Wound System® is sufficiently differentiated to replace certain competitive products, complement other products and procedures by potentially enabling the wound bed to be ready sooner, and enable more procedures to be done sooner and/or in settings where they could not be performed easily before.

Features and benefits of AC5 Advanced Wound System may include that it:

- is a self-assembling wound care matrix and may provide better outcomes across all phases of wound;
- conforms to irregularly shaped wound geometry;
- may be used in either lower acuity (e.g., clinics) or higher acuity (e.g., operating rooms) settings;
- can be used in conjunction with aggressive surgical debridement;
- can be used on a wound whether or not it is bleeding;
- is agnostic to the presence of anti-thrombotic therapy (aka, blood thinners);
- can be used on a chronic, stalled wound that has been previously unresponsive to or failed other treatment regimens;
- provides a protective barrier to mitigate contamination and modulating inflammation;
- donates moisture to the wound;
- can create wound microenvironment conducive to healing;
- aids in epithelial cell migration;
- creates an extracellular matrix-like structure to enable cell and tissue growth;
- is self-healing, in that it can dynamically self-repair around migrating cells;
- may reduce healing time and patient burden;
- is user-friendly, easy to prepare, and easy to apply;
- may be stored at ambient temperature; and
- may reduce treatment costs while improving outcomes in certain patients.

BioSurgery

We are developing BioSurgery products for internal use, including for hemostasis and sealant applications, and gastrointestinal endoscopic surgical procedures, and we believe that our technology will be useful in addressing the constant demand for better performance and safety in minimally invasive surgery ("MIS"), traditional surgery, Natural Orifice Translumenal Endoscopic Surgery, commonly referred to as "NOTES", and other procedures.

While developing our products, we engaged commercial strategy and marketing consultants and communicated directly with care providers to understand the needs of potential customers and to assess product feature preferences.

Surgeons, operating room managers, sales representatives and hospital decision-makers identified several characteristics deemed desirable, including that a product is:

- reliable;
- able to protect the wounds in tissues and organs where used;
- laparoscopic friendly;
- easily handled and applied;
- able to promote a clear field of vision and not obstruct view;
- sufficiently flowable;
- non-sticky (to tissue or equipment);
- permits normal healing;
- agnostic to the presence of antithrombotic medications (“blood thinners”) to whether the patient has bleeding abnormalities;
- non-toxic; and
- not sourced from human or other animal blood or tissue components.

We believe that long-term trends, which support a need for products to better support clinicians in surgical procedures, include:

- a persistent drive to migrate the site of surgical care from inpatient hospital operating room to progressively lower acuity same-day ambulatory settings due to cost and other potential negative impacts of unnecessary hospitalizations, such as infection risk or occupying scarce resources that may be more usefully deployed elsewhere;
- increased use of anticoagulants and other anti-thrombotic agents (also known as blood thinners) due to co-morbidities, but which predispose patients to bleeding;
- the increasingly difficult nature of procedures expected to be performed by surgeons with the least invasive method feasible in the less expensive settings accessible; and
- the desire to lower procedure time to increase operating room throughput, increase shift volume, and lessen in-procedure time for patient’s well-being;

We believe that a motivating factor for some of these trends may be the increased costs associated with procedures performed in hospital operating rooms, which have been estimated to cost between \$2,000 and \$10,000 per hour, according to MedMarket Diligence and others.

These costs likely drive the desire for increased operating room throughput and increased volume of procedures performed in outpatient settings. Both of those trends highlight the need for highly effective products that can decrease operating room time for inpatient procedures and help to increase the safety of performing more types of procedures in less expensive outpatient settings.

Since the early days of modern MIS in the 1990s, the percent of surgeries performed minimally invasively has increased significantly, such that it is now widespread and common. Laparoscopic surgery is among the most recognized types of MIS, although there are many additional types. Advantages of MIS tend to include less scarring, less post-operative pain, less need for pain medications, shorter recovery times, and faster discharge times. However, such procedures often present the surgeon with less margin for error and less capacity to deal with certain risks, such as excessive bleeding, without having to convert the surgery to a traditional open procedure.

A trend to make traditional minimally invasive surgery even less invasive is known NOTES. In NOTES procedures, an endoscope is passed through a natural orifice, such as the mouth, urethra, anus, or vagina, and then through an internal incision in the stomach, vagina, bladder or colon. NOTES advantages include those of MIS to a potentially even greater degree, as well as the lack of external incisions and external scars, improved visibility, and the possibility to avoid managing potential obstacles to surgery, such as extensive adhesions from prior procedures. However, compared to MIS, margin for error in NOTES is even less. NOTES may be performed by surgeons or endoscopists, yet the techniques can be challenging to learn and are in their early stages of development. Practitioners may seek additional tools, including BioSurgery products where relevant, to enable them to operate efficiently, effectively, and safely.

We consider these items while developing our BioSurgery products with the objective of meeting these needs.

We are developing products for hemostasis and sealant applications. Many of the hemostasis products currently available do not possess certain features and handling characteristics that are ideal for use in a laparoscopic setting. For instance, many available products are difficult to use in MIS or NOTES because they tend to be sticky, powdery, fabric-based or are otherwise difficult to insert into and control through the small gauge, yet long, catheters used during these procedures. We believe that the novel features and differentiating characteristics of our BioSurgery products will make them more suitable for such surgeries compared to many or most of the presently available alternatives.

According to a 2015 MedMarket Diligence, LLC report, the market for hemostatic agents and sealants achieved approximately \$4.2 billion in worldwide sales in 2015 and was projected to reach \$4.8 billion in 2017 and surpass \$7.5 billion in 2022. While the majority of those sales are for hemostats, we believe that the projected growth rate for sealants in multiple applications, such as the gastrointestinal track, could become greater as additional products become available.

In spite of the large size of the market for these products, many available hemostatic agents and sealants possess a combination of limitations, including slow onset of action, general unreliability, user-unfriendliness, and risk for adverse effects, such as healing problems, adhesion formation, infection and other safety concerns. Many of the deficiencies of currently available hemostatic agents and sealants are comparable to those of their earlier-generation counterparts, as revolutionary advances in underlying technologies have been elusive.

Participants in the hemostatic and sealant market include large medical device and biopharmaceutical companies, as well as various smaller companies. Commercially available hemostatic agents can cost between \$50 and \$500 per procedure, with the higher value-added products generally priced at the upper end of that range. We believe, however, that approaches to many surgical problems have evolved and will continue to do so, such that what may recently appeared to be an interesting market may be less so in the future if the required tools also evolve. For instance, the endovascular approach to vascular reconstruction may lessen the need for hemostatic agents in certain procedures.

We are also developing products for gastrointestinal and NOTES procedures, endoscopic mucosal resections (“**EMR**”) and endoscopic submucosal dissections (“**ESD**”). Surgical endoscopists are removing more complicated tumors and lesions from the gastrointestinal tract via EMR and ESD, which are endoscopic techniques to remove early-stage cancer and precancerous growths from the lining of the digestive tract through long narrow equipment, which consist of ports, catheters, lights, monitors, and video cameras. This represents the least invasive interventional approach known.

The EMR/ESD market is immature and growing, we believe, because of an increasing elderly population and incidence of gastrointestinal malignancies. The opportunity is noteworthy in North America, Europe, and Asia, where a higher prevalence of certain gastrointestinal malignancies and lower screening rates leads to later discovery and removal of tumors than would be desired. We believe that overall costs of care associated with these procedures, when compared to that of more invasive alternatives, and potentially faster recovery times will encourage a growth trend. It should be noted that these procedures do require that the doctor possess additional non-routine skill and equipment thereby tempering potential adoption curves.

A particular need for which we are developing AC5-G is a product that provides both a durable and safe lift while being inherently hemostatic. The concept is to inject AC5-G beneath a polyp or tumor to be resected or dissected, thus creating separation between the lesion and the underlying healthy tissue.

Incomplete lesion removal, bleeding and perforation are known challenges and risks of EMR/ESD. The objective of a lift is to minimize the risk for perforation into the peritoneum, which can cause significant morbidity and mortality, and increase the probability of visualizing and removing the entire desired lesion. The lift should also be durable, potentially lasting at least two hours, such that the frequency of repeat injections and perforation risk is minimized. Normal and abnormal tissues can also bleed during these procedures, and it can be challenging and time consuming to stop. Surgeons have expressed a desire for an improved agent that can prophylactically or actively address such bleeding. Surgeons have further expressed interest in sealant properties in the event that a perforation occurs during the procedure.

Several companies have products that provide either a lift or are hemostatic. Based on early indicators, we believe that AC5-G provides properties for both lift and hemostasis. AC5-G was featured in a video presentation during the Emerging Technology Session of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) 2020 Annual Meeting, which took place from August 11-13, 2020.

Potential Disadvantages of our Current and Planned Products Compared to the Competition

Some potential disadvantages of our products compared to currently marketed products follow:

- The favorable handling characteristics of AC5 Devices result, in part, from their non-sticky and non-glue-like nature. However, if a surgeon or healthcare provider requires a product to adhere tissues together, or provide similar glue-like action, then AC5 Devices in their current form would not achieve that effect.
- While we project that our products will be sufficiently economical to manufacture at scale, they may not be able to compete from a price perspective with inexpensive products.
- We have generated less data in humans compared to many successful products in the Dermal Sciences or BioSurgery categories.
- While we believe that the flowable nature of our products before they assemble into a dense nanofiber network can provide a meaningful advantage, some surgeons may prefer a solid product in certain applications.

Other Governmental Regulations and Environmental Matters

We are or may become subject to various laws and regulations regarding laboratory practices and the use of animals in testing, as well as environmental laws and regulations governing, among other things, any use and disposal by us of hazardous or potentially hazardous substances in connection with our research. At this time, costs attributable to environmental compliance are not material. In each of these areas, applicable U.S. and foreign government agencies have broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on our business. Additionally, if we are able to successfully obtain approvals for, and commercialize our product candidates, then the Company and our products may become subject to various federal, state and local laws targeting fraud, abuse, privacy and security in the healthcare industry.

Intellectual Property

We are focused on the development of self-assembling compositions, particularly self-assembling peptide compositions, and methods of making and using such compositions primarily in healthcare applications. Suitable applications of these compositions include limiting or preventing the movement of bodily fluids and contaminants within or on the human body, preventing adhesions, treatment of leaky or damaged tight junctions, and reinforcement of weak or damaged vessels, such as aneurysms. Our strategy to date has been to develop an intellectual property portfolio in high-value jurisdictions that tend to uphold intellectual property rights and apply business judgment rules to determine which patent applications to pursue and, if granted, which patents to maintain. The information provided is subject to change if pending patent applications are abandoned, issued patents are allowed to lapse, or new applications are filed.

As of September 15, 2023, we either own or license from others a number of U.S. patents, U.S. patent applications, foreign patents and foreign patent applications.

Six patent portfolios assigned to Arch Biosurgery, Inc. include approximately 50 patents and pending applications in approximately 20 jurisdictions, including approximately 11 patents and pending applications in the US. These portfolios cover self-assembling peptides, formulations and methods of use thereof and self-assembling peptidomimetics and methods of use thereof, including approximately eight issued US patents (US 9,415,084; US 9,162,005; US 9,789,157; US 9,821,022; US 9,339,476; US 10,314,886; US 10,682,386, and 10,869,907) that expire between 2026 and 2034 (absent any potential patent term extension), as well as approximately 30 patents that have been either allowed, issued or granted in foreign jurisdictions.

We have also entered into a license agreement with Massachusetts Institute of Technology and Versitech Limited (“MIT”) pursuant to which we have been granted exclusive rights under two portfolios of patents and non-exclusive rights under another three portfolios of patents.

The two portfolios exclusively licensed from MIT include approximately 30 patents and pending applications drawn to self-assembling peptides, formulations and methods of use thereof and self-assembling peptidomimetics and methods of use thereof in a total of nine jurisdictions. The portfolios include five issued US patents (US 9,511,113; US 9,084,837; US 10,137,166; US 9,327,010; and US 9,364,513) that expire between 2026 and 2027 (absent any potential patent term extension), as well as additional patents that have been either allowed, issued or granted in foreign jurisdictions.

The portfolios non-exclusively licensed from MIT include a number of US and foreign applications, including three issued US patents (US 7,846,891; US 7,713,923; and US 8,901,084) that expire between 2024 and 2026 (absent any potential patent term extension), as well as additional patents that have been either allowed, issued or granted in foreign jurisdictions.

Our license agreement with MIT imposes or imposed certain diligence, capital raising, and other obligations on us, including obligations to raise certain amounts of capital by specific dates. Additionally, we are responsible for all patent prosecution and maintenance fees under that agreement. Our breach of any material terms of our license agreement with MIT could permit the counterparty to terminate the agreement, which could result in our loss of some or all of our rights to use certain intellectual property that is material to our business and our lead product candidate. Our loss of any of the rights granted to us under our license agreement with MIT could materially harm our product development efforts and could cause our business to fail.

AC5, AC5-G, AC5-V, AC5-P, Crystal Clear Surgery, NanoDrape and NanoBioBarrier and associated logos are trademarks and/or registered trademarks of Arch Therapeutics, Inc. and of Arch Biosurgery, Inc.

Employees

As of September 15, 2023, we had ten employees, all of whom are full-time, and make extensive use of third-party contractors, consultants, and advisors to perform many of our present activities. We expect to increase the number of our employees as we increase our operations.

Properties

We do not own any real property. In April 2015, we moved our corporate offices to a property in Framingham, Massachusetts. In July 2017, we entered into a three-year operating lease commencing October 1, 2017 and ending on September 30, 2020 at our current location. During August 2020, we extended the lease through September 30, 2021 at our current location. During October 2021, we extended the lease through March 31, 2022 at our current location. Effective April 1, 2022, our lease is month to month at our current location.

Legal Proceedings

In the ordinary course of business, we may become a party to legal proceedings involving various matters. We are unaware of any such legal proceedings presently pending to which we or our subsidiary is a party or of which any of our property is the subject that management deems to be, individually or in the aggregate, material to our financial condition or results of operations.

Dr. Avtar Dhillon served as our Chairman of the Board from April 2013 through July 2018, and as an advisor to us from July 2018 until his termination on August 6, 2021. As previously disclosed, in August 2021, the U.S. Department of Justice (the “DOJ”) filed a criminal complaint against Dr. Avtar Dhillon, alleging, among other things, his participation in a securities fraud scheme whereby he concealed his ownership of millions of shares of two microcap companies (including the Company) and then secretly directed the shares’ sale, generating approximately \$2.19 million in proceeds. On December 7, 2022, Dr. Avtar Dhillon pleaded guilty to one count of conspiracy to commit securities fraud, one count of securities fraud, and two counts of obstructing a proceeding of the SEC. Sentencing is scheduled for May 23, 2024. At the same time, the SEC charged Dr. Avtar Dhillon with violations of the antifraud and certain other provisions of federal securities laws in connection with the sales of securities of certain public companies, including his sale of shares of the Company. On October 20, 2022, the United States District Court for the Central District of California entered a final judgment as to Dr. Avtar Dhillon, in favor of the SEC, pursuant to which he is (1) prohibited from acting as an officer or director of any issuer that has a class of securities registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or that is required to file reports pursuant to Section 15(d) of the Exchange Act and (2) permanently restrained and enjoined from violating, directly or indirectly, (i) Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, (ii) Section 17(a) of the Securities Act, and (iii) Section 17(b) of the Securities Act. The Company has fully cooperated with the DOJ and the SEC and has not been implicated in or charged with any wrongdoing.

DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Set forth below is certain information regarding our current directors and executive officers:

Name	Position	Age	Director/Officer Since
Dr. Terrence W. Norchi	President, Chief Executive Officer and Chairman of the Board of Directors	58	April 2013
Michael S. Abrams	Chief Financial Officer	52	May 2021
Daniel M. Yrigoyen	Vice President of Sales	53	July 2021
Punit Dhillon	Director	42	July 2018
Laurence Hicks	Director	57	September 2021
Dr. Guy L. Fish	Director	63	December 2021

Dr. Terrence W. Norchi. Terrence W. Norchi, MD, our co-founder, serves as our President and Chief Executive Officer, and Chairman of the Board. Dr. Norchi also served as our Interim Chief Financial Officer through June 26, 2013. Dr. Norchi has served in similar positions since co-founding ABS, our predecessor company in 2006. Prior to ABS, Dr. Norchi was a portfolio manager of one of the world's largest healthcare mutual funds and a pharmaceutical analyst at Putnam Investments from April 2002 to September 2004. Prior to that, he served as the senior global biotech and international pharmaceutical equity analyst at Citigroup Asset Management, and as a sell-side analyst covering non-U.S. pharmaceutical equities at Sanford C. Bernstein in New York City. Dr. Norchi earned an M.B.A. from the Massachusetts Institute of Technology, Sloan School of Management in 1996. Dr. Norchi earned an M.D. degree in 1990 from Northeast Ohio Medical University and completed his internal medicine residency in 1994 at Baystate Medical Center, Tufts University School of Medicine, where he was selected to serve as the Chief Medical Resident. Dr. Norchi brings to our Board and management team invaluable experience and knowledge of our core technology and proposed product candidates as a result of his first-hand experience with the development of that technology, having ushered it from the research laboratory to its current stage of development. His investing experience as a former public company analyst and a portfolio manager provides further insights and value as the company advances toward commercialization. Dr. Norchi serves on the Board of Advisors of the Boston Museum of Science.

Michael S. Abrams. Mr. Abrams has served as the Chief Financial Officer of the Company since May 2021. Prior to joining the Company, Mr. Abrams was the turnaround Chief Financial Officer for RiseIT Solutions, Inc. from February 2019 to April 2021, where he helped return the business to profitability. Prior to RiseIT Solutions, from August 2009 to February 2019, Mr. Abrams served as the Chief Financial Officer and director of FitLife Brands, Inc., a publicly traded entity focused on the development of functional nutritional supplements that promote an active, healthy lifestyle. From August 2004 to December 2016, Mr. Abrams served as Partner and Managing Director of Burnham Hill Capital Group, a private privately held financial services holding company. Mr. Abrams graduated with an MBA with Honors from the Booth School of Business at the University of Chicago and received his BBA with Honors from the University of Massachusetts at Amherst as a William F. Field Alumni scholar, an award given annually to the top finance student in the class.

Daniel M. Yrigoyen. Mr. Yrigoyen has served as the Vice President of Sales of the Company since July 2021. Prior to joining the Company, Mr. Yrigoyen was Vice President, Sales & Channel Distribution for Medela, Inc. from April 2016 to July 2021. Prior to Medela, Mr. Yrigoyen served as General Manager for multiple business units at Hollister, Inc., where he was responsible for the expansion of the wound care product portfolio and led the effort to launch several new and innovative wound care products into the US market. Following these efforts, Mr. Yrigoyen joined the Hollister Global Marketing Organization, where he led similar expansion efforts within key markets of Hollister's international business. Mr. Yrigoyen was an employee at Hollister for over 20 years and brings significant healthcare and distribution experience to the Company. Yrigoyen graduated with an MBA from the Kellogg School of Management at Northwestern University.

Punit Dhillon. Mr. Dhillon joined our Board of Directors in July 2018. Mr. Dhillon was appointed CEO and Chair of Skye Bioscience, Inc. (OTCQB: SKYE) in August 2020 and brings over 20 years of global industry experience to Arch's Board. He is the co-founder and former President & CEO of OncoSec Medical Incorporated (NASDAQ: ONCS), a leading biopharmaceutical company developing cancer immunotherapies for the treatment of solid tumors, where he served as an executive until March 2018 and a director until February 2020. Prior to that, Mr. Dhillon served as the Vice President of Finance and Operations at Inovio Pharmaceuticals, Inc. (NASDAQ: INO), a DNA vaccine development company, from September 2003 until March 2011. Mr. Dhillon is also a director and Audit Committee Chair of Emerald Health Therapeutics, Inc. (CSE: EMH). Mr. Dhillon also co-founded and is the director of YELL Canada, a registered Canadian charity that partners with schools to support entrepreneurial learning. Mr. Dhillon has a Bachelor of Arts with honors in Political Science and a minor in Business Administration from Simon Fraser University. Mr. Dhillon's experience in the medical device and life sciences industry provides value to his role as a member of the Board.

Laurence Hicks. Mr. Hicks joined our Board of Directors in September 2021. He has been the chief executive officer of Healthcare Components Group, a global manufacturer of OEM and replacement parts used for the manufacture and repair of medical devices, since 2021. From 2016 until 2021, when it merged into Healthcare Components Group, Mr. Hicks was chief executive officer of 2506052 Ontario Inc., a holding company for American Optics, Endoscopy Replacement Parts and Micro Optics Europe, which sell components used in the manufacturing and repair of endoscopes worldwide. He has held medical device leadership roles at ACMI, Karl Storz Endoscopy and NeuroTherm. Mr. Hicks' experience in the medical device industry provides value to his role as a member of the Board.

Dr. Guy L. Fish. Dr. Fish joined our Board of Directors in December 2021. He is currently employed by the Greater Lawrence Family Health Centers, a nationally recognized Federally Qualified Health Center, where he has served as the Chief Executive Officer since 2021. Dr. Fish is also the President and Co-Founder of Ivy Consulting Partners, Inc., a boutique consultancy focused on healthcare, corporate and leadership development, and business strategy, a role he has held since 1999. Dr. Fish served as the Chief Executive Officer at Cellanix LLC, a cancer diagnostic company, from 2019 to 2020. From 2002 to 2021, Dr. Fish served in various executive positions at Fletcher Spaght, Inc., a strategy management firm focused on health care innovator companies. From 2006 to 2019, Dr. Fish served as an investor and Senior Vice President at Fletcher Spaght Ventures. Dr. Fish has served as a member of the board of directors of Etiometry, Inc. since 2019, PhaseBio Pharmaceuticals, Inc. (NASDAQ:PHAS) from 2009 to 2018, and Metabolon, Inc. from 2010 to 2017. Dr. Fish holds an MBA degree from Yale University School of Management and a M.D. degree from Yale University School of Medicine. Dr. Fish holds a bachelor's degree in biochemistry from Harvard University. The Company believes that Dr. Fish is qualified to serve on the Board as a result of his extensive leadership experience in the medical field, as well as his record of accomplishment in business strategy and operations.

Board of Director Composition

Our Board currently consists of four members. We have no formal policy regarding board diversity. Our priority in selection of board members is identification of members who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business and understanding of the competitive landscape.

Term of Office of Directors

Our directors are appointed and serve until their successor has been duly elected and qualified, or until the earlier of their death, resignation or removal.

Involvement in Certain Legal Proceedings

No director, executive officer or control person of the Company has been involved in any legal proceeding listed in Item 401(f) of Regulation S-K in the past 10 years.

Director Independence

Our Board of Directors has determined that Mr. Punit Dhillon, Mr. Laurence Hicks and Dr. Guy Fish would qualify as "independent" as that term is defined by Nasdaq Listing Rule 5605(a)(2). On August 15, 2022, we have established separately designated audit, corporate governance and nominating, and compensation board committees. Mr. Dhillon, Mr. Hicks, and Dr. Fish all qualify as "independent" under Nasdaq Listing Rules applicable to all such board committees. Dr. Terrence W. Norchi would not qualify as "independent" under Nasdaq Listing Rules applicable to the Board of Directors generally or to separately designated board committees because he currently serves as our President and Chief Executive Officer.

Subject to some exceptions, Nasdaq Listing Rule 5605(a)(2) provides that an independent director is a person other than an executive officer or other employee of the Company or any other individual having a relationship which, in the opinion of our Board of Directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Under Nasdaq Listing Rule 5605(a)(2) and subject to certain exceptions, a director will not be deemed to be independent if (a) the director is, or at any time during the past three years was, an employee of ours; (b) the director or a member of the director's immediate family or a person living with such director (collectively, a "**Related Party**") has received more than \$120,000 in compensation from us during any twelve-month period within the preceding three years, other than compensation for service as a director or as a non-executive employee (in the case of Related Party), benefits under a tax-qualified retirement plan or non-discretionary compensation; (c) a Related Party is, or in the past three years has been, an executive officer of ours; (d) the director or a Related Party is an executive officer, partner or controlling shareholder of a company that makes payments to, or receives payments from, us in an amount which, in any twelve-month period during our past three fiscal years, exceeds the greater of 5% of the recipient's consolidated gross revenues for that year or \$200,000 (except for payments arising solely from investments in our securities or payments under non-discretionary charitable contribution matching programs); (e) the director or a Related Party is employed as an executive officer of another company where at any time during the preceding three years one of our executive officers served on the compensation committee of such company; and (f) the director or a Related Party is a current partner of our independent public accounting firm, or has worked for such firm in any capacity on our audit at any time during the past three years.

Committees of the Board of Directors

Our Board has established an Audit Committee, a Compensation Committee, and a Nominating and Corporate Governance Committee. Our Board may establish other committees to facilitate the management of our business. The composition and functions of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our Board. Each of these committees operate under a charter that has been approved by our Board, which will be available on our website.

Audit Committee

On August 15, 2022, our Board of Directors established a separate standing audit committee within the meaning of Section 3(a)(58)(A) of the Exchange Act. The Audit Committee consists of Mr. Punit Dhillon, serving as the Chairman of the Audit Committee, Mr. Laurence Hicks, and Dr. Guy Fish. Our Board has determined that the three directors currently serving on our Audit Committee are independent within the meaning of the Nasdaq Marketplace Rules and Rule 10A-3 under the Exchange Act. Our Board of Directors has determined that Mr. Dhillon is an “audit committee financial expert” as defined by applicable Securities and Exchange Commission (“SEC”) rules.

The Audit Committee oversees and monitors our financial reporting process and internal control system, reviews and evaluates the audit performed by our registered independent public accountants and reports to our Board any substantive issues found during the audit. The Audit Committee is directly responsible for the appointment, compensation and oversight of the work of our registered independent public accountants. The Audit Committee reviews and approves all transactions with affiliated parties.

Compensation Committee

Our Compensation Committee consists of Dr. Fish, Mr. Hicks and Mr. Dhillon, with Mr. Hicks serving as the Chairman of the Compensation Committee. Our Board has determined that the three directors currently serving on our Compensation Committee are independent under the listing standards, are “non-employee directors” as defined in rule 16b-3 promulgated under the Exchange Act and are “outside directors” as that term is defined in Section 162(m) of the Internal Revenue Code of 1986, as amended.

The Compensation Committee provides advice and makes recommendations to the Board in the areas of employee salaries, benefit programs and director compensation. The Compensation Committee also reviews and approves corporate goals and objectives relevant to the compensation of our Chief Executive Officer and other officers and makes recommendations in that regard to the Board as a whole.

Nominating and Corporate Governance Committee

Our Nominating and Corporate Governance Committee consists of Dr. Fish, Mr. Hicks and Mr. Dhillon, with Dr. Fish serving as the Chairman of the Nominating and Corporate Governance Committee. The Nominating and Corporate Governance Committee nominates individuals to be elected to the Board by our stockholders. The Nominating and Corporate Governance Committee considers recommendations from stockholders if submitted in a timely manner in accordance with the procedures set forth in our bylaws and will apply the same criteria to all persons being considered. All members of the Nominating and Corporate Governance Committee are independent directors as defined under the Nasdaq listing standards.

Board Leadership Structure and Role in Risk Oversight

Currently, Dr. Norchi serves as the Company’s Chief Executive Officer and Chairman of the Board. Periodically, our Board will assess the roles of Chairman and Chief Executive Officer and the Board leadership structure to ensure the interests of the Company and our stockholders are best served. Our Board believes the current combination of the two roles is satisfactory at present. Dr. Norchi, as our Chief Executive Officer and Chairman, has extensive knowledge of all aspects of the Company and its business. We have no policy requiring the combination or separation of leadership roles and our governing documents do not mandate a particular structure. This has allowed, and will continue to allow, our Board the flexibility to establish the most appropriate structure for the Company at any given time.

While management is responsible for assessing and managing risks for the Company, our Board is responsible for overseeing management’s efforts to assess and manage risk. This oversight is conducted primarily by our full Board, which has responsibility for general oversight of risks. Our Board satisfies this responsibility through regular reports directly from officers responsible for oversight of particular risks within the Company. Our Board believes that full and open communication between management and the Board is essential for effective risk management and oversight.

Code of Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, principal executive officer, principal financial officer, principal accounting officer and all of our other officers and employees and can be found on our website, <http://www.archtherapeutics.com> on our “Corporate Governance” webpage, which can be accessed from the “Investors” tab of our website. We will also provide a copy of our code of business conduct and ethics to any person without charge upon his or her request. Any such request should be directed to our Chief Financial Officer at 235 Walnut Street, Suite 6, Framingham, Massachusetts 01702. We intend to make all required disclosures concerning any amendments to or waivers from our code of business conduct and ethics on our website.

Liability and Indemnification of Directors and Officers

The NRS empower us to indemnify our directors and officers against expenses relating to certain actions, suits or proceedings as provided for therein. In order for such indemnification to be available, the applicable director or officer must not have acted in a manner that constituted a breach of his or her fiduciary duties and involved intentional misconduct, fraud or a knowing violation of law, or must have acted in good faith and reasonably believed that his or her conduct was in, or not opposed to, our best interests. In the event of a criminal action, the applicable director or officer must not have had reasonable cause to believe his or her conduct was unlawful.

We have not entered into separate indemnification agreements with our directors and officers. Our amended and restated bylaws provide that we shall indemnify any director or officer to the fullest extent authorized by the laws of the State of Nevada. Our amended and restated bylaws further provide that we shall pay the expenses incurred by an officer or director (acting in his capacity as such) in defending any action, suit or proceeding in advance of the final disposition of such action, suit or proceeding, subject to the delivery to us by or on behalf of such director or officer of an undertaking to repay the amount of such expenses if it shall ultimately be determined that he or she is not entitled to be indemnified by us as authorized in our bylaws or otherwise.

The NRS further provide that a corporation may purchase and maintain insurance or make other financial arrangements on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise for any liability asserted against him and liability and expenses incurred by him in his capacity as a director, officer, employee or agent, or arising out of his status as such, whether or not the corporation has the authority to indemnify him against such liability and expenses. We have secured a directors’ and officers’ liability insurance policy. We expect that we will continue to maintain such a policy.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

EXECUTIVE COMPENSATION

The following table summarizes all compensation recorded by us in each of the fiscal years ended September 30, 2023, and September 30, 2022 for (i) our principal executive officer; (ii) our two next most highly compensated executive officers whose total compensation exceeded \$100,000 during our last completed fiscal year; and (iii) certain of our other executive officers, whose compensation is voluntarily provided.

Summary Compensation Table

Name	Fiscal Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards (\$)(1)	All other Compensation (\$)	Total (\$)
Dr. Terrence W. Norchi,	2023	450,500	-	-	40,500	-	491,000
<i>President and Chief Executive Officer</i>	2022	450,500	-	-	-	-	450,500
Michael S. Abrams	2023	325,000	-	-	29,160	-	354,160
<i>Chief Financial Officer</i>	2022	325,000	-	-	-	-	325,000
Daniel Yrigoyen	2023	325,000	-	-	16,200	-	341,200
<i>VP of Sales</i>	2022	316,667	-	-	9,075	-	325,742

- (1) Represents the aggregate grant date fair values of awards granted during the fiscal year ended September 30, 2023 and 2022 under ASC Topic 718, which is calculated as of the grant date using a Black-Scholes option-pricing model. Accordingly, the dollar amounts listed do not necessarily reflect the dollar amount of compensation that may be realized by our executive officers. For information on the valuation assumptions with respect to option grants made during the fiscal year ended September 30, 2022 refer to Note 14 “**Stock-Based Compensation**” in our consolidated financial statements in this prospectus.

Employment Agreements with Named Executive Officers

Terrence W. Norchi

On June 25, 2013, we entered into an executive employment agreement with Dr. Terrence W. Norchi, our President and Chief Executive Officer and a member of our Board, which became effective as of June 26, 2013. Dr. Norchi’s employment agreement continues until terminated by Dr. Norchi, or us and provided for an initial annual base salary of \$275,000, and eligibility to receive an annual cash bonus in an amount up to 30% of Dr. Norchi’s then-current annual base salary. In addition, Dr. Norchi’s employment agreement provides that his annual base salary will be reviewed from time to time in accordance with the established procedures of the Company for adjusting salaries for similarly situated employees. Annual bonuses are awarded at the sole discretion of our Board. If Dr. Norchi’s employment is terminated by us (unless such termination is “For Cause” (as defined in his employment agreement)), or by Dr. Norchi for “Good Reason” (as defined in his employment agreement), then Dr. Norchi, upon signing a release in favor of the Company, will be entitled to severance in an amount equal to 12 months of Dr. Norchi’s then-current annual base salary, payable in the form of salary continuation, plus, if Dr. Norchi elects and subject to certain other conditions, payment of Dr. Norchi’s premiums to continue his group health coverage under COBRA until the earlier of (i) 12 months following the date of such termination; or (ii) the date Dr. Norchi becomes covered under another employer’s health plan. In addition, Dr. Norchi’s employment agreement provides that, in the event of a change of control of the Company, termination by Dr. Norchi for Good Reason, termination by the Company for any reason other than For Cause, or termination as a result of Dr. Norchi’s death, all unvested shares under outstanding equity grants to Dr. Norchi, if any, shall automatically accelerate and become fully vested. On March 13, 2014, Dr. Norchi’s employment agreement was amended to increase his annual base salary to \$325,000, retroactively effective as of February 1, 2014, and increase his cash bonus eligibility from 30% of his annual base salary to 35% of his annual base salary. In connection with the Board’s annual review of Dr. Norchi’s base salary, Dr. Norchi’s annual base salary was increased to \$425,000 effective July 1, 2017. In connection with the Board’s annual review of Dr. Norchi’s base salary, Dr. Norchi’s annual base salary was increased to \$450,500 effective August 1, 2019.

Dr. Norchi's employment agreement provides the following definitions of "For Cause" and "Good Reason": (a) "For Cause" is (i) the commission by the executive of a crime involving dishonesty, breach of trust, or physical harm to any person, (ii) executive's engagement by the executive in conduct that is in bad faith and materially injurious to the Company, (iii) commission by the executive of a material breach of the employment agreement which is not cured within 20 days after the executive receives written notice of such breach, (iv) willful refusal by the executive to implement or follow a lawful policy or directive of the Company, which breach is not cured by the executive within 20 days after receiving written notice from the Company, (v) or executive's engagement in misfeasance or malfeasance demonstrated by a pattern of failure to perform job duties diligently and professionally (other than any such failure resulting from Executive's incapacity due to physical or mental illness); and (b) "Good Reason" is, without the executive's written consent, (1) a material reduction in executive's annual base salary, except for reductions that are comparable to reductions generally applicable to similarly situated executives of the Company, (2) the relocation of executive to a facility or location that is more than 50 miles from his primary place of employment and such relocation results in an increase in executive's one-way driving distance by more than 50 miles, or (3) a material and adverse change in executive's authority, duties, or responsibilities with the Company or a material and adverse change in executive's reporting relationship within the Company.

In connection with our entry into the executive employment agreement with Dr. Norchi, effective on June 26, 2013, Dr. Norchi's former employment agreement with ABS was terminated pursuant to a termination agreement and release between Dr. Norchi and ABS.

Michael S. Abrams

On March 31, 2021, we entered into an executive employment agreement with Mr. Abrams, our Chief Financial Officer and Treasurer. The agreement continues until terminated by us or by Mr. Abrams. Pursuant to the terms of the agreement, Mr. Abrams is entitled to an initial annual base salary of \$325,000 and is eligible to receive an annual cash bonus in an amount of up to 30% of Mr. Abrams' then-current annual base salary. Annual bonuses are awarded at the sole discretion of our Board of Directors. In addition, Mr. Abrams' employment agreement provides that his annual base salary will be reviewed by the Board (or any committee thereof), with such input as it may request from the Company's Chief Executive Officer, from time to time but at least on an annual basis, in accordance with the established procedures of the Company for adjusting salaries for similarly situated employees. If Mr. Abrams' employment is terminated by us at any time after 30 days after the start date (unless such termination is "For Cause" (as defined in his employment agreement)), or by Mr. Abrams for "Good Reason" (as defined in his employment agreement), then Mr. Abrams, upon signing a release in favor of the Company, would be entitled to severance in an amount equal to six months of Mr. Abrams' then-current annual base salary, payable in the form of salary continuation, plus, if Mr. Abrams elects and subject to certain other conditions, payment of Mr. Abrams' premiums to continue his group health coverage under COBRA until the earlier of (i) 12 months following the date of such termination; or (ii) the date Mr. Abrams becomes covered under another employer's health plan. In addition, Mr. Abrams' employment agreement provides that, in the event of a change of control of the Company or his employment is terminated by the Company for any reason other than For Cause, all unvested shares under outstanding equity grants to Mr. Abrams, if any, shall automatically accelerate and become fully vested.

The agreement provides the following definitions of "For Cause" and "Good Reason": (a) "For Cause" is (i) Mr. Abrams commits a crime involving dishonesty, breach of trust, or physical harm to any person; (ii) Mr. Abrams willfully engages in conduct that is in bad faith and materially injurious to the Company, including without limitation misappropriation of trade secrets, fraud or embezzlement; (iii) Mr. Abrams commits a material breach of this Agreement or the Proprietary Information Agreement, which breach is not cured within twenty calendar days after written notice to Executive from the Company (to the extent curable); (iv) Mr. Abrams willfully refuses to implement or follow a lawful policy or directive of the Company, which breach is not cured within twenty calendar days after written notice to Executive from the Company; or (v) Mr. Abrams engages in misfeasance or malfeasance demonstrated by a pattern of failure to perform job duties diligently and professionally. The Company may terminate Mr. Abrams' employment For Cause at any time, without any advance notice. The Company shall pay Mr. Abrams all compensation to which Mr. Abrams is entitled up through the date of termination, subject to any other rights or remedies of the Company under law, and thereafter all obligations of the Company under this Agreement shall cease.

On July 12, 2021, we entered into an executive employment agreement with Mr. Yrigoyen, our Vice President of Sales. The agreement continues until terminated by us or by Mr. Yrigoyen. Pursuant to the terms of the agreement, Mr. Yrigoyen is entitled to an initial annual base salary of \$225,000 and is eligible to receive regular commission payments of up to \$8,333.33 per month, depending on the achievement of established objectives; *provided, however*, that for the first nine (9) months of employment, Mr. Yrigoyen shall be entitled to receive the full commission of \$8,333.33 per month regardless of whether the applicable performance objectives are met; this provision was subsequently extended indefinitely pending review from time to time in connection with the Company's ongoing commercialization effort.

In addition, Mr. Yrigoyen's employment agreement provides that his annual base salary will be reviewed by the Board (or any committee thereof), with such input as it may request from the Company's Chief Executive Officer, from time to time but at least on an annual basis, in accordance with the established procedures of the Company for adjusting salaries for similarly situated employees. If Mr. Yrigoyen's employment is terminated by us at any time after 30 days after the start date (unless such termination is "For Cause" (as defined in his employment agreement)), or by Mr. Yrigoyen for "Good Reason" (as defined in his employment agreement), then Mr. Yrigoyen, upon signing a release in favor of the Company, would be entitled to severance in an amount equal to six months of Mr. Yrigoyen's then-current annual base salary, payable in the form of salary continuation, plus, if Mr. Yrigoyen elects and subject to certain other conditions, payment of Mr. Yrigoyen's premiums to continue his group health coverage under COBRA until the earlier of (i) 12 months following the date of such termination; or (ii) the date Mr. Yrigoyen becomes covered under another employer's health plan. In addition, Mr. Yrigoyen's employment agreement provides that, in the event of a change of control of the Company or his employment is terminated by the Company for any reason other than For Cause, all unvested shares under outstanding equity grants to Mr. Yrigoyen, if any, shall automatically accelerate and become fully vested.

The agreement provides the following definitions of "For Cause" and "Good Reason": (a) "For Cause" is (i) Mr. Yrigoyen commits a crime involving dishonesty, breach of trust, or physical harm to any person; (ii) Mr. Yrigoyen willfully engages in conduct that is in bad faith and materially injurious to the Company, including without limitation misappropriation of trade secrets, fraud or embezzlement; (iii) Mr. Yrigoyen commits a material breach of this Agreement or the Proprietary Information Agreement, which breach is not cured within twenty calendar days after written notice to Executive from the Company (to the extent curable); (iv) Mr. Yrigoyen willfully refuses to implement or follow a lawful policy or directive of the Company, which breach is not cured within twenty calendar days after written notice to Mr. Yrigoyen from the Company; or (v) Mr. Yrigoyen engages in misfeasance or malfeasance demonstrated by a pattern of failure to perform job duties diligently and professionally. The Company may terminate Mr. Yrigoyen's employment For Cause at any time, without any advance notice. The Company shall pay Mr. Yrigoyen all compensation to which Mr. Yrigoyen is entitled up through the date of termination, subject to any other rights or remedies of the Company under law, and thereafter all obligations of the Company under this Agreement shall cease.

Outstanding Equity Awards At Fiscal Year-End

The following table summarizes the aggregate number of option and stock awards held by our named executive officers at September 30, 2023:

Name	Option Awards				Stock Awards	
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price a(\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested a(\$)
Dr. Terrence W. Norchi	2,500	- (1)	70	3/23/2024		
	2,000	- (2)	38	1/21/2025		
	1,775	- (3)	56	8/17/2025		
	6,250	- (4)	78	5/2/2026		
	3,250	- (5)	130	2/2/2027		
	1,800	- (6)	85	7/18/2028		
	5,000	- (7)	45.84	12/19/2029		
	5,000	- (8)	20.56	9/26/2031		
	3,334	1,666 (9)	20.56	9/26/2031		
	1,737	4,513 (10)	8.02	11/9/2032		
Michael S. Abrams	2,084	416 (11)	26.58	5/2/2031		
	1,167	583 (12)	20.56	9/26/2031		
	1,250	3,250 (13)	8.02	11/9/2032		
Daniel M. Yrigoyen	542	208 (14)	18	6/29/2031		
	667	333 (15)	20.56	9/26/2031	750 (16)	19,500
	334	416 (17)	12.1	5/23/2032		
	695	1,805 (18)	8.02	11/9/2032		

- (1) Represents an option to purchase 2,500 shares of Common Stock with a grant date of March 23, 2014. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, 25% of the shares shall vest 12 months following the date of grant and 1/24th of the remaining shares shall vest on each of the monthly anniversaries of the grant date, commencing April 23, 2015.
- (2) Represents an option to purchase 2,000 shares of Common Stock with a grant date of January 22, 2015. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, 25% of the shares shall vest 12 months following the date of grant and 1/24th of the remaining shares shall vest on each of the monthly anniversaries of the grant date, commencing February 22
- (3) Represents an option to purchase 1,775 shares of Common Stock with a grant date of August 18, 2015. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, and 1/36th of the remaining shares shall vest on each of the monthly anniversaries of the grant date, commencing September 18, 2015.
- (4) Represents an option to purchase 6,250 shares of Common Stock granted on May 3, 2016. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vesting immediately, the remaining unvested Shares subject to the Option shall vest on each of the next thirty-six (36) monthly anniversaries of the date of grant.
- (5) Represents an option to purchase 3,250 shares of Common Stock granted on February 3, 2017. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vesting immediately, the remaining unvested Shares subject to the Option shall vest on each of the next thirty-six (36) monthly anniversaries of the date of grant.
- (6) Represents an option to purchase 1,800 shares of Common Stock with a grant date of July 19, 2018. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, and 1/36th of the remaining shares shall vest on each of the monthly anniversaries of the grant date, commencing August 19, 2018.
- (7) Represents an option to purchase 5,000 shares of Common Stock with a grant date of December 20, 2019. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, and 1/36th of the remaining shares shall vest on each of the monthly anniversaries of the grant date, commencing January 20, 2019.
- (8) Represents an option to purchase 5,000 shares of Common Stock with a grant date of September 27, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with 33% of the shares vested immediately on the date of grant and the remaining shares to vest in 24 equal installments commencing on the first anniversary on the date of grant.
- (9) Represents an option to purchase 5,000 shares of Common Stock with a grant date of September 27, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.
- (10) Represents an option to purchase 6,250 shares of Common Stock with a grant date of November 10, 2022. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.
- (11) Represents an option to purchase 2,500 shares of Common Stock with a grant date of May 3, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with 30% of the shares vested immediately on the date of grant and the remaining shares to vest in 24 equal installments commencing on the first anniversary on the date of grant.
- (12) Represents an option to purchase 1,750 shares of Common Stock with a grant date of September 27, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.
- (13) Represents an option to purchase 4,500 shares of Common Stock with a grant date of November 10, 2022. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.
- (14) Represents a stock award to receive 750 shares of Common Stock granted on July 30, 2021. The stock award vests as follows; 250 shares on January 12, 2022, 250 shares on July 12, 2022 and 250 shares on January 12, 2023.
- (15) Represents an option to purchase 1,000 shares of Common Stock with a grant date of September 27, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.
- (16) Represents an option to purchase 750 shares of Common Stock with a grant date of July 30, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant and the remaining shares to vest in 24 equal installments commencing on the first anniversary on the date of grant.

(17) Represents an option to purchase 750 shares of Common Stock with a grant date of May 24, 2022. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.

(18) Represents an option to purchase 2,500 shares of Common Stock with a grant date of November 10, 2022. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant

Compensation of Directors

On March 23, 2014, our Board adopted a director compensation policy for non-employee directors. That policy provides that effective the first calendar quarter of 2014, the person serving as the Chairman of our Board receives an aggregate annual cash fee of \$190,000 for that chairperson role, and all other non-employee directors receive an annual cash fee of \$50,000.

The following table summarizes all compensation paid to our non-employee directors during the fiscal year ended September 30, 2023

Director Compensation Table

	Fees Earned or Paid In Cash (\$)	Stock Awards (\$)	Option Awards (\$)	All other Compensation (\$)	Total (\$)
Punit Dhillon (1)	12,500	-	8,100	-	20,600
Laurence Hicks (2)	-	-	8,100	-	8,100
Guy L. Fish (3)	-	-	8,100	-	8,100

(1)Mr. Dhillon was appointed as a member of the Board on July 19, 2018. The aggregate number of shares of Common Stock underlying option awards outstanding as of September 30, 2023 held by Mr. Dhillon was 6,250.

(2)Mr. Hicks was appointed as a member of the Board on September 27, 2021. The aggregate number of shares of Common Stock underlying option awards outstanding as of September 30, 2023 held by Mr. Hicks was 2,500.

(3)Dr. Fish was appointed as a member of the Board on December 31, 2021. The aggregate number of shares of Common Stock underlying option awards outstanding as of September 30, 2023 held by Dr. Fish was 2,500.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Related Party Transactions

During fiscal years 2023 and 2022, other than with respect to matters relating to the Company's compensation arrangements with its executive officers, there were no transactions between the Company or any of its subsidiaries and any "Related Person" (as that term is defined in Item 404 of Regulation S-K) that would be required to be reported pursuant to Item 404 of Regulation S-K other than the following:

On June 22, 2020, the Company entered into a Series J Warrant Issuance Agreement (the "**Keyes Sulat Agreement**") with the Keyes Sulat Revocable Trust (the "**Trust**"), also a holder of outstanding Series D Warrants, resulting in approximately \$82,000 of proceeds as a result of the full exercise of the Trust's Series D Warrants. Under the terms of the Keyes Sulat Agreement, in exchange for fully exercising the Trust's remaining Series D Warrants for 2,273 shares of Common Stock on June 22, 2020, the Trust was issued Series J Warrants to purchase 1,705 shares of Common Stock at an exercise price of \$50.00 over a 1 year term. James R. Sulat, a former member of the Board, is a co-trustee of the Trust, of which members of Mr. Sulat's immediate family are beneficiaries. Mr. Sulat disclosed his interest in the Trust to the Board prior to its approval of the transaction and abstained from voting on the transaction. As of September 15, 2023, no Series J Warrants remain outstanding.

On July 6, 2022 a Board member, Laurence Hicks, and executive officers, Terrence W. Norchi and Michael S. Abrams, invested in the First Closing. The investment made in the First Closing made by the Board member and executive officers totaled \$80,000.

On August 30, 2023 a Board member, Laurence Hicks, and executive officers, Terrence W. Norchi and Michael S. Abrams, invested in the Bridge Offering. The investment made in the Bridge Offering made by the Board member and executive officers totaled approximately \$7,500.

Review, Approval or Ratification of Transactions with Related Persons

Due to the small size of our Company, at this time we have determined to rely on our full Board to review related party transactions and identify and prevent conflicts of interest. Our Board reviews a transaction in light of the affiliations of the director, officer, employee or stockholder and the affiliations of such person's immediate family. Transactions are presented to our Board for approval before they are entered into or, if that is not possible, for ratification after the transaction has occurred. If our Board finds that a conflict of interest exists, then it will determine the appropriate remedial action, if any. Our Board approves or ratifies a transaction if it determines that the transaction is consistent with the best interests of the Company and its stockholders. The procedures described above have been approved by resolutions adopted by our Board.

Subject to some exceptions, Nasdaq Listing Rule 5605(a)(2) provides that an independent director is a person other than an executive officer or other employee of the Company or any other individual having a relationship which, in the opinion of our Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Under Nasdaq Listing Rule 5605(a)(2) and subject to certain exceptions, a director will not be deemed to be independent if (a) the director is, or at any time during the past three years was, an employee of ours; (b) the director or a member of the director's immediate family or a person living with such director (collectively, a "**Related Party**") has received more than \$120,000 in compensation from us during any twelve-month period within the preceding three years, other than compensation for service as a director or as a non-executive employee (in the case of Related Party), benefits under a tax-qualified retirement plan or non-discretionary compensation; (c) a Related Party is, or in the past three years has been, an executive officer of ours; (d) the director or a Related Party is an executive officer, partner or controlling shareholder of a company that makes payments to, or receives payments from, us in an amount which, in any twelve-month period during our past three fiscal years, exceeds the greater of 5% of the recipient's consolidated gross revenues for that year or \$200,000 (except for payments arising solely from investments in our securities or payments under non-discretionary charitable contribution matching programs); (e) the director or a Related Party is employed as an executive officer of another company where at any time during the preceding three years one of our executive officers served on the compensation committee of such company; and (f) the director or a Related Party is a current partner of our independent public accounting firm, or has worked for such firm in any capacity on our audit at any time during the past three years.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth certain information regarding the beneficial ownership of our Common Stock by (i) each person who, to our knowledge, beneficially owns more than 5% of our Common Stock; (ii) each of our directors and named executive officers; and (iii) all of our directors and executive officers as a group. Unless otherwise indicated in the footnotes to the following table, the address of each person named in the table is: c/o Arch Therapeutics, Inc., 235 Walnut St., Suite #6, Framingham, Massachusetts 01702. The information set forth in the table below is based on 4,689,446 shares of our Common Stock outstanding on September 15, 2023. Shares of our Common Stock subject to options, warrants, or other rights currently exercisable or exercisable within 60 days of September 15, 2023 are deemed to be beneficially owned and outstanding for computing the share ownership and percentage of the person holding such options, warrants or other rights, but are not deemed outstanding for computing the percentage of any other person.

The following table is presented after taking into account the applicable ownership limitation to which certain holders of our securities are subject to. In general, the ownership limitation prevents holders from exercising the warrant to the extent such exercise would result in the holder owning more shares than a certain ownership percentage, which is initially set below 5%, and such ownership limitation may be waived at the holder's discretion, provided that such waiver will not become effective until the 61st day after delivery of such waiver notice.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned (1)
<i>5%+ Stockholders:</i>		
Oasis Capital, LLC (2)	300,000	6.40%
Bigger Capital Fund, LP & District 2 Capital Fund LP (3)	300,000	6.40%
Walleye Opportunities Master Fund Ltd (4)	300,000	6.40%
Cavalry Fund I LP (5)	300,000	6.40%
Brandt & Mona Wilson (6)	300,000	6.40%
Ana and Michael Parker (7)	300,000	6.40%
Andrew Stahl (8)	300,000	6.40%
Sixth Borough Capital Fund, LP (9)	300,000	6.40%
<i>Named Executive Officers and Directors:</i>		
Terrence Norchi (10)	113,194	2.39%
Punit Dhillon (11)	5,868	*
Laurence Hicks (12)	21,902	*
Michael Abrams (13)	23,195	*
Daniel Yrigoyen (14)	3,194	*
Guy Fish (15)	2,014	*
Named Officers and Directors as a Group	169,367	3.56%

* Less than 1%.

**Excluding any shares and/or Investor Warrants issued in connection with the over-allotment option, if any.

Shares of our Common Stock subject to options, warrants, or other rights currently exercisable or convertible or exercisable or convertible within 60 days of September 15, 2023, are deemed to be beneficially owned and outstanding for computing the share ownership and percentage of the person holding such options, warrants or other rights, but are not deemed outstanding for computing the percentage of any other person.

- (1) Except as otherwise indicated, we believe that each of the beneficial owners of the Common Stock listed previously, based on information furnished by such owners, has sole investment and voting power with respect to the shares listed as beneficially owned by such owner, subject to community property laws where applicable. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities.

- (2) Represents 300,000 shares of Common Stock owned by Oasis Capital, LLC. Excludes (a) 131,292 shares of Common Stock issuable upon conversion of the First Notes (the **"First Conversion Shares"**); (b) 120,725 First Warrants; (c) 27,353 shares of Common Stock issuable upon conversion of the Second Notes (the **"Second Conversion Shares"**); (d) 50,302 Second Warrants; (e) 76,886 shares of Common Stock issuable upon conversion of the Third Notes (the **"Third Conversion Shares"**); (f) 141,396 Third Warrants; (g) 1,005,251 Bridge Pre-Funded Warrants; and (h) 2,552,766 Common Warrants, all of which are subject to conversion or exercise restrictions that prohibit conversion or exercise until such time as the holder would not beneficially own, after such conversion or exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of September 15, 2023, Oasis Capital, LLC has not waived such limitation.
- (3) Represents 300,000 shares of Common Stock owned by, and split evenly between, Bigger Capital Fund, LP and District 2 Capital Fund LP with a common control person. Excludes (a) 131,292 First Conversion Shares; (b) 120,726 First Warrants; (c) 27,354 Second Conversion Shares; (d) 50,302 Second Warrants; (e) 989,459 Bridge Pre-Funded Warrants with unsatisfied exercise restrictions; and (f) 2,552,652 Common Warrants with unsatisfied exercise restrictions held in the aggregate by Bigger Capital Fund, LP and District 2 Capital Fund LP, all of which are subject to conversion or exercise restrictions that prohibit conversion or exercise until such time as the holder would not beneficially own, after such conversion or exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of September 15, 2023, neither Bigger Capital Fund, LP, nor District 2 Capital Fund LP has waived such limitation.
- (4) Represents 300,000 shares of Common Stock owned by Walleye Opportunities Master Fund Ltd. Excludes (a) 976,278 Bridge PreFunded Warrants with unsatisfied exercise restrictions; and (b) 2,552,556 Common Warrants with unsatisfied exercise restrictions, all of which are subject to exercise restrictions that prohibit exercise until such time as the holder would not beneficially own, after such exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of September 15, 2023, Walleye Opportunities Master Fund Ltd has not waived such limitation.
- (5) Represents 300,000 shares of Common Stock owned by Cavalry Fund I LP. Excludes (a) 52,517 First Conversion Shares; (b) 48,290 First Warrants; (c) 10,941 Second Conversion Shares; (d) 20,121 Second Warrants; (e) 985,064 Bridge Pre-Funded Warrants with unsatisfied exercise restrictions; and (f) 2,552,620 Common Warrants with unsatisfied exercise restrictions, all of which are subject to conversion or exercise restrictions that prohibit conversion or exercise until such time as the holder would not beneficially own, after such conversion or exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of September 15, 2023, Cavalry Fund I LP has not waived such limitation.
- (6) Represents 300,000 shares of Common Stock owned individually by Brandt and Mona Wilson. Excludes (a) 976,278 Bridge PreFunded Warrants with unsatisfied exercise restrictions; and (b) 2,552,556 Common Warrants with unsatisfied exercise restrictions, all of which are subject to exercise restrictions that prohibit exercise until such time as the holder would not beneficially own, after such exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of September 15, 2023, neither Brandt Wilson nor Mona Wilson had waived such limitation.
- (7) Represents (i) 235,445 shares of Common Stock owned individually by Ana Parker, Michael A. Parker's spouse; (ii) 38,055 shares of Common Stock owned individually by Mr. Parker; (iii) 25,000 shares of Common Stock owned through Tungsten, of which Mr. Parker is the sole manager and (iv) 1,500 shares of restricted stock granted to Mr. Parker on September 27, 2021. Excludes (a) 82,465 Bridge Pre-Funded Warrants with unsatisfied exercise restrictions; (b) 549,486 Common Warrants with unsatisfied exercise restrictions; (c) 103,559 First Conversion Shares; (d) 48,290 First Warrant Shares; (e) any of the 17,143 shares of Common Stock that may be acquired upon the exercise of Series I Warrants (which expire October 18, 2024); or (f) any of the 23,438 shares that may be acquired upon the exercise of Series K Warrants (which expire on August 11, 2026), since such warrants cannot be exercised until such time as the holder would not beneficially own, after such exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case such waiver will become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of September 15, 2023, neither Ms. Parker nor Mr. Parker have waived such limitation.

- (8) Represents 300,000 shares of Common Stock owned individually by Andrew Stahl. Excludes (a) 976,278 Bridge PreFunded Warrants with unsatisfied exercise restrictions; and (b) 2,552,556 Common Warrants with unsatisfied exercise restrictions, all of which are subject to exercise restrictions that prohibit exercise until such time as the holder would not beneficially own, after such exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of September 15, 2023, Mr. Stahl had not waived such limitation.
- (9) Represents 300,000 shares of Common Stock owned by Sixth Borough Capital Fund, LP. Excludes (a) 63,869 Bridge PreFunded Warrants with unsatisfied exercise restrictions; and (b) 727,738 Common Warrants with unsatisfied exercise restrictions, all of which are subject to exercise restrictions that prohibit exercise until such time as the holder would not beneficially own, after such exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of September 15, 2023, Sixth Borough Capital Fund, LP has not waived such limitation.
- (10) Represents (a) 50,000 shares of Common Stock held by Twelve Pins Partners, LLC, with respect to which Dr. Norchi is the sole member and holds sole voting and investment control; (b) 7,098 shares issued to Dr. Norchi upon the closing of the Merger in exchange for the cancellation of shares of Common Stock and convertible notes of ABS owned by him immediately prior to the closing of the Merger; (c) 5,650 shares of restricted stock granted to Dr. Norchi on May 3, 2016; (d) 3,250 shares of restricted stock granted to Dr. Norchi on February 3, 2017; (e) 1,800 shares of restricted stock granted to Dr. Norchi on July 19, 2018; (f) 2,626 First Conversion Shares; (g) 2,415 First Warrants; and (h) 363 First Inducement Shares; (i) 33,130 shares subject to options exercisable within 60 days after September 15, 2023; and (j) 6,862 shares of common stock purchased. Excludes 13,724 Common Warrants with unsatisfied exercise restrictions. Dr. Norchi disclaims beneficial ownership of the securities held by Twelve Pins Partners, LLC except to the extent of his pecuniary interest therein
- (11) Represents 5,868 shares of Common Stock subject to options exercisable within 60 days after September 15, 2023
- (12) Represents 3,368 shares of Common Stock subject to options exercisable within 60 days after September 15, 2023. Includes (i) 137 shares of Common Stock, (ii) 3,939 First Conversion Shares, (iii) 3,622 First Warrant Shares, (iv) 544 First Inducement Shares; and (v) 10,292 shares of common stock held by Drake Partners Equity LLC, in which Mr. Hicks has an ownership interest. Excludes 20,584 Common Warrants with unsatisfied exercise restrictions held by Drake Partners Equity LLC, in which Mr. Hicks has an ownership interest.
- (13) Represents (i) 3,939 First Conversion Shares; (ii) 3,622 First Warrant Shares; (iii) 544 First Inducement Shares; (iv) 10,292 shares of common stock purchased, and (v) 4,798 shares of Common Stock subject to options exercisable within 60 days after September 15, 2023. Excludes 20,584 Common Warrants with unsatisfied exercise restrictions.
- (14) Represents 750 shares of restricted stock granted to Mr. Yrigoyen on July 30, 2021, and 2,444 shares of Common Stock subject to options exercisable within 60 days after September 15, 2023.
- (15) Represents 2,014 shares of Common Stock subject to options exercisable within 60 days after September 15, 2023.

LEGAL MATTERS

The validity of the Common Stock being offered hereby has been passed upon for us by McDonald Carano LLP, Reno, Nevada.

EXPERTS

Baker Tilly US, LLP, an independent registered public accounting firm, has audited our consolidated financial statements as of and for the years ended September 30, 2022 and 2021, as stated in its report appearing herein, and such audited consolidated financial statements have been so included in reliance upon the report of such firm given upon its authority as experts in accounting and auditing. The report on the consolidated financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains a website, at <http://www.sec.gov>, that contains registration statements, reports, proxy statements and other information regarding registrants that file electronically with the SEC, including us. Our website address is <http://www.archtherapeutics.com>. We have not incorporated by reference into this prospectus the information on, or that can be accessed through, our website, and you should not consider it to be a part of this document. You should not rely on any information on that website in making your decision to purchase shares of our Common Stock.

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the securities being offered by this prospectus. This prospectus is part of that registration statement. This prospectus does not contain all of the information set forth in the registration statement or the exhibits to the registration statement. For further information with respect to us and the securities we are offering pursuant to this prospectus, you should refer to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract, agreement or other document referred to are not necessarily complete, and you should refer to the copy of that contract or other documents filed as an exhibit to the registration statement. You may read or obtain a copy of the registration statement at the SEC's website referred to above.

Arch Therapeutics, Inc.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of Arch Therapeutics, Inc. and Subsidiary

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Arch Therapeutics, Inc. and Subsidiary (the Company) as of September 30, 2022 and 2021, the related consolidated statements of operations, changes in stockholders' deficit, and cash flows for each of the two years in the period ended September 30, 2022, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of September 30, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended September 30, 2022, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that Arch Therapeutics, Inc. and Subsidiary will continue as a going concern. As discussed in Notes 1 and 2 to the consolidated financial statements, the Company has an accumulated deficit, has suffered significant net losses and negative cash flows from operations, only recently commenced generating limited operating revenues and has limited working capital that raises substantial doubt about its ability to continue as a going concern. Management's plans regarding these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accounting for Complex Financial Instruments

As described in Note 10, the Company entered a transaction (the 2022 Note Offering) that included the issuance of \$4.23 million in aggregate principal of senior secured convertible promissory notes, 63,833 shares of Common Stock, warrants to purchase 425,554 shares of the Company's common stock (the 2022 Warrants) and warrants to purchase 31,510 shares of the Company's common stock (the 2022 Placement Agent Warrants). In addition, in conjunction with the 2022 Note Offering, certain Series 2 note holders exchanged their notes in the aggregate amount of approximately \$700,000 of principal and interest (the Series 2 exchange), for senior secured convertible promissory notes of the Company.

We identified the accounting for these complex financial instruments, including the evaluation for potential embedded derivatives, accounting for the Series 2 exchange, and the classification of the 2022 Warrants and the 2022 Placement Agent Warrants as a critical audit matter. The application of the accounting guidance applicable to the transaction, including the evaluation for potential embedded derivatives, accounting for the Series 2 exchange, and the classification of the related warrants is complex, and therefore, applying such guidance to the contract terms is complex and requires significant management judgement. Auditing these elements involved especially complex auditor judgement due to the nature of the terms of these instruments, and the effort required to address these matters, including the extent of specialized skills and knowledge required.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others:

- Inspecting the agreements associated with the transaction and evaluating the completeness and accuracy of the Company's technical accounting analysis and application of the relevant accounting literature.
- Utilizing personnel with specialized knowledge and skills in technical accounting to assist in assessing management's analysis of the senior secured convertible promissory notes and 2022 Warrants and 2022 Placement Agent warrants, and the Series 2 exchange, including the evaluation of potential embedded derivatives, and the classification of the 2022 Warrants and 2022 Placement Agent warrants including: (i) evaluating the contracts to identify relevant terms that affect the recognition in the consolidated financial statements, and (ii) assessing the appropriateness of conclusions reached by management.

/s/ Baker Tilly US, LLP

We have served as the Company's auditor since 2013.

Tewksbury, Massachusetts

December 28, 2022, except for the effects of the reverse share split described in Note 2, as to which the date is January 23, 2023.

Arch Therapeutics, Inc. and Subsidiary
Consolidated Balance Sheets
As of September 30, 2022 and 2021

	September 30, 2022	September 30, 2021
ASSETS		
Current assets:		
Cash	\$ 746,940	\$ 2,266,639
Inventory	1,414,848	1,093,765
Prepaid expenses and other current assets	436,407	307,341
Total current assets	<u>2,598,195</u>	<u>3,667,745</u>
Long-term assets:		
Property and equipment, net	2,044	5,240
Other assets	3,500	3,500
Total long-term assets	<u>5,544</u>	<u>8,740</u>
Total assets	<u>\$ 2,603,739</u>	<u>\$ 3,676,485</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 1,328,000	\$ 408,083
Accrued expenses and other liabilities	318,505	319,464
Insurance premium financing	247,933	—
Current portion of Series 1 convertible notes	550,000	—
Current portion of accrued interest	127,781	—
Current portion of derivative liability	748,275	1,000,000
Total current liabilities	<u>3,320,494</u>	<u>1,727,547</u>
Long-term liabilities:		
Series 1 convertible notes	—	550,000
Series 2 convertible notes	450,000	1,050,000
Senior secured convertible notes, net of discount and issuance costs	2,362,273	—
Accrued interest	204,575	167,137
Derivative liability	459,200	1,207,475
Total long-term liabilities	<u>3,476,048</u>	<u>2,974,612</u>
Total liabilities	<u>6,796,542</u>	<u>4,702,159</u>
Commitments and contingencies (Note 15)		
Stockholders' equity (deficit):		
Common stock, \$0.001 par value, 12,000,000 shares authorized as of September 30, 2022 and 2021, 1,249,432 and 1,185,849 shares issued as of September 30, 2022 and 2021, and 1,249,682 and 1,183,599 outstanding as of September 30, 2022 and 2021	1,249	1,184
Additional paid-in capital	50,878,721	48,770,061
Accumulated deficit	(55,072,773)	(49,796,919)
Total stockholders' deficit	<u>(4,192,803)</u>	<u>(1,025,674)</u>
Total liabilities and stockholders' deficit	<u>\$ 2,603,739</u>	<u>\$ 3,676,485</u>

The accompanying notes are an integral part of these consolidated financial statements.

Arch Therapeutics, Inc. and Subsidiary
Consolidated Statements of Operations
For the Years Ended September 30, 2022 and 2021

	Fiscal Year Ended September 30, 2022	Fiscal Year Ended September 30, 2021
Revenue	\$ 15,652	\$ 11,565
Operating expenses:		
Cost of revenues	51,489	26,282
Selling, general and administrative expenses	4,519,636	5,009,323
Research and development expenses	1,153,333	1,353,084
Total costs and expenses	<u>5,724,458</u>	<u>6,388,689</u>
Loss from operations	<u>(5,708,806)</u>	<u>(6,377,124)</u>
Other (expense) income:		
Interest expense	(567,048)	(150,531)
Gain on forgiveness of loan	—	178,229
Decrease to fair value of derivative	1,000,000	108,944
Total other income	<u>432,952</u>	<u>136,642</u>
Net loss	<u>\$ (5,275,854)</u>	<u>\$ (6,240,482)</u>
Loss per share - basic and diluted		
Net loss per common share - basic and diluted	\$ (4.40)	\$ (5.67)
Weighted common shares - basic and diluted	1,199,574	1,100,007

The accompanying notes are an integral part of these consolidated financial statements.

Arch Therapeutics, Inc. and Subsidiary
Consolidated Statements of Changes in Stockholders' Deficit
For the Years Ended September 30, 2022 and 2021

<i>Fiscal Year Ended September 30, 2022</i>	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balance at September 30, 2021	1,183,599	\$ 1,184	\$ 48,770,061	\$ (49,796,919)	\$ (1,025,674)
Net loss	—	—	—	(5,275,854)	(5,275,854)
Issuance of common stock and warrants, net of financing costs	63,833	64	1,609,077	—	1,609,141
Vesting of restricted stock Issued	2,000	2	(2)	—	—
Stock-based compensation expense	—	—	499,584	—	499,584
Balance at September 30, 2022	<u>1,249,432</u>	<u>\$ 1,249</u>	<u>\$ 50,878,721</u>	<u>\$ (55,072,773)</u>	<u>\$ (4,192,803)</u>

<i>Fiscal Year Ended September 30, 2021</i>	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balance at September 30, 2020	965,224	\$ 965	\$ 42,054,981	\$ (43,556,437)	(1,500,491)
Net loss	—	—	—	(6,240,482)	(6,240,482)
Issuance of common stock and warrants, net of financing costs	215,625	216	6,219,017	—	6,219,233
Vesting of restricted stock issued	2,750	3	(3)	—	—
Stock-based compensation expense	—	—	496,066	—	496,066
Balance at September 30, 2021	<u>1,183,599</u>	<u>\$ 1,184</u>	<u>\$ 48,770,061</u>	<u>\$ (49,796,919)</u>	<u>\$ (1,025,674)</u>

The accompanying notes are an integral part of these consolidated financial statements.

Arch Therapeutics, Inc. and Subsidiary
Consolidated Statements of Cash Flows
For the Years Ended September 30, 2022 and 2021

	Fiscal Year Ended September 30, 2022	Fiscal Year Ended September 30, 2021
Cash flows from operating activities:		
Net loss	\$ (5,275,854)	\$ (6,240,482)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	3,196	2,587
Stock-based compensation	499,583	496,066
Decrease to fair value of derivative	(1,000,000)	(108,944)
Inventory obsolescence charge	248,073	181,988
Accretion of discount and debt issuance costs on 2022 Notes	302,049	—
Gain on forgiveness of loan	—	(178,229)
Changes in operating assets and liabilities:		
(Increase) decrease in:		
Inventory	(569,156)	(307,760)
Prepaid expenses and other current assets	225,124	(91,668)
Increase (decrease) in:		
Accounts payable	846,869	66,033
Accrued interest	265,000	151,285
Accrued expenses and other liabilities	(959)	70,496
Net cash used in operating activities	(4,456,075)	(5,958,628)
Cash flows from investing activities:		
Purchases of property and equipment	—	(3,275)
Net cash used in investing activities	—	(3,275)
Cash flows from financing activities:		
Repayment of insurance premium financing	(106,257)	—
Proceeds received from convertible notes	—	1,050,000
Proceeds received from senior secured convertible notes	3,525,000	—
Proceeds from issued common stock and warrants, net of financing costs	—	6,219,233
Payment of 2022 Financing debt issuance costs	(482,367)	—
Net cash provided by financing activities	2,936,376	7,269,233
Net (decrease) increase in cash	(1,519,699)	1,307,330
Cash, beginning of year	2,266,639	959,309
Cash, end of year	<u>\$ 746,940</u>	<u>\$ 2,266,639</u>
Non-cash financing activities:		
Financing of insurance premium	\$ 354,190	\$ —
Issuance of restricted stock	\$ 8,959	\$ —
Fair value of 2022 Warrants issued (see Note 10)	\$ 1,470,133	\$ —
Fair value of 2022 Inducement Shares issued (see Note 10)	\$ 314,523	\$ —
Exchange of Series 2 Convertible Notes into Senior Secured Notes (See Note 10)	\$ 699,781	\$ —
Issuance of restricted stock in consideration for services performed	\$ 30,840	\$ 103,750
Fair Value of 2022 Placement Agent Warrants (see Note 10)	\$ 219,894	\$ —
Unpaid issuance costs in accounts Payable	\$ 73,048	\$ —

The accompanying notes are an integral part of these consolidated financial statements.

Notes to the Consolidated Financial Statements

1. DESCRIPTION OF BUSINESS

Arch Therapeutics, Inc. (together with its subsidiary, the “Company” or “Arch”) was incorporated under the laws of the State of Nevada on September 16, 2009, under the name “Almah, Inc.”. Effective June 26, 2013, the Company completed a merger (the “Merger”) with Arch Biosurgery, Inc. (formerly known as Arch Therapeutics, Inc.), a Massachusetts corporation (“ABS”), and Arch Acquisition Corporation (“Merger Sub”), the Company’s wholly owned subsidiary formed for the purpose of the transaction, pursuant to which Merger Sub merged with and into ABS and ABS thereby became the wholly owned subsidiary of the Company. As a result of the acquisition of ABS, the Company abandoned its prior business plan and changed its operations to the business of a biotechnology company. The Company’s principal offices are located in Framingham, Massachusetts.

ABS was incorporated under the laws of the Commonwealth of Massachusetts on March 6, 2006, as Clear Nano Solutions, Inc. On April 7, 2008, ABS changed its name from Clear Nano Solutions, Inc. to Arch Therapeutics, Inc. Effective upon the closing of the Merger, ABS changed its name from Arch Therapeutics, Inc. to Arch Biosurgery, Inc.

In the first quarter of 2021, the Company commenced commercial sales of our first product, AC5® Advanced Wound System, and has devoted substantially all of the Company’s operational effort to the research, development and regulatory programs necessary to turn the Company’s core technology into commercial products. To date, the Company has principally raised capital through the issuance of convertible debt, and the issuance of units consisting of its common stock, \$0.001 par value per share (“Common Stock”), and warrants to purchase Common Stock (“warrants”).

The Company expects to incur substantial expenses for the foreseeable future relating to research, development and commercialization of its potential future products. However, there can be no assurance that the Company will be successful in securing additional resources when needed, on terms acceptable to the Company, if at all. Therefore, there exists substantial doubt about the Company’s ability to continue as a going concern. The consolidated financial statements do not include any adjustments related to the recoverability of assets that might be necessary despite this uncertainty.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accompanying consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America (“US GAAP”).

Basis of Presentation

The consolidated financial statements include the accounts of Arch Therapeutics, Inc. and its wholly owned subsidiary, Arch Biosurgery, Inc., a biotechnology company. All intercompany accounts and transactions have been eliminated in consolidation.

On January 6, 2023, the directors of the Company authorized a reverse share split of the issued and outstanding Common Shares in a ratio of 200:1, effective January 17, 2023 (the “Reverse Share Split”). All information included in these consolidated financial statements has been adjusted, on a retrospective basis, to reflect the Reverse Share Split, unless otherwise stated.

Use of Estimates

Management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from those estimates.

Recently Issued and Adopted Accounting Guidance

In August 2020, the FASB issued ASU 2020-06, “*Debt with Conversion and other Options* (subtopic 470-20) and *Derivatives and Hedging-Contracts in Entity’s Own Equity* (Subtopic 815-40)” (“ASU 2020-06”). The purpose of ASU 2020-06 is to address issues identified as a result of the complexity associated with applying generally accepted accounting principles (“GAAP”) for certain financial instruments with characteristics of liabilities and equity. The amendments in ASU 2020-06 are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2023. Early adoption is permitted but no earlier than fiscal years beginning after December 15, 2020. The Company early adopted ASU 2020-06 using the full retrospective method, during our first quarter of fiscal year 2022, and the impact was considered immaterial on our consolidated financial statements.

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Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. The Company had no cash equivalents as of September 30, 2022 and 2021.

Inventories

Inventories are stated at the lower of cost or net realizable value. The cost of inventories comprises expenditures incurred in acquiring the inventories, the cost of conversion and other costs incurred in bringing them to their existing location and condition. The cost of raw materials, goods-in-process and finished goods are determined on a First in First out (FIFO) basis. When determining net realizable value, appropriate consideration is given to obsolescence, excessive levels, deterioration, and other factors.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist primarily of cash. The Company maintains its cash in bank deposits accounts, which, at times, may exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk on cash.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful life of the related asset. Upon sale or retirement, the cost and accumulated depreciation are eliminated from their respective accounts, and the resulting gain or loss is included in income or loss for the period. Repair and maintenance expenditures are charged to expense as incurred.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment when circumstances indicate the carrying value of an asset may not be recoverable in accordance with FASB ASC Topic 360, *Property, Plant and Equipment*. For assets that are to be held and used, impairment is recognized when the estimated undiscounted cash flows associated with the asset or group of assets is less than their carrying value. If impairment exists, an adjustment is made to write the asset down to its fair value, and a loss is recorded as the difference between the carrying value and fair value. Fair values are determined based on quoted market values, discounted cash flows or internal and external appraisals, as applicable. Assets to be disposed of are carried at the lower of carrying value or estimated net realizable value. For the years ended September 30, 2022 and 2021 there has not been any impairment of long-lived assets.

Leases

The Company determines if an arrangement is a lease at its inception. Operating lease right-of-use ("ROU") assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As our lease does not provide an implicit interest rate, the Company used an incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Income Taxes

In accordance with FASB ASC Topic 740, *Income Taxes* ("ASC 740"), the Company recognizes deferred tax assets and liabilities for the expected future tax consequences or events that have been included in our consolidated financial statements and/or tax returns. Deferred tax assets and liabilities are based upon the differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities and for loss and credit carryforwards using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

The Company provides reserves for potential payments of tax to various tax authorities related to uncertain tax positions when management determines that it is more likely than not that a loss will be incurred related to these matters and the amount of the loss is reasonably determinable.

Revenue

In accordance with FASB ASC Topic 606, *Revenue Recognition*, the Company recognizes revenue through a five-step process: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) a performance obligation is satisfied.

The Company's source of revenue is product sales. Contracts with customers contain a single performance obligation and the Company recognizes revenue from product sales when the Company has satisfied our performance obligation by transferring control of the product to the customers. Control of the product transfers to the customer upon shipment from the Company's third-party warehouse. The Company launched a reimbursement support program in September 2022. Under the terms of the program, the invoice amount may be adjusted through full or partial write-offs based on actual reimbursement amounts paid by for Medicare and Medicaid Services ("CMS") for AC5 units applied and billed by doctors. As such, revenue, if any, for the units shipped in connection with the Company's reimbursement support program will be booked in future periods when all conditions have been satisfied.

Cost of Revenues

Cost of revenues includes product costs, warehousing, overhead allocation and royalty expenses.

Research and Development

The Company expenses internal and external research and development costs, including costs of funded research and development arrangements, in the period incurred.

Accounting for Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with the guidance of FASB ASC Topic 718, *Compensation-Stock Compensation* (“ASC 718”), which requires all share-based payments be recognized in the consolidated financial statements based on their fair values. In accordance with ASC 718, the Company has elected to use the Black-Scholes option pricing model to determine the fair value of options granted and recognizes the compensation cost of share-based awards on a straight-line basis over the vesting period of the award.

The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by the fair value of the common stock and a number of other assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. The expected life for awards uses the simplified method for all “plain vanilla” options, as defined in ASC 718-10-S99, and the contractual term for all other employee and non-employee awards. The risk-free interest rate assumption is based on observed interest rates appropriate for the terms of our awards. The dividend yield assumption is based on history and the expectation of paying no dividends. Stock-based compensation expense, when recognized in the consolidated financial statements, is based on awards that are ultimately expected to vest.

Fair Value Measurements

The Company measures both financial and nonfinancial assets and liabilities in accordance with FASB ASC Topic 820, *Fair Value Measurements and Disclosures*, including those that are recognized or disclosed in the consolidated financial statements at fair value on a recurring basis. The standard created a fair value hierarchy which prioritizes the inputs to valuation techniques used to measure fair value into three broad levels as follows: Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities; Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and Level 3 inputs are unobservable inputs that reflect the Company’s own views about the assumptions market participants would use in pricing the asset or liability.

At September 30, 2022 and 2021, the carrying amounts of cash, accounts payables and accrued expenses and other liabilities approximate fair value because of their short-term nature. The carrying amounts for the Convertible Notes (See Notes 11 and 12) approximate fair value because borrowing rates and the terms are similar to comparable market participants. The carrying amounts of the Derivative Liabilities (See Note 7) are valued using Level 3 inputs and are recognized in the consolidated financial statements at fair value.

Derivative Liabilities

The Company accounts for its warrants and other derivative financial instruments as either equity or liabilities based upon the characteristics and provisions of each instrument, in accordance with FASB ASC Topic 815, *Derivatives and Hedging* (“ASC 815”). Warrants classified as equity are recorded at fair value as of the date of issuance on the Company’s consolidated balance sheets and no further adjustments to their valuation are made. Warrants classified as derivative liabilities and other derivative financial instruments that require separate accounting as liabilities are recorded on the Company’s consolidated balance sheets at their fair value on the date of issuance and will be revalued on each subsequent balance sheet date until such instruments are exercised or expire, with any changes in the fair value between reporting periods recorded as other income or expense. Management estimates the fair value of these liabilities using option pricing models and assumptions that are based on the individual characteristics of the warrants or instruments on the valuation date, as well as assumptions for future financings, expected volatility, expected life, yield, and risk-free interest rate.

Complex Financial Instruments

The Company does not use derivative instruments to hedge exposures to cash flow, market, or foreign currency risks. The Company evaluates its financial instruments, including warrants, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. The Company values its derivatives using the Black-Scholes option-pricing model or other acceptable valuation models, including Monte-Carlo simulations. Derivative instruments are valued at inception, upon events such as an exercise of the underlying financial instrument, and at subsequent reporting periods. The classification of derivative instruments, including whether such instruments should be recorded as liabilities, is re-assessed at the end of each reporting period.

The Company reviews the terms of debt instruments, equity instruments, and other financing arrangements to determine whether there are embedded derivative features, including embedded conversion options that are required to be bifurcated and accounted for separately as a derivative financial instrument. Additionally, in connection with the issuance of financing instruments, the Company may issue freestanding options and warrants, including options or warrants to non-employees in exchange for consulting or other services performed.

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The Company accounts for its common stock warrants in accordance with Accounting Standards Codification (“ASC”) 815 *Derivatives and Hedging* (“ASC 815”). Based upon the provisions of ASC 815, the Company accounts for common stock warrants as liabilities if the warrant requires net cash settlement or gives the holder the option of net cash settlement, or it fails the equity classification criteria. The Company accounts for common stock warrants as equity if the contract requires physical settlement or net physical settlement or if the Company has the option of physical settlement or net physical settlement and the warrants meet the requirements to be classified as equity. Common stock warrants classified as liabilities are initially recorded at fair value on the grant date and remeasured at fair value each balance sheet date with the offset adjustments recorded in change in fair value of warrant liability within the consolidated statements of operations. Common stock warrants classified as equity are initially measured at fair value on the grant date and are not subsequently remeasured.

[Financial Statement Reclassification](#)

Certain balances in the prior year consolidated financial statements have been reclassified for comparison purposes to conform to the presentation in the current year consolidated financial statements. These reclassifications had no effect on the reported results of operations or financial position.

[Subsequent Events](#)

The Company evaluated all events or transactions through December 28, 2022, the date which these consolidated financial statements were issued. Please note the following matters deemed to be subsequent events.

[CMS HCPCS Code Status](#)

On December 5, 2022, the Company announced that the Centers for Medicare and Medicaid Services (“CMS”) made a preliminary recommendation to establish a dedicated Healthcare Common Procedure Coding System (“HCPCS”) Level II billing code specific to AC5® Advanced Wound System (“AC5”). The preliminary recommendation was discussed at CMS’ First Biannual 2022 HCPCS Public Meeting, which was held on November 30, 2022. The HCPCS code would better enable providers to bill third party payors for AC5® Advanced Wound System that is used in doctors’ offices. Although the establishment of a dedicated HCPCS code does not guarantee coverage or reimbursement, a HCPCS code specific to AC5® Advanced Wound System would also enhance the Company’s ability to work directly with payors and expand access in outpatient settings.

[Going Concern Basis of Accounting](#)

As reflected in the consolidated financial statements, the Company has an accumulated deficit as of September 30, 2022, has suffered significant net losses and negative cash flows from operations, only recently commenced generating limited operating revenues, and has limited working capital. The continuation of the Company’s business as a going concern is dependent upon raising additional capital, the ability to successfully market and sell its product and eventually attaining and maintaining profitable operations. In particular, as of September 30, 2022, the Company will be required to raise additional capital, obtain alternative means of financial support, or both, in order to continue to fund operations, and therefore there is substantial doubt about the Company’s ability to continue as a going concern. The Company expects to incur substantial expenses into the foreseeable future for the research, development and commercialization of its current and potential products. In addition, the Company will require additional financing in order to seek to license or acquire new assets, research and develop any potential patents and the related compounds, and obtain any further intellectual property that the Company may seek to acquire. Finally, some of our product candidates or the materials contained therein (such as the Active Pharmaceutical Ingredients for our AC5® product line), are manufactured from facilities in areas impacted by the outbreak of the COVID-19, which could result in shortages due to ongoing efforts to address the outbreak. Historically, the Company has principally funded operations through debt borrowings, the issuance of convertible debt, and the issuance of units consisting of common stock and warrants. Provisions in the Securities Purchase Agreements that the Company entered into on June 28, 2018 (“2018 SPA”), and July 6, 2022 (“2022 SPA”) restrict the Company’s ability to effect or enter into an agreement to effect any issuance by the Company or its subsidiary of Common Stock or securities convertible, exercisable or exchangeable for Common Stock (or a combination of units thereof) involving a Variable Rate Transaction (as defined in the 2018 SPA and 2022 SPA) including, but not limited to, an equity line of credit or “At-the-Market” financing facility until the institutional investors in the 2018 SPA collectively own less than 20% of the Series F Warrants and the Series G Warrants purchased by them pursuant to the and 2018 SPA, respectively and for a period of six months pursuant to the 2022 SPA. In addition, under the 2022 SPA, we are required to complete an uplist to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American by February 15, 2023. See Note 6 for more information on the 2018 Financing, including the terms of the Series F Warrants and Series G Warrants, and Note 10 for more information on the 2022 Note Financing, including the terms of the 2022 Warrants and 2022 Placement Agent Warrants.

The 2021 SPA contains certain restrictions on our ability to conduct subsequent sales of our equity securities (See Note 9). The continued spread of COVID-19 and uncertain market conditions may also limit the Company’s ability to access capital. If the Company is unable to obtain adequate capital, the Company may be required to reduce the scope, delay, or eliminate some or all of its planned activities. These conditions, in the aggregate, raise substantial doubt as to the Company’s ability to continue as a going concern.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The consolidated financial statements do not include any adjustments that might result from this uncertainty.

3. PROPERTY AND EQUIPMENT

At September 30, 2022 and 2021, property and equipment consisted of:

	Estimated Useful Life (in years)	September 30, 2022	September 30, 2021
Furniture and fixtures	5	\$ 9,357	\$ 9,357
Leasehold improvements	Life of Lease	8,983	8,983
Computer equipment	3	14,416	14,416
Lab equipment	5	1,000	1,000
		33,756	33,756
Less – accumulated depreciation		31,712	28,516
Property and equipment, net		<u>\$ 2,044</u>	<u>\$ 5,240</u>

For the years ended September 30, 2022 and 2021 depreciation expense recorded was \$3,196 and \$2,587, respectively.

4. INVENTORIES

Inventories consist of the following:

	September 30, 2022	September 30, 2021
Finished Goods	\$ 9,063	\$ 249,571
Goods-in-process	1,405,785	844,194
Total	<u>\$ 1,414,848</u>	<u>\$ 1,093,765</u>

The Company capitalizes inventory that has been produced for commercial sale and has been determined to have a probable future economic benefit. The determination of whether or not the inventory has a future economic benefit requires estimates by management, to the extent that inventory is expected to expire prior to being sold or used for research and development or used for samples, the Company will write down the value of inventory. In evaluating the net realizable value of the inventory, appropriate consideration is given to obsolescence, excessive levels, deterioration, and other factors.

5. INSURANCE PREMIUM FINANCING

In July 2022, the Company entered into a finance agreement with First Insurance Funding in order to fund a portion of its insurance policies. The amount financed is approximately \$354,000 and incurs interest at a rate of 2.99%. The Company is required to make monthly payments of approximately \$35,000 through April 2023. The outstanding balance as of September 30, 2022 was approximately \$248,000.

6. REGISTERED DIRECT OFFERINGS

On September 30, 2016, the Company filed a registration statement with the SEC utilizing a “shelf” registration process, which was subsequently declared effective by the SEC on October 20, 2016 (such registration statement, the “*Shelf Registration Statement*”). Under the Shelf Registration Statement, the Company may offer and sell any combination of its Common Stock, warrants, debt securities, subscription rights, and/or units comprised of the foregoing to raise up to \$50,000,000 in gross proceeds.

On February 20, 2017, the Company entered into a Securities Purchase Agreement (the “2017 SPA”) with six accredited investors (collectively, the “2017 Investors”) providing for the issuance and sale by the Company to the 2017 Investors of an aggregate of 50,833 units at a purchase price of \$120.00 per unit in a registered offering (the “2017 Financing”). The securities comprising the units sold in the 2017 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant equal to 55% of the shares of Common Stock at an exercise price of \$150.00 per share (“Series F Warrant”) at any time prior to the fifth anniversary of the issuance date of the Series F Warrant subject to certain restrictions on exercise (the “2017 Warrants”) and the shares issuable upon exercise of the 2017 Warrants (the “2017 Warrant Shares”).

On June 28, 2018, the Company entered into a Securities Purchase Agreement (“2018 SPA”) with eight accredited investors (collectively, the “2018 Investors”) providing for the issuance and sale by the Company to the 2018 Investors of an aggregate of 45,350 units at a purchase price of \$100.00 per unit in a registered offering (“2018 Financing”). The securities comprising the units sold in the 2018 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant to purchase up to a number of shares of the Company’s Common Stock equal to 75% of the shares of Common Stock at an exercise price of \$140.00 per share (“Series G Warrant”) at any time prior to the fifth anniversary of the issuance date of the Series G Warrant subject to certain restrictions on exercise (the “2018 Warrants”) and the shares issuable upon exercise of the 2018 Warrants (the “2018 Warrant Shares”).

On May 12, 2019, the Company entered into a Securities Purchase Agreement (“2019 SPA”) with five accredited investors (collectively, the “2019 Investors”) providing for the issuance and sale by the Company to the 2019 Investors of an aggregate of 43,077 units at a purchase price of \$65.00 per unit in a registered offering (“2019 Financing”). The securities comprising the units sold in the 2019 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant to purchase one share of Common Stock at an exercise price of \$80.00 per share (“Series H Warrant”) at any time prior to the fifth anniversary of the issuance date of the Series H Warrant subject to certain restrictions on exercise (the “2019 Warrants”) and the shares issuable upon exercise of the 2019 Warrants (the “2019 Warrant Shares”).

During the years ended September 30, 2022 and 2021, no Series F, Series G or Series H Warrants had been exercised. As of September 30, 2022, up to 34,013 and 43,077 shares may be acquired upon the exercise of the Series G and Series H Warrants, respectively.

During the year ended September 30, 2022, all 27,958 remaining Series F Warrants expired.

7. Derivative Liabilities

The Company accounted for the Series F Warrants, Series G Warrants and the Series H Warrants in accordance with ASC 815-10. Since the Company may be required to purchase its Series F Warrants, Series G Warrants and Series H Warrants for an amount of cash equal to \$36.00, \$22.00 and \$10.66, respectively, for each share of Common Stock (“Minimum”) they are recorded as liabilities at the greater of the Minimum or fair value. They are marked to market each reporting period through the Consolidated Statement of Operations. During the year ended September 30, 2022, the Company recognized income of \$1,000,000 for the expiration of the Series F Warrants.

On the respective closing dates, the derivative liabilities related to the Series G Warrants and Series H Warrants were recorded at an aggregate fair value of \$1,628,113. Given that the fair value of the derivative liabilities was less than the net proceeds, the remaining proceeds were allocated to Common Stock and additional-paid-in-capital. For the fiscal year ended September 30, 2021, the Company recorded income of \$108,944 in connection with the decrease in the fair value of the derivative liability.

Fair Value Measurements Using Significant Unobservable Inputs - Year Ended September 30, 2022 (Level 3)

	Series F	Series G	Series H
Beginning balance at September 30, 2021	\$ 1,000,000	\$ 748,275	\$ 459,200
Issuances	—	—	—
Adjustments for the expiration of warrant	(1,000,000)	—	—
Ending balance at September 30, 2022	<u>\$ —</u>	<u>\$ 748,275</u>	<u>\$ 459,200</u>

Fair Value Measurements Using Significant Unobservable Inputs— Year Ended September 30, 2021 (Level 3)

	Series F	Series G	Series H
Beginning balance at September 30, 2020	\$ 1,000,000	\$ 748,275	\$ 568,144
Issuances	—	—	—
Adjustments to estimated fair value	—	—	(108,944)
Ending balance at September 30, 2021	<u>\$ 1,000,000</u>	<u>\$ 748,275</u>	<u>\$ 459,200</u>

The derivative liabilities are recorded as liabilities at September 30, 2022 using the greater of the minimum value or the Black Scholes Model with the following assumptions. As of September 30, 2022, the derivative liabilities are recorded at their minimum value.

	Series G	Series H
Closing price per share of Common Stock		
Exercise price per share	\$ 140.00	\$ 80.00
Expected volatility	132.97%	122.50%
Risk-free interest rate	4.05%	4.14%
Dividend yield	—	—
Remaining expected term of underlying securities (years)	0.69	1.57

During the year ended September 30, 2022, the Series F Warrants expired.

The derivative liabilities are recorded as liabilities at September 30, 2021 using the greater of the minimum value or the Black Scholes Model with the following assumptions. As of September 30, 2021, the derivative liabilities are recorded at their minimum value.

	Series F	Series G	Series H
Closing price per share of Common Stock	\$ 0.12	\$ 0.12	\$ 0.12
Exercise price per share	\$ 150.00	\$ 140.00	\$ 80.00
Expected volatility	90.28%	87.40%	86.59%
Risk-free interest rate	0.04%	0.19%	0.41%
Dividend yield	—	—	—
Remaining expected term of underlying securities (years)	0.34	1.70	2.58

8. OCTOBER 2019 REGISTERED DIRECT OFFERING

On October 16, 2019, the Company entered into a Securities Purchase Agreement (the “*October 2019 SPA*”) with seven accredited investors (collectively, the “*October 2019 Investors*”) providing for the issuance and sale by the Company to the 2019 Investors of an aggregate of 71,429 units at a purchase price of \$35.00 per unit in a registered offering (“*October 2019 Financing*”). The securities comprising the units sold in the October 2019 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant to purchase one share of Common Stock at an exercise price of \$44.00 per share (“*Series I Warrant*”) at any time prior to the fifth anniversary of the issuance date of the Series I Warrant subject to certain restrictions on exercise and the shares issuable upon exercise of the Series I Warrants (collectively, the “*October 2019 Warrant Shares*”). As of October 18, 2019, the Company recorded the 71,429 shares as Common Stock. Pursuant to the Engagement Agreement (as defined below), the Company also agreed to issue to the Placement Agent, or its designees, warrants to purchase up to 5,358 shares (the “*Placement Agent Warrants*”). The 2019 Placement Agent Warrants have substantially the same terms as the Series I Warrants, except that the exercise price of the Placement Agent Warrants is \$43.75 per share and the term of the Placement Agent Warrants is five years.

The gross proceeds to the Company from the October 2019 Financing, which were received as of October 18, 2019, were approximately \$2.5 million before deducting financing costs of approximately \$333,000 which includes approximately \$158,000 of placement fees. The number of shares of the Company’s Common Stock into which each of the Series I Warrants is exercisable and the exercise price therefore are subject to adjustment, as set forth in the Series I Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise).

The Company engaged H.C. Wainwright as its exclusive institutional investor placement agent (the “*Placement Agent*”) in connection with the October 2019 SPA pursuant to an engagement agreement dated as of October 10, 2019 (the “*2019 Engagement Agreement*”). In consideration for the services provided by the Placement Agent, the Placement Agent was entitled to receive cash fees ranging from 6.0% to 8.2% of the gross proceeds received by the Company, as well as reimbursement for all reasonable expenses incurred by it in connection with its engagement. The Company received gross proceeds of approximately \$2.5 million in the aggregate, resulting in a fee of approximately \$158,000.

During the year ended September 30, 2022, no Series I Warrants or Placement Agent Warrants have been exercised. As of September 30, 2022, up to 71,429 and 5,358 shares may be acquired upon the exercise of the Series I Warrants and Placement Agent Warrants, respectively.

Common Stock

At October 18, 2019 the Closing Date of the October 2019 Financing, the Company issued 71,429 shares of Common Stock.

Equity Value of Warrants

The Company accounted for the Series I Warrants and the Placement Agent Warrants relating to the aforementioned October 2019 Registered Direct Offering in accordance with ASC 815-40. Because the Series I Warrants and the Placement Agent Warrants are indexed to the Company’s stock, they are classified within stockholders’ equity (deficit) in the accompanying consolidated financial statements.

9. 2021 REGISTERED DIRECT OFFERING

On February 11, 2021, the Company entered into a Securities Purchase Agreement (the “*2021 SPA*”) with certain institutional and accredited investors (collectively, “*2021 Investors*”) providing for the issuance and sale by the Company to the 2021 Investors of an aggregate of 215,625 shares (the “*Shares*”) of the Company’s Common Stock, and warrants (the “*Series K Warrants*”) to purchase an aggregate of 161,719 shares (the “*Warrant Shares*”) of Common Stock, at a combined offering price of \$32.00 per share (the “*2021 Financing*”). The Series K Warrants have an exercise price of \$34.00 per share and are exercisable for a period of 5.5 years. The aggregate gross proceeds for the sale of the Shares and Series K Warrants were approximately \$6.9 million, before deducting the Placement Agent’s fees and expenses and other offering expenses payable by the Company, of approximately \$700,000. Pursuant to an engagement agreement dated as of February 8, 2021 (the “*2021 Engagement Agreement*”), by and between the Company and the Placement Agent, the Company agreed to pay the Placement Agent cash fees equal to (i) 7.5% of the gross proceeds received by the Company from certain investors in the 2021 Financing, and (ii) 6.0% of the gross proceeds received by the Company from certain investors that had pre-existing relationships with the Company. In addition, the Placement Agent received a one-time non-accountable expense fee of \$10,000, up to \$50,000 for fees and expenses of legal counsel and other out-of-pocket expenses and \$10,000 for clearing expenses. Pursuant to the 2021 Engagement Agreement, the Company also agreed to issue to the Placement Agent, or its designees, warrants to purchase up to 7.5% of the aggregate number of Shares sold to the 2021 Investors, or warrants to purchase up to 16,172 shares (the “*2021 Placement Agent Warrants*”) of the Company’s Common Stock. The 2021 Placement Agent 2 Warrants have substantially the same terms as the Series K Warrants, except that the exercise price of the 2021 Placement Agent Warrants is \$40.00 per share. The 2021 Engagement Agreement contained indemnity and other customary provisions for transactions of this nature.

The 2021 SPA contained certain restrictions on the Company’s ability to conduct subsequent sales of the Company’s equity securities. In particular, we were prohibited from entering into or effecting a Variable Rate Transaction (as defined in the 2021 SPA) until February 11, 2022; provided, however, the Company may enter into and effect an at-the-market offering facility with the Placement Agent.

The number of shares of the Company’s Common Stock into which each of the Series K Warrants is exercisable and the exercise price therefore are subject to adjustment, as set forth in the Series K Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise). During the fiscal year ended September 30, 2022, no Series K Warrants or 2021 Placement Agent Warrants had been exercised. As of September 30, 2022, up to 161,719 and 16,172 shares may be acquired upon the exercise of the Series K Warrants and Placement Agent Warrants, respectively.

Common Stock

On February 17, 2021 the Closing Date of the 2021 Financing, the Company issued 215,625 shares of Common Stock.

Equity Value of Warrants

The Company accounted for the Series K Warrants and the Placement Agent 2 Warrants relating to the aforementioned February 2021 Registered Direct Offering in accordance with ASC 815-40, *Derivatives and Hedging*. Because the Series K Warrants and the Placement Agent 2 Warrants are indexed to the Company’s stock, they are classified within stockholders’ equity (deficit) in the accompanying consolidated financial statements.

10. 2022 CONVERTIBLE NOTE OFFERING

On July 7, 2022, the Company announced that it had entered into a Securities Purchase Agreement (the “2022SPA”) with certain institutional and accredited individual investors (collectively, the “2022 Investors”) providing for the issuance and sale by the Company to the 2022 Investors of (i) Senior Secured Convertible Promissory Notes (each a “2022 Note” and collectively, the “2022 Notes”) in the aggregate principal amount of \$4.23 million, which includes an aggregate \$0.705 million original issue discount in respect of the 2022 Notes; (ii) Warrants (the “2022 Warrants”), to purchase an aggregate of 425,554 shares (the “2022 Warrant Shares”) of Common Stock; and (iii) 63,833 shares of Common Stock (the “2022 Inducement Shares”) equal to 15% of the principal amount of the 2022 Notes divided by the closing price of the Common Stock immediately prior to the Closing Date (as defined below). The 2022 Notes, 2022 Warrants and 2022 Inducement Shares were issued as part of a convertible note offering authorized by the Company’s board of directors (the “2022 Note Offering”). The aggregate gross proceeds for the sale of the 2022 Notes, 2022 Warrants and 2022 Inducement Shares was approximately \$3.5 million, before deducting debt issuance costs of \$775,000 consisting of fair value of the placement agent’s warrants of approximately \$220,000 and other estimated fees and offering expenses payable by the Company of approximately \$555,000. The closing of the sales of these securities under the 2022 SPA occurred on July 6, 2022 (the “2022 Closing Date”).

The 2022 Notes bear interest on the unpaid principal balance at a rate equal to ten percent (10%) (computed on the basis of the actual number of days elapsed in a 360-day year) per annum accruing from the Closing Date until the 2022 Notes become due and payable at maturity or upon their conversion, acceleration or by prepayment, and may become due and payable upon the occurrence of an event of default under the 2022 Notes. Any amount of principal or interest on the 2022 Notes which is not paid when due shall bear interest at the rate of the lesser of (i) eighteen percent (18%) per annum or (ii) the maximum amount allowed by law from the due date thereof until payment in full.

The 2022 Notes are convertible into shares of Common Stock at the option of each holder of the 2022 Notes from the date of issuance at \$9.14 (the “Conversion Price”) through the later of (i) January 6, 2024 (the “Maturity Date”) and (ii) the date of payment of the Default Amount (as defined in the 2022 Note); *provided, however*, certain 2022 Notes include a provision preventing such conversion if, as a result, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than 4.99% of the outstanding shares of the Common Stock (as applicable, the “Ownership Limitation”) immediately after giving effect to the Conversion; and *provided further*, the holder, upon notice to us, may increase or decrease the Ownership Limitation; *provided that* (i) the Ownership Limitation may only be increased to a maximum of 9.99% of the outstanding shares of the Common Stock; and (ii) any increase in the Ownership Limitation will not become effective until the 61st day after delivery of such waiver notice. The Conversion Price is subject to adjustment as set forth in the 2022 Notes.

The 2022 Notes contain customary events of default, which include, among other things, (i) our failure to pay when due any principal or interest payment under the 2022 Notes; (ii) our insolvency; (iii) delisting of our Common Stock; (iv) our breach of any material covenant or other material term or condition under the 2022 Notes; and (v) our breach of any representations or warranties under the 2022 Notes which cannot be cured within five (5) days. Further, events of default under the 2022 Notes also include (i) the unavailability of Rule 144 on or after six (6) months from the First Closing Date or January 6, 2023; (ii) our failure to deliver the shares of Common Stock to the 2022 Note holder upon exercise by such holder of its conversion rights under the 2022 Note; (iii) our loss of the “bid” price for its Common Stock and/or a market and such loss is not cured during the specified cure periods; and (iv) our failure to complete an uplisting of our Common Stock to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American by February 15, 2023 (an “Uplist Transaction”).

The 2022 Warrants (i) have an exercise price of \$9.94 per share; (ii) have a term of exercise equal to 5 years after their issuance date; (iii) became exercisable immediately after their issuance; and (iv) have a provision preventing the exercisability of such 2022 Warrant if, as a result of the exercise of the 2022 Warrant, the holder, together with its affiliates and any other persons whose beneficial ownership of our Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than the Ownership Limitation. The holder, upon notice to us, may increase or decrease the Ownership Limitation; *provided that* (i) the Ownership Limitation may only be increased to a maximum of 9.99% of the outstanding shares of our Common Stock; and (ii) any increase in the Ownership Limitation will not become effective until the 61st day after delivery of such waiver notice. The number of shares of Common Stock into which each of the 2022 Warrants is exercisable and the exercise price therefor are subject to adjustment as set forth in the 2022 Warrants, including standard antidilution provisions, and adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise). In the event of a Fundamental Transaction (as defined in the 2022 Warrants) holders of the 2022 Warrants would be entitled to receive alternate consideration in connection with such Fundamental Transaction, but only to the extent that holders of our Common Stock were entitled to receive the same. Moreover, as long as the 2022 Notes and 2022 Warrants remaining outstanding, upon the issuance of any security in connection with any potential future financing activity on terms more favorable than the existing terms, the Company has an obligation to notify the holders of the 2022 Notes and 2022 Warrants of such more favorable terms and to use best efforts to effect such terms in the 2022 Notes and 2022 Warrants. Finally, because of the Company’s net loss position, the shares underlying the 2022 Notes on an as converted basis are excluded from the calculation of basic and fully diluted earnings per share. Similarly, because of the Company’s net loss position, there was no impact on the calculation of basic and fully diluted earnings per share related to the classification of the 2022 Warrants as participating securities.

The Company retained a placement agent in connection with the private placement of \$2.4 million of the 2022 Notes to the institutional investors. The Company paid the 2022 Placement Agent 10% of the gross proceeds in the 2022 Placement Agent from certain institutional investors, or \$240,000 and we also reimbursed the 2022 Placement Agent approximately \$58,000 for non-accountable banking fees, legal fees and other expenses. In addition, we issued 2022 Placement Agent Warrants to purchase an aggregate of 31,510 shares of Common Stock. An additional \$1.1 million was raised in connection with the placement of the private placement notes, which included certain accredited investors some of which were Board members and executive officers of the Company. Board member, Laurence Hicks, and executive officers, Terrence W. Norchi and Michael S. Abrams, invested in the 2022 Senior Secured Convertible Notes. The investment made in the 2022 Senior Secured Convertible Notes made by the Board member and executive officers totaled \$80,000.

In addition, as a part of the 2022 Convertible Notes Offering, certain holders (the “*Series Holders*”) of the Company’s 10% Series 2 Convertible Notes (the “*Series Notes*”) agreed to exchange their Series 2 Notes for promissory notes of the Company on substantially similar terms to those of the 2022 Notes (the “*Subordinated Notes*”). The Subordinated Notes are convertible into 76,563 shares of Common Stock at a conversion price of \$9.14. The holders of the Subordinated Notes did not receive warrants or inducement shares. In connection with the issuance of the Subordinated Notes, the Series Holders entered into a subordination agreement on July 6, 2022 (the “*Closing Date*”) to subordinate their rights in respect of the Subordinated Notes to the rights of the Investors in respect of the 2022 Notes. As of July 7, 2022, approximately \$600,000 of the Series 2 Notes and accrued interest of approximately \$100,000 were included in the exchange.

Further, in connection with the 2022 Note Financing, we are required to complete an Uplist Transaction by February 15, 2023 under the terms of the 2022 Notes. If we are unable to complete an Uplist Transaction, then the 2022 Notes will become immediately due and payable and we will be obligated to pay to each 2022 Note holder an amount equal to 125%, multiplied by the sum of the outstanding principal amount of the 2022 Notes plus any accrued and unpaid interest on the unpaid principal amount of the 2022 Notes to the date of payment, plus any default interest and any other amounts owed to the holder, payable in cash or shares of Common Stock.

During the fiscal year ended September 30, 2022, the Company recorded interest expense on the 2022 Notes of approximately \$421,000 consisting of accrued interest of approximately \$119,000 and accretion of original issue discount debt discount and issuance costs of approximately \$302,000.

Allocation of Proceeds

The Company accounted for the Senior Secured Convertible Notes, the 2022 Warrants, and the 2022 Inducement Shares relating to the aforementioned July 2022 Senior Secured Convertible Promissory Notes in accordance with ASC 470-20-25-2 “Debt” which states that the allocation of the proceeds from the financing shall be based on the relative fair values of the securities issued at the time of the issuance. The 2022 Inducement Shares and the 2022 Warrants, which are indexed to the Company’s stock, are classified within stockholders’ equity (deficit) in the accompanying consolidated financial statements. The allocated value of the 2022 Inducement Shares and the 2022 Warrants are \$314,523 and \$1,470,133, respectively. The allocated value of the Senior Secured Convertible Notes are \$1,740,344 were allocated as long-term liabilities in the accompanying consolidated financial statements. The fair value of the 2022 Placement Agent Warrants of \$219,894 are being accounted for as debt issuance costs and are classified within stockholders’ equity (deficit) in the accompanying consolidated financial statements. As of September 30, 2022, the net carrying amount of the Senior Secured Convertible Notes was \$2,362,273 with unamortized debt discount and issuance costs of \$2,567,507.

The 2022 Warrants and the 2022 Placement Agent Warrants were valued as of July 6, 2022 using the Black Scholes Model with the following assumptions:

	2022 Investor Warrants	2022 Placement Agent Warrants
Closing price per share of Common Stock	\$ 9.98	\$ 9.98
Exercise price per share	\$ 9.94	\$ 10.06
Expected volatility	88.44%	88.44%
Risk-free interest rate	2.96%	2.96%
Dividend yield	—	—
Remaining expected term of underlying securities (years)	5.0	5.0

11. SERIES 1 AND SERIES 2 CONVERTIBLE NOTES

On June 4, 2020 and November 6, 2020, the Company issued unsecured 10% Series 1 Convertible Notes (“*Series 1 Notes*”) and Series 2 Convertible Notes (“*Series 2 Notes*”), and collectively with the Series 1 Notes, the “*Convertible Notes*”) in the aggregate principal amount of \$550,000 and \$1,050,000, respectively. The maturity dates of the Series 1 Notes and Series 2 Notes are June 30, 2023 and November 30, 2023, respectively. The Convertible Notes provide, among other things, for (i) a term of approximately three years; (ii) the Company’s ability to prepay the Convertible Notes, in whole or in part, at any time; (iii) the automatic conversion of the Convertible Notes upon a Change of Control (all capitalized terms not otherwise defined to have the meaning ascribed to such terms of the Convertible Notes) into shares of the Company’s Common Stock, at a per share price of \$54.00 and \$50.00 (the “*Conversion Price*”) for the Series 1 Notes and Series 2 Notes, respectively; (iv) the ability of the holders of the Convertible Note (a “*Holder*”) to convert the principal of the Convertible Notes, along with accrued interest, in whole or in part, into shares of Common Stock at the respective Conversion Price; (v) the Company’s ability to convert all Note Obligations outstanding upon a Qualified Equity Financing into shares of Common Stock at the respective Conversion Price; (vi) the Company’s ability to convert the principal of the Convertible Notes, along with accrued interest, in whole or in part, into shares of Common Stock at the respective Conversion Price in the event the volume weighted average price (“*VWAP*”) of the Common Stock equals or exceeds \$64.00 per share for at least fifteen consecutive Trading Days; (vii) the Company’s ability to convert all outstanding Note Obligations into shares of Common Stock at the respective Conversion Price (an “*In-Kind Note Repayment*”) in lieu of repaying the Note Obligations outstanding on the Maturity Date, provided, however, that in the case of an In-Kind Note Repayment, the outstanding Note Obligations will be calculated by increasing by thirty-five percent the aggregate sum of the unpaid Principal Amount held by each Holder and the accrued interest at a rate of ten percent per annum, subject to, with respect to any portion of the Principal Amount that is converted or prepaid before the twelve month anniversary of the Issuance Date, a minimum interest payment equal to ten percent of the amount that is converted or prepaid. As consideration for agreeing to subordinate, the premium applicable in connection with an In-Kind Note Repayment at maturity was increased from thirty-five percent to sixty percent.

Beginning June 22, 2015 and through June 30, 2015, the Company entered into a series of substantially similar subscription agreements with 20 accredited investors providing for the issuance and sale by the Company to the 2015 Investors, in a private placement, of an aggregate of 71,954 Units at a purchase price of \$44.00 per Unit. Each Unit consisted of a share of Common Stock and a Series D Warrant to purchase a share of Common Stock at an exercise price of \$50.00 per share at any time prior to the fifth anniversary of the issuance date of the Series D Warrant and the shares issuable upon exercise of the Series D Warrants.

On June 3, 2020, the Company entered into an agreement (the “*Agreement*”) with the holders of a majority (the “*Majority Holders*”) of the outstanding warrants classified as “*Series D Warrants*”, resulting in approximately \$850,000 of proceeds as a result of the full exercise of all Series D Warrants. Under the terms of the Agreement, in exchange for fully exercising their remaining Series D Warrants for 23,636 shares of Common Stock on June 4, 2020, the Majority Holders were issued warrants to purchase 17,727 shares of Common Stock at an exercise price of \$50.00 over a 1-year term (“*Series J Warrants*”). On November 6, 2020, as consideration for an investment in the Convertible Notes, the Company entered into an amendment to the Series J Warrants with a holder of a Series J Warrant exercisable for up to 16,875 shares of Common Stock, to extend the term of the Series J Warrant from one year to thirty months.

On June 22, 2020, the Company entered into a Series J Warrant Issuance Agreement (the “*Keyes Sulat Agreement*”) with the Keyes Sulat Revocable Trust (the “*Trust*”), also a holder of outstanding Series D Warrants, resulting in approximately \$82,000 of proceeds as a result of the full exercise of the Trust’s Series D Warrants. Under the terms of the Keyes Sulat Agreement, in exchange for fully exercising the Trust’s remaining Series D Warrants for 2,273 shares of Common Stock on June 22, 2020, the Trust was issued Series J Warrants to purchase 1,705 shares of Common Stock at an exercise price of \$50.00 over a one-year term. James R. Sulat, a former member of the Board, is a co-trustee of the Trust, of which members of Mr. Sulat’s immediate family are beneficiaries. Mr. Sulat disclosed his interest in the Trust to the Board prior to its approval of the transaction and abstained from voting on the transaction.

As described in Note 10, above, as a part of the 2022 Convertible Notes Offering, certain holders of the Series Notes agreed to exchange Notes with principal amounts of \$600,000 and accrued interest of approximately \$100,000 for promissory notes of the Company on substantially similar terms to those of the 2022 Notes (the “*Exchanged Notes*”). As of July 6, 2022, \$699,781 of principal and accrued interest of the Series 2 notes was exchanged for the Senior Secured Convertible Notes. In connection with the issuance of the Exchanged Notes, the Series Holders entered into a subordination agreement on the *Closing Date* to subordinate their rights to the rights of the Investors in respect of the 2022 Notes.

During the fiscal years ended September 30, 2022 and 2021, the Company recorded interest expense on the Series 1 and Series 2 Convertible Notes of approximately \$146,000 and \$150,000, respectively.

12. INCOME TAXES

The principal components of the Company's net deferred tax assets consisted of the following at September 30:

	2022	2021
Net operating loss carryforwards	\$ 11,485,524	\$ 10,022,020
Capitalized expenditures	1,535,736	1,703,849
Research and development credit carryforwards	946,243	946,158
Stock based compensation	1,427,946	2,352,432
Property and Equipment	2,616	2,740
Accrued expenses	162,191	57,812
Inventory allowance	70,805	62,946
Gross deferred tax assets	15,631,061	15,147,957
Deferred tax asset valuation allowance	(15,631,061)	(15,147,957)
Net deferred tax assets	\$ -	\$ -

The provision (benefit) for income taxes differs from the tax computed with the statutory federal income tax rate as follows:

	2022	2021
Expected income tax (benefit) at federal statutory rate	21.00%	21.00%
<u>Increase/(Decrease) due to:</u>		
State income taxes – net of federal benefit	3.65%	5.80%
<u>Permanent Differences:</u>		
Key man life insurance	--%	(0.01)%
Stock Based Compensation	(18.10)%	--%
R&D, taken as a credit	(0.23)%	(0.29)%
Adjustment to fair value of derivative	3.98%	0.37%
PPP Loan Forgiveness	--%	0.60%
Other	(1.14)%	(1.41)%
Change in Valuation Allowance	(9.16)%	(26.06)%
Total Income Tax Provision / (Benefit)	--%	--%

As of September 30, 2022 and 2021, the Company had federal net operating loss carryforwards totaling approximately \$42,695,000 and \$37,018,000, respectively, which may be available to offset future taxable income. The pre-2018 federal net operating loss carryforwards total approximately \$21,750,000, and begin to expire in 2026. Due to the CARES Act, federal net operating losses generated in tax years beginning after December 31, 2017 can be carried forward indefinitely. As of September 30, 2022 and 2021, the Company has federal net operating loss carryforwards with an indefinite life of \$20,945,000 and \$15,268,000. As of September 30, 2022 and 2021, the Company had federal research and experimentation credit carryforwards of \$626,000 and \$643,000, respectively, which may be available to offset future income tax liabilities and which would begin to expire in 2028.

As of September 30, 2022 and 2021, the Company had state net operating loss carryforwards of approximately \$40,367,000 and \$36,033,000, respectively, which may be available to offset future taxable income and which would begin to expire in 2030. As of September 30, 2022 and 2021, the Company had state research and development credit carryforwards of \$406,000 and \$384,000, respectively, which may be able to offset future income tax liabilities and which would begin to expire in 2023.

As the Company has not yet achieved profitable operations, management believes the tax benefits as of September 30, 2022 and 2021 did not satisfy the realization criteria set forth in FASB ASC Topic 740, *Income Taxes*, and therefore has recorded a valuation allowance for the entire deferred tax asset. The valuation allowance increased in 2022 by approximately \$483,000 and increased in 2021 by approximately \$1,626,000. The Company's effective income tax rate differed from the federal statutory rate due to state taxes and the Company's full valuation allowance and stock based compensation, the latter of which reduced the Company's effective federal income tax rate to zero.

The Company experienced an ownership change as a result of the Merger described in Note 1, causing a limitation on the annual use of the net operating loss carryforwards, which are subject to a substantial annual limitation due to the ownership change limitations set forth in Internal Revenue Code Section 382 and similar state provisions. A formal Section 382 study has not been performed.

As of September 30, 2022, the Company is open to examination in the U.S. federal and certain state jurisdictions for tax years ended September 30, 2022, 2021, 2010 and 2019. In addition, any loss years remain open to the extent that losses are available for carryover to future years. Therefore, the tax years ended 2006 through 2022 remain open for examination by the IRS.

The Coronavirus Aid, Relief and Economic Security (CARES) Act was enacted on March 27, 2020. The CARES Act affected items such as carryback periods for net operating losses, modifications to the net interest deduction limitations and changes to tax depreciation methods. The company has taken the CARES Act into consideration for the tax year ended September 30, 2022 and continues to evaluate the impact of the CARES act on the business.

13. PAYROLL PROTECTION PROGRAM LOAN

On April 25, 2020, the Company executed a promissory note (the “*PPP Note*”) evidencing an unsecured loan in the amount of \$176,300 under the Paycheck Protection Program (the “*PPP Loan*”). The Paycheck Protection Program (or “*PPP*”) was established under the Cares Act and is administered by the U.S. Small Business Administration (“*SBA*”). The Loan has been made through First Republic Bank (the “*Lender*”).

The PPP Loan had a two-year term and bears interest at a rate of 1.00% per annum. Monthly principal and interest payments are deferred until the SBA makes a decision on our loan forgiveness application. Unless the PPP Loan is forgiven, the Company would have been required to make monthly payments of principal and interest of approximately \$20,000 to the Lender.

The PPP Note contains customary events of default relating to, among other things, payment defaults, providing materially false and misleading representations to the SBA or Lender, or breaching the terms of the PPP Loan documents. The occurrence of an event of default may result in the immediate repayment of all amounts outstanding, collection of all amounts owing from the Company, or filing suit and obtaining judgment.

Under the terms of the CARES Act, PPP Loan recipients can apply for and be granted forgiveness for all or a portion of the loan granted under the PPP. Such forgiveness will be determined, subject to limitations, based on the use of loan proceeds for payment of payroll costs and any payments of mortgage interest, rent, and utilities. However, no assurance is provided that forgiveness for any portion of the PPP Loan will be obtained. During November 2020, the Company applied for forgiveness of the PPP Loan. On May 28, 2021, the Company received notice that the SBA completed review and all principal and interest has been forgiven. For the fiscal year ended September 30, 2021, approximately \$178,000 was recorded to Gain on forgiveness of loan in Other Income in the consolidated statements of operations.

14. STOCK-BASED COMPENSATION

2013 Stock Incentive Plan

On June 18, 2013, the Company established the 2013 Stock Incentive Plan (the “*2013 Plan*”). Under the 2013 Plan, during the fiscal year ended September 30, 2021, a maximum number of 155,571 shares of the Company’s authorized and available common stock could be issued in the form of options, stock appreciation rights, sales or bonuses of restricted stock, restricted stock units or dividend equivalent rights, and an award may consist of one such security or benefit, or two or more of them in any combination or alternative. The 2013 Plan provides that on the first business day of each fiscal year commencing with fiscal year 2014, the number of shares of our common stock reserved for issuance under the 2013 Plan for all awards except for incentive stock option awards will be subject to increase by an amount equal to the lesser of (A) 15,000 Shares, (B) four (4) percent of the number of shares outstanding on the last day of the immediately preceding fiscal year of the Company, or (C) such lesser number of shares as determined by the Company’s Board of Directors (the “*Board*”). The exercise price of each option shall be the fair value as determined in good faith by the Board at the time each option is granted. On October 1, 2021, the aggregate number of authorized shares under the Plan was further increased by 15,000 shares to a total of 170,571 shares.

The exercise price of each option is equal to the closing price of a share of our common stock on the date of grant.

Share-based awards

During the year ended September 30, 2022, the Company granted 2,375 options to employees and directors and 4,250 options to consultants to purchase shares of common stock under the 2013 Plan.

Share-based compensation expense for awards granted during the year ended September 30, 2022 was based on the grant date fair value estimated using the Black-Scholes Option Pricing Model. The following assumptions were used to calculate the fair value of share-based compensation for the year ended September 30, 2022; expected volatility, 79.44% - 119.44%, risk-free interest rate, 0.13% - 2.85%, expected dividend yield, 0%, expected term, 5.6 years.

Common Stock Options

Stock compensation activity under the 2013 Plan for the year ended September 30, 2022 follows:

	Option Shares Outstanding	Weighted Average Exercise Price	Average Remaining Contractual Term (years)	Weighted Aggregate Intrinsic Value
Outstanding at September 30, 2021	124,495	\$ 58.00	1.83	\$ 140,151
Awarded	6,625	\$ 6.00		
Forfeited/Cancelled	(32,494)	\$ 70.00		
Outstanding at September 30, 2022	98,626	\$ 52.00	1.46	\$ 16,900
Vested at September 30, 2022	82,522	\$ 58.00	1.52	\$ —
Vested and expected to vest at September 30, 2022	98,626	\$ 52.00	1.46	\$ 16,900

As of September 30, 2022, 41,366 shares are available for future grants under the 2013 Plan. Share-based compensation expense recorded in the Company's Consolidated Statements of Operations for the year ended September 30, 2022 and 2021 resulting from stock options awarded to the Company's employees, directors and consultants was approximately \$459,000 and \$391,000, respectively. Of this amount during the years ended September 30, 2022 and 2021, \$148,000 and \$124,000, respectively, were recorded as research and development expenses, and \$311,000 and \$267,000, respectively were recorded as general and administrative expenses in the Company's Consolidated Statements of Operations.

During the years ended September 30, 2022 and 2021, no stock options awarded under the 2013 Stock Incentive Plan were exercised for cash. During the years ended September 30, 2022 and 2021, no stock options awarded under the 2013 Stock Incentive Plan were exercised on a cashless basis.

As of September 30, 2022, there is approximately \$181,000 of unrecognized compensation expense related to unvested stock-based compensation arrangements granted under the 2013 Plan. That cost is expected to be recognized over a weighted average period of 2.47 years.

Restricted Stock

On October 14, 2020, the Company awarded 250 shares of Restricted Stock to a consultant. The shares subject to this grant were awarded under the 2013 Plan and vested 90 days from the date of the award.

On January 27, 2021, the Company awarded 2,500 shares of Restricted Stock to a consultant. The shares subject to this grant were awarded under the 2013 Plan and vested immediately.

On July 30, 2021, the Company awarded 750 shares of Restricted Stock to an employee. The shares subject to this grant were awarded under the 2013 Plan and 250 shares vest on each of the following dates: January 12, 2022, July 12, 2022 and January 12, 2023.

On September 27, 2021, the Company awarded 1,500 shares of Restricted Stock to a consultant. The shares subject to this grant were awarded under the 2013 Plan and 1/12 of the shares will vest on each of the next twelve monthly anniversaries.

Restricted stock activity in shares under the 2013 Plan for the years ended September 30, 2022 and 2021 follows:

	2022	2021
Non Vested at September 30, 2021 and 2020	2,250	
Awarded	—	5,000
Vested	(2,000)	(2,750)
Forfeited	—	—
Non Vested at September 30, 2022 and 2021	250	2,250

The weighted average restricted stock award date fair value information for the years ended September 30, 2022 and 2021 follows:

	2022	2021
Non Vested at September 30, 2021 and 2020	\$ 20.00	\$ —
Awarded		26.00
Vested	(20.00)	(32.00)
Forfeited		—
Non Vested at September 30, 2022 and 2021	\$ 18.00	\$ 20.00

For the years ended September 30, 2022 and 2021 compensation expense recorded for the restricted stock awards was approximately \$40,000 and \$105,000, respectively. As of September 30, 2022, there is approximately \$3,000 of unrecognized compensation expense related to unvested stock-based compensation arrangements granted under the 2013 Plan.

15. COMMITMENTS AND CONTINGENCIES

In the ordinary course of business, the Company enters into various agreements containing standard indemnification provisions. The Company's indemnification obligations under such provisions are typically in effect from the date of execution of the applicable agreement through the end of the applicable statute of limitations. The aggregate maximum potential future liability of the Company under such indemnification provisions is uncertain. As of September 30, 2022 and 2021, no amounts have been accrued related to such indemnification provisions.

From time to time, the Company may be exposed to litigation in connection with its operations. The Company's policy is to assess the likelihood of any adverse judgments or outcomes related to legal matters, as well as ranges of probable losses.

MIT Licensing Agreement

In December 2007, the Company entered into a license agreement with MIT pursuant to which the Company acquired an exclusive world-wide license to develop and commercialize technology related to self-assembling peptide compositions, and methods of making and using such compositions in medical and non-medical applications, including claims that cover the Company's proposed products and methods of use thereof. The license also provides non-exclusive rights to additional intellectual property in the fields that cover the Company's proposed products and methods of use thereof, in order to provide freedom to operate. The license provides the Company a right to sublicense the exclusively licensed intellectual property. The Company has not sublicensed the exclusively licensed intellectual property to any party for any field.

In exchange for the licenses granted in the agreement, the Company has paid MIT license maintenance fees and patent prosecution costs. The Company paid license maintenance fees of \$50,000 to MIT in the fiscal years ended September 30, 2022 and 2021. For the years ended September 30, 2022 and 2021, the annual MIT license maintenance fees of \$50,000 are included in accrued expenses and other liabilities on the Consolidated Balance Sheets. The license maintenance fees and patent prosecution costs cover the contract year beginning January 1 through December 31. Annual license maintenance obligations extend through the life of the patents. In addition, MIT is entitled to royalties on applicable future product sales, if any. The annual payments may be applied towards royalties payable to MIT for that year for product sales.

The Company is obligated to indemnify MIT and related parties from losses arising from claims relating to the exercise of any rights granted to the Company under the license, with certain exceptions. The maximum potential amount of future payments the Company could be required to make under this provision is unlimited. The Company considers there to be a low performance risk as of September 30, 2022.

The agreement expires upon the expiration or abandonment of all patents that are issued and licensed to the Company by MIT under such agreement. The Company expects that patents will be issued from presently pending U.S. and foreign patent applications. Any such patent will have a term of 20 years from the filing date of the underlying application. MIT may terminate the agreement immediately, if the Company ceases to carry on its business, if any nonpayment by the Company is not cured or the Company commits a material breach that is not cured. The Company may terminate the agreement for any reason upon six months' notice to MIT.

Leases

The Company's corporate offices are located in Framingham, MA. During July 2017, we entered into a three-year operating lease commencing October 1, 2017 and ending on September 30, 2020 at our current location, pursuant to which we are obliged to pay annual rent of \$38,400 during the first year, \$39,600 during the second year and \$42,000 during the third year. During August 2020, we extended the lease through September 30, 2021 at our current location pursuant to which we are obligated to pay annual rent of \$42,000. During October 2021 we extended the lease for six months through March 31, 2022 at our current location pursuant to which we are obligated to pay \$21,000. As of April 1, 2022 we have converted our current lease to a monthly rental and are obligated to pay \$3,500 per month. As of September 30, 2022 and 2021, there was no ROU asset or liability. We believe our present offices are suitable for our current and planned near-term operations.

16. RISKS AND UNCERTAINTIES - COVID-19 AND GEOPOLITICAL CONFLICTS

The Company sources its materials and services for its products and product candidates from facilities in areas impacted or which may be impacted by the outbreak of the COVID-19 or geopolitical conflicts. The Company's ability to obtain future inventory may be impacted, therefore potentially affecting the Company's future revenue stream. In addition, the Company has historically and principally funded its operations through debt borrowings, the issuance of convertible debt, and the issuance of units consisting of Common Stock and warrants which may also be impacted by economic conditions beyond the Company's control as well as uncertainties resulting from geopolitical conflicts, including the recent war in Ukraine. The extent to which the COVID-19 and recent events in Ukraine will impact the global economy and the Company is uncertain and cannot be reasonably measured.

Arch Therapeutics, Inc. and Subsidiary

Consolidated Balance Sheets

As of June 30, 2023 (Unaudited) and September 30, 2022

	June 30, 2023	September 30, 2022
ASSETS		
Current assets:		
Cash	\$ 86,542	\$ 746,940
Inventory	1,382,938	1,414,848
Prepaid expenses and other current assets	90,538	436,407
Total current assets	1,560,018	2,598,195
Long-term assets:		
Property and equipment, net	728	2,044
Other assets	3,500	3,500
Total long-term assets	4,228	5,544
Total assets	<u>\$ 1,564,246</u>	<u>\$ 2,603,739</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 2,471,162	\$ 1,328,000
Shareholder advances	50,000	-
Shareholder and Third-Party Advances related to Bridge Financing	690,015	-
Accrued expenses and other liabilities	200,522	318,505
Insurance premium financing	-	247,933
Current Portion of Series 2 convertible note	550,000	550,000
Current Portion of Series 1 convertible note	450,000	-
Current Portion of Unsecured convertible notes	1,401,618	-
Current Portion of 2022 Notes	2,945,448	-
Current Portion of Accrued Interest	820,509	127,781
Current portion of derivative liability	-	748,275
Total current liabilities	9,579,274	3,320,494
Long-term liabilities:		
Unsecured convertible notes	-	699,781
Series 2 convertible notes	-	450,000
2022 Notes	-	1,662,492
Accrued interest	-	204,575
Derivative liability	-	459,200
Total long-term liabilities	-	3,476,048
Total liabilities	9,579,274	6,796,542
Commitments and contingencies		
Stockholders' deficit:		
Common stock, \$0.001 par value, 12,000,000 and 4,000,000 shares authorized as of June 30, 2023 and September 30, 2022, 1,285,213 and 1,252,734 shares issued as of June 30, 2023 and September 30, 2022 and 1,285,213 and 1,249,432 shares outstanding as of June 30, 2023 and September 30, 2022, each respectively	1,285	1,252
Additional paid-in capital	51,582,100	50,878,718
Accumulated deficit	(59,598,413)	(55,072,773)
Total stockholders' deficit	(8,015,028)	(4,192,803)
Total liabilities and stockholders' deficit	<u>\$ 1,564,246</u>	<u>\$ 2,603,739</u>

The accompanying notes are an integral part of these consolidated financial statements.

Arch Therapeutics, Inc. and Subsidiary

Consolidated Statements of Operations (Unaudited)

For the Three and Nine Months Ended June 30, 2023 and 2022

	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Nine Months Ended June 30, 2023	Nine Months Ended June 30, 2022
Revenue	\$ 13,293	\$ 6,261	\$ 36,207	\$ 14,086
Operating expenses:				
Cost of revenues	18,529	17,140	54,882	51,363
Selling, general and administrative expenses	870,053	836,215	3,225,753	3,308,227
Research and development expenses	139,048	159,846	471,135	922,120
Total costs and expenses	1,027,630	1,013,201	3,751,770	4,281,710
Loss from operations	(1,014,337)	(1,006,940)	(3,715,563)	(4,267,624)
Other income (expense):				
Interest expense	(808,770)	(39,890)	(1,968,274)	(119,671)
Gain on extinguishment of derivative liabilities	-	-	1,158,197	-
Expiration of derivative liability/Series F warrant	-	-	-	1,000,000
Total other income (expense)	(808,770)	(39,890)	(810,077)	880,329
Net loss	<u>\$ (1,823,107)</u>	<u>\$ (1,046,830)</u>	<u>\$ (4,525,640)</u>	<u>\$ (3,387,295)</u>
Loss per share - basic and diluted				
Net loss per common share - basic and diluted	\$ (1.42)	\$ (0.88)	\$ (3.58)	\$ (2.86)
Weighted common shares - basic and diluted	1,279,967	1,184,738	1,265,340	1,184,266

The accompanying notes are an integral part of these consolidated financial statements.

Arch Therapeutics, Inc. and Subsidiary

Consolidated Statements of Changes in Stockholders' Deficit (Unaudited)

For the Three and Nine Months Ended June 30, 2023 and 2022

Three Months Ended June 30, 2023	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balance at March 31, 2023	1,274,605	\$ 1,275	\$ 51,387,943	\$ (57,775,306)	(6,386,088)
Net loss	-	-	-	(1,823,107)	(1,823,107)
Stock-based compensation expense	-	-	41,259	-	41,259
Issuance of common stock and warrants, net of financing costs	10,608	10	152,898	-	152,908
Exchange of warrants into common stock	-	-	-	-	-
Balance at June 30, 2023	<u>1,285,213</u>	<u>\$ 1,285</u>	<u>\$ 51,582,100</u>	<u>\$ (59,598,413)</u>	<u>\$ (8,015,028)</u>
Nine Months Ended June 30, 2023	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balance at September 30, 2022	1,252,734	\$ 1,252	\$ 50,878,718	\$ (55,072,773)	(4,192,803)
Net loss	-	-	-	(4,525,640)	(4,525,640)
Vesting of restricted stock	250	-	-	-	-
Stock-based compensation expense	-	-	213,809	-	213,809
Issuance of common stock and warrants, net of financing costs	20,210	20	440,308	-	440,328
Exchange of warrants into common stock	12,019	13	49,265	-	49,278
Balance at June 30, 2023	<u>1,285,213</u>	<u>\$ 1,285</u>	<u>\$ 51,582,100</u>	<u>\$ (59,598,413)</u>	<u>\$ (8,015,028)</u>
Three Months Ended June 30, 2022	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance at March 31, 2022	1,184,599	\$ 1,185	\$ 49,076,775	\$ (52,137,384)	\$ (3,059,424)
Net loss	-	-	-	(1,046,830)	(1,046,830)
Vesting of restricted stock	375	-	-	-	-
Stock-based compensation expense	-	-	90,755	-	90,755
Balance at June 30, 2022	<u>1,184,974</u>	<u>\$ 1,185</u>	<u>\$ 49,167,530</u>	<u>\$ (53,184,214)</u>	<u>\$ (4,015,499)</u>
Nine Months Ended June 30, 2022	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balance at September 30, 2021	1,183,599	\$ 1,184	\$ 48,770,061	\$ (49,796,919)	\$ (1,025,674)
Net loss	-	-	-	(3,387,295)	(3,387,295)
Vesting of restricted stock	1,375	1	(1)	-	-
Stock-based compensation expense	-	-	397,470	-	397,470
Balance at June 30, 2022	<u>1,184,974</u>	<u>\$ 1,185</u>	<u>\$ 49,167,530</u>	<u>\$ (53,184,214)</u>	<u>\$ (4,015,499)</u>

The accompanying notes are an integral part of these consolidated financial statements.

Arch Therapeutics, Inc. and Subsidiary

Consolidated Statements of Cash Flows (Unaudited)

For the Nine Months Ended June 30, 2023 and 2022

	Nine Months Ended June 30, 2023	Nine Months Ended June 30, 2022
Cash flows from operating activities:		
Net loss	\$ (4,525,640)	\$ (3,387,295)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	1,316	2,397
Stock-based compensation	213,809	397,470
Decrease to fair value of derivative	-	(1,000,000)
Gain on extinguishment of derivative liabilities	(1,158,197)	-
Accretion of discount and debt issuance costs on 2022 Notes and Unsecured convertible notes	1,480,121	-
Inventory obsolescence charge	-	248,073
Changes in operating assets and liabilities:		
(Increase) decrease in:		
Inventory	31,910	(582,572)
Prepaid expenses and other current assets	345,869	223,854
Increase (decrease) in:		
Accounts payable	1,143,162	1,288,130
Accrued interest	488,153	119,671
Accrued expenses and other current liabilities	(167,983)	(96,370)
Net cash used in operating activities	(2,147,480)	(2,786,642)
Cash flows from financing activities:		
Repayment of insurance premium financing	(247,933)	-
Proceeds from shareholder advances	1,228,015	575,000
Proceeds from Unsecured convertible notes	507,000	-
Net cash provided by financing activities	1,487,082	575,000
Net decrease in cash	(660,398)	(2,211,642)
Cash, beginning of year	746,940	2,266,639
Cash, end of period	\$ 86,542	\$ 54,997
Non-cash financing activities:		
Exchange of Series G and Series H warrants for common stock	\$ 49,278	\$ -
Issuance of restricted stock	\$ 3,019	\$ 29,831
Fair value of warrants issued - second close	\$ 256,439	\$ -
Fair value of inducement shares issued - second close	\$ 25,840	\$ -
Fair value of placement agent warrants - second close	\$ 28,093	\$ -
Fair value of warrants issued - third close	\$ 137,252	\$ -
Fair value of inducement shares issued - third close	\$ 15,656	\$ -
Conversion of shareholder advance into unsecured convertible note	\$ 488,000	\$ -

The accompanying notes are an integral part of these consolidated financial statements.

ARCH THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. BASIS OF PRESENTATION AND DESCRIPTION OF BUSINESS

Organization and Description of Business

Arch Therapeutics, Inc. (together with its subsidiary, the “Company” or “Arch”) was incorporated under the laws of the State of Nevada on September 16, 2009, under the name “Almah, Inc.”. Effective June 26, 2013, the Company completed a merger (the “Merger”) with Arch Biosurgery, Inc. (formerly known as Arch Therapeutics, Inc.), a Massachusetts corporation (“ABS”), and Arch Acquisition Corporation (“Merger Sub”), the Company’s wholly owned subsidiary formed for the purpose of the transaction, pursuant to which Merger Sub merged with and into ABS and ABS thereby became the wholly owned subsidiary of the Company. As a result of the acquisition of ABS, the Company abandoned its prior business plan and changed its operations to the business of a biotechnology company. The Company’s principal offices are located in Framingham, Massachusetts.

ABS was incorporated under the laws of the Commonwealth of Massachusetts on March 6, 2006, as Clear Nano Solutions, Inc. On April 7, 2008, ABS changed its name from Clear Nano Solutions, Inc. to Arch Therapeutics, Inc. Effective upon the closing of the Merger, ABS changed its name from Arch Therapeutics, Inc. to Arch Biosurgery, Inc.

In the first quarter of 2021, the Company commenced commercial sales of our first product, AC5® Advanced Wound System, and has devoted substantially all of the Company’s operational effort to the research, development and regulatory programs necessary to turn the Company’s core technology into commercial products. To date, the Company has principally raised capital through the issuance of convertible debt, and the issuance of units consisting of its common stock, \$0.001 par value per share (“Common Stock”) and warrants to purchase Common Stock (“warrants”).

The Company expects to incur substantial expenses for the foreseeable future relating to research, development and commercialization of its potential future products. However, there can be no assurance that the Company will be successful in securing additional resources when needed, on terms acceptable to the Company, if at all. Therefore, there exists substantial doubt about the Company’s ability to continue as a going concern. The consolidated financial statements do not include any adjustments related to the recoverability of assets that might be necessary despite this uncertainty.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accompanying unaudited interim consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America (“US GAAP”). The interim consolidated financial statements included herein are unaudited; however, they contain all normal recurring accruals and adjustments that, in the opinion of management, are necessary to present fairly the Company’s results of operations and financial position for the interim periods.

Although the Company believes that the disclosures in these unaudited interim consolidated financial statements are adequate to make the information presented not misleading, certain information normally included in the footnotes prepared in accordance with US GAAP has been omitted as permitted by the rules and regulations of the Securities and Exchange Commission (“SEC”). These unaudited interim consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the fiscal year ended September 30, 2022, filed with the SEC on December 28, 2022 (the “Annual Report”).

For a complete summary of the Company’s significant accounting policies, please refer to Note 2 included in Item 8 of the Company’s Annual Report. There have been no material changes to the Company’s significant accounting policies during the nine months ended June 30, 2023.

Basis of Presentation

The consolidated financial statements include the accounts of Arch Therapeutics, Inc. and its wholly owned subsidiary, Arch Biosurgery, Inc., a biotechnology company. All intercompany accounts and transactions have been eliminated in consolidation.

On January 6, 2023, the directors of the Company authorized a reverse share split of the issued and outstanding Common Shares in a ratio of 1:200, effective January 17, 2023 (the “Reverse Share Split”). All information included in these consolidated financial statements has been adjusted, on a retrospective basis, to reflect the Reverse Share Split, unless otherwise stated. All outstanding securities entitling their holders to purchase shares of Common Stock or acquire shares of Common Stock, including stock options, restricted stock units, and warrants, were adjusted as a result of the Reverse Stock Split, as required by the terms of those securities.

Use of Estimates

Management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenue and expense during the reporting periods. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. The Company had no cash equivalents as of June 30, 2023 and September 30, 2022.

Inventories

Inventories are stated at the lower of cost or net realizable value. The cost of inventories comprises expenditures incurred in acquiring the inventories, the cost of conversion and other costs incurred in bringing them to their existing location and condition. The cost of raw materials, goods-in-process and finished goods are determined on a First in First out (FIFO) basis. When determining net realizable value, appropriate consideration is given to obsolescence, excessive levels, deterioration, and other factors.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist primarily of cash. The Company maintains its cash in bank deposits accounts, which, at times, may exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk on cash.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful life of the related asset. Upon sale or retirement, the cost and accumulated depreciation are eliminated from their respective accounts, and the resulting gain or loss is included in income or loss for the period. Repair and maintenance expenditures are charged to expense as incurred.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment when circumstances indicate the carrying value of an asset may not be recoverable in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 360, *Property, Plant and Equipment*. For assets that are to be held and used, impairment is recognized when the estimated undiscounted cash flows associated with the asset or group of assets is less than their carrying value. If impairment exists, an adjustment is made to write the asset down to its fair value, and a loss is recorded as the difference between the carrying value and fair value. Fair values are determined based on quoted market values, discounted cash flows or internal and external appraisals, as applicable. Assets to be disposed of are carried at the lower of carrying value or estimated net realizable value. For the nine months ended June 30, 2023 and 2022 there has not been any impairment of long-lived assets.

Leases

The Company determines if an arrangement is a lease at its inception. Operating lease right-of-use assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. The Company's lease does not provide an implicit interest rate, the Company used an incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Income Taxes

In accordance with FASB ASC Topic 740, *Income Taxes*, the Company recognizes deferred tax assets and liabilities for the expected future tax consequences or events that have been included in the Company's consolidated financial statements and/or tax returns. Deferred tax assets and liabilities are based upon the differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities and for loss and credit carryforwards using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

The Company provides reserves for potential payments of tax to various tax authorities related to uncertain tax positions when management determines that it is more likely than not that a loss will be incurred related to these matters and the amount of the loss is reasonably determinable.

Revenue

In accordance with FASB ASC Topic 606, *Revenue Recognition*, the Company recognizes revenue through a five-step process: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) a performance obligation is satisfied.

The Company's source of revenue is product sales. Contracts with customers contain a single performance obligation and the Company recognizes revenue from product sales when the Company has satisfied our performance obligation by transferring control of the product to the customers. Control of the product transfers to the customer upon shipment from the Company's third-party warehouse. In circumstances where the transaction price is not able to be determined at the time of shipment, the Company does not recognize revenue or any receivable amount until such time that the final transaction price is established.

Cost of Revenue

Cost of revenue includes product costs, warehousing, overhead allocation and royalty expense.

Research and Development

The Company expenses internal and external research and development costs, including costs of funded research and development arrangements, in the period incurred.

Accounting for Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with the guidance of FASB ASC Topic 718, *Compensation-Stock Compensation* (“ASC 718”), which requires all share-based payments be recognized in the consolidated financial statements based on their fair values. In accordance with ASC 718, the Company has elected to use the Black-Scholes Option Pricing Model (the “*Black-Scholes Model*”) to determine the fair value of options granted and recognizes the compensation cost of share-based awards on a straight-line basis over the vesting period of the award.

The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by the fair value of the Common Stock and a number of other assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. The expected life for awards uses the simplified method for all “plain vanilla” options, as defined in ASC 718-10-S99, and the contractual term for all other employee and non-employee awards. The risk-free interest rate assumption is based on observed interest rates appropriate for the terms of the Company’s awards. The dividend yield assumption is based on history and the expectation of paying no dividends. Stock-based compensation expense, when recognized in the consolidated financial statements, is based on awards that are ultimately expected to vest.

Fair Value Measurements

The Company measures both financial and nonfinancial assets and liabilities in accordance with FASB ASC Topic 820, *Fair Value Measurements and Disclosures*, including those that are recognized or disclosed in the consolidated financial statements at fair value on a recurring basis. The standard created a fair value hierarchy which prioritizes the inputs to valuation techniques used to measure fair value into three broad levels as follows: Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities; Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and Level 3 inputs are unobservable inputs that reflect the Company’s own views about the assumptions market participants would use in pricing the asset or liability.

At June 30, 2023 and September 30, 2022, the carrying amounts of cash, accounts payables and accrued expense and other liabilities approximate fair value because of their short-term nature. The carrying amounts for the Series Convertible Notes (See Note 12), 2022 Notes (see Note 11), and Second Notes (see Note 11), and Third Notes (see Note 11) approximate fair value because borrowing rates and terms are similar to comparable market participants.

Derivative Liabilities

The Company accounts for its warrants and other derivative financial instruments as either equity or liabilities based upon the characteristics and provisions of each instrument, in accordance with FASB ASC Topic 815, *Derivatives and Hedging* (“ASC 815”). Warrants classified as equity are recorded at fair value as of the date of issuance on the Company’s consolidated balance sheets and no further adjustments to their valuation are made. Warrants classified as derivative liabilities and other derivative financial instruments that require separate accounting as liabilities are recorded on the Company’s consolidated balance sheets at their fair value on the date of issuance and will be revalued on each subsequent balance sheet date until such instruments are exercised or expire, with any changes in the fair value between reporting periods recorded as other income or expense. Management estimates the fair value of these liabilities using option pricing models and assumptions that are based on the individual characteristics of the warrants or instruments on the valuation date, as well as assumptions for future financings, expected volatility, expected life, yield, and risk-free interest rate. During the nine months ended June 30, 2023, \$1,158,197 was recorded to gain on extinguishment of derivative liability for the exchange of the Series G warrants and Series H warrants and \$49,278 was recorded as part of shareholder's deficit.

Complex Financial Instruments

The Company does not use derivative instruments to hedge exposures to cash flow, market, or foreign currency risks. The Company evaluates its financial instruments, including warrants, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. The Company values its derivatives using the Black-Scholes option-pricing model or other acceptable valuation models, including Monte-Carlo simulations. Derivative instruments are valued at inception, upon events such as an exercise of the underlying financial instrument, and at subsequent reporting periods. The classification of derivative instruments, including whether such instruments should be recorded as liabilities, is re-assessed at the end of each reporting period.

The Company reviews the terms of debt instruments, equity instruments, and other financing arrangements to determine whether there are embedded derivative features, including embedded conversion options that are required to be bifurcated and accounted for separately as a derivative financial instrument. Additionally, in connection with the issuance of financing instruments, the Company may issue freestanding options and warrants, including options or warrants to non-employees in exchange for consulting or other services performed.

The Company accounts for its common stock warrants in accordance with Accounting Standards Codification (“ASC”) 815, *Derivatives and Hedging* (“ASC 815”). Based upon the provisions of ASC 815, the Company accounts for common stock warrants as liabilities if the warrant requires net cash settlement or gives the holder the option of net cash settlement, or it fails the equity classification criteria. The Company accounts for common stock warrants as equity if the contract requires physical settlement or net physical settlement or if the Company has the option of physical settlement or net physical settlement and the warrants meet the requirements to be classified as equity. Common stock warrants classified as liabilities are initially recorded at fair value on the grant date and remeasured at fair value each balance sheet date with the offset adjustments recorded in change in fair value of warrant liability within the consolidated statements of operations. Common stock warrants classified as equity are initially measured at fair value on the grant date and are not subsequently remeasured.

Financial Statement Reclassification

Certain balances in the prior year consolidated financial statements have been reclassified for comparison purposes to conform to the presentation in the current period consolidated financial statements. During the nine-month period ended June 30, 2023, the Company reclassified the carrying amount of Exchanged Notes of \$699,781 (see Note 12) that were previously included in the 2022 Notes payable to Unsecured convertible notes.

Subsequent Events

The Company evaluated all events or transactions through August 11, 2023, the date which these consolidated financial statements were issued. See note 15 for matters deemed to be subsequent events.

Going Concern Basis of Accounting

As reflected in the consolidated financial statements, the Company has an accumulated deficit as of June 30, 2023, has suffered significant net losses and negative cash flows from operations, only recently commenced generating limited operating revenues, and has limited working capital. The continuation of the Company’s business as a going concern is dependent upon raising additional capital, the ability to successfully market and sell its product and eventually attaining and maintaining profitable operations. In particular, as of June 30, 2023, the Company will be required to raise additional capital, obtain alternative means of financial support, or both, in order to continue to fund operations, and therefore there is substantial doubt about the Company’s ability to continue as a going concern. The Company expects to incur substantial expenses into the foreseeable future for the research, development and commercialization of its current and potential products. In addition, the Company will require additional financing in order to seek to license or acquire new assets, research and develop any potential patents and the related compounds, and obtain any further intellectual property that the Company may seek to acquire. Finally, some of our product candidates or the materials contained therein (such as the Active Pharmaceutical Ingredients for our AC5® product line), are manufactured from facilities in areas impacted by the outbreak of the COVID-19, which could result in shortages due to ongoing efforts to address the outbreak. Historically, the Company has principally funded operations through debt borrowings, the issuance of convertible debt, and the issuance of units consisting of common stock and warrants. Provisions in the Securities Purchase Agreements that the Company entered into on July 6, 2022 (“2022 SPA”), and July 7, 2023 (the “2023 SPA”) restrict the Company’s ability to effect or enter into an agreement to effect any issuance by the Company or its subsidiary of Common Stock or securities convertible, exercisable or exchangeable for Common Stock (or a combination of units thereof) with respect to (i) any variable rate debt transactions (as defined in the 2022 SPA), for a period of six months after the date of the 2022 SPA, involving any transaction where the conversion or exercise of the security issued by the Company varies based on the market price of the Common Stock that does not contain a floor price that is more than 50% of the closing price of the Common Stock on the trading day immediately prior to the date of the 2022 SPA, and (ii) any Variable Rate Transaction (as defined in the 2023 SPA) including, but not limited to, an equity line of credit or “At-the-Market” financing facility until twelve (12) months after the closing date of the 2023 SPA. Furthermore, initially, under the 2022 SPA, we were required to complete an uplist to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American by February 15, 2023. This deadline has been subsequently extended on numerous occasions. Most recently, on July 31, 2023, the Company secured waivers from the required holders of the 2022 Notes, Second Notes and Third Notes to extend the deadline to complete an Uplisting Transaction to August 31, 2023. See Note 11 for more information regarding the 2022 Convertible Note Offering including the terms of the 2022 Warrants and 2022 Placement Agent Warrants, as well as for more information regarding the Amendment No. 1 to the 2022 SPA, and Amendment No. 2 to the 2022 SPA.

The 2023 SPA contains certain restrictions on our ability to conduct subsequent sales of any future securities (See Note 15). The continued spread of COVID-19 and uncertain market conditions may also limit the Company’s ability to access capital. If the Company is unable to obtain adequate capital, the Company may be required to reduce the scope, delay, or eliminate some or all of its planned activities. These conditions, in the aggregate, raise substantial doubt as to the Company’s ability to continue as a going concern.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The consolidated financial statements do not include any adjustments that might result from this uncertainty.

3. PROPERTY AND EQUIPMENT

At June 30, 2023 and September 30, 2022, property and equipment consisted of:

	Estimated Useful Life (in years)	June 30, 2023	September 30, 2022
Furniture and fixtures	5	\$ 9,357	\$ 9,357
Leasehold improvements	Life of Lease	8,983	8,983
Computer equipment	3	14,416	14,416
Lab equipment	5	1,000	1,000
		33,756	33,756
Less – accumulated depreciation		33,028	31,712
Property and equipment, net		\$ 728	\$ 2,044

For the three months ended June 30, 2023 and 2022, depreciation expense recorded was \$273 and \$799, respectively. For the nine months ended June 30, 2023 and 2022, depreciation expense recorded was \$1,316 and \$2,397, respectively.

4. INVENTORIES

Inventories consist of the following:

	June 30, 2023	September 30, 2022
Finished Goods	\$ 56,828	\$ 9,063
Goods-in-process	1,326,110	1,405,785
Total	\$ 1,382,938	\$ 1,414,848

The Company capitalizes inventory that has been produced for commercial sale and has been determined to have a probable future economic benefit. The determination of whether or not the inventory has a future economic benefit requires estimates by management. To the extent that inventory is expected to expire prior to being sold or used for research and development or used for samples, the Company will write down the value of inventory. In evaluating the net realizable value of the inventory, appropriate consideration is given to obsolescence, excessive levels, deterioration, and other factors.

5. INSURANCE PREMIUM FINANCING

In July 2022, the Company entered into a finance agreement with First Insurance Funding in order to fund a portion of its insurance policies. The amount financed was approximately \$354,000 and incurred interest at a rate of 2.99%. The Company made monthly payments of approximately \$35,000 through April 2023. The outstanding balance as of June 30, 2023 and September 30, 2022 was approximately \$0 and \$248,000, respectively. As of June 30, 2023, the Company had not entered into a new finance agreement with First Insurance Funding, or any other similar provider.

6. STOCK-BASED COMPENSATION

2013 Stock Incentive Plan

On June 18, 2013, the Company established the 2013 Stock Incentive Plan (the “2013 Plan”). Under the 2013 Plan, as of September 30, 2022, a maximum number of 170,571 shares of the Company’s authorized and available common stock could be issued in the form of options, stock appreciation rights, sales or bonuses of restricted stock, restricted stock units or dividend equivalent rights, and an award may consist of one such security or benefit, or two or more of them in any combination or alternative. The 2013 Plan provides that on the first business day of each fiscal year commencing with fiscal year 2014, the number of shares of our common stock reserved for issuance under the 2013 Plan for all awards except for incentive stock option awards will be subject to increase by an amount equal to the lesser of (A) 15,000 Shares, (B) four (4) percent of the number of shares outstanding on the last day of the immediately preceding fiscal year of the Company, or (C) such lesser number of shares as determined by the Company’s Board of Directors (the “Board”). The exercise price of each option shall be the fair value as determined in good faith by the Board at the time each option is granted. On October 1, 2022, the aggregate number of authorized shares under the Plan was further increased by 15,000 shares to a total of 185,571 shares. On June 18, 2023, the 2013 Stock Incentive Plan expired.

The exercise price of each option is equal to the closing price of a share of the Company’s Common Stock on the date of grant.

Share-Based Awards

During the nine months ended June 30, 2023, the Company awarded 20,875 options to employees and directors and 3,625 options to consultants to purchase shares of Common Stock under the 2013 Plan.

Share-based compensation expense for awards granted during the nine months ended June 30, 2023 was based on the grant date fair value estimated using the Black-Scholes Model.

Common Stock Options

Stock compensation activity under the 2013 Plan for the nine months ended June 30, 2023 follows:

	Option Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at September 30, 2022	98,626	\$ 52.00	1.36	\$ 16,900
Awarded	24,500	\$ 8.00		
Forfeited/Cancelled	(19,101)	\$ 70.00		
Outstanding at June 30, 2023	104,025	\$ 39.00	5.72	—
Vested at June 30, 2023	79,409	\$ 48.00	4.85	—
Vested and expected to vest at June 30, 2023	104,325	\$ 39.00	5.72	—

On June 18, 2023, the 2013 Stock Incentive Plan expired. Therefore no shares are available for future grants under the 2013 Plan as of June 30, 2023.

Share-based compensation expense recorded in the Company's Consolidated Statements of Operations for the three months ended June 30, 2023 and 2022 resulting from options awarded to the Company's employees, directors and consultants was approximately \$41,000 and \$81,000, respectively. Of this amount, during the three months ended June 30, 2023 and 2022, \$7,000 and \$29,000, respectively, were recorded as research and development expense, and \$34,000 and \$52,000, respectively were recorded as general and administrative expense in the Company's Consolidated Statements of Operations. Share-based compensation expense recorded in the Company's Consolidated Statements of Operations for the nine months ended June 30, 2023 and 2022 resulting from options awarded to the Company's employees, directors and consultants was approximately \$211,000 and \$367,000, respectively. Of this amount, during the nine months ended June 30, 2023 and 2022, \$55,000 and \$123,000, respectively, were recorded as research and development expense, and \$156,000 and \$245,000, respectively were recorded as general and administrative expense in the Company's Consolidated Statements of Operations.

During the nine months ended June 30, 2023 and 2022, no options awarded were exercised.

As of June 30, 2023, there is approximately \$200,000 of unrecognized compensation expense related to unvested stock-based compensation arrangements granted under the 2013 Plan. That cost is expected to be recognized over a weighted average period of 2.11 years.

Restricted Stock

Restricted stock activity under the 2013 Plan for the three months ended June 30, 2023 and 2022, in shares, follows:

	Three months Ended	
	June 30, 2023	June 30, 2022
Non Vested at March 31, 2023 and 2022	—	1,250
Vested	—	(375)
Non Vested at June 30, 2023 and 2022	—	875

The weighted grant date fair value average of the restricted stock for the three months ended June 30, 2023 and 2022 follows:

	Three months Ended	
	June 30, 2023	June 30, 2022
Non Vested at March 31, 2023 and 2022	\$ —	\$ 20.00
Vested	—	(20.00)
Non Vested at June 30, 2023 and 2022	\$ —	\$ 20.00

Restricted stock activity under the 2013 Plan for the nine months ended June 30, 2023 and 2022, in shares, follows:

	Nine months Ended	
	June 30, 2023	June 30, 2022
Non Vested at September 30, 2022 and 2021	250	2,250
Vested	(250)	(1,375)
Non Vested at June 30, 2023 and 2022	—	875

The weighted grant date fair value average of the restricted stock for the nine months ended June 30, 2023 and 2022 follows:

	Nine months Ended	
	June 30, 2023	June 30, 2022
Non Vested at September 30, 2022 and 2021	\$ 18.00	\$ 20.00
Vested	(18.00)	(20.00)
Non Vested at June 30, 2023 and 2022	\$ —	\$ 20.00

For the three months ended June 30, 2023 and 2022, compensation expense recorded for the restricted stock awards was approximately \$0 and \$10,000, respectively. For the nine months ended June 30, 2023 and 2022, compensation expense recorded for the restricted stock awards was approximately \$3,000 and \$30,000, respectively.

7. REGISTERED DIRECT OFFERINGS

On September 30, 2016, the Company filed a registration statement with the SEC utilizing a “shelf” registration process, which was subsequently declared effective by the SEC on October 20, 2016 (such registration statement, the “*Shelf Registration Statement*”). Under the Shelf Registration Statement, the Company may offer and sell any combination of its Common Stock, warrants, debt securities, subscription rights, and/or units comprised of the foregoing to raise up to \$50,000,000 in gross proceeds.

On February 20, 2017, the Company entered into a Securities Purchase Agreement (the “*2017 SPA*”) with six accredited investors (collectively, the “*2017 Investors*”) providing for the issuance and sale by the Company to the 2017 Investors of an aggregate of 50,833 units at a purchase price of \$120.00 per unit in a registered offering (the “*2017 Financing*”). The securities comprising the units sold in the 2017 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant equal to 55% of the shares of Common Stock at an exercise price of \$150.00 per share (“*Series F Warrant*”) at any time prior to the fifth anniversary of the issuance date of the Series F Warrant subject to certain restrictions on exercise (the “*2017 Warrants*”) and the shares issuable upon exercise of the 2017 Warrants (the “*2017 Warrant Shares*”).

On June 28, 2018, the Company entered into a Securities Purchase Agreement (“*2018 SPA*”) with eight accredited investors (collectively, the “*2018 Investors*”) providing for the issuance and sale by the Company to the 2018 Investors of an aggregate of 45,350 units at a purchase price of \$100.00 per unit in a registered offering (“*2018 Financing*”). The securities comprising the units sold in the 2018 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant to purchase up to a number of shares of the Company’s Common Stock equal to 75% of the shares of Common Stock at an exercise price of \$140.00 per share (“*Series G Warrant*”) at any time prior to the fifth anniversary of the issuance date of the Series G Warrant subject to certain restrictions on exercise (the “*2018 Warrants*”) and the shares issuable upon exercise of the 2018 Warrants (the “*2018 Warrant Shares*”).

On May 12, 2019, the Company entered into a Securities Purchase Agreement (“*2019 SPA*”) with five accredited investors (collectively, the “*2019 Investors*”) providing for the issuance and sale by the Company to the 2019 Investors of an aggregate of 43,077 units at a purchase price of \$65.00 per unit in a registered offering (“*2019 Financing*”). The securities comprising the units sold in the 2019 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant to purchase one share of Common Stock at an exercise price of \$80.00 per share (“*Series H Warrant*”) at any time prior to the fifth anniversary of the issuance date of the Series H Warrant subject to certain restrictions on exercise (the “*2019 Warrants*”) and the shares issuable upon exercise of the 2019 Warrants (the “*2019 Warrant Shares*”).

On March 10, 2023, the Company entered into exchange agreements (the “*Exchange Agreements*”) with each holder (the “*Warrantheolders*”) of the Company’s outstanding Series G Warrants to purchase shares of the Company’s common stock, par value \$0.001 per share (the “*Common Stock*”) at an exercise price of \$140.00 per share (the “*Series G Warrants*”) and the Company’s outstanding Series H Warrants to purchase shares of Common Stock at an exercise price of \$80.00 per share (the “*Series H Warrants*” and, together with the Series G Warrants, the “*Warrants*”). Pursuant to the Exchange Agreements, the Warrantheolders exchanged 34,013 Series G Warrants for 3,402 shares of Common Stock and 43,077 Series H Warrants for 8,617 shares of Common Stock. All 27,958 remaining Series F Warrants expired during the fiscal year ended September 30, 2022.

8. Derivative Liabilities

The Company accounted for the Series F Warrants, Series G Warrants and the Series H Warrants in accordance with ASC 815-10. Since the Company was required to purchase its Series F Warrants, Series G Warrants and Series H Warrants for an amount of cash equal to \$36.00, \$22.00 and \$10.66, respectively, for each share of Common Stock (the “*Minimum Value*”) they are recorded as liabilities at the greater of the Minimum Value or fair value. They are marked to market each reporting period through the Consolidated Statement of Operations.

On the respective closing dates of June 28, 2018 and May 12, 2019, respectively, the derivative liabilities related to the Series G Warrants and Series H Warrants were recorded at an aggregate fair value of \$1,628,113. Given that the fair value of the derivative liabilities was less than the net proceeds, the remaining proceeds were allocated to Common Stock and additional paid-in-capital.

On March 10, 2023, Arch Therapeutics, Inc. entered into exchange agreements (the “*Exchange Agreements*”) with each holder (the “*Warrantheolders*”) of the Company’s outstanding Series G Warrants to purchase shares of the Company’s common stock, par value \$0.001 per share at an exercise price of \$140.00 per share and the Company’s outstanding Series H Warrants to purchase shares of Common Stock at an exercise price of \$80.00 per share. Pursuant to the Exchange Agreements, the Warrantheolders exchanged 34,013 Series G Warrants for 3,402 shares of Common Stock and 43,077 Series H Warrants for 8,617 shares of Common Stock.

During the three and nine months ended June 30, 2023, \$0 and \$1,158,197, respectively was recorded to gain on extinguishment of derivative liability for the exchange of the Series G warrants and Series H warrants and \$49,278 was recorded as part of shareholder’s deficit. During the three and nine months ended June 30, 2022, \$0 and \$1,000,000, respectively was recorded to decrease the fair value of derivative liability related to the expired Series F warrants.

Fair Value Measurements Using Significant Unobservable Inputs – Nine Months Ended June 30, 2023

(Level 3)	Series G	Series H
Beginning balance at September 30, 2022	\$ 748,275	\$ 459,200
Exchange of warrants into common stock	(13,948)	(35,330)
Extinguishment of derivative liabilities	(734,327)	(423,870)
Ending balance at June 30, 2023	<u>\$ —</u>	<u>\$ —</u>

Fair Value Measurements Using Significant Unobservable Inputs - Nine Months Ended June 30, 2022

(Level 3)	Series F	Series G	Series H
Beginning balance at September 30, 2021	\$ 1,000,000	\$ 748,275	\$ 459,200
Issuances	—	—	—
Adjustments to estimated fair value	—	—	—
	(1,000,000)	—	—
Expiration of derivative liability	—	—	—
Ending balance at June 30, 2022	<u>\$ —</u>	<u>\$ 748,275</u>	<u>\$ 459,200</u>

As of March 10, 2023 and September 30, 2022, the derivative liabilities were valued at the greater of their minimum value or by using the Black Scholes Model with the following assumptions.

As of March 10, 2023, the derivative liabilities are recorded at their minimum value.

	Series G	Series H
Closing price per share of Common Stock	\$ 4.10	\$ 4.10
Exercise price per share	\$ 140.00	\$ 80.00
Expected volatility	179.41%	141.03%
Risk-free interest rate	4.91%	4.75%
Dividend yield	—	—
Remaining expected term of underlying securities (years)	0.24	1.31

As of September 30, 2022, the derivative liabilities are recorded at their minimum value.

	Series G	Series H
Closing price per share of Common Stock	\$ 3.84	\$ 3.84
Exercise price per share	\$ 140.00	\$ 80.00
Expected volatility	132.97%	122.50%
Risk-free interest rate	4.05%	4.14%
Dividend yield	—	—
Remaining expected term of underlying securities (years)	0.69	1.57

9. OCTOBER 2019 REGISTERED DIRECT OFFERING

On October 16, 2019, the Company entered into a Securities Purchase Agreement (*the “October 2019 SPA”*) with seven accredited investors (collectively, the “*October 2019 Investors*”) providing for the issuance and sale by the Company to the 2019 Investors of an aggregate of 71,429 units at a purchase price of \$35.00 per unit in a registered offering (“*October 2019 Financing*”). The securities comprising the units sold in the October 2019 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant to purchase one share of Common Stock at an exercise price of \$44.00 per share (“*Series I Warrant*”) at any time prior to the fifth anniversary of the issuance date of the Series I Warrant subject to certain restrictions on exercise and the shares issuable upon exercise of the Series I Warrants (collectively, the “*October 2019 Warrant Shares*”). As of October 18, 2019, the Company recorded the 71,429 shares as Common Stock. Pursuant to the Engagement Agreement (as defined below), the Company also agreed to issue to the Placement Agent, or its designees, warrants to purchase up to 5,358 shares (the “*Placement Agent Warrants*”). The 2019 Placement Agent Warrants have substantially the same terms as the Series I Warrants, except that the exercise price of the Placement Agent Warrants is \$43.75 per share and the term of the Placement Agent Warrants is five years.

The gross proceeds to the Company from the October 2019 Financing, which were received as of October 18, 2019, were approximately \$2.5 million before deducting financing costs of approximately \$333,000 which includes approximately \$158,000 of placement fees. The number of shares of the Company’s Common Stock into which each of the Series I Warrants is exercisable and the exercise price therefore are subject to adjustment, as set forth in the Series I Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise).

The Company engaged H.C. Wainwright as its exclusive institutional investor placement agent (the “*Placement Agent*”) in connection with the October 2019 SPA pursuant to an engagement agreement dated as of October 10, 2019 (the “*2019 Engagement Agreement*”). In consideration for the services provided by the Placement Agent, the Placement Agent was entitled to receive cash fees ranging from 6.0% to 8.2% of the gross proceeds received by the Company, as well as reimbursement for all reasonable expenses incurred by it in connection with its engagement. The Company received gross proceeds of approximately \$2.5 million in the aggregate, resulting in a fee of approximately \$158,000.

During the three and nine months ended June 30, 2023 and 2022, no Series I Warrants or Placement Agent Warrants were exercised. As of June 30, 2023, up to 71,429 and 5,358 shares may be acquired upon the exercise of the Series I Warrants and Placement Agent Warrants, respectively.

Equity Value of Warrants

The Company accounted for the Series I Warrants and the Placement Agent Warrants relating to the aforementioned October 2019 Financing in accordance with ASC 815-40. Because the Series I Warrants and the Placement Agent Warrants are indexed to the Company's Common Stock, they are classified within stockholders' deficit in the accompanying consolidated financial statements.

10. 2021 REGISTERED DIRECT OFFERING

On February 11, 2021, the Company entered into a Securities Purchase Agreement (the "*2021 SPA*") with certain institutional and accredited investors (collectively, "*2021 Investors*") providing for the issuance and sale by the Company to the 2021 Investors of an aggregate of 215,625 shares (the "Shares") of the Company's Common Stock, and warrants (the "*Series K Warrants*") to purchase an aggregate of 161,719 shares (the "*Warrant Shares*") of Common Stock, at a combined offering price of \$32.00 per share (the "*2021 Financing*"). The Series K Warrants have an exercise price of \$34.00 per share and are exercisable for a period of 5.5 years. The aggregate gross proceeds for the sale of the Shares and Series K Warrants were approximately \$6.9 million, before deducting the Placement Agent's fees and expenses and other offering expenses payable by the Company, of approximately \$700,000. Pursuant to an engagement agreement dated as of February 8, 2021 (the "*2021 Engagement Agreement*"), by and between the Company and the Placement Agent, the Company agreed to pay the Placement Agent cash fees equal to (i) 7.5% of the gross proceeds received by the Company from certain investors in the 2021 Financing, and (ii) 6.0% of the gross proceeds received by the Company from certain investors that had pre-existing relationships with the Company. In addition, the Placement Agent received a one-time non-accountable expense fee of \$10,000, up to \$50,000 for fees and expenses of legal counsel and other out-of-pocket expenses and \$10,000 for clearing expenses. Pursuant to the 2021 Engagement Agreement, the Company also agreed to issue to the Placement Agent, or its designees, warrants to purchase up to 7.5% of the aggregate number of Shares sold to the 2021 Investors, or warrants to purchase up to 16,172 shares (the "*2021 Placement Agent Warrants*") of the Company's Common Stock. The 2021 Placement Agent 2 Warrants have substantially the same terms as the Series K Warrants, except that the exercise price of the 2021 Placement Agent Warrants is \$40.00 per share. The 2021 Engagement Agreement contained indemnity and other customary provisions for transactions of this nature.

The 2021 SPA contained certain restrictions on the Company's ability to conduct subsequent sales of the Company's equity securities. In particular, we were prohibited from entering into or effecting a Variable Rate Transaction (as defined in the 2021 SPA) until February 11, 2022; provided, however, the Company may enter into and effect an at-the-market offering facility with the Placement Agent.

The number of shares of the Company's Common Stock into which each of the Series K Warrants is exercisable and the exercise price therefore are subject to adjustment, as set forth in the Series K Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise).

During the three and nine months ended June 30, 2023, no Series K Warrants or Placement Agent 2 Warrants were exercised. As of June 30, 2023, up to 161,719 and 16,172 shares may be acquired upon the exercise of the Series K Warrants and Placement Agent Warrants, respectively.

Common Stock

On February 17, 2021, the Closing Date of the 2021 Financing, the Company issued 215,625 shares of Common Stock.

Equity Value of Warrants

The Company accounted for the Series K Warrants and the Placement Agent 2 Warrants relating to the aforementioned February 2021 Registered Direct Offering in accordance with ASC 815-40, *Derivatives and Hedging*. Because the Series K Warrants and the Placement Agent 2 Warrants are indexed to the Company's stock, they are classified within stockholders' deficit in the accompanying consolidated financial statements.

11. 2022 CONVERTIBLE NOTE OFFERING, SECOND NOTES OFFERING, AND THIRD NOTES OFFERING

On July 7, 2022, the Company announced that it had entered into a Securities Purchase Agreement (the “2022 SPA”) with certain institutional and accredited individual investors (collectively, the “2022 Investors”) providing for the issuance and sale by the Company to the 2022 Investors of (i) Senior Secured Convertible Promissory Notes (each a “2022 Note” and collectively, the “2022 Notes”) in the aggregate principal amount of \$4.23 million, which includes an aggregate \$0.705 million original issue discount in respect of the 2022 Notes; (ii) warrants (the “2022 Warrants”), to purchase an aggregate of 425,554 shares (the “2022 Warrant Shares”) of Common Stock; and (iii) 63,833 shares of Common Stock (the “2022 Inducement Shares”) equal to 15% of the principal amount of the 2022 Notes divided by the closing price of the Common Stock immediately prior to the Closing Date (as defined below). The 2022 Notes, 2022 Warrants and 2022 Inducement Shares were issued as part of a convertible note offering authorized by the Company’s board of directors (the “2022 Convertible Note Offering”). The aggregate gross proceeds for the sale of the 2022 Notes, 2022 Warrants and 2022 Inducement Shares was approximately \$3.5 million, before deducting debt issuance costs of \$775,000 consisting of fair value of the placement agent’s warrants of approximately \$220,000 and other estimated fees and offering expenses payable by the Company of approximately \$555,000. The closing of the sales of these securities under the 2022 SPA occurred on July 6, 2022 (the “2022 Closing Date”).

On January 18, 2023, the Company entered into Amendment No. 1 to the 2022 SPA (the “Amendment” and, together with the 2022 SPA, the “Amended 2022 SPA”), with certain Investors in connection with the Second Closing of the 2022 Convertible Note Offering for the issuance and sale by the Company to such Investors of an aggregate of (i) Unsecured Convertible Promissory Notes (each a “Second Note” and collectively, the “Second Notes”) in the aggregate principal amount of \$636,000, which includes an aggregate \$106,000 original issue discount in respect of the Second Notes; (ii) warrants (the “Second Warrants”) to purchase an aggregate of 127,968 shares (the “Second Warrant Shares”) of Common Stock; and (iii) 9,598 shares of Common Stock (the “Second Inducement Shares”). The aggregate gross proceeds for the sale of the Second Notes, Second Warrants and Second Inducement Shares was approximately \$530,000, before deducting the placement agent’s fees and other estimated fees and offering expenses payable by the Company of approximately \$15,000. The second closing of the sales of these securities under the Amended 2022 SPA occurred on January 18, 2023 (the “Second Closing Date”).

On May 15, 2023, the Company entered into Amendment No. 2 to the 2022 SPA related to the 2022 Convertible Note Offering (the “Second Amendment” and, together with the Amendment and the 2022 SPA, the “Second Amended 2022 SPA”), with an Investor in connection with the third closing of the 2022 Convertible Note Offering for the issuance and sale by the Company to an Investor of an aggregate of (i) Unsecured Convertible Promissory Notes (each a “Third Note” and collectively, the “Third Notes”) in the aggregate principal amount of \$702,720, which includes an aggregate \$214,720 original issue discount in respect of the Third Notes; (ii) warrants (the “Third Warrants”) to purchase an aggregate of 141,396 shares (the “Third Warrant Shares”) of Common Stock; and (iii) 10,608 shares of Common Stock (the “Third Inducement Shares”). The aggregate gross proceeds for the sale of the Third Notes, Third Warrants and Third Inducement Shares was approximately \$488,000, before deducting any estimated fees and offering expenses payable by the Company. The Company did not engage a placement agent in connection with the issuance of the Third Notes, Third Warrants, and Third Inducement Shares. The third closing of the sales of these securities under the Amended SPA occurred on May 15, 2023 (the “Third Closing Date”). The 2022 Notes, the Second Notes and the Third Notes bear interest on the unpaid principal balance at a rate equal to ten percent (10%) (computed on the basis of the actual number of days elapsed in a 360-day year) per annum accruing from the Closing Date until the 2022 Notes, Second Notes and Third Notes become due and payable at maturity or upon their conversion, acceleration or by prepayment, and may become due and payable upon the occurrence of an event of default under the 2022 Notes, Second Notes and Third Notes. Any amount of principal or interest on the 2022 Notes, the Second Notes and Third Notes which is not paid when due shall bear interest at the rate of the lesser of (i) eighteen percent (18%) per annum or (ii) the maximum amount allowed by law from the due date thereof until payment in full.

The 2022 Notes, the Second Notes and the Third Notes are convertible into shares of Common Stock at the option of each holder of the 2022 Notes, the Second Notes, and the Third Notes from the date of issuance at \$9.14 (the “Conversion Price”) through the later of (i) January 6, 2024 (the “Maturity Date”) or (ii) the date of payment of the Default Amount (as defined in the 2022 Notes); provided, however, certain 2022 Notes, Second Notes and Third Notes include a provision preventing such conversion if, as a result, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than 4.99% or 9.99% of the Common Stock (as applicable, the “Ownership Limitation”) immediately after giving effect to the Conversion; and provided further, the holder, upon notice to us, may increase or decrease the Ownership Limitation; (i) the Ownership Limitation may only be increased to a maximum of 9.99% of the Common Stock; and (ii) any increase in the Ownership Limitation will not become effective until the 61st day after delivery of such waiver notice. The Conversion Price is subject to adjustment as set forth in the 2022 Notes, Second Notes, and Third Notes.

The 2022 Notes, Second Notes and Third Notes contain customary events of default, which include, among other things, (i) the Company’s failure to pay when due any principal or interest payment under the 2022 Notes, Second Notes, and Third Notes; (ii) our insolvency; (iii) delisting of the Company’s Common Stock; (iv) the Company’s breach of any material covenant or other material term or condition under the 2022 Notes, Second Notes and/or Third Notes; and (v) the Company’s breach of any representations or warranties under the 2022 Notes, Second Notes and Third Notes which cannot be cured within five (5) days. Further, events of default under the 2022 Notes, Second Notes and Third Notes also include (i) the unavailability of Rule 144 on or after January 6, 2023; (ii) our failure to deliver the shares of Common Stock to the 2022 Notes, Second Notes, and/or Third Notes holder upon exercise by such holder of its conversion rights under the 2022 Notes, Second Notes, and/or Third Notes; (iii) our loss of the “bid” price for its Common Stock and/or a market and such loss is not cured during the specified cure periods; and (iv) our failure to complete an uplisting of our Common Stock to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American by August 31, 2023 (as amended) (an “Uplist Transaction”).

The 2022 Warrants, Second Warrants and Third Warrants (i) have an exercise price of \$9.94 per share; (ii) have a term of exercise equal to 5 years after their issuance date; (iii) became exercisable immediately after their issuance; and (iv) have a provision preventing the exercisability of such 2022 Warrants, the Second Warrants and the Third Warrants if, as a result of the exercise of the 2022 Warrants, Second Warrants, and/or Third Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of our Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than the Ownership Limitation. The holder, upon notice to us, may increase or decrease the Ownership Limitation; provided that (i) the Ownership Limitation may only be increased to a maximum of 9.99% of our Common Stock; and (ii) any increase in the Ownership Limitation will not become effective until the 61st day after delivery of such waiver notice. The number of shares of Common Stock into which each of the 2022 Warrants, Second Warrants, and Third Warrants is exercisable and the exercise price therefor are subject to adjustment as set forth in the 2022 Warrants, Second Warrants, and Third Warrants, including standard antidilution provisions, and adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise). In the event of a Fundamental Transaction (as defined in the 2022 Warrants, Second Warrants, and Third Warrants) holders of the 2022 Warrants, Second Warrants, and Third Warrants would be entitled to receive alternate consideration in connection with such Fundamental Transaction, but only to the extent that holders of our Common Stock were entitled to receive the same. Moreover, as long as the 2022 Notes, Second Notes, and Third Notes, and 2022 Warrants, Second Warrants, and Third Warrants remaining outstanding, upon the issuance of any security in connection with any potential future financing activity on terms more favorable than the existing terms, the Company has an obligation to notify the holders of the 2022 Notes, Second Notes, and Third Notes, and the 2022 Warrants, Second Warrants, and Third Warrants of such more favorable terms, and to use best efforts to effect such terms in the 2022 Notes, Second Notes, and Third Notes, and the 2022 Warrants, Second Warrants, and Third Warrants. Finally, because of the Company’s net loss position, the shares underlying the 2022 Notes, Second Notes, and Third Notes on an as converted basis are excluded from the calculation of basic and fully diluted earnings per share. Similarly, because of the Company’s net loss position, there was no impact on the calculation of basic and fully diluted earnings per share related to the classification of the 2022 Warrants, Second Warrants, and Third Warrants as participating securities.

The Company retained a placement agent in connection with the private placement of \$2.4 million of the 2022 Notes to the institutional investors. The Company paid the 2022 Placement Agent 10% of the gross proceeds received from certain institutional investors, or \$240,000 and we also reimbursed the 2022 Placement Agent approximately \$58,000 for non-accountable banking fees, legal fees and other expenses. In addition, we issued 2022 Placement Agent Warrants to purchase an aggregate of 31,510 shares of Common Stock. An additional \$1.1 million was raised in connection with the placement of the private placement notes, which included certain accredited investors some of which were Board members and executive officers of the Company. Board member, Laurence Hicks, and executive officers, Terrence W. Norchi and Michael S. Abrams, invested in the 2022 Notes. The investment made in the 2022 Notes made by the Board member and executive officers totaled \$80,000.

The Company's agreement with the 2022 Placement Agent was still effective at the time of the private placement of \$0.5 million of the Second Notes to certain institutional investors. Per the terms of a termination agreement dated February 21, 2023 by and between the Company and the 2022 Placement Agent (the "Placement Agent Termination Agreement"), the Company owes the 2022 Placement Agent 10% of the gross proceeds received from certain institutional investors, or \$50,000, and, such amount was deferred until the Company completes an additional financing with gross proceeds of at least \$1 million. In addition, per the Placement Agent Termination Agreement, we agreed to issue 2022 Placement Agent Warrants to purchase an aggregate of 6,565 shares of Common Stock.

In addition, as a part of the 2022 Convertible Note Offering, certain holders of the Company's 10% Series 2 Convertible Notes agreed to exchange their Series 2 Notes for promissory notes of the Company on substantially similar terms to those of the 2022 Notes (the "Exchanged Notes"). The Exchanged Notes are convertible into 76,563 shares of Common Stock at a conversion price of \$9.14. The holders of the Exchanged Notes did not receive warrants or inducement shares. In connection with the issuance of the Exchanged Notes, the holders of the Series 2 Notes that participated in the exchange, entered into a subordination agreement on July 6, 2022 (the "Closing Date") to subordinate their rights in respect of the Exchanged Notes to the rights of the Investors in respect of the 2022 Notes. As of July 7, 2022, approximately \$600,000 of the Series 2 Notes and accrued interest of approximately \$100,000 were included in the exchange.

Further, in connection with the 2022 Convertible Note Offering, we initially were required to complete an Uplist Transaction by February 15, 2023 under the terms of the 2022 Notes. If we are unable to complete or secure an extension to the Uplist Transaction deadline, then the 2022 Notes, Second Notes, and Third Notes will become immediately due and payable and we will be obligated to pay to each holder of the 2022 Notes, Second Notes, and Third Notes an amount equal to 125%, multiplied by the sum of the outstanding principal amount of the 2022 Notes, Second Notes, and Third Notes plus any accrued and unpaid interest on the unpaid principal amount of the 2022 Notes, Second Notes, and Third Notes to the date of payment, plus any default interest and any other amounts owed to the holder, payable in cash or shares of Common Stock. The Company has secured waivers from all required holders of the 2022 Notes, Second Notes, and Third Notes to extend the deadline to complete an uplist from (i) February 15, 2023 to March 15, 2023, (ii) March 15, 2023 to April 15, 2023, (iii) April 15, 2023 to May 15, 2023, (iv) May 15, 2023 to June 15, 2023, (v) June 15, 2023 to July 1, 2023, (vi) July 1, 2023 to July 31, 2023 and (vii) July 31, 2023 to August 31, 2023. No consideration was paid by the Company in connection with any of the Uplist Transaction deadline extensions.

On March 10, 2023, the Company entered into an amendment ("Amendment No. 2 to the First Notes") with the required holders of the Company's outstanding 2022 Notes issued in connection with a private placement financing the Company completed on July 6, 2022 (the "First Closing"). On March 10, 2023, the Company also entered into an amendment ("Amendment No. 2 to the Second Notes" and, together with Amendment No. 2 to the First Notes, "Amendment No. 2 to the 2022 Notes") with each of the required holders of Company's outstanding Second Notes issued in connection with a private placement financing the Company completed on January 18, 2023.

Under Amendment No. 2 to the 2022 Notes, the following amendments to the 2022 Notes, and Second Notes will be effective at the moment in time immediately preceding the consummation of the offering in connection with the uplist of the Common Stock to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (the "Uplist Transaction"). If a holder of the 2022 Notes and/or the Second Notes elects to participate in the Uplist Transaction (each, a "Participating Holder") for an amount equal to no less than 50% of the Participating Holder's original investment amount in the 2022 Convertible Note Offering, such holder will be entitled to repayment of the principal amount of their 2022 Notes and/or Second Notes upon closing of the Uplist Transaction. In addition, the Company will issue to each Participating Holder a new convertible promissory note equal to the product of 2.4 and the sum of any prepayment premiums and total interest payable on such Participating Holder's 2022 Notes and/or Second Notes (the "2023 Notes"). The 2023 Notes will have a maturity date of July 6, 2024 and will be on substantially the same terms as the Second Notes. For non-Participating Holders (each, a "Non-Participating Holder"), the maturity date of the 2022 Notes and/or Second Notes held by such Non-Participating Holder will be extended to July 6, 2024. Further, each Non-Participating Holder will waive their right to demand repayment of any portion of the outstanding balance of such holder's 2022 Notes and Second Notes upon an Uplist Transaction. Notwithstanding the foregoing, if the registration statement filed in connection with the Uplist Transaction is not declared effective by 11:59 P.M. (EST) on June 15, 2023 (the "Amendment No. 2 Termination Date"), Amendment No. 2 to the 2022 Notes will automatically terminate and shall be of no further force or effect without any further action by the Company or the Requisite Holders, provided, that the Amendment No. 2 Termination Date may be extended by the written approval of the Company and required holders of the 2022 Notes, Second Notes and Third Notes which purchased at least 50% plus \$1.00 of the 2022 Notes, Second Notes, and Third Notes based on the initial principal amounts thereunder (the "Requisite Holders"). Amendment No. 2 to the 2022 Notes was superseded by Amendment No. 8 to the 2022 Notes, Amendment No. 8 to the Second Notes and Amendment No. 3 to the Third Notes, and therefore, it is of no further force or effect.

During the three months ended June 30, 2023, the Company recorded interest expense on the 2022 Notes, the Second Notes, and the Third Notes of approximately \$784,000 consisting of accrued interest of approximately \$150,000 and accretion of original issue debt discount and issuance costs of approximately \$634,000. During the nine months ended June 30, 2023, the Company recorded interest expense on the 2022 Notes, the Second Notes, and the Third Notes of approximately \$1,893,000 consisting of accrued interest of approximately \$413,000 and accretion of original issue debt discount and issuance costs of approximately \$1,480,000.

Allocation of Proceeds

The Company accounted for the 2022 Notes, Second Notes, and Third Notes, and the 2022 Warrants, the Second Warrants, and the Third Warrants, and the 2022 Inducement Shares, Second Inducement Shares and the Third Inducement Shares in accordance with ASC 470-20-25-2 "Debt" which states that the allocation of the proceeds from the financing shall be based on the relative fair values of the securities issued at the time of the issuance. The 2022 Inducement Shares, the Second Inducement Shares, and the Third Inducement Shares and the 2022 Warrants, the Second Warrants, and the Third Warrants which are indexed to the Company's stock, are classified within stockholders' deficit in the accompanying consolidated financial statements. The allocated value of the 2022 Inducement Shares and the 2022 Warrants are \$314,523 and \$1,470,133, respectively. The allocated value of the Second Inducement Shares and the Second Warrants are \$25,840 and \$256,439, respectively. The allocated value of the Third Inducement Shares and the Third Warrants are \$18,394 and \$164,136, respectively. The allocated value of the 2022 Notes of \$1,740,344 are allocated as short-term liabilities in the accompanying consolidated financial statements. The allocated value of the Second Notes of \$247,721 are allocated as short-term liabilities in the accompanying consolidated financial statements. The allocated value of the Third Notes of \$305,470 is allocated as short-term liabilities in the accompanying consolidated financial statements. The fair value of the 2022 Placement Agent Warrants and the Second Placement Agent Warrants of \$219,894 and \$28,093, respectively, are being accounted for as debt issuance costs and are classified within stockholders' deficit in the accompanying consolidated financial statements. As of June 30, 2023 and September 30, 2022, the net carrying amount of the 2022 Notes was \$2,945,448 and \$1,662,492, respectively, with unamortized debt discount and issuance costs of \$1,284,552 and \$2,567,507, respectively. Effective September 30, 2022, the Company reclassified the carrying amount of the Exchanged Notes of \$699,781 (see Note 12) that were previously included in 2022 Notes payable to Unsecured convertible notes. After the reclassification, the Unsecured convertible notes included both the Second Notes and the Exchanged Notes. As of June 30, 2023, the net carrying amount of the Second Notes was \$345,845 with unamortized debt discount and issuance costs of \$290,155, all of which is included in Unsecured convertible notes. In addition, as of June 30, 2023, the net carrying amount of the Third Notes was \$355,992 with unamortized debt discount and issuance costs of \$346,728, all of which is included in Unsecured convertible notes.

The 2022 Warrants and the 2022 Placement Agent Warrants were valued as of July 6, 2022 using the Black Scholes Model with the following assumptions:

	2022 Warrants	2022 Placement Agent Warrants
Closing price per share of Common Stock	\$ 9.98	\$ 9.98
Exercise price per share	\$ 9.94	\$ 10.06
Expected volatility	88.44%	88.44%
Risk-free interest rate	2.96%	2.96%
Dividend yield	—	—
Remaining expected term of underlying securities (years)	5.0	5.0

The Second Warrants and the Second Placement Agent Warrants were valued as of January 18, 2023 using the Black Scholes Model with the following assumptions:

	Second Warrants	Second Placement Agent Warrants
Closing price per share of Common Stock	\$ 5.76	\$ 5.76
Exercise price per share	\$ 9.94	\$ 10.06
Expected volatility	111.31%	111.31%
Risk-free interest rate	3.43%	3.43%
Dividend yield	—	—
Remaining expected term of underlying securities (years)	5.0	5.0

The Third Warrants were valued as of May 15, 2023 using the Black Scholes Model with the following assumptions:

	Third Warrants
Closing price per share of Common Stock	\$ 2.77
Exercise price per share	\$ 9.94
Expected volatility	114.33%
Risk-free interest rate	3.46%
Dividend yield	—
Remaining expected term of underlying securities (years)	5.0

12. SERIES CONVERTIBLE NOTES

On June 4, 2020 and November 6, 2020, the Company issued unsecured 10% Series 1 Convertible Notes (“Series 1 Notes”) and Series 2 Convertible Notes (“Series 2 Notes”), and collectively with the Series 1 Notes, the “Series Convertible Notes”) in the aggregate principal amount of \$550,000 and \$1,050,000, respectively. The maturity dates of the Series 1 Notes and Series 2 Notes are June 30, 2023 and November 30, 2023, respectively. On July 12, 2023, the Company secured countersigned notices of conversion from all remaining holders of the Series 1 Convertible Notes and provided instructions to its transfer agent to issue a total of 59,912 shares of Common Stock in full satisfaction of all previously outstanding Series 1 Convertible Notes. The Series Convertible Notes provide, among other things, for (i) a term of approximately three years; (ii) the Company’s ability to prepay the Series Convertible Notes, in whole or in part, at any time; (iii) the automatic conversion of the Series Convertible Notes upon a Change of Control (all capitalized terms not otherwise defined to have the meaning ascribed to such terms of the Series Convertible Notes) into shares of the Company’s Common Stock, at a per share price of \$54.00 and \$50.00 (the “Conversion Price”) for the Series 1 Notes and Series 2 Notes, respectively; (iv) the ability of the holders of the Series Convertible Notes (each a “Holder”, and together, the “Holders”) to convert the principal of the Series Convertible Notes, along with accrued interest, in whole or in part, into shares of Common Stock at the respective Conversion Price; (v) the Company’s ability to convert all Note Obligations outstanding upon a Qualified Equity Financing into shares of Common Stock at the respective Conversion Price; (vi) the Company’s ability to convert the principal of the Series Convertible Notes, along with accrued interest, in whole or in part, into shares of Common Stock at the respective Conversion Price in the event the volume weighted average price (“VWAP”) of the Common Stock equals or exceeds \$64.00 per share for at least fifteen consecutive Trading Days; (vii) the Company’s ability to convert all outstanding Note Obligations into shares of Common Stock at the respective Conversion Price (an “In Kind Note Repayment”) in lieu of repaying the Note Obligations outstanding on the Maturity Date, provided, however, that in the case of an In-Kind Note Repayment, the outstanding Note Obligations will be calculated by increasing by thirty-five percent the aggregate sum of the unpaid Principal Amount held by each Holder and the accrued interest at a rate of ten percent per annum, subject to, with respect to any portion of the Principal Amount that is converted or prepaid before the twelve month anniversary of the Issuance Date, a minimum interest payment equal to ten percent of the amount that is converted or prepaid. As consideration for agreeing to subordinate to the 2022 Notes, the premium applicable in connection with an In-Kind Note Repayment at maturity was increased from thirty-five percent to sixty percent. As consideration for agreeing to provide for an In-Kind Note Repayment upon the earlier of i) maturity or ii) the completion of an Uplist Transaction, the premium applicable in connection with an In-Kind Note Repayment at either maturity or simultaneous with an Uplist Transaction was further increased from sixty percent to three hundred and fifty percent.

As described in Note 11 above, as a part of the 2022 Convertible Note Offering, certain holders of the Series 2 Notes agreed to exchange their Series 2 Notes with an aggregate principal amount of \$600,000 and accrued interest of approximately \$100,000 for promissory notes of the Company on substantially similar terms to those of the 2022 Notes (the “Exchanged Notes”). As of July 6, 2022, \$699,781 of principal and accrued interest of the Series 2 notes was exchanged for the Exchanged Notes.

On March 10, 2023, the Company entered into an amendment (the “Series 2 Note Amendment” and, together with the Series 1 Amendment, the “Series Note Amendments”) with each of the holders of the Company’s outstanding Series 2 Convertible Notes (as amended, the “Series 2 Notes” and, together with the Series 1 Notes, the “Series Convertible Notes”). Pursuant to the Series Note Amendments, the Company can elect to convert the principal and accrued interest under the Series Convertible Notes (the “Series Note Obligations”) at or after the effective time of the Uplisting Transaction, or the maturity date. In the event the Company exercises such option, the Series Note Obligations will be deemed to equal the product of 4.5 (which was previously 1.6 prior to the Series Note Amendments) and the outstanding Series Note Obligations. Notwithstanding the foregoing, if the registration statement filed in connection with the Uplist Transaction is not declared effective by 11:59 P.M. (EST) on or before the Uplisting Transaction deadline under the 2022 Notes and Second Notes, which was originally February 15, 2023, or such later extended date as provided for therein (the “Series Note Amendments Termination Date”), the Series Note Amendments will automatically terminate without any further action by the Company or the holders of the Series Convertible Notes. The Series Note Amendments Termination Date will be automatically extended upon any extension of the Uplisting Transaction deadline under the 2022 Notes, Second Notes, and Third Notes. As previously discussed herein, the deadline to complete the Uplist Transaction was extended on multiple previous occasions. As of July 31, 2023 the Uplist Transaction deadline under the 2022 Notes, Second Notes, and Third Notes is August 31, 2023. No consideration was paid by the Company in connection with any of the extensions of the Uplisting Transaction deadline under the 2022 Notes, Second Notes, and/or Third Notes.

During the three months ended June 30, 2023 and 2022, the Company recorded interest expense on the Series Convertible Notes of approximately \$25,000 and \$40,000, respectively. During the nine months ended June 30, 2023 and 2022, the Company recorded interest expense on the Series Convertible Notes of approximately \$75,000 and \$120,000, respectively.

13. RISKS AND UNCERTAINTIES – COVID-19 AND GEOPOLITICAL CONFLICTS

The Company sources its materials and services for its products and product candidates from facilities in areas impacted or which may be impacted by the outbreak of the COVID-19 or geopolitical conflicts. The Company's ability to obtain future inventory may be impacted, therefore potentially affecting the Company's future revenue stream. In addition, the Company has historically and principally funded its operations through debt borrowings, the issuance of convertible debt, and the issuance of units consisting of Common Stock and warrants which may also be impacted by economic conditions beyond the Company's control as well as uncertainties resulting from geopolitical conflicts, including the recent war in Ukraine. The extent to which the COVID-19 and recent events in Ukraine will impact the global economy and the Company is uncertain and cannot be reasonably measured.

14. SHAREHOLDER ADVANCES AND PREFUNDINGS RELATED TO THE ANTICIPATED BRIDGE FINANCING

Through May 12, 2023, the Company raised \$538,000 in the form of shareholder advances from two different investors to support operations in advance of the Company's prospective Uplisting Transaction. On May 15, 2023, \$488,000 of these shareholder advances, which were contributed by a single investor, were converted to an Unsecured convertible note (the "Third Note") in connection with the Third Closing of the 2022 Convertible Note Offering (see Notes 11 and 15). The remaining \$50,000 that was raised by the Company in the form of shareholder advances was repaid per the agreed terms on July 7, 2023 for \$60,000.

On May 18, 2023 and May 31, 2023, the Company raised \$340,000 and \$350,015 from a shareholder and a third-party investor, respectively, to support operations in advance of the Company's anticipated closing of the Bridge Offering (as defined below, see Note 15). On July 7, 2023, the amount prefunded by the current shareholder was included in the first closing of the Bridge Offering. The amount prefunded by the third party investor is expected to be included in a subsequent closing of the Bridge Offering.

15. SUBSEQUENT EVENTS

On July 1, 2023, the "Company" entered into an amendment ("Amendment No. 7 to the First Notes") with the holders of the Company's outstanding 2022 Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, and June 15, 2023, issued in connection with a private placement financing the Company completed on July 6, 2022 (the "First Closing"). On July 1, 2023, the Company also entered into an amendment ("Amendment No. 7 to the Second Notes") with the holders of the Company's outstanding Second Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, and June 15, 2023, issued in connection with a private placement financing the Company completed on January 18, 2023 (the "Second Closing"). On July 1, 2023, the Company also entered into an amendment ("Amendment No. 2 to the Third Notes and, together with Amendment No. 7 to the First Notes and Amendment No. 7 to the Second Notes, the "Amendments to the 2022 Notes") with the holders of the Company's outstanding Third Notes, as amended on June 15, 2023, issued in connection with a private placement financing the Company completed on May 15, 2023 (the "Third Closing").

Under the Amendments to the 2022 Notes, the 2022 Notes, Second Notes, and Third Notes were amended to extend the date of the completion of an uplist to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (such transaction, an "Uplist Transaction") from July 31, 2023 to August 31, 2023.

As a result of the entry into the Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Exchanged Notes, the Exchanged Notes were automatically amended to extend the date of completion of an Uplist Transaction from July 31, 2023 to August 31, 2023. Also, as a result of the entry into the Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Series 1 Unsecured Convertible Promissory Notes and Series 2 Unsecured Convertible Promissory Notes, each as amended on March 10, 2023, the Series Note Amendments Termination Date set forth under Amendment No. 1 to the Series 1 Unsecured Convertible Promissory Notes and Amendment No. 1 to the Series 2 Unsecured Convertible Promissory Notes was automatically amended to extend from July 31, 2023 to August 31, 2023. Additional information related to such matters can be found in the Form 8-K filed by the Company with Securities and Exchange Commission on July 7, 2023.

On July 7, 2023, the Company announced that it had entered into a Securities Purchase Agreement (the "2023 SPA") with certain institutional and accredited individual investors (collectively, the "Investors") providing for the issuance and sale by the Company to the Investors of an aggregate of (i) 1,749,245 shares (the "Shares") of common stock, par value \$0.001, of the Company (the "Common Stock") at a purchase price of \$0.275 per share; (ii) 4,996,199 warrants (the "Pre-Funded Warrants") at a purchase price of \$0.274 per Pre-Funded Warrant, to purchase an aggregate of 4,996,199 shares of Common Stock (the "Pre-Funded Warrant Shares"); and (iii) 13,490,888 warrants (the "Common Warrants") to purchase an aggregate 13,490,888 shares of Common Stock (the "Common Stock Warrants Shares"). The Shares, Pre-Funded Warrants, and Common Warrants were issued as part of a private placement offering authorized by the Company's board of directors (the "Bridge Offering"). The Company engaged an investment bank in connection with Bridge Offering. Per the terms of that agreement, the Company is obligated to pay the placement agent a fee of 8% of gross proceeds received and issue placement agent warrants to purchase that number of securities equal to 5% of the aggregate number of securities sold in the offering.

Pursuant to the lock-up agreement provided for by the SPA, the Investors agreed that they would either (A) purchase securities, for cash, in an offering conducted in conjunction with an uplist of the Common Stock to any of, and in compliance with the rules of, the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (the "Uplist Transaction") with an aggregate purchase price equal to at least 4.3 multiplied by the aggregate purchase price paid by the Investor for the Shares, Pre-Funded Warrants and Common Warrants under the SPA or (B) be subject to a lock-up provision not to sell or otherwise transfer any of the Shares, Pre-Funded Warrant Shares or Common Warrant Shares acquired by them in the Bridge Offering until the one-year anniversary of the Closing Date. The aggregate gross proceeds for the sale of the Shares, Pre-Funded Warrants, and Common Warrants will be approximately \$1.85 million, before deducting the placement agent's fees and other estimated fees and offering expenses payable by the Company. The closing of the sales of these securities under the SPA occurred on July 7, 2023 (the "Closing Date").

The 2023 SPA also provides additional provisions including: i) certain adjustments that would require the Company to issue additional securities to the Investors if the effective offering price to the public of Common Stock in connection with the next underwritten public offering is less than \$4.00 per share; ii) a requirement to register the Shares, Pre-Funded Warrant Shares, and Common Stock Warrant Shares on a subsequent registration statement or statements; and, iii) certain restrictions on the Company's ability to conduct subsequent sales of its equity securities and certain business activities. Additional information related to such matters can be found in the Form 8-K filed by the Company with Securities and Exchange Commission on July 13, 2023.

On July 7, 2023, the Company entered into an amendment (“Amendment No. 8 to the First Notes”) with the holders of the Company’s outstanding 2022 Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, and July 1, 2023, issued in connection with a private placement financing the Company completed on July 6, 2022 (the “First Closing”). On July 1, 2023, the Company also entered into an amendment (“Amendment No. 8 to the Second Notes”) with the holders of the Company’s outstanding Second Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, and July 1, 2023, issued in connection with a private placement financing the Company completed on January 18, 2023 (the “Second Closing”). On July 1, 2023, the Company also entered into an amendment (“Amendment No. 3 to the Third Notes”, and, together with Amendment No. 8 to the First Notes and Amendment No. 8 to the Second Notes, the “Amendments to the 2022 Notes”) with the holders of the Company’s outstanding Third Notes, as amended on June 15, 2023, and as subsequently amended on July 1, 2023, issued in connection with a private placement financing the Company completed on May 15, 2023 (the “Third Closing”).

Under the Amendments to the 2022 Notes, the following amendments to the 2022 Notes, Second Notes, and Third Notes will be simultaneously effective upon the closing of an offering conducted in conjunction with an uplist of the Common Stock to any of, and in compliance with the rules of, the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (the “Uplist Transaction”). The Specified Percentage (as defined below) of the then outstanding principal amount of the 2022 Notes, Second Notes, and Third Notes shall automatically convert (the “Automatic Conversion”) into shares of Common Stock, with the conversion price for purposes of such Automatic Conversion being equal to the lower of (i) the per unit price at which any units (each unit being comprised of one share or share equivalent and accompanying warrants, if any) are sold in the Uplist Transaction or (ii) the price at which warrants issued in the Uplist Transaction are exercisable (but in no event increased above the conversion price in effect immediately prior to the pricing of the Uplist Transaction).

In addition, if the Holder (as defined below) (i) participates in the Uplist Transaction and in the Bridge Offering for a combined (taking into account the Holder’s aggregate investment in the Uplist Transaction and the Bridge Offering) amount equal to no less than fifty percent (50%) of the Holder’s original purchase price under the 2022 Notes, Second Notes, and Third Notes, and (ii) the Holder’s amount of participation in the Uplist Transaction is at least 4.3 times the Holder’s amount of participation in the Bridge Offering, then the Holder shall receive a pre-funded warrant (the “Participating Pre-Funded Warrant”) to purchase a number of shares of Common Stock equal to the Specified Number (as defined below) times the dollar amount under the 2022 Notes that was converted in the Automatic Conversion. The Participating Pre-Funded Warrant (i) shall have an exercise price of \$0.001 per share, (ii) may be exercised on a cashless basis, (iii) shall be exercisable by the Holder at any time commencing on the 90th day after issuance, (iv) may be redeemed by the Company for cash at a redemption price of \$0.82 per share underlying the Participating Pre-Funded Warrant with any such redemption made pro rata to all holders of the Participating Pre-Funded Warrants, (v) and shall contain a customary beneficial ownership limitation provision. Additionally, the holder of the Participating Pre-Funded Warrants will agree that, until January 6, 2024, it shall not offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of, or announce the intention to otherwise dispose of, the Participating Pre-Funded Warrant.

“Specified Percentage” means the greater of: (i) the percentage specified by the Company by notice to the 2022 Note holders (the “Holders”, and each a “Holder”) at least five business days prior to the closing of the Uplist Transaction, which percentage shall be the percentage necessary to ensure the applicable Nasdaq requirements regarding the Uplist Transaction are satisfied, and (ii) the percentage specified by the Holder by notice to the Company at least three business days prior to the closing of the Uplist Transaction (which percentage may be different for each 2022 Note, Second Note, and/or Third Note as determined by each Holder thereof); provided, that in no event shall the Specified Percentage for the 2022 Notes, Second Notes, and/or Third Notes (A) exceed twenty five percent (25%) unless otherwise agreed in writing by the Holder, or (B) exceed fifty percent (50%) unless otherwise agreed in writing by the Company.

“Specified Number” means, if the Specified Percentage is 50%, 2.4, which number shall be increased by 1.6% for each percentage point decrease in the Specified Percentage, such increase being compounded iteratively for each percentage point decrease in the Specified Percentage, with the result rounded to two decimal places. Additional information related to such matters can be found in the Form 8-K filed by the Company with Securities and Exchange Commission on July 13, 2023.

Additionally, on July 7, 2023, the Company entered into an amendment (the “Omnibus Amendment to Notes and Warrants”) with the Holders of the 2022 Notes, Second Notes, and Third Notes amending the 2022 Notes, Second Notes, and Third Notes and related warrants issued at each of the First Closing, Second Closing, and Third Closing (the “First Warrants”, “Second Warrants” and “Third Warrants”, respectively, and collectively, the “2022 Warrants”). Under the Omnibus Amendment to Notes and Warrants, the 2022 Notes, Second Notes, Third Notes, and related warrants were amended (i) to modify the Most Favored Nation provisions therein to exclude the Bridge Offering, and (ii) to prohibit the Company from engaging in any capital raising transactions, subject to certain exceptions, until the earlier of (A) July 7, 2027, and (B) the first date on which all Holders hold less than 20% of the original amount of the Participating Pre-Funded Warrants received by each Holder, respectively, in connection with the Automatic Conversion. Additional information related to such matters can be found in the Form 8-K filed by the Company with Securities and Exchange Commission on July 13, 2023.

On July 7, 2023 the Company paid \$60,000 to a shareholder that had previously advanced the Company \$50,000 to support operations. The payment satisfied all remaining obligations in connection with the \$538,000 of shareholder advances received by the Company through May 12, 2023. The additional \$488,000 was issued as a Third Note (see Note 11).

On July 11, 2023, the Company entered into a finance agreement with First Insurance Funding in order to fund a portion of its insurance policies. The amount financed is approximately \$310,000 and incurs interest at a rate of 7.49%. Per the terms of its agreement with First Insurance Funding, the Company is required to make monthly payments of approximately \$32,000 through April 2024.

On July 12, 2023, the Company secured countersigned notices of conversion from all remaining holders of the Series 1 Convertible Notes, and provided instructions to its transfer agent to issue a total of 59,912 shares of Common Stock in full satisfaction of all previously outstanding Series 1 Convertible Notes. Pursuant to the Series 1 Convertible Notes, the Company can elect to convert the principal and accrued interest under the Series Convertible Notes obligation (the “Series Note Obligations”) upon the earlier of the effective time of the Uplisting Transaction, or the maturity date. In the case of an In-Kind Note Repayment, the outstanding Note Obligations will be calculated by increasing by thirty-five percent the aggregate sum of the unpaid Principal Amount held by each Holder and the accrued interest at a rate of ten percent per annum, subject to, with respect to any portion of the Principal Amount that is converted or prepaid before the twelve month anniversary of the Issuance Date, a minimum interest payment equal to ten percent of the amount that is converted or prepaid. As consideration for agreeing to subordinate to the 2022 Notes, the premium applicable in connection with an In-Kind Note Repayment at maturity was increased from thirty-five percent to sixty percent. In the event the Company exercises such option, the Series Note Obligations will be deemed to equal the product of 4.5 (which was previously 1.6 prior to the Series Note Amendments) and the outstanding Series Note Obligations.

On July 18, 2023, the Board of the Directors of the Company executed a unanimous written consent that, among other things, approved, subject to the approval of a majority of the stockholders of the Company, the following: 1) amend the Amended and Restated Articles of Incorporation (the “Articles”) to a) increase the number of authorized shares of common stock, par value \$0.001 (the “Common Stock”) from 12 million to 350 million, b) create 5,000,000 shares of “blank check” preferred stock, and c) approve a reverse split at a ratio of between 1.5-for-1 and 20-for-1 without any proportionate decrease in the number of authorized shares; 2) amend the Bylaws of the Company to a) allow action by written consent of stockholders representing more than 50% of the total number of shares of Common Stock currently issued and outstanding, and b) establish that holders of thirty-three and one-third (33.3333%) of the total number of shares of Common Stock currently issued and outstanding shall constitute a quorum at any meeting of stockholders for the transaction of business, except as otherwise provided by the NRS or by the Articles; and, 3) approve the 2023 Omnibus Equity Incentive Plan with an initial reservation of 455,169 shares, options or other such grants. Additional information related to such matters can be found in the Form 8-K filed by the Company with Securities and Exchange Commission on July 24, 2023.

On July 31, 2023, Arch Therapeutics, Inc. (the “Company”) entered into an amendment (“Amendment No. 9 to the First Notes”) with the holders of the Company’s outstanding 2022 Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023 and July 7, 2023 issued in connection with a private placement financing the Company completed on July 6, 2022 (the “First Closing”). On July 31, 2023, the Company also entered into an amendment (“Amendment No. 9 to the Second Notes”) with the holders of the Company’s outstanding Second Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, and July 7, 2023 issued in connection with a private placement financing the Company completed on January 18, 2023 (the “Second Closing”). On July 31, 2023, the Company also entered into an amendment (“Amendment No. 4 to the Third Notes and, together with Amendment No. 9 to the First Notes and Amendment No. 9 to the Second Notes, the “Amendments to the 2022 Notes”) with the holders of the Company’s outstanding Third Notes, as amended on June 15, 2023, and as subsequently amended on July 1, 2023 and July 7, 2023 issued in connection with a private placement financing the Company completed on May 15, 2023 (the “Third Closing”).

Under the Amendments to the 2022 Notes, the 2022 Notes, Second Notes, and Third Notes were amended to extend the date of the completion of an uplist to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (such transaction, an “Uplist Transaction”) from July 31, 2023 to August 31, 2023.

As a result of the entry into the Amendments to the 2022 Notes, and pursuant to the terms of the Company’s outstanding Exchanged Notes, the Exchanged Notes were automatically amended to extend the date of completion of an Uplist Transaction from July 31, 2023 to August 31, 2023. Additional information related to such matters can be found in the Form 8-K filed by the Company with Securities and Exchange Commission on August 4, 2023.

ARCH THERAPEUTICS, INC.

3,364,527 Shares of Common Stock

Up to 146,473 Shares of Common Stock underlying the Second Notes and Third Notes

Up to 783,564 Shares of Common Stock underlying the 2022 Notes upon Automatic Conversion

Up to 275,930 Shares of Common Stock underlying the 2022 Warrants and

2022 Placement Agent Warrants

Up to 81,690,984 Shares of Common Stock underlying the Common Warrants, Bridge Pre-Funded Warrants, Exchange Investor Warrants, and Bridge Placement Agent Warrants

Up to 8,305,767 Shares of Common Stock underlying the Participating Pre-Funded Warrants and 2022 Note Conversion Pre-Funded Warrants

PRELIMINARY PROSPECTUS

Prospectus dated ____, 2023

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

As used in this Part II, unless the context indicates or otherwise requires, the terms “we”, “us”, “our”, and the “Company” refer to Arch Therapeutics, Inc., a Nevada corporation, and its consolidated subsidiary, and the term “ABS” refers to Arch Biosurgery, Inc., a private Massachusetts corporation that, through a reverse merger acquisition completed on June 26, 2013, or the Merger, has become our wholly owned subsidiary.

Item 13. Other Expenses of Issuance and Distribution.

The estimated expenses payable by us in connection with the offering described in this registration statement (other than the underwriting discount and commissions) will be as follows:

EXPENSE	AMOUNT
SEC/FINRA Expenses	\$ 9,881
Nasdaq listing and filing fees	\$ 50,000
Reimbursement to underwriters for expenses	\$ 150,000
Legal fees and expenses	\$ 400,000
Accounting fees and expenses	\$ 60,000
Printing and engraving expenses	\$ 100,000
Miscellaneous expenses	\$ 5,119
	<u>\$ 775,000</u>

Item 14. Indemnification of Directors and Officers.

We have not entered into separate indemnification agreements with our directors and officers. Our amended and restated bylaws provide that we shall indemnify any director or officer to the fullest extent authorized by the laws of the State of Nevada. Our amended and restated bylaws further provide that we shall pay the expenses incurred by an officer or director (acting in his or her capacity as such) in defending any action, suit or proceeding in advance of the final disposition of such action, suit or proceeding, subject to the delivery to us by or on behalf of such director or officer of an undertaking to repay the amount of such expenses if it shall ultimately be determined that he or she is not entitled to be indemnified by us as authorized in our bylaws or otherwise.

The Nevada Revised Statutes provide us with the power to indemnify any of our directors, officers, employees and agents as follows:

- a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, except an action by or in the right of the corporation, by reason of the fact that he or she is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses, including attorneys' fees, judgments, fines and amounts paid in settlement actually and reasonably incurred by him or her in connection with the action, suit or proceeding if he or she acted in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful;
- a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that he or she is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses, including amounts paid in settlement and attorneys' fees actually and reasonably incurred by him or her in connection with the defense or settlement of the action or suit if he or she acted in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the corporation. Indemnification may not be made for any claim, issue or matter as to which such a person has been adjudged by a court of competent jurisdiction, after exhaustion of all appeals therefrom, to be liable to the corporation or for amounts paid in settlement to the corporation, unless and only to the extent that the court in which the action or suit was brought or other court of competent jurisdiction determines upon application that in view of all the circumstances of the case, the person is fairly and reasonably entitled to indemnity for such expenses as the court deems proper; and
- to the extent that a director, officer, employee or agent of a corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding, or in defense of any claim, issue or matter therein, the corporation must indemnify him or her against expenses, including attorneys' fees, actually and reasonably incurred by him or her in connection with the defense.

The Nevada Revised Statutes provide that a corporation may make any discretionary indemnification only as authorized in the specific case upon a determination that indemnification of the director, officer, employee or agent is proper in the circumstances. The determination must be made:

- by the stockholders of the corporation;
- by the board of directors of the corporation by majority vote of a quorum consisting of directors who were not parties to the action, suit or proceeding;
- if a majority vote of a quorum consisting of directors who were not parties to the action, suit or proceeding so orders, by independent legal counsel in a written opinion;
- if a quorum consisting of directors who were not parties to the action, suit or proceeding cannot be obtained, by independent legal counsel in a written opinion; or
- by court order.

The Nevada Revised Statutes further provide that a corporation may purchase and maintain insurance or make other financial arrangements on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise for any liability asserted against him or her and liability and expenses incurred by him or her in his or her capacity as a director, officer, employee or agent, or arising out of his or her status as such, whether or not the corporation has the authority to indemnify him or her against such liability and expenses. We have secured a directors' and officers' liability insurance policy. We expect that we will continue to maintain such a policy.

Item 15. Recent Sales of Unregistered Securities.

2022 Notes Offering

First Notes

On July 6, 2022, we entered into a Securities Purchase Agreement, or the 2022 SPA, with certain institutional and accredited individual investors providing for the issuance and sale of an aggregate of (i) 63,833 First Inducement Shares; (ii) First Notes in the aggregate principal amount of \$4.23 million that are convertible into an aggregate of 462,801 Conversion Shares; (iii) First Warrants to purchase up to 425,554 First Warrant Shares; and (iv) First Placement Agent Warrants to purchase up to 31,510 shares of Common Stock.

The First Notes become due and payable on January 6, 2024, or the Maturity Date, and may not be prepaid, in whole or in part, at any time without the written consent of the lead investor, with such prepayment amounts subject to adjustment as a result of certain time-based prepayment premiums set forth in the First Notes; provided, that, the written consent of the lead investor is not required in connection with a prepayment made from the proceeds of an Uplist Transaction. The First Notes bear interest on the unpaid principal balance at a rate equal to ten percent (10%) (computed on the basis of the actual number of days elapsed in a 360-day year) per annum accruing from the First Closing Date until the First Notes become due and payable at maturity or upon their conversion, acceleration or by prepayment, and may become due and payable upon the occurrence of an event of default under the First Notes. Any amount of principal or interest on the First Notes which is not paid when due shall bear interest at the rate of the lesser of (i) eighteen percent (18%) per annum or (ii) the maximum amount allowed by law from the due date thereof until payment in full.

The First Notes are convertible into shares of Common Stock at the option of each holder of the First Notes from the date of issuance at the Conversion Price of \$9.14 through the later of (i) the Maturity Date and (ii) the date of payment of the Default Amount (as defined in the First Note); *provided, however*, certain First Notes include a provision preventing such conversion if, as a result, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder's, would be deemed to beneficially own more than 4.99% of the outstanding shares of the Common Stock, or as applicable, the Ownership Limitation, immediately after giving effect to the Conversion; and *provided further*, the holder, upon notice to us, may increase or decrease the Ownership Limitation; *provided that* (i) the Ownership Limitation may only be increased to a maximum of 9.99% of the outstanding shares of the Common Stock; and (ii) any increase in the Ownership Limitation will not become effective until the 61st day after delivery of such waiver notice. The Conversion Price is subject to adjustment as set forth in the First Notes.

The First Notes contain customary events of default, which include, among other things, (i) our failure to pay when due any principal or interest payment under the First Notes; (ii) our insolvency; (iii) delisting of our Common Stock; (iv) our breach of any material covenant or other material term or condition under the First Notes; and (v) our breach of any representations or warranties under the First Notes which cannot be cured within five (5) days. Further, events of default under the First Notes also include (i) the unavailability of Rule 144 on or after six (6) months from the First Closing Date or January 6, 2023; (ii) our failure to deliver the shares of Common Stock to the First Note holder upon exercise by such holder of its conversion rights under the First Notes; (iii) our loss of the "bid" price for its Common Stock and/or a market and such loss is not cured during the specified cure periods; (iv) our failure to complete an uplist to any of The Nasdaq Global Market, The Nasdaq Capital Market, NYSE or NYSE American by March 15, 2023, or an Uplist Transaction; and (v) upon completion of an Uplist Transaction, our failure to repay the outstanding balance of the First Notes within two days of receipt of a First Note holder's demand for repayment.

The First Warrants (i) have an exercise price of \$9.94 per share; (ii) have a term of exercise equal to 5 years after their issuance date; (iii) became exercisable immediately after their issuance; and (iv) have a provision preventing the exercisability of such First Warrant if, as a result of the exercise of the First Warrant, the holder, together with its affiliates and any other persons whose beneficial ownership of our Common Stock would be aggregated with the holder's, would be deemed to beneficially own more than the Ownership Limitation. The holder, upon notice to us, may increase or decrease the Ownership Limitation; provided that (i) the Ownership Limitation may only be increased to a maximum of 9.99% of the outstanding shares of our Common Stock; and (ii) any increase in the Ownership Limitation will not become effective until the 61st day after delivery of such waiver notice. The number of shares of Common Stock into which each of the First Warrants is exercisable and the exercise price therefor are subject to adjustment as set forth in the First Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise).

Pursuant to the 2022 Engagement Letter, that we entered into with Maxim, we agreed, among other things, to (i) pay Maxim 10% of the gross proceeds in the First Closing from certain institutional investors, or \$240,000, and (ii) issue Maxim, or its designees, warrants to purchase up to 10% of the aggregate number of shares sold to the institutional investors in the First Closing, or warrants to purchase up to 31,510 shares of Common Stock. The First Placement Agent Warrants have substantially the same terms as the First Warrants, except that the exercise price of the First Placement Agent Warrants is \$10.06 per share and are not exercisable until six (6) months from the date of issuance. We also reimbursed Maxim approximately \$58,000 for non-accountable banking fees, legal fees and other expenses. The First Inducement Shares, First Notes, First Warrants and First Placement Agent Warrants were issued and sold in reliance upon an exemption from registration afforded by Section 4(a)(2) of the Securities Act. On February 22, 2023, we terminated the 2022 Engagement Letter with Maxim, in which we agreed, among other things, to pay Maxim a tail fee of up to 2% of the aggregate amounts invested by certain participating holders in this offering at closing.

Exchange Notes

In connection with the 2022 SPA, on July 6, 2022, we issued certain investor notes (the “**Exchanged Notes**”) in the aggregate principal amount of \$699,780.93 in the Notes Exchange (as defined below). The Exchanged Notes are convertible into 76,563 shares of Common Stock at a conversion price of \$9.14 in exchange for their Series Convertible Notes (the “**Notes Exchange**”). The terms of the Exchanged Notes are substantially similar to those of the First Notes. In connection with the issuance of the Exchanged Notes, the Series Convertible Notes holders entered into a subordination agreement on July 6, 2022 to subordinate their rights in respect of the Exchanged Notes to the rights of the investors respect of the First Notes.

Second Notes

On January 18, 2023, we entered into an amendment to the 2022 SPA related to the 2022 Private Placement Financing with certain institutional and accredited individual investors in connection with the Second Closing of the 2022 Private Placement Financing providing for the issuance and sale of an aggregate of (i) 9,598 Second Inducement Shares; (ii) Second Notes in the aggregate principal amount of \$636,000; and (iii) Second Warrants to purchase up to 127,968 Second Warrant Shares at an exercise price of \$9.94 per share. The terms of the Second Notes and Second Warrants are substantially similar to those of the First Notes and First Warrants, except that the Second Notes are unsecured. In connection with the Second Closing, we agreed to (i) pay Maxim 10% of the gross proceeds in the Second Closing from the institutional investors, or \$50,000, and (ii) issue 2022 Placement Agent Warrants to purchase up to 6,565 2022 Placement Agent Warrant Shares to Maxim pursuant to the 2022 Engagement Letter. The 2022 Placement Agent Warrants have substantially the same terms as the Second Warrants, except that the exercise price of the 2022 Placement Agent Warrants is \$10.06 per share and are not exercisable until six (6) months from the date of issuance. The Second Inducement Shares, Second Notes, Second Warrants and 2022 Placement Agent Warrant Shares were issued and sold in reliance upon an exemption from registration afforded by Section 4(a)(2) of the Securities Act.

Third Notes

On May 15, 2023, we entered into an amendment to the 2022 SPA related to the 2022 Private Placement Financing with an Investor in connection with the Third Closing of the 2022 Private Placement Financing providing for the issuance and sale by the Company to an Investor of an aggregate of (i) Third Notes in the aggregate principal amount of \$702,720, which includes an aggregate \$214,720 original issue discount in respect of the Third Notes; (ii) Third Warrants to purchase an aggregate of 141,396 Third Warrant Shares at an exercise price of \$9.94 per share; and (iii) 10,608 Third Inducement Shares. The aggregate gross proceeds for the sale of the Third Notes, Third Warrants, and Third Inducement Shares was approximately \$488,000, before deducting any estimated fees and offering expenses payable by the Company. The terms of the Third Notes and Third Warrants are substantially similar to those of the Second Notes and Second Warrants. The Company did not engage a placement agent in connection with the issuance of the Third Notes, Third Warrants, and Third Inducement Shares. The Third Notes, Third Warrants, and Third Inducement Shares were issued and sold in reliance upon an exemption from registration afforded by Section 4(a)(2) of the Securities Act.

2022 Note Modifications

On July 7, 2023, the Company entered into an Amendment No. 8 to the First Notes with the holders of the Company’s outstanding First Notes, as separately amended on February 14, 2023, March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 31, 2023, and August 30, 2023, issued in connection with the First Closing. On July 7, 2023, the Company also entered into Amendment No. 8 to the Second Notes with the holders of the Company’s outstanding Second Notes, as separately amended on February 14, 2023, March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 31, 2023, and August 30, 2023, issued in connection with the Second Closing. On July 7, 2023, the Company also entered into Amendment No. 3 to the Third Notes with the holders of the Company’s outstanding Third Notes, as separately amended on June 15, 2023, July 1, 2023, July 31, 2023, and August 30, 2023, issued in connection the Third Closing.

Under the Amendments to the 2022 Notes, the following amendments to the 2022 Notes will be simultaneously effective upon the closing of the Uplist Transaction. The Specified Percentage (as defined below) of the then outstanding principal amount of the 2022 Notes shall automatically convert (the “**Automatic Conversion**”) into Conversion Shares, with the conversion price for purposes of such Automatic Conversion being equal to the lower of (i) the per unit price at which any units (each unit being comprised of one share or share equivalent and accompanying warrants, if any) are sold in the Uplist Transaction or (ii) the price at which warrants issued in the Uplist Transaction are exercisable (but in no event increased above the conversion price in effect immediately prior to the pricing of the Uplist Transaction).

In addition, if the Holder (i) participates in the Uplist Transaction and in the Bridge Offering for a combined (taking into account the Holder’s aggregate investment in the Uplist Transaction and the Bridge Offering) amount equal to no less than fifty percent (50%) of the Holder’s original purchase price under the 2022 Notes and (ii) the Holder’s amount of participation in the Uplist Transaction is at least 4.3 times the Holder’s amount of participation in the Bridge Offering, then the Holder shall receive a Participating Pre-Funded Warrant to purchase a number Conversion Warrant Shares equal to the Specified Number (as defined below) times the dollar amount under the 2022 Notes that was converted in the Automatic Conversion. The Participating Pre-Funded Warrant (i) shall have an exercise price of \$0.001 per share, (ii) may be exercised on a cashless basis, (iii) shall be exercisable by the Holder at any time commencing on the 90th day after issuance, (iv) may be redeemed by the Company for cash at a redemption price of \$0.82 per share underlying the Participating Pre-Funded Warrant, with any such redemption made pro rata to all holders of the Participating Pre-Funded Warrants, (v) and shall contain a customary beneficial ownership limitation provision. Additionally, the holder of the Participating Pre-funded Warrants will agree that, until January 6, 2024, it shall not offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of, or announce the intention to otherwise dispose of, the Participating Pre-Funded Warrant.

“Specified Percentage” means the greater of: (i) the percentage specified by the Company by notice to the Holders at least five business days prior to the closing of the Uplist Transaction, which percentage shall be the percentage necessary to ensure the applicable Nasdaq requirements regarding the Uplist Transaction are satisfied, and (ii) the percentage specified by the Holder by notice to the Company at least three business days prior to the closing of the Uplist Transaction (which percentage may be different for each 2022 Note as determined by each Holder thereof); provided, that in no event shall the Specified Percentage for the 2022 Notes (A) exceed twenty five percent (25%) unless otherwise agreed in writing by the Holder, or (B) exceed fifty percent (50%) unless otherwise agreed in writing by the Company.

“Specified Number” means, if the Specified Percentage is 50%, 2.4, which number shall be increased by 1.6% for each percentage point decrease in the Specified Percentage, such increase being compounded iteratively for each percentage point decrease in the Specified Percentage, with the result rounded to two decimal places.

On July 7, 2023, the Company entered the “Omnibus Amendment to Notes and Warrants with the Holders of the 2022 Notes, amending the 2022 Notes and the 2022 Warrants issued at each of the First Closing, Second Closing, and Third Closing. Under the Omnibus Amendment to Notes and Warrants, the 2022 Notes and 2022 Warrants were amended (i) to modify the Most Favored Nation provisions therein to exclude the Bridge Offering and (ii) to prohibit the Company from engaging in any capital raising transactions, subject to certain exceptions, until the earlier of (A) July 7, 2027, and (B) the first date on which all Holders hold less than 20% of the original amount of the Participating Pre-Funded Warrants received by each Holder, respectively, in connection with the Automatic Conversion.

Additionally, on September 30, 2023, the Company entered into Amendment No. 11 to the First Notes with the holders of the Company’s outstanding First Notes, as amended, issued in connection with the First Closing. On September 30, 2023, the Company also entered Amendment No. 11 to the Second Notes with the holders of the Company’s outstanding Second Notes, as amended, issued in connection with the Second Closing. On September 30, 2023, the Company also entered into Amendment No. 6 to the Third Notes with the holders of the Company’s outstanding Third Notes, as amended, issued in connection with the Third Closing.

Under Amendment No. 11 to the 2022 Notes, the following amendments to the 2022 Notes will be simultaneously effective upon the closing of the Uplist Transaction. The date for completion of the Uplist Transaction was extended from September 30, 2023, to October 31, 2023. Additionally, upon the Automatic Conversion, a Holder shall receive 2022 Note Conversion Pre-Funded Warrants in lieu of shares of Common Stock otherwise issuable to the Holder to the extent that the sum of (1) the number of shares of Common Stock beneficially owned by the Holder and its affiliates (other than shares of Common Stock which may be deemed beneficially owned through the ownership of the unconverted portion of the Notes or the unexercised or unconverted portion of any other security of the Borrower subject to a limitation on conversion or exercise analogous to the limitations contained herein) and (2) the number of shares of Common Stock issuable upon the Automatic Conversion with respect to which the determination of this sentence is being made, would result in beneficial ownership by the Holder and its affiliates of more than 4.99% (or 9.99% if elected in writing by the Holder prior to the Automatic Conversion) of the outstanding shares of Common Stock. For purposes of the immediately preceding sentence, beneficial ownership shall be determined in accordance with Section 13(d) of the Exchange Act, and Regulations 13D-G thereunder, provided, that the limit may be waived by the Holder (up to a maximum of 9.99%) upon, at the election of the Holder, not less than 61 days' prior notice to the Borrower, and the provisions of the conversion limitation shall continue to apply until such 61st day (or such later date, as determined by the Holder, as may be specified in such notice of waiver). The 2022 Note Conversion Pre-Funded Warrants shall have a nominal exercise price of \$0.001 per share, may be exercised on a cashless basis, shall be exercisable immediately upon issuance and shall contain a customary beneficial ownership limitation provision.

Series G and Series H Warrant Exchange

On March 10, 2023, we entered into Exchange Agreements with each of the holders of Series G Warrants and Series H Warrants, pursuant to which we exchanged 34,013 Series G Warrants for 3,402 shares of Common Stock and 43,077 Series H Warrants for 8,616 shares of Common Stock. The shares of Common Stock were issued in reliance upon an exemption from registration pursuant to Section 3(a)(9) of the Securities Act.

2021 Offering

On February 11, 2021, we entered into a Securities Purchase Agreement, or the 2021 SPA, with certain institutional and accredited investors providing for the issuance and sale of an aggregate of (i) 215,625 shares of our Common Stock (the “**2021 SPA Shares**”); and (ii) Series K Warrants to purchase an aggregate of 161,719 shares of Common Stock, at a combined offering price of \$32.00 per share and related Series K Warrant. The Series K Warrants (i) have an exercise price of \$34.00 per share; (ii) have a term of exercise equal to 5.5 years after their issuance date; (iii) were exercisable immediately after their issuance; and (iv) have a provision preventing the exercisability of such Series K Warrant if, as a result of the exercise of the Series K Warrant, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder's, would be deemed to beneficially own more the Ownership Limitation (all capitalized terms in this paragraph not otherwise defined to have the meaning ascribed to such terms in the 2021 SPA) immediately after giving effect to the exercise of the Series K Warrant. The holder, upon notice to the Company, may increase or decrease the Ownership Limitation; provided that (i) the Ownership Limitation may only be increased to a maximum of 9.99% of the outstanding shares of the Company's Common Stock; and (ii) any increase in the Ownership Limitation will not become effective until the 61st day after delivery of such waiver notice. The number of shares of the Company's Common Stock into which each of the Series K Warrants is exercisable and the exercise price therefor are subject to adjustment as set forth in the Series K Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise).

Pursuant to an engagement agreement that we entered into with H.C. Wainwright & Co., or the 2021 Placement Agent, we agreed, among other things, to issue the 2021 Placement Agent, or its designees, warrants to purchase up to 7.5% of the aggregate number of shares sold to investors in the 2021 Private Placement Financing, or warrants to purchase up to 16,172 shares, or the 2021 Placement Agent Warrants. The 2021 Placement Agent Warrants have substantially the same terms as the Series K Warrants, except that the exercise price of the 2021 Placement Agent Warrants is \$40.00 per share.

The issuance and sale of the 2021 SPA Shares, Series K Warrants, 2021 Placement Agent Warrants, Exchanged Notes, and the shares of Common Stock issuable upon conversion of the Exchanged Notes and upon the exercise of the Series K Warrants and the 2021 Placement Agent Warrants were issued and sold in reliance upon an exemption from registration afforded by Section 4(a)(2) of the Securities Act and Rule 506(b) promulgated under Securities Act.

2020 Offering

On June 4, 2020 and June 22, 2020, we issued Series J Warrants to purchase up to an aggregate of 19,432 shares of Common Stock at an exercise price of \$50.00 per share to certain holders of our Series D Warrants as an inducement for those holders to exercise their Series D Warrants. The Series J Warrants were exercisable immediately upon their issuance and, as originally issued, had a term of exercise equal to one year after their issuance date; *however*, on November 6, 2020, the Series J Warrant to purchase up to 16,875 shares of Common Stock was amended to extend the term by an additional eighteen (18) months. The number of shares of our Common Stock into which each of the Series J Warrants were exercisable and the exercise price thereof were subject to adjustment as set forth in the Series J Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise). In addition, the Series J Warrants provided that they would not be exercisable in the event and to the extent that the exercise thereof would have resulted in the holder of the Series J Warrant, together with any person whose beneficial ownership would have been aggregated with the holder, beneficially owning more than 4.99% of the outstanding shares of our Common Stock; however, the holder could have increased such ownership limitation to 9.99% of the outstanding shares of our Common Stock, in which case the ownership limitation increase would have become effective 61 days after the holder requested such increase. In addition, each Series J Warrant provided the holder with “piggy back” registration rights under certain circumstances. The Series J Warrant and the shares of Common Stock issuable thereunder were issued and sold in reliance upon an exemption from registration afforded by Section 4(a)(2) of the Securities Act.

Series 1 and 2 Notes

On June 4, 2020, we issued unsecured 10% Series 1 Convertible Notes in the aggregate principal amount of \$550,000 (the **Series 1 Convertible Notes**). The Series 1 Convertible Notes provide, among other things, for (i) a term of approximately three (3) years; (ii) the Company’s ability to prepay the Series 1 Convertible Notes, in whole or in part, at any time; (iii) the automatic conversion of the Series 1 Convertible Notes upon a Change of Control (all capitalized terms in this paragraph not otherwise defined to have the meaning ascribed to such terms in the Series 1 Convertible Notes) into shares of Common Stock at a per share price of \$54.00 (the **“Series 1 Conversion Price”**); (iv) the ability of a holder of a Series 1 Convertible Note to convert the Convertible Note and accrued interest, in whole or in part, into shares of Common Stock at the Series 1 Conversion Price (the **“Series 1 Conversion Shares”**); (v) the Company’s ability to convert all Note Obligations outstanding upon a Qualified Equity Financing into shares of Common Stock at the Series 1 Conversion Price; (vi) the Company’s ability to convert the Series 1 Convertible Notes and accrued interest, in whole or in part, into shares of Common Stock at the Series 1 Conversion Price in the event the volume weighted average price (“VWAP”) of the Common Stock equals or exceeds \$64.00 per share for at least fifteen (15) consecutive Trading Days; (vii) the Company’s ability to convert all outstanding Note Obligations into shares of Common Stock at the Series 1 Conversion Price (an **“Series 1 In-Kind Note Repayment”**) in lieu of repaying the Note Obligations outstanding on the Maturity Date, June 30, 2023; provided, however, that in the case of a Series 1 In-Kind Note Repayment, the outstanding Note Obligations will be calculated by increasing by thirty-five percent (35%) the aggregate sum of the unpaid Principal Amount held by each holder and the accrued interest at a rate of ten percent (10%) per annum, subject to, with respect to any portion of the Principal Amount that is converted or prepaid before the twelve month anniversary of the Issuance Date, a minimum interest payment equal to ten percent (10%) of the amount that is converted or prepaid. The Series 1 Convertible Notes and Series 1 Conversion Shares were issued and sold in reliance upon an exemption from registration afforded by Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated under the Securities Act.

On November 6, 2020, we issued unsecured 10% Series 2 Convertible Notes in the aggregate principal amount of \$1,050,000 (the **Series 2 Convertible Notes**). The Series 2 Convertible Notes provide, among other things, for (i) a term of approximately three (3) years; (ii) the Company’s ability to prepay the Series 2 Convertible Notes, in whole or in part, at any time; (iii) the automatic conversion of the Series 2 Convertible Notes upon a Change of Control (all capitalized terms in this paragraph not otherwise defined to have the meaning ascribed to such terms in the Series 2 Convertible Notes) into shares of Common Stock, at a per share price of \$50.00 (the **“Series 2 Conversion Price”**); (iv) the ability of a holder of a Series 2 Convertible Note to convert the Series 2 Convertible Note and accrued interest, in whole or in part, into shares of Common Stock at the Series 2 Conversion Price (the **“Series 2 Conversion Shares”**); (v) the Company’s ability to convert all Note Obligations outstanding upon a Qualified Equity Financing into shares of Common Stock at the Series 2 Conversion Price; (vi) the Company’s ability to convert the Series 2 Convertible Notes and accrued interest, in whole or in part, into shares of Common Stock at the Series 2 Conversion Price in the event the VWAP of the Common Stock equals or exceeds \$64.00 per share for at least fifteen (15) consecutive Trading Days; (vii) the Company’s ability to convert all outstanding Note Obligations into shares of Common Stock at the Series 2 Conversion Price (an **“Series 2 In-Kind Note Repayment”**) in lieu of repaying the Note Obligations outstanding on the Maturity Date, November 30, 2023; provided, however, that in the case of a Series 2 In-Kind Note Repayment, the outstanding Note Obligations will be calculated by increasing by thirty-five percent (35%) the aggregate sum of the unpaid Principal Amount held by each holder and the accrued interest at a rate of ten percent (10%) per annum, subject to, with respect to any portion of the Principal Amount that is converted or prepaid before the twelve month anniversary of the Issuance Date, a minimum interest payment equal to ten percent (10%) of the amount that is converted or prepaid. The Series 2 Convertible Notes and Series 2 Conversion Shares were issued and sold in reliance upon an exemption from registration afforded by Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated under the Securities Act.

On March 10, 2023, we entered into amendments with the holders of the Series 1 Convertible Notes (the “**Series 1 Note Amendment**”) and Series 2 Convertible Notes (the “**Series 2 Note Amendment**” and, together with the Series 1 Note Amendment, the “**Series Note Amendments**”) to modify certain terms as of the moment in time immediately preceding the consummation of the Uplist Transaction (the “**Effective Time**”). Pursuant to the Series Note Amendments, the Company can elect to convert the principal and accrued interest under the Series Convertible Notes (the “**Series Note Obligations**”) at or after the Effective Time. In the event the Company exercises this option, the Series Note Obligations will be deemed to equal the product of 4.5 (which was previously 1.6 prior to the Series Note Amendments) (such figure, the “**Conversion Rate**”) and the outstanding Series Note Obligations. Notwithstanding the foregoing, if the registration statement filed in connection with the Uplist Transaction, which this offering is intended to qualify as, is not declared effective by 11:59 P.M. (EST) on March 15, 2023 or such later extended date as provided for therein (the “**Series Note Amendments Termination Date**”), the Series Note Amendments will automatically terminate without any further action by the Company or the Series Convertible Notes holders. The Series Note Amendments Termination Date will be automatically extended upon any extension of the First Note Amendment Termination Date (as defined in Amendment No. 8 to the 2022 Notes). As a result of Amendment No. 11 to the 2022 Notes, the Series Note Amendments Termination Date was automatically extended from September 30, 2023, to October 31, 2023.

On July 12, 2023, the Company secured countersigned notices of conversion from all remaining holders of the Series 1 Convertible Notes and provided instructions to its transfer agent to issue a total of 59,912 shares of Common Stock in full satisfaction of all previously outstanding Series 1 Convertible Notes, which had an aggregate of \$718,918 of principal and interest outstanding at the time of conversion. As of September 15, 2023, there was \$587,959 of principal and accrued interest (through maturity) outstanding under the Series 2 Notes.

Item 16. Exhibits and Financial Statement Schedules

Exhibits

EXHIBIT INDEX

Exhibit No.	Exhibit Title	Filed Herewith	Incorporated By Reference			
			Form	Exhibit No.	File No.	Filing Date
1.1	Form of Underwriting Agreement	X				
1.2	Form of Warrant Agency Agreement	X				
1.3	Form of Pre-Funded Warrant Agency Agreement	X				
3.1	Restated Articles of Incorporation of Arch Therapeutics, Inc.		10-Q	3.1	000-54986	07/23/2020
3.2	Amended and Restated Bylaws, as adopted on August 15, 2022		8-K/A	3.1	000-54986	08/17/2022
3.3	Amendment No. 1 to the Amended and Restated Bylaws, as adopted on July 18, 2023		8-K	3.1	000-54986	7/24/2023
4.1	Description of Securities		10-K	4.1	000-54986	12/11/2020
4.2	Form of Investor Warrant	X				
4.3	Form of Underwriter Warrant	X				
4.4	Form of Pre-Funded Warrant	X				
4.4	Form of Pre-Funded Warrant		10-Q	4.1	000-54986	8/11/2023
4.5	Form of Common Warrant		10-Q	4.2	000-54986	8/11/2023
4.6	Form of Placement Agent Warrant		8-K	4.3	000-54986	09/07/2023
5.1*	Opinion of McDonald Carano LLP					
5.2*	Opinion of Lowenstein Sandler LLP					
10.1#	Executive Employment Agreement dated June 26, 2013 between Arch Therapeutics, Inc. and Terrence W. Norchi		8-K	10.8	333-178883	6/26/2013
10.2#	First Amendment to Executive Employment Agreement, dated March 23, 2014, by and between Arch Therapeutics, Inc. and Terrence W. Norchi Stock		8-K	10.1	000-54986	3/27/2014
10.3#	Arch Therapeutics, Inc. 2013 Stock Incentive Plan		8-K	10.1	333-178883	6/24/2013

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10.4#	Form of Stock Option Award Agreement under Arch Therapeutics, Inc. 2013 Stock Incentive Plan	10-Q	10.13	000-54986	8/14/2013
10.5#	Form of Restricted Stock Unit Award Agreement under Arch Therapeutics, Inc. 2013 Stock Incentive Plan	10-Q	10.14	000-54986	8/14/2013
10.6#	Form of Restricted Stock Bonus Award Agreement under Arch Therapeutics, Inc. 2013 Stock Incentive Plan	10-Q	10.15	000-54986	8/14/2013
10.7#	Form of Restricted Stock Award Agreement	8-K	10.2	000-54986	5/6/2016
10.8	Amended and Restated Exclusive Patent License Agreement dated May 23, 2011 between ABS and the Massachusetts Institute of Technology, as amended by the First Amendment to Amended and Restated Exclusive Patent License Agreement dated May 15, 2012 between ABS and the Massachusetts Institute of Technology, and further amended by the Second Amendment to Amended and Restated Exclusive Patent License Agreement dated February 1, 2013 between ABS and the Massachusetts Institute of Technology, as further amended by the Third Amendment to Amended and Restated Exclusive Patent License Agreement dated April 30, 2013 between ABS and the Massachusetts Institute of Technology, and as further amended by the Letter Agreement dated June 10, 2013 between ABS and the Massachusetts Institute of Technology	8-K	10.6	333-178883	6/26/2013
10.9	Form of Warrant to Purchase Shares of Common Stock dated September 30, 2013 issued by Arch Therapeutics, Inc. to the Massachusetts Life Sciences Center ((included as Exhibit B in Exhibit 10.22))	8-K	10.2	000-54986	10/4/2013
10.10	Form of MLSC Subordination Agreement	8-K	10.1	000-54986	09/09/2013
10.11	Amendment Agreement to Arch Therapeutics, Inc. Accelerator Funding Agreement dated September 28, 2016 by and between Arch Therapeutics, Inc. and Massachusetts Life Sciences Center	8-K	10.1	000-54986	09/29/2016
10.12	Form of Subscription Agreement	8-K	10.1	000-54986	3/13/2015
10.13†	Project Agreement by and between Arch Therapeutics, Inc. and the National University of Ireland Galway dated May 28, 2015	8-K	10.1	000-54986	08/07/2015
10.14	2018 Securities Purchase Agreement	8-K	10.1	000-54986	06/29/2018
10.15	Form of Series G Warrants	8-K	10.2	000-54986	06/29/2018

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10.16#	<u>Offer Letter to Join the Board of Directors of Arch Therapeutics, Inc. dated July 19, 2018, by and between Arch Therapeutics, Inc. and Punit Dhillon</u>	8-K	10.4	000-54986	07/20/2018
10.17	<u>May 2019 Securities Purchase Agreement</u>	8-K	10.1	000-54986	05/13/2019
10.18	<u>Form of Series H Warrants</u>	8-K	10.2	000-54986	05/13/2019
10.19	<u>Form of October 2019 Securities Purchase Agreement</u>	8-K	10.1	000-54986	10/18/2019
10.20	<u>Form of Series I Warrants</u>	8-K	10.2	000-54986	10/18/2019
10.21	<u>2019 Engagement Agreement</u>	8-K	10.3	000-54986	10/18/2019
10.22	<u>Form of 2019 Placement Agent Warrant</u>	8-K	10.4	000-54986	10/18/2019
10.23	<u>Form of Amendment to Series D Warrants to Purchase Common Stock</u>	8-K	10.1	000-54986	06/05/2020
10.24	<u>Form of Series J Warrant</u>	8-K	10.2	000-54986	06/05/2020
10.25	<u>Form of Series 1 Convertible Notes</u>	8-K	10.3	000-54986	06/05/2020
10.25.1	<u>Form of Amendment No. 1 to Series 1 Notes, dated March 10, 2023</u>	8-K	10.6	000-54986	03/17/2023
10.26	<u>Amendment to Series J Warrant to Purchase Common Stock</u>	8-K	10.1	000-54986	11/10/2020
10.27	<u>Form of Series 2 Convertible Notes</u>	8-K	10.2	000-54986	11/10/2020
10.27.1	<u>Form of Amendment No. 1 to Series 2 Notes, dated March 10, 2023</u>	8-K	10.7	000-54986	03/17/2023
10.28	<u>Form of 2021 Securities Purchase Agreement</u>	8-K	10.1	000-54986	02/12/2021
10.29	<u>Form of Series K Warrant</u>	8-K	10.2	000-54986	02/12/2021
10.30	<u>2021 Engagement Agreement</u>	8-K	10.3	000-54986	02/12/2021
10.31	<u>Form of 2021 Placement Agent Warrant</u>	8-K	10.4	000-54986	02/12/2021
10.32	<u>Form of Registration Rights Agreement</u>	8-K	10.5	000-54986	02/12/2021

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10.33	<u>Executive Employment Agreement, effective May 3, 2021, by and between Arch Therapeutics, Inc. and Michael S. Abrams</u>	8-K	10.2	000-54986	05/3/2021
10.34	<u>Employment Agreement, effective June 30, 2021, by and between Arch Therapeutics, Inc. and Dan M. Yrigoyen</u>	8-K	10.1	000-54986	08/11/2021
10.35	<u>First Amendment to Employment Agreement, effective August 9, 2021, by and between Arch Therapeutics, Inc. and Dan M. Yrigoyen</u>	8-K	10.2	000-54986	08/11/2021
10.36	<u>Form of Securities Purchase Agreement, dated July 6, 2022, by and among the Company and the signatories thereto</u>	8-K	10.1	000-54986	07/8/2022
10.37	<u>Form of First Notes</u>	8-K	10.2	000-54986	07/8/2022
10.37.1	<u>Form of First Notes Amendment</u>	8-K	10.1	000-54986	02/16/2023
10.37.2	<u>Form of Amendment No. 2 to First Notes, dated March 10, 2023</u>	8-K	10.2	000-54986	03/17/2023
10.37.3	<u>Form of Amendment No. 3 to First Notes, dated March 15, 2023</u>	8-K	10.4	000-54986	03/17/2023
10.37.4	<u>Form of Amendment No. 4 to First Notes, dated April 15, 2023</u>	8-K	10.1	000-54986	04/20/2023
10.37.5	<u>Form of Amendment No. 5 to First Notes</u>	10-Q	10.5	000-54986	05/23/2023
10.37.6	<u>Form of Amendment No. 6 to First Notes, dated June 15, 2023</u>	8-K	10.1	000-54986	06/22/2023
10.37.7	<u>Form of Amendment No. 7 to First Notes, dated July 1, 2023</u>	8-K	10.1	000-54986	07/07/2023
10.37.8	<u>Form of Amendment No. 8 to First Notes</u>	10-Q	10.17	000-54986	08/11/2023
10.37.9	<u>Form of Amendment No. 9 to First Notes, dated July 31, 2023</u>	8-K	10.1	000-54986	08/4/2023
10.37.10	<u>Form of Amendment No. 10 to First Notes, dated August 30, 2023</u>	8-K	10.1	000-54986	09/06/2023
10.38	<u>Form of First Warrant</u>	8-K	10.3	000-54986	07/08/2022
10.39	<u>Form of Registration Rights Agreement, dated July 6, 2022, by and among the Company and the signatories thereto</u>	8-K	10.4	000-54986	07/08/2022
10.40^	<u>Form of Security Agreement, dated July 6, 2022, by and among the Company and the signatories thereto</u>	8-K	10.5	000-54986	07/08/2022

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10.41	Form of Second Note	8-K	10.2	000-54986	01/20/2023
10.41.1	Form of Second Note Amendment	8-K	10.2	000-54986	02/16/2023
10.41.2	Form of Amendment No. 2 to Second Notes, dated March 10, 2023	8-K	10.3	000-54986	03/17/2023
10.41.3	Form of Amendment No. 3 to Second Notes, dated March 15, 2023	8-K	10.5	000-54986	03/17/2023
10.41.4	Form of Amendment No. 4 to Second Notes, dated April 15, 2023	8-K	10.2	000-54986	04/20/2023
10.41.5	Form of Amendment No. 5 to Second Notes	10-Q	10.6	000-54986	05/23/2023
10.41.6	Form of Amendment No. 6 to Second Notes, dated June 15, 2023	8-K	10.2	000-54986	06/22/2023
10.41.7	Form of Amendment No. 7 to Second Notes, dated July 1, 2023	8-K	10.2	000-54986	07/07/2023
10.41.8	Form of Amendment No. 8 to Second Notes	10-Q	10.18	000-54986	08/11/2023
10.41.9	Form of Amendment No. 9 to Second Notes, dated July 31, 2023	8-K	10.2	000-54986	08/4/2023
10.41.10	Form of Amendment No. 10 to Second Notes, dated August 30, 2023	8-K	10.2	000-54986	09/06/2023
10.42	Form of Second Warrant	8-K	10.3	000-54986	01/20/2023
10.43	Form of Amended and Restated Registration Rights Agreement, dated January 18, 2023, by and among the Company and the signatories thereto	8-K	10.4	000-54986	01/20/2023
10.43.1	Form of Amendment No. 1 to the A&R Registration Rights Agreement	8-K	10.3	000-54986	04/20/2023
10.44^	Form of Amendment No. 1 to Securities Purchase Agreement, dated January 18, 2023, by and among the Company and the signatories thereto	8-K	10.1	000-54986	01/20/2023
10.45^	Form of Amendment No. 2 to Securities Purchase Agreement, dated May 15, 2023, by and among the Company and the signatories thereto	10-Q	10.1	000-54986	05/23/2023
10.46	Form of Exchange Agreement, dated March 10, 2023	8-K	10.1	000-54986	03/17/2023

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10.47	Form of Third Note	10-Q	10.2	000-54986	05/23/2023
10.47.1	Form of Amendment No. 1 to Third Notes, dated June 15, 2023	8-K	10.3	000-54986	06/22/2023
10.47.2	Form of Amendment No. 2 to Third Notes, dated July 1, 2023	8-K	10.3	000-54986	07/07/2023
10.47.3	Form of Amendment No. 3 to Third Notes	10-Q	10.19	000-54986	08/11/2023
10.47.4	Form of Amendment No. 4 to Third Notes, dated July 31, 2023	8-K	10.3	000-54986	08/04/2023
10.47.5	Form of Amendment No. 5 to Third Notes, dated August 30, 2023	8-K	10.3	000-54986	09/06/2023
10.48	Form of Third Warrant	10-Q	10.3	000-54986	05/23/2023
10.49	Form of Second A&R Registration Rights Agreement	10-Q	10.4	000-54986	05/23/2023
10.49.1	Form of Amendment No. 1 to Second A&R Registration Rights Agreement	8-K	10.4	000-54986	09/06/2023
10.50#	Arch Therapeutics, Inc. Amended and Restated 2023 Omnibus Equity Incentive Plan	8-K	10.1	000-54986	08/23/2023
10.51	Form of Omnibus Amendment to Notes and Warrants	10-Q	10.20	000-54986	08/11/2023
10.52^	Form of Securities Purchase Agreement, dated July 7, 2023, by and among the Company and the signatories thereto	10-Q	10.24	000-54986	08/11/2023
10.52.1	Form of Amendment No. 1 to Securities Purchase Agreement	8-K	10.5	000-54986	09/06/2023

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10.53	Form of Registration Rights Agreement, dated July 7, 2023, by and among the Company and the signatories thereto	10-Q	10.25	000-54986	08/11/2023
10.53.1	Form of Amendment No. 1 to Registration Rights Agreement	10-K	10.6	000-54986	09/06/2023
21.1	List of Subsidiaries	8-K	21.1	333-178883	06/26/2013
23.1	Consent of Baker Tilly US, LLP, Independent Registered Public Accounting Firm				X
23.2*	Consent of McDonald Carano LLP (included in Exhibit 5.1)				
23.3*	Consent of Lowenstein Sandler LLP (included in Exhibit 5.2)				
24.1**	Power of Attorney (included in the signature page to this registration statement)	S-1	24.1	333-268008	10/26/2022
101.INS	Inline XBRL Instance Document				
101.SCH	Inline XBRL Taxonomy Extension Schema Document				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document and included in Exhibit 101)				
107 **	Filing fee table				X

* To be filed by amendment.

**Previously filed.

^ Pursuant to Item 601(b)(10) of Regulation S-K, certain identified information has been excluded from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed. Further, the schedules and exhibits to this agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission upon request.

† Confidential treatment has been granted as to certain portions of these Exhibits.

Management contract or compensatory plan or arrangement.

Financial Statement Schedules

All financial statement schedules are omitted because they are not applicable or the required information is shown in the consolidated financial statements or notes thereto.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:
 - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
 - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and
 - (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement; provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or 15(d) of the Exchange Act that are incorporated by reference in the registration statement.
- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of the securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered that remain unsold at the termination of the offering.
- (4) That, for the purpose of determining liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A (§ 230.430A of Title 17 of the Code of Federal Regulations), shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.
- (5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this Registration Statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

- (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424 (§230.424 of Title 17 of the Code of Federal Regulations);
- (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
- (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
- (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

- (6) The undersigned registrant hereby undertakes that:
- (i) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance on Rule 430A and contained in a form of prospectus filed by the undersigned registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective; and
 - (ii) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (7) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Framingham, State of Massachusetts, on October 5, 2023.

Arch Therapeutics, Inc.

By: /s/ Terrence W. Norchi, MD
Terrence W. Norchi, MD
President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

<u>SIGNATURE</u>	<u>TITLE</u>	<u>DATE</u>
<u>/s/ Terrence W. Norchi, MD</u> Terrence W. Norchi, MD	President, Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	October 5, 2023
<u>/s/ Michael S. Abrams</u> Michael S. Abrams	Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	October 5, 2023
<u>*</u> Punit Dhillon	Director	October 5, 2023
<u>*</u> Guy Fish, MD	Director	October 5, 2023
<u>*</u> Laurence Hicks	Director	October 5, 2023

*By: */s/ Terrence W. Norchi, Attorney-in-Fact*

UNDERWRITING AGREEMENT

[●], 2023

DAWSON JAMES SECURITIES, INC.
101 N. Federal Highway Suite 600
Newport Beach, CA 92660

*As Representative of the several Underwriters
named on Schedule 1 attached hereto*

Ladies and Gentlemen:

The undersigned, Arch Therapeutics, Inc., a Nevada corporation (the “Company”), hereby confirms its agreement (this “Agreement”) with Dawson James Securities Inc. (the “Representative”) and with the other underwriters, if any, named on Schedule 1 hereto for which the Representative is acting as representative (the Representative and such other underwriters being collectively called the “Underwriters” or, individually, an “Underwriter”) as follows:

1. Purchase and Sale of Shares and Warrants.

(a) Firm Shares and Firm Warrants.

(i) Nature and Purchase of Firm Shares and Firm Warrants.

(A) On the basis of the representations and warranties herein contained, but subject to the terms and conditions herein set forth, the Company agrees to issue and sell to the Underwriters an aggregate of [] units (each a “Unit,” and collectively, the “Units”), each comprised of one share (individually, “Firm Share”; collectively, the “Firm Shares”) of Company common stock, par value \$0.001 per share (the “Common Shares”), or in lieu of a Common Share, and (ii) a warrant to purchase one Common Share at an exercise price of \$[●] per share (individually, “Firm Warrant” and, collectively, the “Firm Warrants”). To the extent that the purchase of Firm Shares would cause the beneficial ownership of a purchaser in the Offering, together with its affiliates and certain related parties, to exceed 9.99% of the Common Shares, the Company agrees to issue the Underwriters, for delivery to such purchasers, at the election of the purchasers, a number of Pre-Funded Warrants (individually “Pre-Funded Warrant”; collectively, the “Pre-Funded Warrants”), which are initially convertible on a 1-for-1 basis into Common Shares, at an exercise price of \$0.001 per Common Share in lieu of the Firm Shares. The Firm Warrants, the Firm Shares and the Pre-Funded Warrants are hereafter collectively referred to as the “Firm Securities”.

(B) The Underwriters, severally and not jointly, agree to purchase from the Company the number of Units set forth opposite their respective names on Schedule 1 attached hereto and made a part hereof. The combined purchase price for one Unit shall be \$[●] (92% of the public offering price per Unit of \$[●]) which shall be allocated as \$[●] per Firm Share (or Pre-Funded Warrant) and \$[0.0092] per Firm Warrant; *provided, that* with respect to directed offers from investors introduced to the Offering by the Company, the combined purchase price for one Unit shall be \$[●] (96% of the public offering price per Unit of \$[●]) which shall be allocated as \$[●] per Firm Share (or Pre-Funded Warrant) and \$[0.0096] per Firm Warrant. The Units are to be offered initially to the public at the offering price set forth on the cover page of the Prospectus (as defined in Section 2(a)(B) hereof) (the “Purchase Price”). The Firm Shares (or Pre-Funded Warrants) and the Firm Warrants will be separated immediately upon issuance.

(ii) Securities Payment and Delivery.

(A) Delivery and payment for the Units shall be made no later than 2:00 p.m., Eastern Time, on the second (2^d) Business Day following the effective date (the “Effective Date”) of the Registration Statement (as defined in Section 2(a)(i)(A) below) (or the third (3^d) Business Day following the Effective Date if the Registration Statement is declared effective after 4:01 p.m., Eastern Time) or at such other time as shall be agreed upon by the Representative and the Company, at the offices of ArentFox Schiff LLP, 1717 K Street NW, Washington DC 20006 (“Representative’s Counsel”), or at such other place (or by electronic transmission) as shall be agreed upon by the Representative and the Company. The hour and date of delivery and payment for the Units is called the “Closing Date.”

(B) Payment for the Units shall be made on the Closing Date by wire transfer in federal (same day) funds, payable to the order of the Company upon delivery of the certificates (in form and substance satisfactory to the Underwriters) (or through the facilities of the Depository Trust Company ("DTC")), for the account of the Underwriters. The Firm Shares and Firm Warrants underlying the Units shall be registered in such name or names and in such authorized denominations as the Representative may request in writing prior to the Closing Date. The Company shall not be obligated to sell or deliver the Firm Shares and Firm Warrants underlying the Units except upon tender of payment by the Representative for all of the Units or via delivery versus payment for the Units. The term "Business Day" means any day other than a Saturday, a Sunday or a legal holiday or a day on which banking institutions are authorized or obligated by law to close in New York, New York.

(b) Over-Allotment Option.

(i) Option Securities. For the purposes of covering any over-allotments in connection with the distribution and sale of the Units, the Company hereby grants to the Representative an option (the "Over-Allotment Option") to purchase, in the aggregate, (a) up to [●] additional Common Shares (15% of the Firm Shares and Pre-Funded Warrants underlying the Units) at a purchase price per share of \$[●] (92% of the public offering price allocated to each Firm Share) (the "Option Shares") and together with the Firm Shares, the "Shares"), and/or (b) [●] warrants to purchase an aggregate of [●] Common Shares (15% of the Firm Warrants) at a purchase price of \$[0.0092] per warrant (92% of the public offering price allocated to each set of Firm Warrants) (the "Option Warrants") and together with the Firm Warrants, the "Warrants"), which may be purchased in any combination of Option Shares and/or Option Warrants. The Option Shares and the Option Warrants are referred to as the "Option Securities". The Firm Securities and the Option Securities are collectively referred to as the "Public Securities." The Public Securities shall be issued directly by the Company and shall have the rights and privileges described in the Registration Statement, the Pricing Disclosure Package and the Prospectus referred to below. The offering and sale of the Public Securities is hereinafter referred to as the "Offering."

(ii) Exercise of Over-Allotment Option. The Over-Allotment Option granted pursuant to Section 1(b)(i) hereof may be exercised by the Representative as to all (at any time) or any part (from time to time) of the Option Securities within 45 days after the Closing Date. An Underwriter shall not be under any obligation to purchase any Option Securities prior to the exercise of the Over-Allotment Option by the Representative. The Over-Allotment Option granted hereby may be exercised by the giving of oral notice to the Company from the Representative, which must be confirmed in writing by overnight mail or by email or other electronic transmission setting forth the number of Option Shares and/or Option Warrants to be purchased and the date and time for delivery of and payment for the Option Shares and/or Option Warrants, as the case may be (each, an "Option Closing Date"), which shall not be earlier than one (1) Business Day nor later than five (5) full Business Days after the date of the written notice or such other time as shall be agreed upon by the Company and the Representative, at the offices of the Representative's Counsel, or at such other place (including remotely by electronic transmission) as shall be agreed upon by the Company and the Representative. If such delivery and payment for the Option Shares and/or Option Warrants does not occur on the Closing Date, each Option Closing Date will be as set forth in the notice. Upon exercise of the Over-Allotment Option, the Company will become obligated to convey to the Representative, and, subject to the terms and conditions set forth herein, the Representative will become obligated to purchase, the number of Option Shares and/or Option Warrants specified in such notice.

(iii) Payment and Delivery. Payment for the Option Shares and/or Option Warrants shall be made on the Option Closing Date by wire transfer in federal (same day) funds, payable to the order of the Company upon delivery to the Representative of certificates (in form and substance satisfactory to the Representative) representing the Option Shares and/or Option Warrants (or through the facilities of the DTC or Deposit/Withdrawal at Custodian transfer) for the account of the Representative. The Option Shares and/or Option Warrants shall be registered in such name or names and in such authorized denominations as the Representative may request in writing prior to the Option Closing Date. The Company shall not be obligated to sell or deliver the Option Shares and/or Option Warrants except upon tender of payment by the Representative for the applicable Option Shares and/or Option Warrants.

(c) Representative's Warrant.

(i) Representative's Warrant. The Company hereby agrees to issue to the Representative (and/or its designees) on the Closing Date a warrant for the purchase of the number of Common Shares equal to 5.0% of the Firm Shares and the Common Shares underlying the Pre-Funded Warrants and Firm Warrants underlying the Units issued in the Offering, pursuant to a warrant agreement in the form attached hereto as Exhibit A (the "Representative's Warrant"), at an initial exercise price of \$[●] per share, which is equal to 125% of the public offering price for one Unit. The Representative's Warrant and the Common Shares issuable upon exercise of the Representative's Warrant are hereinafter referred to together as the "Representative's Securities." The Representative understands and agrees that there are significant restrictions pursuant to FINRA Rule 5110 against transferring the Representative's Warrant and the underlying securities during the 180 days after the commencement date of sales in the Offering and by its acceptance thereof shall agree that it will not sell, transfer, assign, pledge or hypothecate the Representative's Warrant, or any portion thereof, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of such securities for a period of 180 days after the commencement date of sales in the Offering, except as expressly permitted by FINRA Rule 5110(e), and only if any such transferee agrees to the foregoing lock-up restrictions.

(i i) Delivery. Delivery of the Representative's Warrant shall be made on the Closing Date, and shall be issued in the name or names and in such authorized denominations as the Representative may reasonably request.

2. Representations and Warranties of the Company. The Company represents and warrants to the Underwriters as of the Applicable Time (as defined below) and as of the Closing Date, or any Option Closing Date, as follows:

(a) Registration Matters.

(i) Pursuant to the Securities Act

(A) The Company has filed with the U.S. Securities and Exchange Commission (the "Commission") a registration statement, and amendments thereto, on Form S-1 (File No. 333-268008), including any related prospectus or prospectuses (the "Prospectus"), for the registration of the Public Securities, the Representative's Securities and the Underlying Common Stock (as defined below) under the Securities Act of 1933, as amended (the "Securities Act"), which registration statement and amendment or amendments have been prepared by the Company in conformity in all material respects with the requirements of the Securities Act and the rules and regulations of the Commission under the Securities Act (the "Securities Act Regulations") and will contain all material statements that are required to be stated therein in accordance with the Securities Act and the Securities Act Regulations. Except as the context may otherwise require, such registration statement, as amended, on file with the Commission at the time the registration statement became effective (including the Preliminary Prospectus included in the registration statement, financial statements, schedules, exhibits and all other documents filed as a part thereof and all information deemed to be a part thereof as of the Effective Date pursuant to paragraph (b) of Rule 430A of the Securities Act Regulations (the "Rule 430A Information")), is referred to herein as the "Registration Statement." If the Company files any registration statement pursuant to Rule 462(b) of the Securities Act Regulations, then after such filing, the term "Registration Statement" shall include such registration statement filed pursuant to Rule 462(b). The Registration Statement has been declared effective by the Commission on the date hereof.

(B) Each prospectus used prior to the effectiveness of the Registration Statement, and each prospectus that omitted the Rule 430A Information that was used after such effectiveness and prior to the execution and delivery of this Agreement, is herein called a "Preliminary Prospectus." The Preliminary Prospectus, subject to completion, dated [____], 2023, that was included in the Registration Statement immediately prior to the Applicable Time is hereinafter called the "Pricing Prospectus." The final prospectus in the form first furnished to the Underwriters for use in the Offering is hereinafter called the "Prospectus." Any reference to the "most recent Preliminary Prospectus" shall be deemed to refer to the latest Preliminary Prospectus included in the Registration Statement.

(C) The term “Pricing Disclosure Package” means (i) the Preliminary Prospectus, as most recently amended or supplemented immediately prior to the Applicable Time (as defined herein), and (ii) the information included on Schedule 2 of this Agreement.

(D) “Applicable Time” means 4:30 p.m., Eastern Time, on the date of this Agreement.

(ii) Pursuant to the Exchange Act. The Company has filed with the Commission a Form 8-A providing for the registration pursuant to Section 12(b) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), of the Firm Securities. The registration of the Firm Securities under the Exchange Act will be effective on or prior to the date hereof. The Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Common Shares or Warrants under the Exchange Act, nor has the Company received any notification that the Commission is contemplating terminating such registration.

(b) Stock Exchange Listing. The Common Shares and Warrants have been approved for listing on The Nasdaq Capital Market (the “Exchange”), and the Company has taken no action designed to, or likely to have the effect of, delisting the Common Shares or Warrants from the Exchange, nor has the Company received any notification that the Exchange is contemplating terminating such listing. The Company is in compliance with all continued listing criteria and rules of the Exchange, including but not limited to newly-adopted Rule 5608.

(c) No Stop Orders, etc. Neither the Commission nor, to the Company’s knowledge, any state regulatory authority has issued any order preventing or suspending the use of the Registration Statement, any Preliminary Prospectus or the Prospectus or has instituted or, to the Company’s knowledge, threatened to institute, any proceedings with respect to such an order. The Company has complied with each request (if any) from the Commission for additional information.

(d) Organization; Good Standing; No Subsidiaries. The Company has been duly incorporated and is validly existing as entities in good standing under the laws of the State of Nevada, with power and authority to own, lease and operate its respective properties and conduct its respective businesses as described in the Preliminary Prospectus, and has been duly qualified as foreign corporation for the transaction of business and is in good standing under the laws of each other jurisdiction in which it owns or leases properties or conducts any business so as to require such qualification, except where the failure so to qualify or be in good standing would not have a Material Adverse Change (as defined in Section 2(f)(i)). The Company is not in violation or default of any of the provisions of its certificate of incorporation, bylaws or other organizational or charter documents. Other than [____], the Company does not have any direct or indirect subsidiaries.

(e) Disclosures in Registration Statement.

(i) Compliance with Securities Act and 10b-5 Representation.

(A) Each of the Registration Statement and any post-effective amendment thereto, at the time it became effective, complied in all material respects with the requirements of the Securities Act and the Securities Act Regulations. Each Preliminary Prospectus, including the prospectus filed as part of the Registration Statement as originally filed or as part of any amendment or supplement thereto, and the Prospectus, at the time each was filed with the Commission, complied in all material respects with the requirements of the Securities Act and the Securities Act Regulations. Each Preliminary Prospectus delivered to the Underwriters for use in connection with this Offering and the Prospectus was or will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(B) Neither the Registration Statement nor any amendment thereto, at its respective effective time, contained, contains or will contain an untrue statement of a material fact or omitted, omits or will omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading; provided, however, that this representation and warranty shall not apply to the Underwriters’ Information (as defined below).

(C) The Pricing Disclosure Package, as of the Applicable Time, at the Closing Date or at any Option Closing Date, did not and does not, and will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided, however, that this representation and warranty shall not apply to statements made or statements omitted in reliance upon and in conformity with written information furnished to the Company with respect to the Underwriters by the Representative expressly for use in the Registration Statement, the Preliminary Prospectus or the Prospectus or any amendment thereof or supplement thereto. The parties acknowledge and agree that such information provided by or on behalf of any Underwriter consists solely of the following disclosure contained in the following paragraphs in the “Underwriting” section of the Prospectus: (i) the names of the several underwriters, and (ii) the information under the subsections “Discounts and Commissions; Expenses”; “Discretionary Accounts,” “Price Stabilization, Short Positions and Penalty Bids;” and “Electronic Distribution” (the “Underwriters’ Information”); and

(D) Neither the Prospectus nor any amendment or supplement thereto (including any prospectus wrapper), as of its issue date, at the time of any filing with the Commission pursuant to Rule 424(b), or at the Closing Date, included, includes or will include an untrue statement of a material fact or omitted, omits or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided, however, that this representation and warranty shall not apply to the Underwriters’ Information.

(i i) Disclosure of Agreements. The agreements and documents described in the Registration Statement, the Pricing Disclosure Package and the Prospectus conform in all material respects to the descriptions thereof contained therein and there are no agreements or other documents required by the Securities Act and the Securities Act Regulations to be described in the Registration Statement, the Pricing Disclosure Package and the Prospectus or to be filed with the Commission as exhibits to the Registration Statement, that have not been so described or filed. Each agreement or other instrument (however characterized or described) to which the Company is a party or by which it is or may be bound or affected and (i) that is referred to in the Registration Statement, the Pricing Disclosure Package and the Prospectus, and (ii) is material to the Company’s business, has been duly authorized and validly executed by the Company, is in full force and effect in all material respects and is enforceable against the Company and, to the Company’s knowledge, the other parties thereto, in accordance with its terms, except (w) for such agreements or instruments for enforceability of which would not reasonably be expected to result, individually or in the aggregate, in a Material Adverse Change, (x) as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting creditors’ rights generally, (y) as enforceability of any indemnification or contribution provision may be limited under the federal and state securities laws, and (z) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefor may be brought. Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, none of such agreements or instruments has been assigned by the Company, and neither the Company nor, to the Company’s knowledge, any other party is in material default thereunder and, to the Company’s knowledge, no event has occurred that, with the lapse of time or the giving of notice, or both, would constitute a material default thereunder, except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, or which would not reasonably be expected to result, individually or in the aggregate, in a Material Adverse Change. To the Company’s best knowledge, performance by the Company of the material provisions of such agreements or instruments will not result in a violation of any existing applicable law, rule, regulation, judgment, order or decree of any governmental agency or court, domestic or foreign, having jurisdiction over the Company or any of its assets or businesses (each, a “Governmental Entity”), including, without limitation, those relating to environmental laws and regulations, except such violations which would not reasonably be expected to result, individually or in the aggregate, in a Material Adverse Change.

(iii) Prior Securities Transactions. Since the beginning of the last two full fiscal years, no securities of the Company have been sold by the Company or by or on behalf of, or for the benefit of, any person or persons controlling, controlled by or under common control with the Company, except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Preliminary Prospectus.

(iv) Regulations. The disclosures in the Registration Statement, the Pricing Disclosure Package and the Prospectus concerning the effects of federal, state, local and foreign laws, rules and regulations relating to the Company’s business as currently contemplated are correct in all material respects and no other such regulations are required to be disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus which are not so disclosed.

(f) Changes After Dates in Registration Statement.

(i) No Material Adverse Change. Since the respective dates as of which information is given in the Registration Statement, the Pricing Disclosure Package and the Prospectus, except as otherwise specifically stated therein: (i) there has been no material adverse change in the financial position or results of operations of the Company, nor, to the Company's knowledge, any change or development that, singularly or in the aggregate, would involve a material adverse change in or affecting the condition (financial or otherwise), results of operations, business or assets of the Company, taken as a whole (a "Material Adverse Change"); (ii) there have been no material transactions entered into by the Company, other than as contemplated pursuant to this Agreement; and (iii) no officer or director of the Company has resigned from any position with the Company.

(ii) Recent Securities Transactions, etc. Subsequent to the respective dates as of which information is given in the Registration Statement, the Pricing Disclosure Package and the Prospectus, and except as may otherwise be indicated or contemplated herein or disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company has not: (i) issued any securities (other than (i) grants under any stock compensation plan and (ii) Common Shares issued upon exercise or conversion of option, warrants or convertible securities described in the Registration Statement, the Pricing Disclosure Package and the Prospectus) or incurred any liability or obligation, direct or contingent, for borrowed money; or (ii) declared or paid any dividend or made any other distribution on or in respect to its capital stock.

(g) Independent Accountants. To the knowledge of the Company, Baker Tilly US, LLP, during such time as it was engaged by the Company (the "Auditors"), has been and is an independent registered public accounting firm as required by the Securities Act and the Securities Act Regulations and the Public Company Accounting Oversight Board. During such time period in which the Auditors served as the Company's independent registered public accounting firm, the Auditors did not or have not, during the periods covered by the financial statements included in the Registration Statement, the Pricing Disclosure Package and the Prospectus, provided to the Company any non-audit services, as such term is used in Section 10A(g) of the Exchange Act.

(h) Financial Statements, etc. The financial statements, including the notes thereto and supporting schedules included in the Registration Statement, the Pricing Disclosure Package and the Prospectus, fairly present in all material respects the financial position and the results of operations of the Company at the dates and for the periods to which they apply; and such financial statements have been prepared in conformity with United States generally accepted accounting principles ("GAAP"), consistently applied throughout the periods involved (provided that unaudited interim financial statements are subject to year-end audit adjustments that are not expected to be material in the aggregate and do not contain all footnotes required by GAAP); and the supporting schedules included in the Registration Statement present fairly in all material respects the information required to be stated therein. Except as included therein, no historical or pro forma financial statements are required to be included in the Registration Statement, the Pricing Disclosure Package or the Prospectus under the Securities Act or the Securities Act Regulations. The pro forma and pro forma as adjusted financial information and the related notes, if any, included in the Registration Statement, the Pricing Disclosure Package and the Prospectus have been properly compiled and prepared in all material respects in accordance with the applicable requirements of the Securities Act and the Securities Act Regulations and present fairly in all material respects the information shown therein, and the assumptions used in the preparation thereof are reasonable and the adjustments used therein are appropriate to give effect to the transactions and circumstances referred to therein. All disclosures contained in the Registration Statement, the Pricing Disclosure Package or the Prospectus regarding "non-GAAP financial measures" (as such term is defined by the rules and regulations of the Commission), if any, comply with Regulation G of the Exchange Act and Item 10 of Regulation S-K of the Securities Act, to the extent applicable. Each of the Registration Statement, the Pricing Disclosure Package and the Prospectus discloses all material off-balance sheet transactions, arrangements, obligations (including contingent obligations), and other relationships of the Company with unconsolidated entities or other persons that may have a material current or future effect on the Company's financial condition, changes in financial condition, results of operations, liquidity, capital expenditures, capital resources, or significant components of revenues or expenses. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, (a) the Company has not incurred any material liabilities or obligations, direct or contingent, or entered into any material transactions other than in the ordinary course of business, (b) the Company has not declared or paid any dividends or made any distribution of any kind with respect to its capital stock, (c) there has not been any change in the capital stock of the Company (other than (i) grants under any stock compensation plan and (ii) Common Shares issued upon exercise or conversion of option, warrants or convertible securities described in the Registration Statement, the Pricing Disclosure Package and the Prospectus), and (d) there has not been any Material Adverse Change in the Company's long-term or short-term debt.

(i) Authorized Capital; Options, etc. The Company had, at the date or dates indicated in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the duly authorized, issued and outstanding capitalization as set forth therein. Based on the assumptions stated in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company will have on the Closing Date the adjusted stock capitalization set forth therein. Except as set forth in, or contemplated by, the Registration Statement, the Pricing Disclosure Package and the Prospectus, on the Effective Date, as of the Applicable Time, and on the Closing Date, there will be no stock options, warrants, or other rights to purchase or otherwise acquire any authorized, but unissued Common Shares or any security convertible or exercisable into Common Shares, or any contracts or commitments to issue or sell Common Shares or any such options, warrants, rights or convertible securities.

(j) Valid Issuance of Securities, etc.

(i) Outstanding Securities. All issued and outstanding securities of the Company issued prior to the transactions contemplated by this Agreement have been duly authorized and validly issued and are fully paid and non-assessable; the holders thereof have no rights of rescission with respect thereto, and are not subject to personal liability by reason of being such holders; and none of such securities were issued in violation of the preemptive rights of any holders of any security of the Company or similar contractual rights granted by the Company. The offers and sales of the outstanding Common Shares were at all relevant times either registered under the Securities Act and the applicable state securities or "blue sky" laws or, based in part on the representations and warranties of the purchasers of such shares, exempt from such registration requirements. The authorized Common Shares and other outstanding securities conform in all material respects to all statements relating thereto contained in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

(ii) Securities Sold Pursuant to this Agreement. The Public Securities and the Representative's Securities have been duly authorized for issuance and sale and, when issued and paid for in accordance with the terms of this Agreement, will be validly issued, fully paid and non-assessable; the holders thereof are not and will not be subject to personal liability by reason of being such holders; the Public Securities and Representative's Securities are not and will not be subject to the preemptive rights of any holders of any security of the Company or similar contractual rights granted by the Company; and all corporate action required to be taken for the authorization, issuance and sale of the Public Securities and Representative's Securities has been duly and validly taken. The Public Securities and Representative's Securities conform in all material respects to all statements with respect thereto contained in the Registration Statement, the Pricing Disclosure Package and the Prospectus. The Common Shares issuable upon exercise of the Warrants and the Representative's Warrant (the "Underlying Common Stock") have been duly authorized and reserved for issuance by all necessary corporate action on the part of the Company and when paid for and issued in accordance with such Warrants or the Representative's Warrant, or exercised on a cashless basis as set forth in such Warrants or Representative's Warrant, if applicable, as the case may be, such shares of Underlying Common Stock will be validly issued, fully paid and non-assessable.

(k) Registration Rights of Third Parties. Except as set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus, no holders of any securities of the Company or any rights exercisable for or convertible or exchangeable into securities of the Company have the right to require the Company to register any such securities of the Company under the Securities Act or to include any such securities in a registration statement to be filed by the Company.

(l) Validity and Binding Effect of Agreements. This Agreement, the Warrant Agreement by and between the Company and Empire Stock Transfer (the "Warrant Agreement"), and the Representative's Warrant have been duly and validly authorized by the Company and, when executed and delivered, will constitute, the valid and binding agreements of the Company, enforceable against the Company in accordance with their respective terms, except: (i) as such enforceability may be limited by bankruptcy, insolvency, reorganization, fraudulent conveyance, fraudulent transfer, moratorium or similar laws affecting creditors' rights generally; (ii) as enforceability of any indemnification or contribution provision may be limited under the federal and state securities laws; and (iii) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefor may be brought.

(m) No Conflicts, etc. The execution, delivery and performance by the Company of this Agreement, the Warrant Agreement, the Representative's Warrant and all ancillary documents, the consummation by the Company of the transactions herein and therein contemplated and the compliance by the Company with the terms hereof and thereof do not and will not, with or without the giving of notice or the lapse of time or both: (i) result in a material breach of, or conflict with any of the terms and provisions of, or constitute a material default under, or result in the creation, modification, termination or imposition of any material lien, charge or encumbrance upon any property or assets of the Company pursuant to the terms of any agreement or instrument to which the Company is a party; (ii) result in any violation of the provisions of the Company's certificate of incorporation (as the same may be amended or restated from time to time, the "Charter") or the by-laws of the Company (as the same may be amended or restated from time to time, the "Bylaws"); or (iii) violate any existing law, rule, regulation, judgment, order or decree of any Governmental Entity applicable to the Company as of the date hereof (including, without limitation, those promulgated by the Food and Drug Administration of the U.S. Department of Health and Human Services (the "FDA") or by any foreign, federal, state or local regulatory authority performing functions similar to those performed by the FDA), except in the case of clauses (i) and (iii) above for any such breaches, conflicts or violations which would not reasonably be expected to result in a Material Adverse Change.

(n) Regulatory. Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus or as would not reasonably be expected to result, individually or in the aggregate, in a Material Adverse Change: (i) the Company has not received any FDA Form 483, written notice of adverse finding, warning letter or other correspondence or written notice from the FDA or any other Governmental Entity alleging or asserting noncompliance with any Applicable Laws (as defined in clause (ii) below) or Authorizations (as defined in clause (iii) below); (ii) the Company is and has been in material compliance with statutes, laws, ordinances, rules and regulations applicable to the Company, including, without limitation, all statutes, laws, ordinances, rules and regulations for the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product manufactured or distributed by the Company, including, without limitation, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq., similar laws of other Governmental Entities and the regulations promulgated pursuant to such laws (collectively, "Applicable Laws"); (iii) the Company possesses all licenses, certificates, approvals, clearances, consents, authorizations, qualifications, registrations, permits, and supplements or amendments thereto required by any such Applicable Laws and/or to carry on its businesses as now conducted ("Authorizations") and such Authorizations are valid and in full force and effect and the Company is not in violation of any term of any such Authorizations; (iv) the Company has not received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any Governmental Entity or third party alleging that any product, operation or activity is in violation of any Applicable Laws or Authorizations or has any knowledge that any such Governmental Entity or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding, nor, to the Company's knowledge, has there been any material noncompliance with or violation of any Applicable Laws by the Company that could reasonably be expected to require the issuance of any such communication or result in an investigation, corrective action, or enforcement action by the FDA or any other Governmental Entity; (v) the Company has not received written notice that any Governmental Entity has taken, is taking or intends to take action to limit, suspend, modify or revoke any Authorizations or has any knowledge that any such Governmental Entity has threatened or is considering such action; (vi) the Company has filed, obtained, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were, in all material respects, complete, correct and not misleading on the date filed (or were corrected or supplemented by a subsequent submission); and (vii) the Company has not, either voluntarily or involuntarily, initiated, conducted or issued, or caused to be initiated, conducted or issued, any recall, market withdrawal or replacement, safety alert, post-sale warning, "dear doctor" letter, or other notice or action relating to the alleged lack of safety or efficacy of any product or any alleged product defect or violation and, to the Company's knowledge, no third party has initiated, conducted or intends to initiate or conduct such notice or action. Neither the Company nor, to the Company's knowledge, any of its directors, officers, employees or agents (in their capacities as such) has been convicted of any crime under any Applicable Laws or has been the subject of an FDA debarment proceeding. The Company has not been or is now subject to FDA's Application Integrity Policy. To the Company's knowledge, neither the Company, nor any of its directors, officers, employees or agents (in their capacities as such), has made, or caused the making of, any false statements on, or material omissions from, any other records or documentation prepared or maintained to comply with the requirements of the FDA or any other Governmental Entity. Neither the Company nor, to the Company's knowledge, any of its directors, officers, employees or agents (in their capacities as such), have with respect to each of the following statutes, or regulations promulgated thereto, as applicable, : (i) engaged in activities under 42 U.S.C. §§ 1320a-7b or 1395nn; (ii) knowingly engaged in any activities under 42 U.S.C. § 1320a-7b or the Federal False Claims Act, 31 U.S.C. § 3729; or (iii) knowingly and willfully engaged in any activities under 42 U.S.C. § 1320a-7b, which are prohibited, cause for civil penalties, or mandatory or permissive exclusion from Medicare, Medicaid, or any other State Health Care Program or Federal Health Care Program.

(o) Clinical Studies. The studies, tests and clinical trials conducted by or on behalf of the Company were and, if still pending, are being conducted in accordance with experimental protocols, procedures and controls pursuant to all Applicable Laws and Authorizations, except where such failure to comply would not, individually or in the aggregate, result in a Material Adverse Change; the descriptions of the results of such studies, tests and trials contained in the Registration Statement, the Pricing Disclosure Package and the Prospectus are accurate and complete in all material respects and fairly present the data derived from such studies, tests and trials; except to the extent disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company has no knowledge of any studies, tests or trials, the results of which the Company believes reasonably call into question the study, test, or trial results described or referred to in the Registration Statement, the pricing Disclosure Package and the Prospectus when viewed in the context in which such results are described and the clinical state of development; and the Company has not received any written notices or correspondence from any Governmental Entity requiring the termination, suspension or material modification of any studies, tests or preclinical or clinical trials conducted by or on behalf of the Company.

(p) No Defaults; Violations. Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, no default exists in the due performance and observance of any term, covenant or condition of any material license, contract, indenture, mortgage, deed of trust, note, loan or credit agreement, or any other agreement or instrument evidencing an obligation for borrowed money, or any other material agreement or instrument to which the Company is a party or by which the Company may be bound or to which any of the properties or assets of the Company is subject, except as would not reasonably be expected to result, individually or in the aggregate, in a Material Adverse Change. The Company is not (i) in violation of any term or provision of its Charter or Bylaws, or (ii) except as would not reasonably be expected to result, individually or in the aggregate, in a Material Adverse Change, in violation of any franchise, license, permit, applicable law, rule, regulation, judgment or decree of any Governmental Entity applicable to the Company.

(q) Corporate Power; Licenses; Consents.

(i) Conduct of Business. Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company has all requisite corporate power and authority, and has all necessary authorizations, approvals, orders, licenses, certificates and permits of and from all governmental regulatory officials and bodies that it needs as of the date hereof to conduct its business purpose as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, except where such failure to have such necessary authorizations, approvals, orders, licenses, certificates and permits would not reasonably be expected to result in a Material Adverse Change.

(i i) Transactions Contemplated Herein. The Company has all corporate power and authority to enter into this Agreement and to carry out the provisions and conditions hereof, and all consents, authorizations, approvals and orders required in connection therewith have been obtained. No consent, authorization or order of, and no filing with, any court, government agency or other body is required for the valid issuance, sale and delivery of the Public Securities and the consummation of the transactions and agreements contemplated by this Agreement and as contemplated by the Registration Statement, the Pricing Disclosure Package and the Prospectus, except with respect to applicable federal and state securities laws, the rules and regulations of the Financial Industry Regulatory Authority, Inc. (“FINRA”) and the rules and regulations of the Exchange, and except with respect to such consent, authorization, order or filing that would not reasonably be expected to have a Material Adverse Change.

(r) Litigation: Governmental Proceedings. There is no material action, suit, proceeding, inquiry, arbitration, investigation, litigation or governmental proceeding pending or, to the Company's knowledge, threatened against, or involving the Company or, to the Company's knowledge, any executive officer or director which has not been disclosed in the Registration Statement, the Pricing Disclosure Package, the Prospectus or in connection with the Company's listing application for the additional listing of the Shares on the Exchange and which is required to be disclosed, in each case individually or in the aggregate.

(s) Good Standing. The Company has been duly organized and is validly existing as a corporation and is in good standing under the laws of the State of Nevada as of the date hereof, and is duly qualified to do business and is in good standing in each other jurisdiction in which its ownership or lease of property or the conduct of business requires such qualification, except where the failure to qualify, singularly or in the aggregate, would not have or reasonably be expected to result in a Material Adverse Change.

(t) Insurance. The Company carries or is entitled to the benefits of insurance, with, to the Company's knowledge, reputable insurers, and in such amounts and covering such risks which the Company believes are reasonably adequate, and all such insurance is in full force and effect. The Company has no reason to believe that it will not be able (i) to renew its existing insurance coverage as and when such policies expire or (ii) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not reasonably be expected to result in a Material Adverse Change.

(u) Transactions Affecting Disclosure to FINRA.

(i) Finder's Fees. Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, there are no claims, payments, arrangements, agreements or understandings relating to the payment of a finder's, consulting or origination fee by the Company or any executive officer or director of the Company (each, an, "Insider") with respect to the sale of the Public Securities hereunder or any other arrangements, agreements or understandings of the Company or, to the Company's knowledge, any of its stockholders that may affect the Underwriters' compensation, as determined by FINRA.

(ii) Payments Within 180 Days. The Company has not made any direct or indirect payments (in cash, securities or otherwise) to: (i) any U.S. person, as a finder's fee, consulting fee or otherwise, in consideration of such person raising capital for the Company or introducing to the Company persons who raised or provided capital to the Company; (ii) any FINRA member; or (iii) any person or entity that has any direct or indirect affiliation or association with any FINRA member, within the 180 days prior to the date of the initial filing of the Registration Statement, other than the payment to the Underwriters as provided hereunder in connection with the Offering.

(iii) Use of Proceeds. None of the net proceeds of the Offering will be paid by the Company to any participating FINRA member or its affiliates, except as specifically authorized herein.

(iv) FINRA Affiliation. There is no (i) officer or director of the Company, (ii) to the Company's knowledge, beneficial owner of 5% or more of any class of the Company's securities or (iii) to the Company's knowledge, beneficial owner of the Company's unregistered equity securities which were acquired during the 180-day period immediately preceding the filing of the Registration Statement that, in each such case, is an affiliate or associated person of a FINRA member participating in the Offering (as determined in accordance with the rules and regulations of FINRA).

(v) Information. To the Company's knowledge, all information provided by the Company's officers and directors in their FINRA Questionnaires to Representative's Counsel specifically for use by Representative's Counsel in connection with its Public Offering System filings (and related disclosure) with FINRA is true, correct and complete in all material respects.

(v) Foreign Corrupt Practices Act. Neither the Company nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company (acting in such capacity) or any other person acting on behalf of the Company (acting in such capacity), has, directly or indirectly, given or agreed to give any money, gift or similar benefit (other than legal price concessions to customers in the ordinary course of business) to any customer, supplier, employee or agent of a customer or supplier, or official or employee of any governmental agency or instrumentality of any government (domestic or foreign) or any political party or candidate for office (domestic or foreign) or other person who was, is, or may be in a position to help or hinder the business of the Company (or assist it in connection with any actual or proposed transaction) that (i) might subject the Company to any damage or penalty in any civil, criminal or governmental litigation or proceeding, (ii) if not given in the past, might reasonably be expected to have had a Material Adverse Change or (iii) if not continued in the future, might adversely affect the assets, business, operations or prospects of the Company. The Company has taken reasonable steps to ensure that its accounting controls and procedures are sufficient to cause the Company to comply in all material respects with the Foreign Corrupt Practices Act of 1977, as amended.

(w) Compliance with OFAC. Neither the Company nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company (acting in such capacity) or any other person acting on behalf of the Company (acting in such capacity), is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury ("OFAC").

(x) Money Laundering Laws. The operations of the Company are and have been conducted at all times in compliance in all material respects with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all applicable jurisdictions, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any Governmental Entity (collectively, the "Money Laundering Laws"); and no action, suit or proceeding by or before any Governmental Entity involving the Company with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(y) Officers' Certificate. Any certificate signed by any duly authorized officer of the Company in connection with the Offering and delivered to the Representative or to Representative's Counsel shall be deemed a representation and warranty by the Company to the Underwriters as to the matters covered thereby.

(z) Related Party Transactions. There are no business relationships or related party transactions involving the Company or any other person required to be described in the Registration Statement, the Pricing Disclosure Package and the Prospectus that have not been described as required.

(aa) Board of Directors. The qualifications of the persons serving as board members and the overall composition of the board comply with the Exchange Act, the Exchange Act Regulations, the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder (the "Sarbanes-Oxley Act") applicable to the Company and the listing rules of the Exchange. At least one member of the Audit Committee of the Board of Directors of the Company qualifies as an "audit committee financial expert," as such term is defined under Regulation S-K and the listing rules of the Exchange.

(bb) Sarbanes-Oxley Compliance.

(i) Disclosure Controls. The Pricing Disclosure Package and the Prospectus, the Company has developed and currently maintains disclosure controls and procedures that will comply with Rule 13a-15 or 15d-15 under the Exchange Act Regulations applicable to it, and, except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, such controls and procedures are as of the date hereof effective to ensure that all material information concerning the Company will be made known on a timely basis to the individuals responsible for the preparation of the Company's Exchange Act filings and other public disclosure documents.

(ii) Compliance. The Company is in compliance with the provisions of the Sarbanes-Oxley Act applicable to it, and has implemented or will implement such programs and has taken or will take reasonable steps to ensure the Company's future compliance (not later than the relevant statutory and regulatory deadlines therefor) with all of the provisions of the Sarbanes-Oxley Act, except where the failure to be in compliance would not have or reasonably be expected to result in a Material Adverse Change.

(cc) Accounting Controls. The Company maintains systems of “internal control over financial reporting” (as defined under Rules 13a-15 and 15d-15 under the Exchange Act Regulations) that comply in all material respects with the requirements of the Exchange Act and have been designed by, or under the supervision of, its principal executive and principal financial officers, or persons performing similar functions, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP, including, but not limited to, internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management’s general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management’s general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company has no knowledge of any material weaknesses in its internal controls. The Auditors and the Audit Committee of the Board of Directors of the Company have been advised of: (i) all significant deficiencies and material weaknesses, if any, in the design or operation of internal controls over financial reporting which are known to the Company’s management and that have adversely affected or are reasonably likely to adversely affect the Company’s ability to record, process, summarize and report financial information; and (ii) any fraud, if any, known to the Company’s management, whether or not material, that involves management or other employees who have a significant role in the Company’s internal controls over financial reporting.

(dd) No Investment Company Status. The Company is not and, after giving effect to the Offering and the application of the proceeds thereof as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, will not be, required to register as an “investment company,” as defined in the Investment Company Act of 1940, as amended.

(ee) No Labor Disputes. No labor dispute with the employees of the Company exists or, to the knowledge of the Company, is imminent.

(ff) Intellectual Property Rights. To the Company’s knowledge, the Company has, or can acquire on reasonable terms, ownership of and/or license to, or otherwise has the right to use, all inventions, know-how (including trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures), patents and patent rights trademarks, service marks and trade names and copyrights (collectively “Intellectual Property”) material to carrying on its businesses as described in the Pricing Prospectus. The Company has not received any written notice relating to any Intellectual Property, including written notice of: (A) infringement or misappropriation of, or conflict with, any Intellectual Property of a third party; (B) asserted rights of others with respect to any Intellectual Property of the Company; or (C) assertions that any Intellectual Property of the Company is invalid or otherwise inadequate to protect the interest of the Company, that in each case (if the subject of any unfavorable decision, ruling or finding), individually or in the aggregate, would have or would reasonably be expected to have a Material Adverse Change. To the Company’s knowledge, there are no third parties who have been able to establish any material rights to any Intellectual Property, except for the retained rights of the owners or licensors of any Intellectual Property that is licensed to the Company. There is no pending or, to the Company’s knowledge, threatened action, suit, proceeding or claim by others: (A) challenging the validity, enforceability or scope of any Intellectual Property of the Company in any material respect or (B) challenging the Company’s rights in or to any Intellectual Property in any material respect or (C) that the Company materially infringes, misappropriates or otherwise violates or conflicts with any Intellectual Property or other proprietary rights of others. The Company has complied in all material respects with the terms of each agreement described in the Registration Statement, Pricing Disclosure Package or Prospectus pursuant to which any Intellectual Property is licensed to the Company, except for such noncompliance as did not have a Material Adverse Change, and all such agreements related to products currently made or sold by the Company, or to product candidates currently under development, are in full force and effect. All patents issued in the name of, or assigned to, or licensed to the Company, and all patent applications made by or on behalf of the Company (collectively, the “Company Patents”) have been duly and properly filed, except for such failures to file as would reasonably be expected to result in a Material Adverse Change. The Company has no knowledge of any material information that was required to be disclosed to the United States Patent and Trademark Office (the “PTO”) but that was not disclosed to the PTO with respect to any issued Company Patent, or that is required to be disclosed and has not yet been disclosed in any pending application in the Company Patents and that would preclude the grant of a patent on such application. To the Company’s knowledge, the Company is the sole owner or exclusive licensee of the Company Patents.

(gg) Taxes. The Company has filed all returns (as hereinafter defined) required to be filed with taxing authorities prior to the date hereof or has duly obtained extensions of time for the filing thereof. The Company has paid all taxes (as hereinafter defined) shown as due on such returns that were filed and has paid all taxes imposed on or assessed against the Company, except (i) such taxes the Company is challenging in good faith and (ii) for such exceptions as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Change. The provisions for taxes payable, if any, shown on the financial statements filed with or as part of the Registration Statement are sufficient for all material accrued and unpaid taxes, whether or not disputed, and for all periods to and including the dates of such consolidated financial statements. Except as would not reasonably be expected to result in a Material Adverse Change, (i) no issues have been raised (and are currently pending) by any taxing authority in connection with any of the returns or taxes asserted as due from the Company, and (ii) no waivers of statutes of limitation with respect to the returns or collection of taxes have been given by or requested from the Company. The term “taxes” mean all federal, state, local, foreign and other net income, gross income, gross receipts, sales, use, ad valorem, transfer, franchise, profits, license, lease, service, service use, withholding, payroll, employment, excise, severance, stamp, occupation, premium, property, windfall profits, customs, duties or other taxes, fees, assessments or charges of any kind whatever, together with any interest and any penalties, additions to tax or additional amounts with respect thereto. The term “returns” means all returns, declarations, reports, statements and other documents required to be filed in respect to taxes.

(hh) Employee Benefit Laws. The operations of the Company are and have, in the last three (3) years, been conducted at all times in material compliance with the Employee Retirement Income Security Act of 1974, as amended, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the “Employee Benefit Laws”) and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company with respect to the Employee Benefit Laws is pending or, to the knowledge of the Company, threatened.

(ii) Compliance with Laws. The Company in the last three (3) years: (A) to its knowledge is and at all times has been in compliance with all Applicable Laws, except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Change; (B) has not received any written correspondence from any Governmental Entity alleging or asserting noncompliance with any Applicable Laws or any Authorizations; (C) possesses all material Authorizations and such Authorizations are valid and in full force and effect and the Company is not in material violation of any term of any such Authorizations, in each case except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Change; (D) has not received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any Governmental Entity or third party alleging that any product operation or activity is in violation of any Applicable Laws or Authorizations and has no knowledge that any such Governmental Entity or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding; (E) has not received written notice that any Governmental Entity has taken, is taking or intends to take action to limit, suspend, modify or revoke any Authorizations; and (F) has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and correct in all material respects on the date filed (or were corrected or supplemented by a subsequent submission).

(jj) Ineligible Issuer. At the time of filing the Registration Statement and any post-effective amendment thereto, at the time of effectiveness of the Registration Statement and any amendment thereto, at the earliest time thereafter that the Company or another offering participant made a bona fide offer (within the meaning of Rule 164(h)(2) of the Securities Act Regulations) of the Public Securities and at the date hereof, the Company was not and is not an “ineligible issuer,” as defined in Rule 405, without taking account of any determination by the Commission pursuant to Rule 405 that it is not necessary that the Company be considered an ineligible issuer.

(kk) Industry Data. The statistical and market-related data included in each of the Registration Statement, the Pricing Disclosure Package and the Prospectus are based on or derived from sources that the Company reasonably and in good faith believes are reliable and accurate or represent the Company’s good faith estimates that are made on the basis of data derived from such sources.

(11) Forward-Looking Statements. No forward-looking statement (within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act) contained in the Registration Statement, the Pricing Disclosure Package or the Prospectus has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith.

(mm) Website. To the knowledge of the Company, none of the information on (or hyperlinked from) the Company's website at www.archtherapeutics.com includes or constitutes a "free writing prospectus" as defined in Rule 405 under the Securities Act.

(nn) Emerging Growth Company. From the time of the initial submission of the Registration Statement to the Commission (or, if earlier, the first date on which the Company engaged directly in or through any Person authorized to act on its behalf in any Testing-the Waters Communication) through the date hereof, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the Securities Act (an "Emerging Growth Company").

(oo) Testing-the-Waters Communications. The Company has not (i) alone engaged in any Testing-the-Waters Communications, and (ii) authorized anyone other than the Representative to engage in Testing-the-Waters Communications. The Company confirms that the Representative has been authorized to act on its behalf in undertaking Testing-the-Waters Communications. The Company has not distributed any Written Testing-the-Waters Communications. "Testing-the-Waters Communication" means any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the Securities Act. "Written Testing-the-Waters Communication" means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the Securities Act.

(pp) Margin Securities. The Company owns no "margin securities" as that term is defined in Regulation U of the Board of Governors of the Federal Reserve System (the "Federal Reserve Board"), and none of the proceeds of Offering will be used, directly or indirectly, for the purpose of purchasing or carrying any margin security, for the purpose of reducing or retiring any indebtedness which was originally incurred to purchase or carry any margin security or for any other purpose which might cause any of the Common Shares to be considered a "purpose credit" within the meanings of Regulation T, U or X of the Federal Reserve Board.

(qq) Integration. Neither the Company, nor any of its affiliates, nor any person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause the Offering to be integrated with prior offerings by the Company for purposes of the Securities Act that would require the registration of any such securities issued in such prior offerings under the Securities Act.

(rr) Confidentiality and Non-Competition. To the Company's knowledge, no director, officer, key employee or consultant of the Company is subject to any confidentiality, non-disclosure, non-competition agreement or non-solicitation agreement with any employer (other than the Company) or prior employer that could reasonably be expected to materially affect his ability to be and act in his respective capacity of the Company or reasonably be expected to result in a Material Adverse Change.

(ss) Smaller Reporting Company. The Company is a "smaller reporting company," as defined in Rule 12b-2 of the Exchange Act Regulations.

3. Covenants of the Company. The Company covenants and agrees as follows:

(a) Amendments to Registration Statement. The Company shall deliver to the Representative, prior to filing, any amendment or supplement to the Registration Statement or Prospectus proposed to be filed after the Effective Date and not file any such amendment or supplement to which the Representative shall reasonably object in writing; provided however, that this Section 3(a) shall not be applicable with respect to any supplements to the Registration Statement filed solely for the purpose of supplementing the Registration Statement or Prospectus with a report filed with the Commission by the Company pursuant to the Exchange Act.

(b) Federal Securities Laws.

(i) Compliance. The Company shall comply with the requirements of Rule 430A of the Securities Act Regulations, and will notify the Representative promptly, and confirm the notice in writing, (i) when any amendment or supplement to the Prospectus shall have been filed; (ii) of the receipt of any comments from the Commission related to the Prospectus or Offering; (iii) of any request by the Commission for any amendment or supplement to the Prospectus or for additional information; (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment or of any order preventing or suspending the use of any Preliminary Prospectus or the Prospectus, or of the suspension of the qualification of the Public Securities and Representative's Securities for offering or sale in any jurisdiction, or of the initiation or, to the Company's knowledge, threatening, of any proceedings for any of such purposes or of any examination pursuant to Section 8(d) or 8(e) of the Securities Act concerning the Registration Statement; and (v) if the Company becomes the subject of a proceeding under Section 8A of the Securities Act in connection with the Offering of the Public Securities and Representative's Securities. The Company shall effect all filings required under Rule 424(b) of the Securities Act Regulations, in the manner and within the time period required by Rule 424(b) (without reliance on Rule 424(b)(8)), and shall take such steps as it deems necessary to ascertain promptly whether the form of prospectus transmitted for filing under Rule 424(b) was received for filing by the Commission and, in the event that it was not, it will promptly file such prospectus. The Company shall use its commercially reasonable efforts to prevent the issuance of any stop order, prevention or suspension and, if any such order is issued, to obtain the lifting thereof at the earliest possible moment.

(ii) Continued Compliance. The Company shall comply with the Securities Act, the Securities Act Regulations, the Exchange Act and the Exchange Act Regulations so as to permit the completion of the distribution of the Public Securities as contemplated in this Agreement and in the Registration Statement, the Pricing Disclosure Package and the Prospectus. If at any time when a prospectus relating to the Public Securities is (or, but for the exception afforded by Rule 172 of the Securities Act Regulations ("Rule 172"), would be) required by the Securities Act to be delivered in connection with sales of the Public Securities, any event shall occur or condition shall exist as a result of which it is necessary, in the opinion of counsel for the Underwriters or for the Company, to (i) amend or supplement the Pricing Disclosure Package or the Prospectus in order that the Pricing Disclosure Package or the Prospectus, as the case may be, will not include any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein not misleading in the light of the circumstances existing at the time it is delivered to a purchaser or (ii) amend the Registration Statement or amend or supplement the Pricing Disclosure Package or the Prospectus, as the case may be, in order to comply with the requirements of the Securities Act or the Securities Act Regulations, the Company will promptly (A) give the Representative notice of such event; (B) prepare any amendment or supplement as may be necessary to correct such statement or omission or to make the Registration Statement, the Pricing Disclosure Package or the Prospectus comply with such requirements and, a reasonable amount of time prior to any proposed filing or use, furnish the Representative with copies of any such amendment or supplement and (C) file with the Commission any such amendment or supplement; provided that the Company shall not file or use any such amendment or supplement to which the Representative or counsel for the Representative shall reasonably object. The Company will furnish to the Underwriters such number of copies of such amendment or supplement as the Underwriters may reasonably request. The Company has given the Representative notice of any filings made pursuant to the Exchange Act or the Exchange Act Regulations within 48 hours prior to the Applicable Time. The Company shall give the Representative notice of its intention to make any such filing from the Applicable Time until the later of the Closing Date and the exercise in full or expiration of the Over-allotment Option specified in Section 1(b) hereof.

(iii) Exchange Act Registration. The Company shall use its commercially reasonable efforts to maintain the registration of the Common Shares and Warrants under the Exchange Act.

(c) Delivery to the Underwriters of Registration Statements. The Company has delivered or made available or shall deliver or make available to the Representative and counsel for the Representative, without charge, signed copies of the Registration Statement as originally filed and each amendment thereto (including exhibits filed therewith) and signed copies of all consents and certificates of experts, and will also deliver to the Underwriters, without charge, a conformed copy of the Registration Statement as originally filed and each amendment thereto (without exhibits) for each of the Underwriters. The copies of the Registration Statement and each amendment thereto furnished to the Underwriters will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(d) Delivery to the Underwriters of Prospectuses. The Company has delivered or made available or will deliver or make available to each Underwriter, without charge, as many copies of each Preliminary Prospectus as such Underwriter reasonably requested, and the Company hereby consents to the use of such copies for purposes permitted by the Securities Act. The Company will furnish to each Underwriter, without charge, during the period when a prospectus relating to the Public Securities is (or, but for the exception afforded by Rule 172, would be) required to be delivered under the Securities Act, such number of copies of the Prospectus (as amended or supplemented) as such Underwriter may reasonably request. The Prospectus and any amendments or supplements thereto furnished to the Underwriters will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(e) Events Requiring Notice to the Representative. During the period when a prospectus relating to the Public Securities is (or, but for the exception afforded by Rule 172, would be) required by the Securities Act to be delivered in connection with sales of the Public Securities, the Company shall notify the Representative immediately and confirm the notice in writing: (i) of the issuance by the Commission of any stop order or of the initiation, or to the Company's knowledge, the threatening, of any proceeding for that purpose; (ii) of the issuance by any state securities commission of any proceedings for the suspension of the qualification of the Public Securities for offering or sale in any jurisdiction or of the initiation, or to the Company's knowledge, the threatening, of any proceeding for that purpose; (iii) of the delivery to the Commission for filing of any amendment or supplement to the Prospectus; (iv) of the receipt of any comments or request for any additional information from the Commission related to the Prospectus; and (v) of the happening of any event during the period described in this Section 3(e) that, in the judgment of the Company, makes any statement of a material fact made in the Pricing Disclosure Package or the Prospectus untrue or that requires the making of any changes in in the Pricing Disclosure Package or the Prospectus in order to make the statements therein, in light of the circumstances under which they were made, not misleading. If the Commission or any state securities commission shall enter a stop order or suspend such qualification at any time, the Company shall use its commercially reasonable efforts to obtain promptly the lifting of such order.

(f) Listing. The Company shall use its commercially reasonable efforts to maintain the listing of the shares of Common Shares and Warrants on the Exchange for a period of three (3) years.

(g) Transfer Agent; Warrant Agent. The Company shall maintain a transfer agent and registrar for the Common Stock and a Warrant Agent for the Warrants.

(h) Payment of Expenses. The Company hereby agrees to pay on the Closing Date all expenses incident to the performance of the obligations of the Company under this Agreement, including, but not limited to: (1) all filing fees and expenses relating to the registration of the Public Securities with the Commission; (2) all FINRA Public Offering filing fees; (3) all fees and expenses relating to the listing of the Public Securities on the Exchange; (4) all fees, expenses and disbursements, if any, relating to the registration or qualification of the Public Securities under the "blue sky" securities laws of such states and other jurisdictions as the Underwriter may reasonably designate (including, without limitation, all filing and registration fees, and the reasonable fees and disbursements of "blue sky" counsel, which will be Representative's Counsel and with such fees and expenses of Representative's counsel will be limited to \$10,000; (5) all fees, expenses and disbursements relating to the registration, qualification or exemption of the Public Securities under the securities laws of such foreign jurisdictions as the Underwriter may reasonably designate; (6) the costs of all mailing and printing of the Offering documents; (7) transfer and/or stamp taxes, if any, payable upon the transfer of Public Securities from the Company to the Underwriters; (8) the fees and expenses of the Company's accountants; (9) the fees and expenses of the Company's legal counsel and other agents and representatives; (10) up to \$10,000 to cover "road show" expenses of \$3,000; and (11) diligence expenses and legal fees of Representative's counsel of \$140,000. The Representative may deduct from the net proceeds of the Offering payable to the Company on the Closing Date, the expenses set forth herein (less any amounts previously advanced against such actual reimbursable expense) to be paid by the Company to the Underwriters, provided, however, that in the event that the Offering is terminated, the Company agrees to reimburse the Underwriters pursuant to Section 8(c) hereof.

(i) Application of Net Proceeds. The Company shall apply the net proceeds from the Offering received by it in a manner consistent with the application thereof described under the caption "Use of Proceeds" in the Prospectus.

(j) Rule 158. The Company will timely file such reports pursuant to the Exchange Act as are necessary in order to make generally available to its security holders as soon as practicable an earnings statement for the purposes of, and to provide to the Underwriters the benefits contemplated by, Rule 158(a) under Section 11(a) of the Securities Act.

(k) Stabilization. Neither the Company nor, to its knowledge, any of its employees, directors or stockholders (without the consent of the Representative) has taken or shall take, directly or indirectly, any action designed to or that has constituted or that might reasonably be expected to cause or result in, under Regulation M of the Exchange Act, or otherwise, stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Public Securities.

(l) FINRA. For a period of 90 days from the later of the Closing Date or Option Closing Date, the Company shall advise the Representative (who shall make an appropriate filing with FINRA) if it has knowledge that (i) any officer or director of the Company, (ii) any beneficial owner of 5% or more of any class of the Company's securities or (iii) any beneficial owner of the Company's unregistered equity securities which were acquired during the 180 days immediately preceding the filing of the Registration Statement, is or becomes an affiliate or associated person of a FINRA member participating in the Offering (as determined in accordance with the rules and regulations of FINRA).

(m) No Fiduciary Duties. The Company acknowledges and agrees that the Underwriters' responsibility to the Company is solely contractual in nature and that none of the Underwriters or their affiliates or any selling agent shall be deemed to be acting in a fiduciary capacity, or otherwise owes any fiduciary duty to the Company or any of its affiliates in connection with the Offering and the other transactions contemplated by this Agreement.

(n) OFAC. The Company will not, directly or indirectly, use the proceeds of the Offering hereunder, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity, for the purpose of financing the activities of any person currently subject to any U.S. sanctions administered by OFAC.

(o) Company Lock-Up Agreement. The Company, on behalf of itself and any successor entity, agrees that, without the prior written consent of the Representative, it will not, for a period of six (6) months after the date of this Agreement (the "Lock-Up Period"), (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of capital stock of the Company or any securities convertible into or exercisable or exchangeable for shares of capital stock of the Company; (ii) file or caused to be filed any registration statement with the Commission relating to the offering of any shares of capital stock of the Company or any securities convertible into or exercisable or exchangeable for shares of capital stock of the Company, other than pursuant to existing registration rights in favor of stockholders of the Company or on Form S-8 or successor form thereto; or (iii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of capital stock of the Company, whether any such transaction described in clause (i), (ii) or (iii) above is to be settled by delivery of shares of capital stock of the Company or such other securities, in cash or otherwise. The restrictions contained in this Section 3(o) shall not apply to (i) the Common Shares and Warrants to be sold hereunder and the issuance of the Representative's Warrant, (ii) the issuance by the Company of Common Shares upon the exercise of a stock option or warrant or the conversion of a security outstanding on the date hereof and disclosed in the Registration Statement, the Pricing Disclosure Package or the Prospectus, and (iii) the issuance by the Company of stock options or shares of capital stock of the Company under any equity compensation plan of the Company disclosed in the Registration Statement, the Pricing Disclosure Package or the Prospectus.

4. Conditions of Underwriters' Obligations. The obligations of the Underwriters to purchase and pay for the Public Securities, as provided herein, shall be subject to (i) the continuing accuracy of the representations and warranties of the Company as of the date hereof and as of each of the Closing Date, and any Option Closing Date; (ii) the accuracy of the statements of officers of the Company made pursuant to the provisions hereof; (iii) the performance by the Company of its obligations hereunder; and (iv) the following conditions:

(a) Regulatory Matters.

(i) Effectiveness of Registration Statement. The Registration Statement has become effective not later than 5:00 p.m., Eastern Time, on the date of this Agreement or such later date and time as shall be consented to in writing by the Representative, and, at each of the Closing Date and any Option Closing Date, no stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto shall have been issued under the Securities Act, no order preventing or suspending the use of any Preliminary Prospectus or the Prospectus shall have been issued and no proceedings for any of those purposes have been instituted or are pending or, to the Company's knowledge, contemplated by the Commission. The Company has complied with each request (if any) from the Commission for additional information. The Prospectus containing the Rule 430A Information shall have been filed with the Commission in the manner and within the time frame required by Rule 424(b) (without reliance on Rule 424(b)(8)) or a post-effective amendment providing such information shall have been filed with, and declared effective by, the Commission in accordance with the requirements of Rule 430A.

(ii) FINRA Clearance. On or before the date of this Agreement, the Representative shall have received clearance from FINRA as to the amount of compensation allowable or payable to the Underwriters as described in the Registration Statement.

(iii) Exchange Stock Market Clearance. On the Closing Date, the Firm Shares and Firm Warrants shall have been approved for listing on the Exchange.

(b) Company Counsel Matters.

(i) Closing Date Opinion of Counsel. On the Closing Date, the Representative shall have received the favorable opinion and negative assurance letter of Lowenstein Sandler LLP, counsel to the Company, dated the Closing Date and addressed to the Representative, substantially in form and substance reasonably satisfactory to the Representative.

(ii) Option Closing Date Opinion of Counsel. On each Option Closing Date, if any, the Representative shall have received the favorable opinion of Lowenstein Sandler LLP, dated the Option Closing Date, addressed to the Representative and in form and substance reasonably satisfactory to the Representative, confirming as of the Option Closing Date, the statements made by such counsel in its respective opinions delivered on the Closing Date.

(iii) Reliance. In rendering such opinions, such counsel may rely: (i) as to matters involving the application of laws other than the laws of the United States and jurisdictions in which they are admitted, to the extent such counsel deems proper and to the extent specified in such opinion, if at all, upon an opinion or opinions (in form and substance reasonably satisfactory to the Representative) of other counsel reasonably acceptable to the Representative, familiar with the applicable laws; and (ii) as to matters of fact, to the extent they deem proper, on certificates or other written statements of officers of the Company and officers of departments of various jurisdictions having custody of documents respecting the corporate existence or good standing of the Company; provided, that copies of any such statements or certificates shall be delivered to Representative's Counsel if requested.

(c) Comfort Letters.

(i) Comfort Letter. At the time this Agreement is executed, the Representative shall have received from the Auditor a cold comfort letter containing statements and information of the type customarily included in accountants' comfort letters with respect to the financial statements and certain financial information contained in the Registration Statement, the Pricing Disclosure Package and the Prospectus, addressed to the Representative and in form and substance satisfactory in all respects to the Representative and to the Auditor, dated as of the date of this Agreement.

(ii) Bring-Down Comfort Letter. At each of the Closing Date and the Option Closing Date, if any, the Representative shall have received from the Auditor a letter, dated as of the Closing Date or the Option Closing Date, as applicable, to the effect that the Auditor reaffirms the statements made in the letter furnished pursuant to Section 4(c)(i), except that the specified date referred to shall be a date not more than three (3) Business Days prior to the Closing Date or the Option Closing Date, as applicable.

(d) Officers' Certificates.

(i) Officers' Certificate. The Company shall have furnished to the Representative a certificate, dated the Closing Date and any Option Closing Date, as applicable, of its President and Chief Executive Officer and its Chief Financial Officer stating (on behalf of the Company and not in an individual capacity) that (i) such officers have carefully examined the Registration Statement, the Pricing Disclosure Package, and the Prospectus and, to their knowledge, the Registration Statement and each amendment thereto, as of the Applicable Time and as of the Closing Date or Option Closing Date, as applicable, did not include any untrue statement of a material fact and did not omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading, and the Pricing Disclosure Package, as of the Applicable Time and as of the Closing Date or Option Closing Date, as applicable, the Prospectus and each amendment or supplement thereto, as of the respective date thereof and as of the Closing Date or Option Closing Date, as applicable, did not include any untrue statement of a material fact and did not omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances in which they were made, not misleading, (ii) since the effective date of the Registration Statement, no event has occurred which should have been set forth in a supplement or amendment to the Registration Statement, the Pricing Disclosure Package or the Prospectus, (iii) to their knowledge after reasonable investigation, as of the Closing Date or Option Closing Date, as applicable, the representations and warranties of the Company in this Agreement are true and correct in all material respects (except for those representations and warranties qualified as to materiality, which shall be true and correct in all respects and except for those representations and warranties which refer to facts existing at a specific date, which shall be true and correct as of such date) and the Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied hereunder at or prior to the Closing Date or Option Closing Date, as applicable, and (iv) there has not been, subsequent to the date of the most recent audited financial statements included in the Pricing Disclosure Package, any Material Adverse Change, or any change or development that, singularly or in the aggregate, would reasonably be expected to involve a Material Adverse Change, except as set forth in the Prospectus.

(ii) Secretary's Certificate. At each of the Closing Date or Option Closing Date, as applicable, the Representative shall have received a certificate of the Company signed by the Secretary of the Company, dated the Closing Date, or Option Closing Date, as applicable, certifying: (i) that each of the Charter and Bylaws is true and complete, has not been modified and is in full force and effect; (ii) that the resolutions of the Company's Board of Directors relating to the Offering are in full force and effect and have not been modified; (iii) the good standing of the Company; and (iv) as to the incumbency of the officers of the Company. The documents referred to in such certificate shall be attached to such certificate.

(e) No Material Changes. Prior to and on each of the Closing Date or Option Closing Date, as applicable: (i) there shall have been no Material Adverse Change that, singularly or in the aggregate, would reasonably be expected to involve a Material Adverse Change, from the latest dates as of which such condition is set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus; (ii) no action, suit or proceeding, at law or in equity, shall have been pending or threatened against the Company or any Insider before or by any court or federal or state commission, board or other administrative agency wherein an unfavorable decision, ruling or finding would reasonably be expected to result in a Material Adverse Change, except as set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus; (iii) no stop order shall have been issued under the Securities Act and no proceedings therefor shall have been initiated or threatened by the Commission; and (iv) the Registration Statement, the Pricing Disclosure Package and the Prospectus and any amendments or supplements thereto shall contain all material statements which are required to be stated therein in accordance with the Securities Act and the Securities Act Regulations and shall conform in all material respects to the requirements of the Securities Act and the Securities Act Regulations, and neither the Registration Statement, the Pricing Disclosure Package nor the Prospectus nor any amendment or supplement thereto shall contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

(f) Other Agreements to be Delivered. The Company has caused each of its officers and directors and certain stockholders to deliver to the Representative an executed Lock-Up Agreement, in a form substantially similar to that attached hereto as Exhibit B (the "Lock-Up Agreement"), prior to the execution of this Agreement. On the Closing Date, the Company shall have delivered to the Representative an executed copy of the Warrant Agreement and the Representative's Warrant.

(g) Additional Documents. At the Closing Date or Option Closing Date, as applicable, Representative's Counsel shall have been furnished with such documents and opinions as they may reasonably require for the purpose of enabling Representative's Counsel to deliver an opinion to the Underwriters, or in order to evidence the accuracy of any of the representations or warranties, or the fulfillment of any of the conditions, herein contained; and all proceedings taken by the Company in connection with the issuance and sale of the Public Securities and Representative's Securities as herein contemplated shall be satisfactory in form and substance to the Representative and Representative's Counsel.

5. Indemnification.

(a) Indemnification of the Underwriters. The Company agrees to indemnify and hold harmless each Underwriter, its affiliates and each person controlling such Underwriter (within the meaning of Section 15 of the Securities Act), and the directors, officers, agents and employees of each Underwriter, its affiliates and each such controlling person (each Underwriter, and each such entity or person hereafter is referred to as an "Indemnified Person") from and against any losses (other than losses of profits), claims, damages, judgments, assessments, costs and other liabilities (collectively, the "Liabilities"), and shall reimburse each Indemnified Person for all fees and expenses (including the reasonable fees and expenses of counsel for the Indemnified Persons, except as otherwise expressly provided in this Agreement) (collectively, the "Expenses") and agrees to advance payment of such Expenses as they are incurred by an Indemnified Person in investigating, preparing, pursuing or defending any actions, whether or not any Indemnified Person is a party thereto, arising out of or based upon any untrue statement or alleged untrue statement of a material fact contained in (i) the Registration Statement, the Pricing Disclosure Package, the Preliminary Prospectus, or the Prospectus (as from time to time each may be amended and supplemented); (ii) any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the Offering, including any "road show" or investor presentations made to investors by the Company (whether in person or electronically); or (iii) any application or other document or written communication (in this Section 5, collectively called "application") executed by the Company or based upon written information furnished by the Company in any jurisdiction in order to qualify the Public Securities and Representative's Securities under the securities laws thereof or filed with the Commission, any state securities commission or agency, the Exchange or any other national securities exchange; or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading, unless such statement or omission was made in reliance upon, and in conformity with, the Underwriters' Information.

(b) Procedure. Upon receipt by an Indemnified Person of notice of an action against such Indemnified Person with respect to which indemnity may reasonably be expected to be sought under this Agreement, such Indemnified Person shall promptly notify the Company in writing; provided that failure by any Indemnified Person so to notify the Company shall not relieve the Company from any obligation or liability which the Company may have on account of this Section 5 or otherwise to such Indemnified Person, except to the extent the Company is materially prejudiced as a proximate result of such failure. An Indemnified Person shall have the right to require that the Company assume the defense of any such action (including the employment of counsel designated by the Company and reasonably satisfactory to the Representative). Any Indemnified Person shall have the right to employ separate counsel in any such action and participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of such Indemnified Person unless: (i) the Company has failed promptly to assume the defense and employ counsel reasonably satisfactory to the Representative for the benefit of the Underwriters and the other Indemnified Persons or (ii) such Indemnified Person shall have been advised that in the opinion of counsel that there is an actual or potential conflict of interest that prevents (or makes it imprudent for) the counsel engaged by the Company for the purpose of representing the Indemnified Person, to represent both such Indemnified Person and any other person represented or proposed to be represented by such counsel. The Company shall not be liable for the fees and expenses of more than one separate counsel (together with local counsel), representing all Indemnified Persons who are parties to such action), which counsel (together with any local counsel) for the Indemnified Persons shall be selected by the Representative, subject to the Company's approval (which shall not be unreasonably withheld). The Company shall not be liable for any settlement of any action effected without its written consent (which shall not be unreasonably withheld). In addition, the Company shall not, without the prior written consent of the Underwriters, settle, compromise or consent to the entry of any judgment in or otherwise seek to terminate any pending or threatened action in respect of which advancement, reimbursement, indemnification or contribution may be sought hereunder (whether or not such Indemnified Person is a party thereto) unless such settlement, compromise, consent or termination (i) includes an unconditional release of that Indemnified Person from all Liabilities arising out of such action for which indemnification or contribution may be sought hereunder and (ii) does not include a statement as to or an admission of fault, culpability or a failure to act, by or on behalf of any Indemnified Person. The advancement, reimbursement, indemnification and contribution obligations of the Company required hereby shall be made by periodic payments of the amount thereof during the course of the investigation or defense, as every Liability and Expense is incurred and is due and payable, and in such amounts as fully satisfy each and every Liability and Expense as it is incurred (and in no event later than 30 days following the date of any invoice therefore); provided, however, that the Indemnified Persons shall repay such amounts to the extent it ultimately is determined that such persons are not entitled to indemnification hereunder.

(c) Indemnification of the Company. Each Underwriter, severally and not jointly, agrees to indemnify and hold harmless the Company, its directors, its officers, employees and persons who control the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act against any and all Liabilities, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions made in the Registration Statement, any Preliminary Prospectus, the Pricing Disclosure Package or Prospectus or any amendment or supplement thereto or in any application, in reliance upon, and in strict conformity with, the Underwriters' Information. In case any action shall be brought against the Company or any other person so indemnified based on any Preliminary Prospectus, the Registration Statement, the Pricing Disclosure Package or Prospectus or any amendment or supplement thereto or in any application, and in respect of which indemnity may be sought against any Underwriter, such Underwriter shall have the rights and duties given to the Company, and the Company and each other person so indemnified shall have the rights and duties given to the several Underwriters by the provisions of Section 5(b). The Company agrees promptly to notify the Representative of the commencement of any litigation or proceedings against the Company or any of its officers, directors or any person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, in connection with the issuance and sale of the Public Securities or in connection with the Registration Statement, the Pricing Disclosure Package, or the Prospectus; provided that failure by the Company so to notify the Representative shall not relieve any Underwriter from any obligation or liability which such Underwriter may have on account of this Section 5 or otherwise to the Company, except to the extent such Underwriter is materially prejudiced as a proximate result of such failure.

(d) Contribution. If the indemnification provided for in this Section 5 shall for any reason be unavailable to or insufficient to hold harmless an indemnified party under Section 5(a) or 5(c) in respect of any Liabilities and Expenses referred to therein, then each indemnifying party shall, in lieu of indemnifying such indemnified party, contribute to the amount paid or payable by such indemnified party as a result of such Liabilities and Expenses, (i) in such proportion as shall be appropriate to reflect the relative benefits received by the Company, on the one hand, and each of the Underwriters, on the other hand, from the Offering, or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and the Underwriters, on the other hand, in connection with the matters as to which such Liabilities or Expenses relate, as well as any other relevant equitable considerations. The relative benefits received by the Company, on the one hand, and the Underwriters, on the other hand, with respect to such Offering shall be deemed to be in the same proportion as the total proceeds from the Offering purchased under this Agreement (after deducting all underwriting discounts, commissions and other fees but before deducting expenses) received by the Company bear to the total underwriting discount, fees and commissions actually received by the Underwriters in connection with the Offering, in each case as set forth in the table on the cover page of the Prospectus. The relative fault of the Company, on the one hand, and the Underwriters, on the other hand, shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company, on the one hand, or the Underwriters, on the other hand, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such untrue statement, omission, act or failure to act; provided that the parties hereto agree that the written information furnished to the Company through the Representative by or on behalf of any Underwriter for use in any Preliminary Prospectus, any Registration Statement or the Prospectus, or in any amendment or supplement thereto, consists solely of the Underwriters' Information. The Company and the Underwriters agree that it would not be just and equitable if contributions pursuant to this subsection (d) were determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation which does not take into account the equitable considerations referred to above in this subsection (d). Notwithstanding the above, no person guilty of fraudulent misrepresentation within the meaning of Section 11(f) of the Securities Act shall be entitled to contribution from a party who was not guilty of fraudulent misrepresentation.

(c) Survival. The advancement, reimbursement, indemnity and contribution obligations set forth in this Section 5 shall remain in full force and effect regardless of any termination of, or the completion of any Indemnified Person's services under or in connection with, this Agreement. Each Indemnified Person is an intended third-party beneficiary of this Section 5, and has the right to enforce the provisions of Section 5 as if he/she/it was a party to this Agreement.

6. Default by an Underwriter.

(a) Default Not Exceeding 10% of Public Securities. If any Underwriter or Underwriters shall default in its or their obligations to purchase the Firm Securities, and if the number of the Firm Securities with respect to which such default relates does not exceed in the aggregate 10% of the number of Firm Securities that all Underwriters have agreed to purchase hereunder, then such Firm Securities to which the default relates shall be purchased by the non-defaulting Underwriters in proportion to their respective commitments hereunder.

(b) Default Exceeding 10% of Public Securities. In the event that the default addressed in Section 6(a) relates to more than 10% of the Firm Securities, the Representative may in its discretion arrange for itself or for another party or parties to purchase such Firm Securities to which such default relates on the terms contained herein. If, within thirty six (36) hours after such default relating to more than 10% of the Firm Securities, the Representative does not arrange for the purchase of such Firm Securities, then the Company shall be entitled to a further period of thirty six (36) hours within which to procure another party or parties satisfactory to the Representative to purchase said Firm Securities on such terms. In the event that neither the Representative nor the Company arrange for the purchase of the Firm Securities to which a default relates as provided in this Section 6, this Agreement will automatically be terminated by the Representative or the Company without liability on the part of the Company (except as provided in Sections 3(f) and 5 hereof) or the several Underwriters (except as provided in Section 5 hereof); provided that if any such default occurs with respect to any Option Shares, this Agreement will not terminate in respect of the Firm Securities; and provided, further, that nothing herein shall relieve a defaulting Underwriter of its liability, if any, to the other Underwriters and to the Company for damages occasioned by its default hereunder.

(c) Postponement of Closing Date. In the event that the Firm Securities to which the default relates are to be purchased by the non-defaulting Underwriters, or are to be purchased by another party or parties as aforesaid, the Representative or the Company shall have the right to postpone the Closing Date for a reasonable period, but not in any event exceeding seven (7) Business Days, in order to effect whatever changes may thereby be made necessary in the Registration Statement, the Pricing Disclosure Package or the Prospectus or in any other documents and arrangements, and the Company agrees to file promptly any amendment to the Registration Statement, the Pricing Disclosure Package or the Prospectus that in the opinion of counsel for the Underwriter may thereby be made necessary. The term "Underwriter" as used in this Agreement shall include any party substituted under this Section 6 with like effect as if it had originally been a party to this Agreement with respect to such Securities.

7. Additional Covenants.

(a) Prohibition on Press Releases and Public Announcements. The Company shall not issue press releases or engage in any other publicity, without the Representative's prior written consent (such consent not to be unreasonably withheld), for a period ending at 5:00 p.m., Eastern Time, on the first (1st) Business Day following the forty-fifth (45th) day after the Closing Date, other than normal and customary releases issued in the ordinary course of the Company's business or such press release or communication is required by law.

(b) Right of First Refusal. During the period ending 12 months after the Closing Date, if and only if the closing of the purchase of the Firm Securities hereunder actually occurs, the Company grants the Representative the right of first refusal to act as lead or joint-lead investment banker, lead or joint-lead book runner and/or lead or joint placement agent at the Representative's discretion, for each and every future public and private equity, equity-linked or debt (excluding commercial bank debt) offering, including all equity linked financings during such 12 month period, of the Company, or any successor to or subsidiary of the Company on terms customary to the Representative.

8. Effective Date of this Agreement and Termination Thereof.

(a) Effective Date. This Agreement shall become effective when both the Company and the Representative have executed the same and delivered counterparts of such signatures to the other party.

(b) Termination. The Representative shall have the right to terminate this Agreement at any time prior to any Closing Date, (i) if any domestic or international event or act or occurrence has materially disrupted, or in Representative's opinion will in the immediate future materially disrupt, general securities markets in the United States; or (ii) if trading on the New York Stock Exchange or The Nasdaq Stock Market LLC shall have been suspended or materially limited, or minimum or maximum prices for trading shall have been fixed, or maximum ranges for prices for securities shall have been required by FINRA or by order of the Commission or any other Government Entity having jurisdiction; or (iii) if the United States shall have become involved in a new war or a material increase in major hostilities; or (iv) if a banking moratorium has been declared by a New York State or federal authority; or (v) if a moratorium on foreign exchange trading has been declared which materially adversely impacts the United States securities markets; or (vi) if the Company shall have sustained a material loss by fire, flood, accident, hurricane, earthquake, theft, sabotage or other calamity or malicious act which, whether or not such loss shall have been insured, will, in Representative's opinion, make it inadvisable to proceed with the delivery of the Firm Securities; or (vii) if the Company is in material breach of its representations, warranties or covenants hereunder; or (viii) if the Representative shall have knowledge after the date hereof of such a Material Adverse Change in the conditions of the Company, or such adverse material change in general market conditions, in each case, as in the Representative's reasonable judgment would make it impracticable to proceed with the offering, sale and/or delivery of the Public Securities or to enforce contracts made by the Underwriters for the sale of the Public Securities. Section 5 of this Agreement shall survive any termination of this Agreement.

(c) Expenses. Notwithstanding anything to the contrary in this Agreement, except in the case of a default by the Underwriters pursuant to Section 6(b) above, in the event that this Agreement shall not be carried out for any reason whatsoever, within the time specified herein or any extensions thereof pursuant to the terms herein, the Company shall be obligated to pay to the Representative its actual and accountable out-of-pocket expenses related to the transactions contemplated herein then due and payable and upon demand the Company shall pay the full amount thereof to the Representative (less amounts previously advanced to the Underwriters); provided that any such reimbursement shall be subject to the limits set forth in Section 3(h); provided, further, however, that such expense cap in no way limits or impairs the indemnification and contribution provisions of this Agreement. Notwithstanding the foregoing, any advance received by the Representative will be reimbursed to the Company to the extent not actually incurred in compliance with FINRA Rule 5110(g)(4)(A).

(d) Indemnification. Notwithstanding any contrary provision contained in this Agreement, any election hereunder or any termination of this Agreement, and whether or not this Agreement is otherwise carried out, the provisions of Section 5 shall remain in full force and effect and shall not be in any way affected by, such election or termination or failure to carry out the terms of this Agreement or any part hereof.

(e) Representations, Warranties, Agreements to Survive. All representations, warranties and agreements contained in this Agreement or in certificates of officers of the Company submitted pursuant hereto, shall remain operative and in full force and effect regardless of (i) any investigation made by or on behalf of any Underwriter or its affiliates or selling agents, any person controlling any Underwriter, its officers or directors or any person controlling the Company or (ii) delivery of and payment for the Public Securities.

9. Miscellaneous.

(a) Notices. All communications hereunder, except as herein otherwise specifically provided, shall be in writing and addressed to the other party at its address set forth below (or to such other address that the receiving party may designate from time to time in accordance with this Section 9(a)), and shall be deemed to have been given (a) three (3) days after mailing if sent by certified mail return receipt requested, (b) one (1) day after mailing if sent by receipted overnight carrier (i.e. Federal Express), provided that proof of delivery or rejection is obtained, or (c) when delivered if by hand or sent by email to the physical address or email address set forth below.

If to the Representative:

Dawson James Securities, Inc.
101 N. Federal Highway Suite 600
Boca Raton, Florida 33432
Email: [●]
Attention: [●]

With copies to (*which shall not constitute notice*):

ArentFox Schiff LLP
1717 K Street, NW
Washington, DC 20001
ralph.demartino@afslaw.com
Attention: Ralph V. De Martino

If to the Company:

Arch Therapeutics, Inc.
235 Walnut Street
Suite 6
Framingham, MA 01702
Email: []
Attention: []

With copies to (*which shall not constitute notice*):

Lowenstein Sandler LLP
One Lowenstein Drive
Roseland, NJ 07068
Email: []
Attention: []

(b) Headings. The headings contained herein are for the sole purpose of convenience of reference, and shall not in any way limit or affect the meaning or interpretation of any of the terms or provisions of this Agreement.

(c) Amendment. This Agreement may only be amended by a written instrument executed by each of the parties hereto.

(d) Entire Agreement. This Agreement (together with the other agreements and documents being delivered pursuant to or in connection with this Agreement) constitutes the entire agreement of the parties hereto with respect to the subject matter hereof and thereof, and supersedes all prior agreements and understandings of the parties, oral and written, with respect to the subject matter hereof. Notwithstanding anything to the contrary set forth herein, it is understood and agreed by the parties hereto that all other terms and conditions of that certain engagement letter between the Company and Representative, dated as of February 21, 2023 shall remain in full force and effect.

(e) Binding Effect. This Agreement shall inure solely to the benefit of and shall be binding upon the Representative, the Underwriters, each Indemnified Person referred to in Section 5, the Company and the controlling persons, directors and officers referred to in Section 5 hereof, and their respective successors, legal representatives, heirs and assigns, and no other person shall have or be construed to have any legal or equitable right, remedy or claim under or in respect of or by virtue of this Agreement or any provisions herein contained. The term "successors and assigns" shall not include a purchaser, in its capacity as such, of securities from any of the Underwriters.

(f) Governing Law; Consent to Jurisdiction; Trial by Jury. This Agreement shall be governed by and construed and enforced in accordance with the laws of the State of New York, without giving effect to conflict of laws principles thereof. The Company hereby agrees that any action, proceeding or claim arising out of, or relating in any way to this Agreement shall be brought and enforced in the New York Supreme Court, County of New York, or in the United States District Court for the Southern District of New York, and irrevocably submits to such jurisdiction, which jurisdiction shall be exclusive. The Company hereby waives any objection to such exclusive jurisdiction and that such courts represent an inconvenient forum. Any such process or summons to be served upon the Company may be served by transmitting a copy thereof by registered or certified mail, return receipt requested, postage prepaid, addressed to it at the address set forth in Section 9(a) hereof. Such mailing shall be deemed personal service and shall be legal and binding upon the Company in any action, proceeding or claim. THE COMPANY (ON ITS BEHALF AND, TO THE EXTENT PERMITTED BY APPLICABLE LAW, ON BEHALF OF ITS STOCKHOLDERS AND AFFILIATES) AND EACH OF THE UNDERWRITERS HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.

(g) Execution in Counterparts. This Agreement may be executed in one or more counterparts, and by the different parties hereto in separate counterparts, each of which shall be deemed to be an original, but all of which taken together shall constitute one and the same agreement, and shall become effective when one or more counterparts has been signed by each of the parties hereto and delivered to each of the other parties hereto. Delivery of a signed counterpart of this Agreement by email/pdf transmission shall constitute valid and sufficient delivery thereof.

(h) Waiver, etc. The failure of any of the parties hereto to at any time enforce any of the provisions of this Agreement shall not be deemed or construed to be a waiver of any such provision, nor to in any way effect the validity of this Agreement or any provision hereof or the right of any of the parties hereto to thereafter enforce each and every provision of this Agreement. No waiver of any breach, non-compliance or non-fulfillment of any of the provisions of this Agreement shall be effective unless set forth in a written instrument executed by the party or parties against whom or which enforcement of such waiver is sought; and no waiver of any such breach, non-compliance or non-fulfillment shall be construed or deemed to be a waiver of any other or subsequent breach, non-compliance or non-fulfillment.

[Signature Page Follows]

[Signature Page]
Underwriting Agreement

If the foregoing correctly sets forth the understanding between the Underwriters and the Company, please so indicate in the space below.

Very truly yours,

Arch therapeutics, Inc.

By: _____
Name:
Title:

Confirmed as of the date first written above
mentioned, on behalf of itself and as
Representative of the several Underwriters
named on Schedule 1 hereto:

Dawson James Securities, Inc.

By: _____
Name:
Title:

SCHEDULE 1

Underwriter	Total Number of Firm Securities to be Purchased
Dawson James Securities, Inc.	[•]
	[•]
Total:	[•]

SCHEDULE 2

Pricing Information

Number of Firm Shares: [●]

Number of Firm Warrants: [●] Warrants

Number of Option Shares: [●]

Number of Option Warrants: [●] Warrants

Public Offering Price per one Firm Share and one Warrant: \$[●]

Underwriting Discount per one Firm Share and one Warrant: \$[●] (8.0%)

Price per Option Share: \$[●]

Underwriting Discount per Option Share: \$[●]

Price per Option Warrant: \$0.01

Underwriting Discount per Option Warrant: \$0.0092 (8.0%)

EXHIBIT A

Form of Representative's Warrant

EXHIBIT B

Form of Lock-Up Agreement

WARRANT AGENCY AGREEMENT

WARRANT AGENCY AGREEMENT, dated as of September [], 2023 (“Agreement”), between Arch Therapeutics, Inc., a Nevada corporation (the “Company”), and Empire Stock Transfer, a [federally chartered trust company] (the “Warrant Agent”).

WITNESSETH

WHEREAS, pursuant to a registered offering by the Company of units (the “Units”), each consisting of (a) one share of common stock, par value \$0.001 per share (the “Common Stock”), or, in lieu of Common Stock, one pre-funded warrant to purchase a share of Common Stock (the “Pre-Funded Warrants”), and (b) one warrant to purchase a share of Common Stock (the “Common Warrants”), pursuant to an effective registration statement on Form S-1 (File No. 333-268008) (the “Registration Statement”), the Company wishes to issue the Common Warrants in book entry form entitling the respective holders of the Common Warrants (the “Holders”, which term shall include a Holder’s transferees, successors and assigns and “Holder” shall include, if the Common Warrants are held in “street name,” a Participant (as defined below) or a designee appointed by such Participant) to purchase an aggregate of up to [] shares of Common Stock upon the terms and subject to the conditions hereinafter set forth (the “Offering”);

WHEREAS, the shares of Common Stock and Common Warrants to be issued in connection with the Offering shall be immediately separable and will be issued separately, but will be purchased together in the Offering; and

WHEREAS, the Company wishes the Warrant Agent to act on behalf of the Company, and the Warrant Agent is willing so to act, in connection with the issuance, registration, transfer, exchange, exercise and replacement of the Common Warrants and, in the Warrant Agent’s capacity as the Company’s transfer agent, the delivery of the Warrant Shares (as defined below).

NOW, THEREFORE, in consideration of the premises and the mutual agreements herein set forth, the parties hereby agree as follows:

Section 1. Certain Definitions. For purposes of this Agreement, the following terms have the meanings indicated:

(a) “Business Day” means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which The Nasdaq Stock Market is authorized or required by law or other governmental action to close.

(b) “Close of Business” on any given date means 5:00 p.m., New York City time, on such date; provided, however, that if such date is not a Business Day it means 5:00 p.m., New York City time, on the next succeeding Business Day.

(c) “Person” means an individual, corporation, association, partnership, limited liability company, joint venture, trust, unincorporated organization, government or political subdivision thereof or governmental agency or other entity.

(d) “Warrant Certificate” means a certificate issued to a Holder, representing such number of Warrant Shares as is indicated therein, provided that any reference to the delivery of a Warrant Certificate in this Agreement shall include delivery of notice from the Depositary or a Participant (each as defined below) of the transfer or exercise of Warrant in the form of a Global Warrant (as defined below).

(e) “Warrant Shares” means the shares of Common Stock underlying the Common Warrants and issuable upon exercise of the Common Warrants.

All other capitalized terms used but not otherwise defined herein shall have the meaning ascribed to such terms in the Common Warrant.

Section 2. Appointment of Warrant Agent. The Company hereby appoints the Warrant Agent to act as agent for the Company in accordance with the terms and conditions hereof, and the Warrant Agent hereby accepts such appointment.

Section 3. Global Warrants.

(a) The Common Warrants shall be issuable in book entry form (the “Global Warrants”). All of the Common Warrants shall initially be represented by one or more Global Warrants, in the form of the Warrant Certificate, deposited with the Warrant Agent and registered in the name of Cede & Co., a nominee of The Depository Trust Company (the “Depository”), or as otherwise directed by the Depository. Ownership of beneficial interests in the Common Warrants shall be shown on, and the transfer of such ownership shall be effected through, records maintained by (i) the Depository or its nominee for each Global Warrant or (ii) institutions that have accounts with the Depository (such institution, with respect to a Common Warrant in its account, a “Participant”).

(b) If the Depository subsequently ceases to make its book-entry settlement system available for the Common Warrants, the Company may instruct the Warrant Agent regarding other arrangements for book-entry settlement. In the event that the Common Warrants are not eligible for, or it is no longer necessary to have the Warrants available in, book-entry form, the Warrant Agent shall provide written instructions to the Depository to deliver to the Warrant Agent for cancellation each Global Warrant, and the Company shall instruct the Warrant Agent to deliver to each Holder a Warrant Certificate.

(c) A Holder has the right to elect at any time or from time to time a Warrant Exchange (as defined below) pursuant to a Warrant Certificate Request Notice (as defined below). Upon written notice by a Holder to the Warrant Agent for the exchange of some or all of such Holder’s Global Warrants for a Warrant Certificate evidencing the same number of Common Warrants, which request shall be in the form attached hereto as Annex A (a “Warrant Certificate Request Notice” and the date of delivery of such Warrant Certificate Request Notice by the Holder, the “Warrant Certificate Request Notice Date” and the deemed surrender upon delivery by the Holder of a number of Global Warrants for the same number of Common Warrants evidenced by a Warrant Certificate, a “Warrant Exchange”), the Warrant Agent shall promptly effect the Warrant Exchange and shall promptly issue and deliver to the Holder a Warrant Certificate for such number of Common Warrants in the name set forth in the Warrant Certificate Request Notice. Such Warrant Certificate shall be dated the original issue date of the Common Warrants and shall be manually executed by an authorized signatory of the Company. In connection with a Warrant Exchange, the Company agrees to deliver, or to direct the Warrant Agent to deliver, the Warrant Certificate to the Holder within three (3) Business Days of the Warrant Certificate Request Notice pursuant to the delivery instructions in the Warrant Certificate Request Notice (“Warrant Certificate Delivery Date”). If the Company fails for any reason to deliver to the Holder the Warrant Certificate subject to the Warrant Certificate Request Notice by the Warrant Certificate Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each \$1,000 of Warrant Shares evidenced by such Warrant Certificate (based on the VWAP (as defined in the Common Warrant) of the Common Stock on the Warrant Certificate Request Notice Date), \$10 per Business Day (increasing to \$20 per Business Day on the fifth Business Day after such liquidated damages begin to accrue) for each Business Day after such Warrant Certificate Delivery Date until such Warrant Certificate is delivered or, prior to delivery of such Warrant Certificate, the Holder rescinds such Warrant Exchange. The Company covenants and agrees that, upon the date of delivery of the Warrant Certificate Request Notice, the Holder shall be deemed to be the holder of the Warrant Certificate and, notwithstanding anything to the contrary set forth herein, the Warrant Certificate shall be deemed for all purposes to contain all of the terms and conditions of the Common Warrants evidenced by such Warrant Certificate and the terms of this Agreement, other than Section 3(c), which shall not apply to the Common Warrants evidenced by a Warrant Certificate. In the event a beneficial owner requests a Warrant Exchange, upon issuance of the paper Warrant Certificate, the Company shall act as warrant agent and the terms of the paper Warrant Certificate so issued shall exclusively govern in respect thereof. For purposes of clarity, if there is a conflict between the express terms of this Agreement and any Warrant Certificate with respect to the terms of the Common Warrants, the terms of such Warrant Certificate shall govern and control.

Section 4. Form of Warrant. The Common Warrants, together with the form of election to purchase Common Stock (the “Exercise Notice”) and the form of assignment to be printed on the reverse thereof, whether a Warrant Certificate or a Global Warrant, shall be substantially in the form of Exhibit 1 hereto.

Section 5. Countersignature and Registration.

(a) The Common Warrants shall be executed on behalf of the Company by its Chief Executive Officer, Chief Financial Officer or other authorized officer, either manually or by facsimile signature, and have affixed thereto the Company's seal or a facsimile thereof which shall be attested by the Secretary or an Assistant Secretary of the Company, either manually or by facsimile signature. The Common Warrants shall be countersigned by the Warrant Agent either manually or by facsimile signature and shall not be valid for any purpose unless so countersigned. In case any officer of the Company who shall have signed a Common Warrant shall cease to be such officer of the Company before countersignature by the Warrant Agent and issuance and delivery by the Company, such Common Warrant, nevertheless, may be countersigned by the Warrant Agent, issued and delivered with the same force and effect as though the person who signed such Common Warrant had not ceased to be such officer of the Company; and any Common Warrant may be signed on behalf of the Company by any person who, at the actual date of the execution of such Common Warrant, shall be a proper officer of the Company to sign such Common Warrant, although at the date of the execution of this Warrant Agreement any such person was not such an officer.

(b) The Warrant Agent will keep or cause to be kept, at one of its offices, or at the office of one of its agents, books for registration and transfer of the Warrant Certificates issued hereunder. Such books shall show the names and addresses of the respective Holders of the Warrant Certificates, the number of warrants evidenced on the face of each of such Warrant Certificate and the date of each of such Warrant Certificate. The Warrant Agent will create a special account for the issuance of Warrant Certificates.

Section 6. Transfer, Split Up, Combination and Exchange of Warrant Certificates; Mutilated, Destroyed, Lost or Stolen Warrant Certificates

(a) Subject to the provisions of the Common Warrant and the last sentence of this first paragraph of Section 6 and subject to applicable law, rules or regulations, or any "stop transfer" instructions the Company may give to the Warrant Agent, at any time after the closing date of the Offering, and at or prior to the Close of Business on the Termination Date, any Warrant Certificate or Warrant Certificates or Global Warrant or Global Warrants may be transferred, split up, combined or exchanged for another Warrant Certificate or Warrant Certificates or Global Warrant or Global Warrants, entitling the Holder to purchase a like number of shares of Common Stock as the Warrant Certificate or Warrant Certificates or Global Warrant or Global Warrants surrendered then entitled such Holder to purchase. Any Holder desiring to transfer, split up, combine or exchange any Warrant Certificate or Global Warrant shall make such request in writing delivered to the Warrant Agent, and shall surrender the Warrant Certificate or Warrant Certificates to be transferred, split up, combined or exchanged at the principal office of the Warrant Agent, provided that no such surrender is applicable to the Holder of a Global Warrant. Any requested transfer of Warrants, whether a Global Warrant or a Warrant Certificate, shall be accompanied by reasonable evidence of authority of the party making such request that may be reasonably required by the Warrant Agent. Thereupon the Warrant Agent shall, subject to the last sentence of this first paragraph of Section 6, countersign and deliver to the Person entitled thereto any Warrant Certificate or Global Warrant, as the case may be, as so requested. The Company may require payment from the Holder of a sum sufficient to cover any tax or governmental charge that may be imposed in connection with any transfer, split up, combination or exchange of Common Warrants. The Company shall compensate the Warrant Agent per the fee schedule mutually agreed upon by the parties hereto and provided separately on the date hereof.

(b) Upon receipt by the Warrant Agent of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of a Warrant Certificate, which evidence shall include an affidavit of loss, or in the case of mutilated certificates, the certificate or portion thereof remaining, and, in case of loss, theft or destruction, of indemnity or security acceptable to the Company and the Warrant Agent (but shall not include the posting of any bond by a Holder), and satisfaction of any other reasonable requirements established by Section 8-405 of the Uniform Commercial Code as in effect in the State of Delaware, and reimbursement to the Company and the Warrant Agent of all reasonable expenses incidental thereto, and upon surrender to the Warrant Agent and cancellation of the Warrant Certificate if mutilated, the Company will make and deliver a new Warrant Certificate of like tenor to the Warrant Agent for delivery to the Holder in lieu of the Warrant Certificate so lost, stolen, destroyed or mutilated.

Section 7. Exercise of Warrants; Exercise Price; Termination Date.

(a) The Common Warrants shall be exercisable commencing on the Initial Exercise Date. The Common Warrants shall cease to be exercisable and shall terminate and become void, and all rights thereunder and under this Agreement shall cease, at or prior to the Close of Business on the Termination Date. Subject to the foregoing and to Section 7(b) below, the Holder of a Common Warrant may exercise the Common Warrant in whole or in part upon providing the items required by Section 7(c) below to the Warrant Agent at the principal office of the Warrant Agent or to the office of one of its agents as may be designated by the Warrant Agent from time to time. In the case of the Holder of a Global Warrant, the Holder shall deliver the executed Exercise Notice and payment of the Exercise Price pursuant to Section 2(a) of the Common Warrant. Notwithstanding any other provision in this Agreement, a holder whose interest in a Global Warrant is a beneficial interest in a Global Warrant held in book-entry form through the Depositary (or another established clearing corporation performing similar functions), shall effect exercises by delivering to the Depositary (or such other clearing corporation, as applicable) the appropriate instruction form for exercise, complying with the procedures to effect exercise that are required by the Depositary (or such other clearing corporation, as applicable). The Company acknowledges that the bank accounts maintained by the Warrant Agent in connection with the services provided under this Agreement will be in its name and that the Warrant Agent may receive investment earnings in connection with the investment at Warrant Agent risk and for its benefit of funds held in those accounts from time to time. Neither the Company nor the Holders will receive interest on any deposits or Exercise Price. No ink-original Exercise Notice shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Exercise Notice be required.

(b) Upon receipt of an Exercise Notice for a cashless exercise pursuant to Section 2(c) of the Common Warrant (each, a "Cashless Exercise"), the Company will promptly calculate and transmit to the Warrant Agent the number of Warrant Shares issuable in connection with such Cashless Exercise and deliver a copy of the Exercise Notice to the Warrant Agent, which shall issue such number of Warrant Shares in connection with such Cashless Exercise.

(c) Upon the Warrant Agent's receipt, at or prior to the Close of Business on the Termination Date set forth in a Common Warrant, of the executed Exercise Notice, accompanied by payment of the Exercise Price pursuant to Section 2(a) of the Common Warrant, the shares to be purchased (other than in the case of a Cashless Exercise), an amount equal to any applicable tax, governmental charge or expense reimbursement referred to in Section 6 by certified check or bank draft payable to the order of the Company and, in the case of an exercise of a Common Warrant in the form of a Warrant Certificate for all of the Warrant Shares represented thereby, the Warrant Certificate, the Warrant Agent shall cause the Warrant Shares underlying such Common Warrant to be delivered to or upon the order of the Holder of such Common Warrant, registered in such name or names as may be designated by such Holder, no later than the Warrant Share Delivery Date. If the Company is then a participant in the DWAC system of the Depositary and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by Holder or (B) the Common Warrant is being exercised via Cashless Exercise, then the certificates for Warrant Shares shall be transmitted by the Warrant Agent to the Holder by crediting the account of the Holder's broker with the Depositary through its DWAC system. For the avoidance of doubt, if the Company becomes obligated to pay any amounts to any Holders pursuant to Section 2(d)(iv) of the Common Warrant, such obligation shall be solely that of the Company and not that of the Warrant Agent. Notwithstanding anything else to the contrary in this Agreement, except in the case of a Cashless Exercise, if any Holder fails to duly deliver payment to the Warrant Agent of an amount equal to the aggregate Exercise Price of the Warrant Shares to be purchased upon exercise of such Holder's Common Warrant as set forth in Section 7(a) hereof, the Warrant Agent will not be obligated to deliver certificates representing any such Warrant Shares (via DWAC or otherwise) until following receipt of such payment, and the applicable Warrant Share Delivery Date shall be deemed extended by one day for each day (or part thereof) until such payment is delivered to the Warrant Agent.

(d) The Warrant Agent shall deposit all funds received by it in payment of the Exercise Price for all Warrants in the account of the Company maintained with the Warrant Agent for such purpose (or to such other account as directed by the Company in writing) and shall advise the Company via telephone at the end of each day on which funds for the exercise of any Common Warrant are received of the amount so deposited to its account. The Warrant Agent shall promptly confirm such telephonic advice to the Company in writing.

(e) In case the Holder of any Warrant Certificate exercises fewer than all Common Warrants evidenced thereby and surrenders such Warrant Certificate in connection with such partial exercise, a new Warrant Certificate evidencing the number of Warrant Shares equivalent to the number of Warrant Shares remaining unexercised may be issued by the Warrant Agent to the Holder of such Warrant Certificate or to his duly authorized assigns in accordance with Section 2(d)(ii) of the Common Warrant, subject to the provisions of Section 6 hereof.

Section 8. Cancellation and Destruction of Warrant Certificates. All Warrant Certificates surrendered for the purpose of exercise, transfer, split up, combination or exchange shall, if surrendered to the Company or to any of its agents, be delivered to the Warrant Agent for cancellation or in canceled form, or, if surrendered to the Warrant Agent, shall be canceled by it, and no Warrant Certificates shall be issued in lieu thereof except as expressly permitted by any of the provisions of this Agreement. The Company shall deliver to the Warrant Agent for cancellation and retirement, and the Warrant Agent shall so cancel and retire, any other Warrant Certificate purchased or acquired by the Company otherwise than upon the exercise thereof. The Warrant Agent shall deliver all canceled Warrant Certificates to the Company, or shall, at the written request of the Company, destroy such canceled Warrant Certificates, and in such case shall deliver a certificate of destruction thereof to the Company, subject to any applicable law, rule or regulation requiring the Warrant Agent to retain such canceled certificates.

Section 9. Certain Representations: Reservation and Availability of Shares of Common Stock or Cash.

(a) This Agreement has been duly authorized, executed and delivered by the Company and, assuming due authorization, execution and delivery hereof by the Warrant Agent, constitutes a valid and legally binding obligation of the Company enforceable against the Company in accordance with its terms, and the Common Warrants have been duly authorized, executed and issued by the Company and, assuming due authentication thereof by the Warrant Agent pursuant hereto and payment therefor by the Holders as provided in the Registration Statement, constitute valid and legally binding obligations of the Company enforceable against the Company in accordance with their terms and entitled to the benefits hereof; in each case except as enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium and other similar laws relating to or affecting creditors' rights generally or by general equitable principles (regardless of whether such enforceability is considered in a proceeding in equity or at law).

(b) The Company covenants and agrees that it will cause to be reserved and kept available out of its authorized and unissued shares of Common Stock or its authorized and issued shares of Common Stock held in its treasury, free from preemptive rights, the number of shares of Common Stock that will be sufficient to permit the exercise in full of all outstanding Common Warrants.

(c) The Warrant Agent will create a special account for the issuance of Common Stock upon the exercise of Common Warrants.

(d) The Company further covenants and agrees that it will pay when due and payable any and all federal and state transfer taxes and charges which may be payable in respect of the original issuance or delivery of the Warrant Certificates or certificates evidencing Common Stock upon exercise of the Common Warrants. The Company shall not, however, be required to pay any tax or governmental charge which may be payable in respect of any transfer involved in the transfer or delivery of Warrant Certificates or the issuance or delivery of certificates for Common Stock in a name other than that of the Holder of the Warrant Certificate evidencing Common Warrants surrendered for exercise or to issue or deliver any certificate for shares of Common Stock upon the exercise of any Common Warrants until any such tax or governmental charge shall have been paid (any such tax or governmental charge being payable by the Holder of such Warrant Certificate at the time of surrender) or until it has been established to the Company's reasonable satisfaction that no such tax or governmental charge is due.

Section 10. Common Stock Record Date. Each Holder shall be deemed to have become the holder of record for the Warrant Shares pursuant to Section 2(d)(i) of the Common Warrants.

Section 11. Adjustment of Exercise Price, Number of Shares of Common Stock or Number of the Company Warrants. The Exercise Price, the number of shares covered by each Common Warrant and the number of Common Warrants outstanding are subject to adjustment from time to time as provided in Section 3 of the Common Warrant. In the event that at any time, as a result of an adjustment made pursuant to Section 3 of the Common Warrant, the Holder of any Common Warrant thereafter exercised shall become entitled to receive any shares of capital stock of the Company other than shares of Common Stock, thereafter the number of such other shares so receivable upon exercise of any Common Warrant shall be subject to adjustment from time to time in a manner and on terms as nearly equivalent as practicable to the provisions with respect to the shares contained in Section 3 of the Common Warrant, and the provisions of Sections 7, 9 and 13 of this Agreement with respect to the shares of Common Stock shall apply on like terms to any such other shares. All Common Warrants originally issued by the Company subsequent to any adjustment made to the Exercise Price pursuant to the Common Warrant shall evidence the right to purchase, at the adjusted Exercise Price, the number of shares of Common Stock purchasable from time to time hereunder upon exercise of the Common Warrants, all subject to further adjustment as provided herein.

Section 12. Certification of Adjusted Exercise Price or Number of Shares of Common Stock. Whenever the Exercise Price or the number of shares of Common Stock issuable upon the exercise of each Common Warrant is adjusted as provided in Section 11 or 13, the Company shall (a) promptly prepare a certificate setting forth the Exercise Price of each Common Warrant as so adjusted, and a brief statement of the facts accounting for such adjustment, (b) promptly file with the Warrant Agent and with each transfer agent for the Common Stock a copy of such certificate and (c) instruct the Warrant Agent to send a brief summary thereof to each Holder of a Common Warrant.

Section 13. Fractional Shares of Common Stock.

(a) The Company shall not issue fractions of Common Warrants or distribute a Global Warrant or Warrant Certificates that evidence fractional Common Warrants. Whenever any fractional Common Warrant would otherwise be required to be issued or distributed, the actual issuance or distribution shall reflect a rounding of such fraction either up or down to the nearest whole Common Warrant.

(b) The Company shall not issue fractions of shares of Common Stock upon exercise of Common Warrants or distribute stock certificates that evidence fractional shares of Common Stock. Whenever any fraction of a share of Common Stock would otherwise be required to be issued or distributed, the actual issuance or distribution in respect thereof shall be made in accordance with Section 2(d)(v) of the Common Warrant.

Section 14. Conditions of the Warrant Agent's Obligations. The Warrant Agent accepts its obligations herein set forth upon the terms and conditions hereof, including the following to all of which the Company agrees and to all of which the rights hereunder of the Holders from time to time of the Common Warrant shall be subject:

(a) Compensation and Indemnification. The Company agrees promptly to pay the Warrant Agent the compensation detailed on Exhibit 2 hereto for all services rendered by the Warrant Agent and to reimburse the Warrant Agent for reasonable out-of-pocket expenses (including reasonable counsel fees) incurred without gross negligence, bad faith or willful misconduct by the Warrant Agent in connection with the services rendered hereunder by the Warrant Agent. The Company also agrees to indemnify the Warrant Agent for, and to hold it harmless against, any loss, liability or expense incurred without gross negligence, bad faith or willful misconduct on the part of the Warrant Agent, arising out of or in connection with its acting as Warrant Agent hereunder, including the reasonable costs and expenses of defending against any claim of such liability.

(b) Agent for the Company. In acting under this Warrant Agreement and in connection with the Warrant Certificates, the Warrant Agent is acting solely as agent of the Company and does not assume any obligations or relationship of agency or trust for or with any of the Holders of Warrant Certificates or beneficial owners of Common Warrants.

(c) Counsel. The Warrant Agent may consult with counsel satisfactory to it, which may include counsel for the Company, and the written advice of such counsel shall be full and complete authorization and protection in respect of any action taken, suffered or omitted by it hereunder in good faith and in accordance with the advice of such counsel.

(d) Documents. The Warrant Agent shall be protected and shall incur no liability for or in respect of any action taken or omitted by it in reliance upon any Warrant Certificate, notice, direction, consent, certificate, affidavit, statement or other paper or document reasonably believed by it to be genuine and to have been presented or signed by the proper parties.

(e) Certain Transactions. The Warrant Agent, and its officers, directors and employees, may become the owner of, or acquire any interest in, Common Warrants, with the same rights that it or they would have if it were not the Warrant Agent hereunder, and, to the extent permitted by applicable law, it or they may engage or be interested in any financial or other transaction with the Company and may act on, or as depository, trustee or agent for, any committee or body of Holders of Warrant Securities or other obligations of the Company as freely as if it were not the Warrant Agent hereunder. Nothing in this Warrant Agreement shall be deemed to prevent the Warrant Agent from acting as trustee under any indenture to which the Company is a party.

(f) No Liability for Interest. Unless otherwise agreed with the Company, the Warrant Agent shall have no liability for interest on any monies at any time received by it pursuant to any of the provisions of this Agreement or of the Warrant Certificates.

(g) No Liability for Invalidity. The Warrant Agent shall have no liability with respect to any invalidity of this Agreement or any of the Warrant Certificates (except as to the Warrant Agent's countersignature thereon).

(h) No Responsibility for Representations. The Warrant Agent shall not be responsible for any of the recitals or representations herein or in the Warrant Certificates (except as to the Warrant Agent's countersignature thereon), all of which are made solely by the Company.

(i) No Implied Obligations. The Warrant Agent shall be obligated to perform only such duties as are herein and in the Common Warrants specifically set forth and no implied duties or obligations shall be read into this Agreement or the Common Warrants against the Warrant Agent. The Warrant Agent shall not be under any obligation to take any action hereunder which may tend to involve it in any expense or liability, the payment of which within a reasonable time is not, in its reasonable opinion, assured to it. The Warrant Agent shall not be accountable or under any duty or responsibility for the use by the Company of any of the Common Warrants authenticated by the Warrant Agent and delivered by it to the Company pursuant to this Agreement or for the application by the Company of the proceeds of the Common Warrants. The Warrant Agent shall have no duty or responsibility in case of any default by the Company in the performance of its covenants or agreements contained herein or in the Common Warrants or in the case of the receipt of any written demand from a Holder of a Warrant Certificate with respect to such default, including, without limiting the generality of the foregoing, any duty or responsibility to initiate or attempt to initiate any proceedings at law.

Section 15. Purchase or Consolidation or Change of Name of Warrant Agent. Any corporation into which the Warrant Agent or any successor Warrant Agent may be merged or with which it may be consolidated, or any corporation resulting from any merger or consolidation to which the Warrant Agent or any successor Warrant Agent shall be party, or any corporation succeeding to the corporate trust business of the Warrant Agent or any successor Warrant Agent, shall be the successor to the Warrant Agent under this Agreement without the execution or filing of any paper or any further act on the part of any of the parties hereto, provided that such corporation would be eligible for appointment as a successor Warrant Agent under the provisions of Section 17. In case at the time such successor Warrant Agent shall succeed to the agency created by this Agreement any of the Common Warrants shall have been countersigned but not delivered, any such successor Warrant Agent may adopt the countersignature of the predecessor Warrant Agent and deliver such Common Warrants so countersigned; and in case at that time any of the Common Warrants shall not have been countersigned, any successor Warrant Agent may countersign such Common Warrants either in the name of the predecessor Warrant Agent or in the name of the successor Warrant Agent; and in all such cases such Common Warrants shall have the full force provided in the Common Warrants and in this Agreement.

In case at any time the name of the Warrant Agent shall be changed and at such time any of the Common Warrants shall have been countersigned but not delivered, the Warrant Agent may adopt the countersignature under its prior name and deliver Common Warrants so countersigned; and in case at that time any of the Common Warrants shall not have been countersigned, the Warrant Agent may countersign such Common Warrants either in its prior name or in its changed name; and in all such cases such Common Warrants shall have the full force provided in the Common Warrants and in this Agreement.

Section 16. Duties of Warrant Agent. The Warrant Agent undertakes the duties and obligations imposed by this Agreement upon the following terms and conditions, by all of which the Company, by its acceptance hereof, shall be bound:

(a) The Warrant Agent may consult with legal counsel reasonably acceptable to the Company (who may be legal counsel for the Company), and the opinion of such counsel shall be full and complete authorization and protection to the Warrant Agent as to any action taken or omitted by it in good faith and in accordance with such opinion.

(b) Whenever in the performance of its duties under this Agreement the Warrant Agent shall deem it necessary or desirable that any fact or matter be proved or established by the Company prior to taking or suffering any action hereunder, such fact or matter (unless other evidence in respect thereof be herein specifically prescribed) may be deemed to be conclusively proved and established by a certificate signed by the Chief Executive Officer or Chief Financial Officer of the Company; and such certificate shall be full authentication to the Warrant Agent for any action taken or suffered in good faith by it under the provisions of this Agreement in reliance upon such certificate.

(c) Subject to the limitation set forth in Section 14, the Warrant Agent shall be liable hereunder only for its own gross negligence, bad faith or willful misconduct, or for a breach by it of this Agreement.

(d) The Warrant Agent shall not be liable for or by reason of any of the statements of fact or recitals contained in this Agreement or in the Common Warrants (except its countersignature thereof) by the Company or be required to verify the same, but all such statements and recitals are and shall be deemed to have been made by the Company only.

(e) The Warrant Agent shall not be under any responsibility in respect of the validity of this Agreement or the execution and delivery hereof (except the due execution hereof by the Warrant Agent) or in respect of the validity or execution of any Common Warrant (except its countersignature thereof); nor shall it be responsible for any breach by the Company of any covenant or condition contained in this Agreement or in any Common Warrant; nor shall it be responsible for the adjustment of the Exercise Price or the making of any change in the number of shares of Common Stock required under the provisions of Section 11 or 13 or responsible for the manner, method or amount of any such change or the ascertaining of the existence of facts that would require any such adjustment or change (except with respect to the exercise of Common Warrants evidenced by Warrant Certificates after actual notice of any adjustment of the Exercise Price); nor shall it by any act hereunder be deemed to make any representation or warranty as to the authorization or reservation of any shares of Common Stock to be issued pursuant to this Agreement or any Common Warrant or as to whether any shares of Common Stock will, when issued, be duly authorized, validly issued, fully paid and nonassessable.

(f) Each party hereto agrees that it will perform, execute, acknowledge and deliver or cause to be performed, executed, acknowledged and delivered all such further and other acts, instruments and assurances as may reasonably be required by the other party hereto for the carrying out or performing by any party of the provisions of this Agreement.

(g) The Warrant Agent is hereby authorized to accept instructions with respect to the performance of its duties hereunder from the Chief Executive Officer or Chief Financial Officer of the Company, and to apply to such officers for advice or instructions in connection with its duties, and it shall not be liable and shall be indemnified and held harmless for any action taken or suffered to be taken by it in good faith in accordance with instructions of any such officer, provided Warrant Agent carries out such instructions without gross negligence, bad faith or willful misconduct.

(h) The Warrant Agent and any shareholder, director, officer or employee of the Warrant Agent may buy, sell or deal in any of the Common Warrants or other securities of the Company or become pecuniarily interested in any transaction in which the Company may be interested, or contract with or lend money to the Company or otherwise act as fully and freely as though it were not Warrant Agent under this Agreement. Nothing herein shall preclude the Warrant Agent from acting in any other capacity for the Company or for any other legal entity.

(i) The Warrant Agent may execute and exercise any of the rights or powers hereby vested in it or perform any duty hereunder either itself or by or through its attorney or agents, and the Warrant Agent shall not be answerable or accountable for any act, default, neglect or misconduct of any such attorney or agents or for any loss to the Company resulting from any such act, default, neglect or misconduct, provided reasonable care was exercised in the selection and continued employment thereof.

Section 17. Change of Warrant Agent. The Warrant Agent may resign and be discharged from its duties under this Agreement upon 10 days' notice in writing sent to the Company and to each transfer agent of the Common Stock, and to the Holders of the Warrant Certificates. The Company may remove the Warrant Agent or any successor Warrant Agent upon 30 days' notice in writing, sent to the Warrant Agent or successor Warrant Agent, as the case may be, and to each transfer agent of the Common Stock, and to the Holders of the Warrant Certificates. If the Warrant Agent shall resign or be removed or shall otherwise become incapable of acting, the Company shall appoint a successor to the Warrant Agent. If the Company shall fail to make such appointment within a period of 30 days after such removal or after it has been notified in writing of such resignation or incapacity by the resigning or incapacitated Warrant Agent or by the Holder of a Warrant Certificate (who shall, with such notice, submit his Warrant Certificate for inspection by the Company), then the Holder of any Warrant Certificate may apply to any court of competent jurisdiction for the appointment of a new Warrant Agent, provided that, for purpose of this Agreement, the Company shall be deemed to be the Warrant Agent until a new warrant agent is appointed. Any successor Warrant Agent, whether appointed by the Company or by such a court, shall be a corporation organized and doing business under the laws of the United States or of a state thereof, in good standing, which is authorized under such laws to exercise corporate trust powers and is subject to supervision or examination by federal or state authority and which has at the time of its appointment as Warrant Agent a combined capital and surplus of at least \$50,000,000. After appointment, the successor Warrant Agent shall be vested with the same powers, rights, duties and responsibilities as if it had been originally named as Warrant Agent without further act or deed; but the predecessor Warrant Agent shall deliver and transfer to the successor Warrant Agent any property at the time held by it hereunder, and execute and deliver any further assurance, conveyance, act or deed necessary for the purpose. Not later than the effective date of any such appointment, the Company shall file notice thereof in writing with the predecessor Warrant Agent and each transfer agent of the Common Stock, and mail a notice thereof in writing to the Holders of the Warrant Certificates. However, failure to give any notice provided for in this Section 17, or any defect therein, shall not affect the legality or validity of the resignation or removal of the Warrant Agent or the appointment of the successor Warrant Agent, as the case may be.

Section 18. Issuance of New Warrants. Notwithstanding any of the provisions of this Agreement or of the Common Warrants to the contrary, the Company may, at its option, issue a new Global Warrant or Warrant Certificates, if any, evidencing Common Warrants in such form as may be approved by its Board of Directors to reflect any adjustment or change in the Exercise Price per share and the number or kind or class of shares of stock or other securities or property purchasable under the Global Warrant or Warrant Certificates, if any, made in accordance with the provisions of this Agreement.

Section 19. Notices. Notices or demands authorized by this Agreement to be given or made (i) by the Warrant Agent or by the Holder of any Warrant Certificate to or on the Company, (ii) subject to the provisions of Section 17, by the Company or by the Holder of any Warrant Certificate to or on the Warrant Agent or (iii) by the Company or the Warrant Agent to the Holder of any Warrant Certificate, shall be deemed given (a) on the date delivered, if delivered personally, (b) on the first Business Day following the deposit thereof with Federal Express or another recognized overnight courier, if sent by Federal Express or another recognized overnight courier, (c) on the fourth Business Day following the mailing thereof with postage prepaid, if mailed by registered or certified mail (return receipt requested), and (d) the date of transmission, if such notice or communication is delivered via facsimile or email attachment at or prior to 5:30 p.m. (New York City time) on a Business Day and (e) the next Business Day after the date of transmission, if such notice or communication is delivered via facsimile or email attachment on a day that is not a Business Day or later than 5:30 p.m. (New York City time) on any Business Day, in each case to the parties at the following addresses (or at such other address for a party as shall be specified by like notice):

- (a) If to the Company, to:

Arch Therapeutics, Inc.
235 Walnut St., Suite 6
Framingham, MA 01702
Attention: CEO

- (b) If to the Warrant Agent, to:

Empire Stock Transfer
1859 Whitney Mesa Drive
Henderson, Nevada 89014
Attention: []

For any notice delivered by email to be deemed given or made, such notice must be followed by notice sent by overnight courier service to be delivered on the next business day following such email, unless the recipient of such email has acknowledged via return email receipt of such email.

(c) If to the Holder of any Warrant Certificate, to the address of such Holder as shown on the registry books of the Company. Any notice required to be delivered by the Company to the Holder of any Common Warrant may be given by the Warrant Agent on behalf of the Company. Notwithstanding any other provision of this Agreement, where this Agreement provides for notice of any event to a Holder of any Warrant Certificate, for a Global Warrant, such notice shall be sufficiently given if given to the Depositary (or its designee) pursuant to the procedures of the Depositary or its designee.

Section 20. Supplements and Amendments.

(a) The Company and the Warrant Agent may from time to time supplement or amend this Agreement without the approval of any Holders of Warrant Certificates in order to cure any ambiguity, to correct or supplement any provision contained herein which may be defective or inconsistent with any other provisions herein, or to make any other provisions with regard to matters or questions arising hereunder which the Company and the Warrant Agent may deem necessary or desirable and which shall not adversely affect the interests of the Holders of the Warrants Certificates in any material respect.

(b) In addition to the foregoing, with the consent of Holders of Warrants, the Company and the Warrant Agent may modify this Agreement for the purpose of adding any provisions to or changing in any manner or eliminating any of the provisions of this Warrant Agreement or modifying in any manner the rights of the Holders of the Warrant Certificates; provided, however, that no modification of the terms (including but not limited to the adjustments described in Section 11) upon which the Common Warrants are exercisable or the rights of the holders of Common Warrants to receive liquidated damages or other payments in cash from the Company or reducing the percentage required for consent to modification of this Agreement may be made without the consent of the Holder of each outstanding warrant certificate affected thereby. As a condition precedent to the Warrant Agent's execution of any amendment, the Company shall deliver to the Warrant Agent a certificate from a duly authorized officer of the Company that states that the proposed amendment complies with the terms of this Section 20.

Section 21. Successors. All covenants and provisions of this Agreement by or for the benefit of the Company or the Warrant Agent shall bind and inure to the benefit of their respective successors and assigns hereunder.

Section 22. Benefits of this Agreement. Nothing in this Agreement shall be construed to give any Person other than the Company, the Holders of Warrant Certificates and the Warrant Agent any legal or equitable right, remedy or claim under this Agreement; but this Agreement shall be for the sole and exclusive benefit of the Company, the Warrant Agent and the Holders of the Warrant Certificates.

Section 23. Governing Law. This Agreement and each Common Warrant issued hereunder shall be governed by, and construed in accordance with, the laws of the State of New York without giving effect to the conflicts of law principles thereof.

Section 24. Counterparts. This Agreement may be executed in any number of counterparts and each of such counterparts shall for all purposes be deemed to be an original, and all such counterparts shall together constitute but one and the same instrument.

Section 25. Captions. The captions of the sections of this Agreement have been inserted for convenience only and shall not control or affect the meaning or construction of any of the provisions hereof.

Section 26. Information. The Company agrees to promptly provide to the Holders of the Common Warrants any information it provides to all holders of the Common Stock, except to the extent any such information is publicly available on the EDGAR system (or any successor thereof) of the Securities and Exchange Commission.

Section 27. Force Majeure. Notwithstanding anything to the contrary contained herein, Warrant Agent shall not be liable for any delays or failures in performance resulting from acts beyond its reasonable control including, without limitation, acts of God, terrorist acts, shortage of supply, breakdowns or malfunctions, interruptions or malfunction of computer facilities, or loss of data due to power failures or mechanical difficulties with information storage or retrieval systems, labor difficulties, war, or civil unrest, it being understood that the Warrant Agent shall use reasonable best efforts which are consistent with accepted practices in the banking industry to resume performance as soon as practicable under the circumstances; provided, however, that this provision shall not, in any respect, affect the obligations of the Company to the Holders under the terms of the Common Warrants.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the day and year first above written.

ARCH THERAPEUTICS, INC.

By: _____
Name:
Title:

EMPIRE STOCK TRANSFER

By: _____
Name:
Title:

Annex A: Form of Warrant Certificate Request Notice

WARRANT CERTIFICATE REQUEST NOTICE

To: Empire Stock Transfer as Warrant Agent for Arch Therapeutics, Inc. (the “Company”)

The undersigned Holder of Common Stock Purchase Warrants (“Warrants”) in the form of Global Warrants issued by the Company hereby elects to receive a Warrant Certificate evidencing the Warrants held by the Holder as specified below:

1. Name of Holder of Warrants in form of Global Warrants: _____
2. Name of Holder in Warrant Certificate (if different from name of Holder of Warrants in form of Global Warrants): _____
3. Number of Warrants in name of Holder in form of Global Warrants: _____
4. Number of Warrants for which Warrant Certificate shall be issued: _____
5. Number of Warrants in name of Holder in form of Global Warrants after issuance of Warrant Certificate, if any: _____
6. Warrant Certificate shall be delivered to the following address:

The undersigned hereby acknowledges and agrees that, in connection with this Warrant Exchange and the issuance of the Warrant Certificate, the Holder is deemed to have surrendered the number of Warrants in form of Global Warrants in the name of the Holder equal to the number of Warrants evidenced by the Warrant Certificate.

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____

Signature of Authorized Signatory of Investing Entity: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Date: _____

Exhibit 1: Form of Warrant

WARRANT AGENCY AGREEMENT

WARRANT AGENCY AGREEMENT, dated as of September [], 2023 (“Agreement”), between Arch Therapeutics, Inc., a Nevada corporation (the “Company”), and Empire Stock Transfer, a [federally chartered trust company] (the “Warrant Agent”).

WITNESSETH

WHEREAS, pursuant to a registered offering by the Company of units (the “Units”), each consisting of (a) one share of common stock, par value \$0.001 per share (the “Common Stock”), or, in lieu of Common Stock, one pre-funded warrant to purchase a share of Common Stock (the “Pre-Funded Warrants”), and (b) one warrant to purchase a share of Common Stock (the “Common Warrants”), pursuant to an effective registration statement on Form S-1 (File No. 333-268008) (the “Registration Statement”), the Company wishes to issue the Pre-Funded Warrants in book entry form entitling the respective holders of the Pre-Funded Warrants (the “Holders”, which term shall include a Holder’s transferees, successors and assigns and “Holder” shall include, if the Pre-Funded Warrants are held in “street name,” a Participant (as defined below) or a designee appointed by such Participant) to purchase an aggregate of up to [] shares of Common Stock upon the terms and subject to the conditions hereinafter set forth (the “Offering”);

WHEREAS, the shares of Common Stock and Pre-Funded Warrants to be issued in connection with the Offering shall be immediately separable and will be issued separately, but will be purchased together in the Offering; and

WHEREAS, the Company wishes the Warrant Agent to act on behalf of the Company, and the Warrant Agent is willing so to act, in connection with the issuance, registration, transfer, exchange, exercise and replacement of the Pre-Funded Warrants and, in the Warrant Agent’s capacity as the Company’s transfer agent, the delivery of the Warrant Shares (as defined below).

NOW, THEREFORE, in consideration of the premises and the mutual agreements herein set forth, the parties hereby agree as follows:

Section 1. Certain Definitions. For purposes of this Agreement, the following terms have the meanings indicated:

(a) “Business Day” means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which The Nasdaq Stock Market is authorized or required by law or other governmental action to close.

(b) “Close of Business” on any given date means 5:00 p.m., New York City time, on such date; provided, however, that if such date is not a Business Day it means 5:00 p.m., New York City time, on the next succeeding Business Day.

(c) “Person” means an individual, corporation, association, partnership, limited liability company, joint venture, trust, unincorporated organization, government or political subdivision thereof or governmental agency or other entity.

(d) “Warrant Certificate” means a certificate issued to a Holder, representing such number of Warrant Shares as is indicated therein, provided that any reference to the delivery of a Warrant Certificate in this Agreement shall include delivery of notice from the Depositary or a Participant (each as defined below) of the transfer or exercise of Warrant in the form of a Global Warrant (as defined below).

(e) “Warrant Shares” means the shares of Common Stock underlying the Pre-Funded Warrants and issuable upon exercise of the Pre-Funded Warrants.

All other capitalized terms used but not otherwise defined herein shall have the meaning ascribed to such terms in the Pre-Funded Warrant.

Section 2. Appointment of Warrant Agent. The Company hereby appoints the Warrant Agent to act as agent for the Company in accordance with the terms and conditions hereof, and the Warrant Agent hereby accepts such appointment.

Section 3. Global Warrants.

(a) The Pre-Funded Warrants shall be issuable in book entry form (the “Global Warrants”). All of the Pre-Funded Warrants shall initially be represented by one or more Global Warrants, in the form of the Warrant Certificate, deposited with the Warrant Agent and registered in the name of Cede & Co., a nominee of The Depository Trust Company (the “Depository”), or as otherwise directed by the Depository. Ownership of beneficial interests in the Pre-Funded Warrants shall be shown on, and the transfer of such ownership shall be effected through, records maintained by (i) the Depository or its nominee for each Global Warrant or (ii) institutions that have accounts with the Depository (such institution, with respect to a Pre-Funded Warrant in its account, a “Participant”).

(b) If the Depository subsequently ceases to make its book-entry settlement system available for the Pre-Funded Warrants, the Company may instruct the Warrant Agent regarding other arrangements for book-entry settlement. In the event that the Pre-Funded Warrants are not eligible for, or it is no longer necessary to have the Warrants available in, book-entry form, the Warrant Agent shall provide written instructions to the Depository to deliver to the Warrant Agent for cancellation each Global Warrant, and the Company shall instruct the Warrant Agent to deliver to each Holder a Warrant Certificate.

(c) A Holder has the right to elect at any time or from time to time a Warrant Exchange (as defined below) pursuant to a Warrant Certificate Request Notice (as defined below). Upon written notice by a Holder to the Warrant Agent for the exchange of some or all of such Holder’s Global Warrants for a Warrant Certificate evidencing the same number of Pre-Funded Warrants, which request shall be in the form attached hereto as Annex A (a “Warrant Certificate Request Notice” and the date of delivery of such Warrant Certificate Request Notice by the Holder, the “Warrant Certificate Request Notice Date” and the deemed surrender upon delivery by the Holder of a number of Global Warrants for the same number of Pre-Funded Warrants evidenced by a Warrant Certificate, a “Warrant Exchange”), the Warrant Agent shall promptly effect the Warrant Exchange and shall promptly issue and deliver to the Holder a Warrant Certificate for such number of Pre-Funded Warrants in the name set forth in the Warrant Certificate Request Notice. Such Warrant Certificate shall be dated the original issue date of the Pre-Funded Warrants and shall be manually executed by an authorized signatory of the Company. In connection with a Warrant Exchange, the Company agrees to deliver, or to direct the Warrant Agent to deliver, the Warrant Certificate to the Holder within three (3) Business Days of the Warrant Certificate Request Notice pursuant to the delivery instructions in the Warrant Certificate Request Notice (“Warrant Certificate Delivery Date”). If the Company fails for any reason to deliver to the Holder the Warrant Certificate subject to the Warrant Certificate Request Notice by the Warrant Certificate Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each \$1,000 of Warrant Shares evidenced by such Warrant Certificate (based on the VWAP (as defined in the Pre-Funded Warrant) of the Common Stock on the Warrant Certificate Request Notice Date), \$10 per Business Day (increasing to \$20 per Business Day on the fifth Business Day after such liquidated damages begin to accrue) for each Business Day after such Warrant Certificate Delivery Date until such Warrant Certificate is delivered or, prior to delivery of such Warrant Certificate, the Holder rescinds such Warrant Exchange. The Company covenants and agrees that, upon the date of delivery of the Warrant Certificate Request Notice, the Holder shall be deemed to be the holder of the Warrant Certificate and, notwithstanding anything to the contrary set forth herein, the Warrant Certificate shall be deemed for all purposes to contain all of the terms and conditions of the Pre-Funded Warrants evidenced by such Warrant Certificate and the terms of this Agreement, other than Section 3(c), which shall not apply to the Pre-Funded Warrants evidenced by a Warrant Certificate. In the event a beneficial owner requests a Warrant Exchange, upon issuance of the paper Warrant Certificate, the Company shall act as warrant agent and the terms of the paper Warrant Certificate so issued shall exclusively govern in respect thereof. For purposes of clarity, if there is a conflict between the express terms of this Agreement and any Warrant Certificate with respect to the terms of the Pre-Funded Warrants, the terms of such Warrant Certificate shall govern and control.

Section 4. Form of Warrant. The Pre-Funded Warrants, together with the form of election to purchase Common Stock (the “Exercise Notice”) and the form of assignment to be printed on the reverse thereof, whether a Warrant Certificate or a Global Warrant, shall be substantially in the form of Exhibit 1 hereto.

Section 5. Countersignature and Registration.

(a) The Pre-Funded Warrants shall be executed on behalf of the Company by its Chief Executive Officer, Chief Financial Officer or other authorized officer, either manually or by facsimile signature, and have affixed thereto the Company's seal or a facsimile thereof which shall be attested by the Secretary or an Assistant Secretary of the Company, either manually or by facsimile signature. The Pre-Funded Warrants shall be countersigned by the Warrant Agent either manually or by facsimile signature and shall not be valid for any purpose unless so countersigned. In case any officer of the Company who shall have signed a Pre-Funded Warrant shall cease to be such officer of the Company before countersignature by the Warrant Agent and issuance and delivery by the Company, such Pre-Funded Warrant, nevertheless, may be countersigned by the Warrant Agent, issued and delivered with the same force and effect as though the person who signed such Pre-Funded Warrant had not ceased to be such officer of the Company; and any Pre-Funded Warrant may be signed on behalf of the Company by any person who, at the actual date of the execution of such Pre-Funded Warrant, shall be a proper officer of the Company to sign such Pre-Funded Warrant, although at the date of the execution of this Warrant Agreement any such person was not such an officer.

(b) The Warrant Agent will keep or cause to be kept, at one of its offices, or at the office of one of its agents, books for registration and transfer of the Warrant Certificates issued hereunder. Such books shall show the names and addresses of the respective Holders of the Warrant Certificates, the number of warrants evidenced on the face of each of such Warrant Certificate and the date of each of such Warrant Certificate. The Warrant Agent will create a special account for the issuance of Warrant Certificates.

Section 6. Transfer, Split Up, Combination and Exchange of Warrant Certificates; Mutilated, Destroyed, Lost or Stolen Warrant Certificates

(a) Subject to the provisions of the Pre-Funded Warrant and the last sentence of this first paragraph of Section 6 and subject to applicable law, rules or regulations, or any "stop transfer" instructions the Company may give to the Warrant Agent, at any time after the closing date of the Offering, and at or prior to the Close of Business on the Termination Date, any Warrant Certificate or Warrant Certificates or Global Warrant or Global Warrants may be transferred, split up, combined or exchanged for another Warrant Certificate or Warrant Certificates or Global Warrant or Global Warrants, entitling the Holder to purchase a like number of shares of Common Stock as the Warrant Certificate or Warrant Certificates or Global Warrant or Global Warrants surrendered then entitled such Holder to purchase. Any Holder desiring to transfer, split up, combine or exchange any Warrant Certificate or Global Warrant shall make such request in writing delivered to the Warrant Agent, and shall surrender the Warrant Certificate or Warrant Certificates to be transferred, split up, combined or exchanged at the principal office of the Warrant Agent, provided that no such surrender is applicable to the Holder of a Global Warrant. Any requested transfer of Warrants, whether a Global Warrant or a Warrant Certificate, shall be accompanied by reasonable evidence of authority of the party making such request that may be reasonably required by the Warrant Agent. Thereupon the Warrant Agent shall, subject to the last sentence of this first paragraph of Section 6, countersign and deliver to the Person entitled thereto any Warrant Certificate or Global Warrant, as the case may be, as so requested. The Company may require payment from the Holder of a sum sufficient to cover any tax or governmental charge that may be imposed in connection with any transfer, split up, combination or exchange of Pre-Funded Warrants. The Company shall compensate the Warrant Agent per the fee schedule mutually agreed upon by the parties hereto and provided separately on the date hereof.

(b) Upon receipt by the Warrant Agent of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of a Warrant Certificate, which evidence shall include an affidavit of loss, or in the case of mutilated certificates, the certificate or portion thereof remaining, and, in case of loss, theft or destruction, of indemnity or security acceptable to the Company and the Warrant Agent (but shall not include the posting of any bond by a Holder), and satisfaction of any other reasonable requirements established by Section 8-405 of the Uniform Commercial Code as in effect in the State of Delaware, and reimbursement to the Company and the Warrant Agent of all reasonable expenses incidental thereto, and upon surrender to the Warrant Agent and cancellation of the Warrant Certificate if mutilated, the Company will make and deliver a new Warrant Certificate of like tenor to the Warrant Agent for delivery to the Holder in lieu of the Warrant Certificate so lost, stolen, destroyed or mutilated.

Section 7. Exercise of Warrants; Exercise Price; Termination Date.

(a) The Pre-Funded Warrants shall be exercisable commencing on the Initial Exercise Date. The Pre-Funded Warrants shall cease to be exercisable and shall terminate and become void, and all rights thereunder and under this Agreement shall cease, at or prior to the Close of Business on the Termination Date. Subject to the foregoing and to Section 7(b) below, the Holder of a Pre-Funded Warrant may exercise the Pre-Funded Warrant in whole or in part upon providing the items required by Section 7(c) below to the Warrant Agent at the principal office of the Warrant Agent or to the office of one of its agents as may be designated by the Warrant Agent from time to time. In the case of the Holder of a Global Warrant, the Holder shall deliver the executed Exercise Notice and payment of the Exercise Price pursuant to Section 2(a) of the Pre-Funded Warrant. Notwithstanding any other provision in this Agreement, a holder whose interest in a Global Warrant is a beneficial interest in a Global Warrant held in book-entry form through the Depositary (or another established clearing corporation performing similar functions), shall effect exercises by delivering to the Depositary (or such other clearing corporation, as applicable) the appropriate instruction form for exercise, complying with the procedures to effect exercise that are required by the Depositary (or such other clearing corporation, as applicable). The Company acknowledges that the bank accounts maintained by the Warrant Agent in connection with the services provided under this Agreement will be in its name and that the Warrant Agent may receive investment earnings in connection with the investment at Warrant Agent risk and for its benefit of funds held in those accounts from time to time. Neither the Company nor the Holders will receive interest on any deposits or Exercise Price. No ink-original Exercise Notice shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Exercise Notice be required.

(b) Upon receipt of an Exercise Notice for a cashless exercise pursuant to Section 2(c) of the Pre-Funded Warrant (each, a “Cashless Exercise”), the Company will promptly calculate and transmit to the Warrant Agent the number of Warrant Shares issuable in connection with such Cashless Exercise and deliver a copy of the Exercise Notice to the Warrant Agent, which shall issue such number of Warrant Shares in connection with such Cashless Exercise.

(c) Upon the Warrant Agent’s receipt, at or prior to the Close of Business on the Termination Date set forth in a Pre-Funded Warrant, of the executed Exercise Notice, accompanied by payment of the Exercise Price pursuant to Section 2(a) of the Pre-Funded Warrant, the shares to be purchased (other than in the case of a Cashless Exercise), an amount equal to any applicable tax, governmental charge or expense reimbursement referred to in Section 6 by certified check or bank draft payable to the order of the Company and, in the case of an exercise of a Pre-Funded Warrant in the form of a Warrant Certificate for all of the Warrant Shares represented thereby, the Warrant Certificate, the Warrant Agent shall cause the Warrant Shares underlying such Pre-Funded Warrant to be delivered to or upon the order of the Holder of such Pre-Funded Warrant, registered in such name or names as may be designated by such Holder, no later than the Warrant Share Delivery Date. If the Company is then a participant in the DWAC system of the Depositary and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by Holder or (B) the Pre-Funded Warrant is being exercised via Cashless Exercise, then the certificates for Warrant Shares shall be transmitted by the Warrant Agent to the Holder by crediting the account of the Holder’s broker with the Depositary through its DWAC system. For the avoidance of doubt, if the Company becomes obligated to pay any amounts to any Holders pursuant to Section 2(d)(iv) of the Pre-Funded Warrant, such obligation shall be solely that of the Company and not that of the Warrant Agent. Notwithstanding anything else to the contrary in this Agreement, except in the case of a Cashless Exercise, if any Holder fails to duly deliver payment to the Warrant Agent of an amount equal to the aggregate Exercise Price of the Warrant Shares to be purchased upon exercise of such Holder’s Pre-Funded Warrant as set forth in Section 7(a) hereof, the Warrant Agent will not be obligated to deliver certificates representing any such Warrant Shares (via DWAC or otherwise) until following receipt of such payment, and the applicable Warrant Share Delivery Date shall be deemed extended by one day for each day (or part thereof) until such payment is delivered to the Warrant Agent.

(d) The Warrant Agent shall deposit all funds received by it in payment of the Exercise Price for all Warrants in the account of the Company maintained with the Warrant Agent for such purpose (or to such other account as directed by the Company in writing) and shall advise the Company via telephone at the end of each day on which funds for the exercise of any Pre-Funded Warrant are received of the amount so deposited to its account. The Warrant Agent shall promptly confirm such telephonic advice to the Company in writing.

(e) In case the Holder of any Warrant Certificate exercises fewer than all Pre-Funded Warrants evidenced thereby and surrenders such Warrant Certificate in connection with such partial exercise, a new Warrant Certificate evidencing the number of Warrant Shares equivalent to the number of Warrant Shares remaining unexercised may be issued by the Warrant Agent to the Holder of such Warrant Certificate or to his duly authorized assigns in accordance with Section 2(d)(ii) of the Pre-Funded Warrant, subject to the provisions of Section 6 hereof.

Section 8. Cancellation and Destruction of Warrant Certificates. All Warrant Certificates surrendered for the purpose of exercise, transfer, split up, combination or exchange shall, if surrendered to the Company or to any of its agents, be delivered to the Warrant Agent for cancellation or in canceled form, or, if surrendered to the Warrant Agent, shall be canceled by it, and no Warrant Certificates shall be issued in lieu thereof except as expressly permitted by any of the provisions of this Agreement. The Company shall deliver to the Warrant Agent for cancellation and retirement, and the Warrant Agent shall so cancel and retire, any other Warrant Certificate purchased or acquired by the Company otherwise than upon the exercise thereof. The Warrant Agent shall deliver all canceled Warrant Certificates to the Company, or shall, at the written request of the Company, destroy such canceled Warrant Certificates, and in such case shall deliver a certificate of destruction thereof to the Company, subject to any applicable law, rule or regulation requiring the Warrant Agent to retain such canceled certificates.

Section 9. Certain Representations: Reservation and Availability of Shares of Common Stock or Cash.

(a) This Agreement has been duly authorized, executed and delivered by the Company and, assuming due authorization, execution and delivery hereof by the Warrant Agent, constitutes a valid and legally binding obligation of the Company enforceable against the Company in accordance with its terms, and the Pre-Funded Warrants have been duly authorized, executed and issued by the Company and, assuming due authentication thereof by the Warrant Agent pursuant hereto and payment therefor by the Holders as provided in the Registration Statement, constitute valid and legally binding obligations of the Company enforceable against the Company in accordance with their terms and entitled to the benefits hereof; in each case except as enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium and other similar laws relating to or affecting creditors' rights generally or by general equitable principles (regardless of whether such enforceability is considered in a proceeding in equity or at law).

(b) The Company covenants and agrees that it will cause to be reserved and kept available out of its authorized and unissued shares of Common Stock or its authorized and issued shares of Common Stock held in its treasury, free from preemptive rights, the number of shares of Common Stock that will be sufficient to permit the exercise in full of all outstanding Pre-Funded Warrants.

(c) The Warrant Agent will create a special account for the issuance of Common Stock upon the exercise of Pre-Funded Warrants.

(d) The Company further covenants and agrees that it will pay when due and payable any and all federal and state transfer taxes and charges which may be payable in respect of the original issuance or delivery of the Warrant Certificates or certificates evidencing Common Stock upon exercise of the Pre-Funded Warrants. The Company shall not, however, be required to pay any tax or governmental charge which may be payable in respect of any transfer involved in the transfer or delivery of Warrant Certificates or the issuance or delivery of certificates for Common Stock in a name other than that of the Holder of the Warrant Certificate evidencing Pre-Funded Warrants surrendered for exercise or to issue or deliver any certificate for shares of Common Stock upon the exercise of any Pre-Funded Warrants until any such tax or governmental charge shall have been paid (any such tax or governmental charge being payable by the Holder of such Warrant Certificate at the time of surrender) or until it has been established to the Company's reasonable satisfaction that no such tax or governmental charge is due.

Section 10. Common Stock Record Date. Each Holder shall be deemed to have become the holder of record for the Warrant Shares pursuant to Section 2(d)(i) of the Pre-Funded Warrants.

Section 11. Adjustment of Exercise Price, Number of Shares of Common Stock or Number of the Company Warrants. The Exercise Price, the number of shares covered by each Pre-Funded Warrant and the number of Pre-Funded Warrants outstanding are subject to adjustment from time to time as provided in Section 3 of the Pre-Funded Warrant. In the event that at any time, as a result of an adjustment made pursuant to Section 3 of the Pre-Funded Warrant, the Holder of any Pre-Funded Warrant thereafter exercised shall become entitled to receive any shares of capital stock of the Company other than shares of Common Stock, thereafter the number of such other shares so receivable upon exercise of any Pre-Funded Warrant shall be subject to adjustment from time to time in a manner and on terms as nearly equivalent as practicable to the provisions with respect to the shares contained in Section 3 of the Pre-Funded Warrant, and the provisions of Sections 7, 9 and 13 of this Agreement with respect to the shares of Common Stock shall apply on like terms to any such other shares. All Pre-Funded Warrants originally issued by the Company subsequent to any adjustment made to the Exercise Price pursuant to the Pre-Funded Warrant shall evidence the right to purchase, at the adjusted Exercise Price, the number of shares of Common Stock purchasable from time to time hereunder upon exercise of the Pre-Funded Warrants, all subject to further adjustment as provided herein.

Section 12. Certification of Adjusted Exercise Price or Number of Shares of Common Stock. Whenever the Exercise Price or the number of shares of Common Stock issuable upon the exercise of each Pre-Funded Warrant is adjusted as provided in Section 11 or 13, the Company shall (a) promptly prepare a certificate setting forth the Exercise Price of each Pre-Funded Warrant as so adjusted, and a brief statement of the facts accounting for such adjustment, (b) promptly file with the Warrant Agent and with each transfer agent for the Common Stock a copy of such certificate and (c) instruct the Warrant Agent to send a brief summary thereof to each Holder of a Pre-Funded Warrant.

Section 13. Fractional Shares of Common Stock.

(a) The Company shall not issue fractions of Pre-Funded Warrants or distribute a Global Warrant or Warrant Certificates that evidence fractional Pre-Funded Warrants. Whenever any fractional Pre-Funded Warrant would otherwise be required to be issued or distributed, the actual issuance or distribution shall reflect a rounding of such fraction either up or down to the nearest whole Pre-Funded Warrant.

(b) The Company shall not issue fractions of shares of Common Stock upon exercise of Pre-Funded Warrants or distribute stock certificates that evidence fractional shares of Common Stock. Whenever any fraction of a share of Common Stock would otherwise be required to be issued or distributed, the actual issuance or distribution in respect thereof shall be made in accordance with Section 2(d)(v) of the Pre-Funded Warrant.

Section 14. Conditions of the Warrant Agent's Obligations. The Warrant Agent accepts its obligations herein set forth upon the terms and conditions hereof, including the following to all of which the Company agrees and to all of which the rights hereunder of the Holders from time to time of the Pre-Funded Warrant shall be subject:

(a) Compensation and Indemnification. The Company agrees promptly to pay the Warrant Agent the compensation detailed on Exhibit 2 hereto for all services rendered by the Warrant Agent and to reimburse the Warrant Agent for reasonable out-of-pocket expenses (including reasonable counsel fees) incurred without gross negligence, bad faith or willful misconduct by the Warrant Agent in connection with the services rendered hereunder by the Warrant Agent. The Company also agrees to indemnify the Warrant Agent for, and to hold it harmless against, any loss, liability or expense incurred without gross negligence, bad faith or willful misconduct on the part of the Warrant Agent, arising out of or in connection with its acting as Warrant Agent hereunder, including the reasonable costs and expenses of defending against any claim of such liability.

(b) Agent for the Company. In acting under this Warrant Agreement and in connection with the Warrant Certificates, the Warrant Agent is acting solely as agent of the Company and does not assume any obligations or relationship of agency or trust for or with any of the Holders of Warrant Certificates or beneficial owners of Pre-Funded Warrants.

(c) Counsel. The Warrant Agent may consult with counsel satisfactory to it, which may include counsel for the Company, and the written advice of such counsel shall be full and complete authorization and protection in respect of any action taken, suffered or omitted by it hereunder in good faith and in accordance with the advice of such counsel.

(d) Documents. The Warrant Agent shall be protected and shall incur no liability for or in respect of any action taken or omitted by it in reliance upon any Warrant Certificate, notice, direction, consent, certificate, affidavit, statement or other paper or document reasonably believed by it to be genuine and to have been presented or signed by the proper parties.

(e) Certain Transactions. The Warrant Agent, and its officers, directors and employees, may become the owner of, or acquire any interest in, Pre-Funded Warrants, with the same rights that it or they would have if it were not the Warrant Agent hereunder, and, to the extent permitted by applicable law, it or they may engage or be interested in any financial or other transaction with the Company and may act on, or as depository, trustee or agent for, any committee or body of Holders of Warrant Securities or other obligations of the Company as freely as if it were not the Warrant Agent hereunder. Nothing in this Warrant Agreement shall be deemed to prevent the Warrant Agent from acting as trustee under any indenture to which the Company is a party.

(f) No Liability for Interest. Unless otherwise agreed with the Company, the Warrant Agent shall have no liability for interest on any monies at any time received by it pursuant to any of the provisions of this Agreement or of the Warrant Certificates.

(g) No Liability for Invalidity. The Warrant Agent shall have no liability with respect to any invalidity of this Agreement or any of the Warrant Certificates (except as to the Warrant Agent's countersignature thereon).

(h) No Responsibility for Representations. The Warrant Agent shall not be responsible for any of the recitals or representations herein or in the Warrant Certificates (except as to the Warrant Agent's countersignature thereon), all of which are made solely by the Company.

(i) No Implied Obligations. The Warrant Agent shall be obligated to perform only such duties as are herein and in the Pre-Funded Warrants specifically set forth and no implied duties or obligations shall be read into this Agreement or the Pre-Funded Warrants against the Warrant Agent. The Warrant Agent shall not be under any obligation to take any action hereunder which may tend to involve it in any expense or liability, the payment of which within a reasonable time is not, in its reasonable opinion, assured to it. The Warrant Agent shall not be accountable or under any duty or responsibility for the use by the Company of any of the Pre-Funded Warrants authenticated by the Warrant Agent and delivered by it to the Company pursuant to this Agreement or for the application by the Company of the proceeds of the Pre-Funded Warrants. The Warrant Agent shall have no duty or responsibility in case of any default by the Company in the performance of its covenants or agreements contained herein or in the Pre-Funded Warrants or in the case of the receipt of any written demand from a Holder of a Warrant Certificate with respect to such default, including, without limiting the generality of the foregoing, any duty or responsibility to initiate or attempt to initiate any proceedings at law.

Section 15. Purchase or Consolidation or Change of Name of Warrant Agent. Any corporation into which the Warrant Agent or any successor Warrant Agent may be merged or with which it may be consolidated, or any corporation resulting from any merger or consolidation to which the Warrant Agent or any successor Warrant Agent shall be party, or any corporation succeeding to the corporate trust business of the Warrant Agent or any successor Warrant Agent, shall be the successor to the Warrant Agent under this Agreement without the execution or filing of any paper or any further act on the part of any of the parties hereto, provided that such corporation would be eligible for appointment as a successor Warrant Agent under the provisions of Section 17. In case at the time such successor Warrant Agent shall succeed to the agency created by this Agreement any of the Pre-Funded Warrants shall have been countersigned but not delivered, any such successor Warrant Agent may adopt the countersignature of the predecessor Warrant Agent and deliver such Pre-Funded Warrants so countersigned; and in case at that time any of the Pre-Funded Warrants shall not have been countersigned, any successor Warrant Agent may countersign such Pre-Funded Warrants either in the name of the predecessor Warrant Agent or in the name of the successor Warrant Agent; and in all such cases such Pre-Funded Warrants shall have the full force provided in the Pre-Funded Warrants and in this Agreement.

In case at any time the name of the Warrant Agent shall be changed and at such time any of the Pre-Funded Warrants shall have been countersigned but not delivered, the Warrant Agent may adopt the countersignature under its prior name and deliver Pre-Funded Warrants so countersigned; and in case at that time any of the Pre-Funded Warrants shall not have been countersigned, the Warrant Agent may countersign such Pre-Funded Warrants either in its prior name or in its changed name; and in all such cases such Pre-Funded Warrants shall have the full force provided in the Pre-Funded Warrants and in this Agreement.

Section 16. Duties of Warrant Agent. The Warrant Agent undertakes the duties and obligations imposed by this Agreement upon the following terms and conditions, by all of which the Company, by its acceptance hereof, shall be bound:

(a) The Warrant Agent may consult with legal counsel reasonably acceptable to the Company (who may be legal counsel for the Company), and the opinion of such counsel shall be full and complete authorization and protection to the Warrant Agent as to any action taken or omitted by it in good faith and in accordance with such opinion.

(b) Whenever in the performance of its duties under this Agreement the Warrant Agent shall deem it necessary or desirable that any fact or matter be proved or established by the Company prior to taking or suffering any action hereunder, such fact or matter (unless other evidence in respect thereof be herein specifically prescribed) may be deemed to be conclusively proved and established by a certificate signed by the Chief Executive Officer or Chief Financial Officer of the Company; and such certificate shall be full authentication to the Warrant Agent for any action taken or suffered in good faith by it under the provisions of this Agreement in reliance upon such certificate.

(c) Subject to the limitation set forth in Section 14, the Warrant Agent shall be liable hereunder only for its own gross negligence, bad faith or willful misconduct, or for a breach by it of this Agreement.

(d) The Warrant Agent shall not be liable for or by reason of any of the statements of fact or recitals contained in this Agreement or in the Pre-Funded Warrants (except its countersignature thereof) by the Company or be required to verify the same, but all such statements and recitals are and shall be deemed to have been made by the Company only.

(e) The Warrant Agent shall not be under any responsibility in respect of the validity of this Agreement or the execution and delivery hereof (except the due execution hereof by the Warrant Agent) or in respect of the validity or execution of any Pre-Funded Warrant (except its countersignature thereof); nor shall it be responsible for any breach by the Company of any covenant or condition contained in this Agreement or in any Pre-Funded Warrant; nor shall it be responsible for the adjustment of the Exercise Price or the making of any change in the number of shares of Common Stock required under the provisions of Section 11 or 13 or responsible for the manner, method or amount of any such change or the ascertaining of the existence of facts that would require any such adjustment or change (except with respect to the exercise of Pre-Funded Warrants evidenced by Warrant Certificates after actual notice of any adjustment of the Exercise Price); nor shall it by any act hereunder be deemed to make any representation or warranty as to the authorization or reservation of any shares of Common Stock to be issued pursuant to this Agreement or any Pre-Funded Warrant or as to whether any shares of Common Stock will, when issued, be duly authorized, validly issued, fully paid and nonassessable.

(f) Each party hereto agrees that it will perform, execute, acknowledge and deliver or cause to be performed, executed, acknowledged and delivered all such further and other acts, instruments and assurances as may reasonably be required by the other party hereto for the carrying out or performing by any party of the provisions of this Agreement.

(g) The Warrant Agent is hereby authorized to accept instructions with respect to the performance of its duties hereunder from the Chief Executive Officer or Chief Financial Officer of the Company, and to apply to such officers for advice or instructions in connection with its duties, and it shall not be liable and shall be indemnified and held harmless for any action taken or suffered to be taken by it in good faith in accordance with instructions of any such officer, provided Warrant Agent carries out such instructions without gross negligence, bad faith or willful misconduct.

(h) The Warrant Agent and any shareholder, director, officer or employee of the Warrant Agent may buy, sell or deal in any of the Pre-Funded Warrants or other securities of the Company or become pecuniarily interested in any transaction in which the Company may be interested, or contract with or lend money to the Company or otherwise act as fully and freely as though it were not Warrant Agent under this Agreement. Nothing herein shall preclude the Warrant Agent from acting in any other capacity for the Company or for any other legal entity.

(i) The Warrant Agent may execute and exercise any of the rights or powers hereby vested in it or perform any duty hereunder either itself or by or through its attorney or agents, and the Warrant Agent shall not be answerable or accountable for any act, default, neglect or misconduct of any such attorney or agents or for any loss to the Company resulting from any such act, default, neglect or misconduct, provided reasonable care was exercised in the selection and continued employment thereof.

Section 17. Change of Warrant Agent. The Warrant Agent may resign and be discharged from its duties under this Agreement upon 10 days' notice in writing sent to the Company and to each transfer agent of the Common Stock, and to the Holders of the Warrant Certificates. The Company may remove the Warrant Agent or any successor Warrant Agent upon 30 days' notice in writing, sent to the Warrant Agent or successor Warrant Agent, as the case may be, and to each transfer agent of the Common Stock, and to the Holders of the Warrant Certificates. If the Warrant Agent shall resign or be removed or shall otherwise become incapable of acting, the Company shall appoint a successor to the Warrant Agent. If the Company shall fail to make such appointment within a period of 30 days after such removal or after it has been notified in writing of such resignation or incapacity by the resigning or incapacitated Warrant Agent or by the Holder of a Warrant Certificate (who shall, with such notice, submit his Warrant Certificate for inspection by the Company), then the Holder of any Warrant Certificate may apply to any court of competent jurisdiction for the appointment of a new Warrant Agent, provided that, for purpose of this Agreement, the Company shall be deemed to be the Warrant Agent until a new warrant agent is appointed. Any successor Warrant Agent, whether appointed by the Company or by such a court, shall be a corporation organized and doing business under the laws of the United States or of a state thereof, in good standing, which is authorized under such laws to exercise corporate trust powers and is subject to supervision or examination by federal or state authority and which has at the time of its appointment as Warrant Agent a combined capital and surplus of at least \$50,000,000. After appointment, the successor Warrant Agent shall be vested with the same powers, rights, duties and responsibilities as if it had been originally named as Warrant Agent without further act or deed; but the predecessor Warrant Agent shall deliver and transfer to the successor Warrant Agent any property at the time held by it hereunder, and execute and deliver any further assurance, conveyance, act or deed necessary for the purpose. Not later than the effective date of any such appointment, the Company shall file notice thereof in writing with the predecessor Warrant Agent and each transfer agent of the Common Stock, and mail a notice thereof in writing to the Holders of the Warrant Certificates. However, failure to give any notice provided for in this Section 17, or any defect therein, shall not affect the legality or validity of the resignation or removal of the Warrant Agent or the appointment of the successor Warrant Agent, as the case may be.

Section 18. Issuance of New Warrants. Notwithstanding any of the provisions of this Agreement or of the Pre-Funded Warrants to the contrary, the Company may, at its option, issue a new Global Warrant or Warrant Certificates, if any, evidencing Pre-Funded Warrants in such form as may be approved by its Board of Directors to reflect any adjustment or change in the Exercise Price per share and the number or kind or class of shares of stock or other securities or property purchasable under the Global Warrant or Warrant Certificates, if any, made in accordance with the provisions of this Agreement.

Section 19. Notices. Notices or demands authorized by this Agreement to be given or made (i) by the Warrant Agent or by the Holder of any Warrant Certificate to or on the Company, (ii) subject to the provisions of Section 17, by the Company or by the Holder of any Warrant Certificate to or on the Warrant Agent or (iii) by the Company or the Warrant Agent to the Holder of any Warrant Certificate, shall be deemed given (a) on the date delivered, if delivered personally, (b) on the first Business Day following the deposit thereof with Federal Express or another recognized overnight courier, if sent by Federal Express or another recognized overnight courier, (c) on the fourth Business Day following the mailing thereof with postage prepaid, if mailed by registered or certified mail (return receipt requested), and (d) the date of transmission, if such notice or communication is delivered via facsimile or email attachment at or prior to 5:30 p.m. (New York City time) on a Business Day and (e) the next Business Day after the date of transmission, if such notice or communication is delivered via facsimile or email attachment on a day that is not a Business Day or later than 5:30 p.m. (New York City time) on any Business Day, in each case to the parties at the following addresses (or at such other address for a party as shall be specified by like notice):

- (a) If to the Company, to:

Arch Therapeutics, Inc.
235 Walnut St., Suite 6
Framingham, MA 01702
Attention: CEO

- (b) If to the Warrant Agent, to:

Empire Stock Transfer
1859 Whitney Mesa Drive
Henderson, Nevada 89014
Attention:

For any notice delivered by email to be deemed given or made, such notice must be followed by notice sent by overnight courier service to be delivered on the next business day following such email, unless the recipient of such email has acknowledged via return email receipt of such email.

(c) If to the Holder of any Warrant Certificate, to the address of such Holder as shown on the registry books of the Company. Any notice required to be delivered by the Company to the Holder of any Pre-Funded Warrant may be given by the Warrant Agent on behalf of the Company. Notwithstanding any other provision of this Agreement, where this Agreement provides for notice of any event to a Holder of any Warrant Certificate, for a Global Warrant, such notice shall be sufficiently given if given to the Depositary (or its designee) pursuant to the procedures of the Depositary or its designee.

Section 20. Supplements and Amendments.

(a) The Company and the Warrant Agent may from time to time supplement or amend this Agreement without the approval of any Holders of Warrant Certificates in order to cure any ambiguity, to correct or supplement any provision contained herein which may be defective or inconsistent with any other provisions herein, or to make any other provisions with regard to matters or questions arising hereunder which the Company and the Warrant Agent may deem necessary or desirable and which shall not adversely affect the interests of the Holders of the Warrants Certificates in any material respect.

(b) In addition to the foregoing, with the consent of Holders of Warrants, the Company and the Warrant Agent may modify this Agreement for the purpose of adding any provisions to or changing in any manner or eliminating any of the provisions of this Warrant Agreement or modifying in any manner the rights of the Holders of the Warrant Certificates; provided, however, that no modification of the terms (including but not limited to the adjustments described in Section 11) upon which the Pre-Funded Warrants are exercisable or the rights of the holders of Pre-Funded Warrants to received liquidated damages or other payments in cash from the Company or reducing the percentage required for consent to modification of this Agreement may be made without the consent of the Holder of each outstanding warrant certificate affected thereby. As a condition precedent to the Warrant Agent's execution of any amendment, the Company shall deliver to the Warrant Agent a certificate from a duly authorized officer of the Company that states that the proposed amendment complies with the terms of this Section 20.

Section 21. Successors. All covenants and provisions of this Agreement by or for the benefit of the Company or the Warrant Agent shall bind and inure to the benefit of their respective successors and assigns hereunder.

Section 22. Benefits of this Agreement. Nothing in this Agreement shall be construed to give any Person other than the Company, the Holders of Warrant Certificates and the Warrant Agent any legal or equitable right, remedy or claim under this Agreement; but this Agreement shall be for the sole and exclusive benefit of the Company, the Warrant Agent and the Holders of the Warrant Certificates.

Section 23. Governing Law. This Agreement and each Pre-Funded Warrant issued hereunder shall be governed by, and construed in accordance with, the laws of the State of New York without giving effect to the conflicts of law principles thereof.

Section 24. Counterparts. This Agreement may be executed in any number of counterparts and each of such counterparts shall for all purposes be deemed to be an original, and all such counterparts shall together constitute but one and the same instrument.

Section 25. Captions. The captions of the sections of this Agreement have been inserted for convenience only and shall not control or affect the meaning or construction of any of the provisions hereof.

Section 26. Information. The Company agrees to promptly provide to the Holders of the Pre-Funded Warrants any information it provides to all holders of the Common Stock, except to the extent any such information is publicly available on the EDGAR system (or any successor thereof) of the Securities and Exchange Commission.

Section 27. Force Majeure. Notwithstanding anything to the contrary contained herein, Warrant Agent shall not be liable for any delays or failures in performance resulting from acts beyond its reasonable control including, without limitation, acts of God, terrorist acts, shortage of supply, breakdowns or malfunctions, interruptions or malfunction of computer facilities, or loss of data due to power failures or mechanical difficulties with information storage or retrieval systems, labor difficulties, war, or civil unrest, it being understood that the Warrant Agent shall use reasonable best efforts which are consistent with accepted practices in the banking industry to resume performance as soon as practicable under the circumstances; provided, however, that this provision shall not, in any respect, affect the obligations of the Company to the Holders under the terms of the Pre-Funded Warrants.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the day and year first above written.

ARCH THERAPEUTICS, INC.

By: _____
Name:
Title:

EMPIRE STOCK TRANSFER

By: _____
Name:
Title:

Annex A: Form of Warrant Certificate Request Notice

WARRANT CERTIFICATE REQUEST NOTICE

To: Empire Stock Transfer as Warrant Agent for Arch Therapeutics, Inc. (the “Company”)

The undersigned Holder of Common Stock Purchase Warrants (“Warrants”) in the form of Global Warrants issued by the Company hereby elects to receive a Warrant Certificate evidencing the Warrants held by the Holder as specified below:

1. Name of Holder of Warrants in form of Global Warrants: _____
2. Name of Holder in Warrant Certificate (if different from name of Holder of Warrants in form of Global Warrants): _____
3. Number of Warrants in name of Holder in form of Global Warrants: _____
4. Number of Warrants for which Warrant Certificate shall be issued: _____
5. Number of Warrants in name of Holder in form of Global Warrants after issuance of Warrant Certificate, if any: _____
6. Warrant Certificate shall be delivered to the following address:

The undersigned hereby acknowledges and agrees that, in connection with this Warrant Exchange and the issuance of the Warrant Certificate, the Holder is deemed to have surrendered the number of Warrants in form of Global Warrants in the name of the Holder equal to the number of Warrants evidenced by the Warrant Certificate.

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____

Signature of Authorized Signatory of Investing Entity: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Date: _____

Exhibit 1: Form of Warrant

**COMMON STOCK PURCHASE WARRANT
ARCH THERAPEUTICS, INC.**

Warrant Shares: _____

Initial Exercise Date: September [], 2023
CUSIP:

THIS COMMON STOCK PURCHASE WARRANT (the “Warrant”) certifies that, for value received, CEDE & CO. or its assigns (the “Holder”) is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the date hereof (the “Initial Exercise Date”) and on or prior to 5:00 p.m. (New York City time) on September [], 2028 (the “Termination Date”) but not thereafter, to subscribe for and purchase from Arch Therapeutics, Inc., a Nevada corporation (the “Company”), up to _____ shares (as subject to adjustment hereunder, the “Warrant Shares”) of Common Stock. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b). This Warrant shall initially be issued and maintained in the form of a security held in book-entry form and the Depository Trust Company or its nominee (“DTC”) shall initially be the sole registered holder of this Warrant, subject to a Holder’s right to elect to receive a Warrant in certificated form pursuant to the terms of the Warrant Agency Agreement, in which case this sentence shall not apply.

Section 1. Definitions. In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated in this Section 1:

“Affiliate” means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

“Bid Price” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the bid price of the Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

“Board of Directors” means the board of directors of the Company.

“Business Day” means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the City of New York are authorized or required by law or other governmental action to close; provided, however, for clarification, commercial banks shall not be deemed to be authorized or required by law to remain closed due to “stay at home”, “shelter-in-place”, “non-essential employee” or any other similar orders or restrictions or the closure of any physical branch locations at the direction of any governmental authority so long as the electronic funds transfer systems (including for wire transfers) of commercial banks in The City of New York generally are open for use by customers on such day.

“Commission” means the United States Securities and Exchange Commission.

“Common Stock” means the common stock of the Company, par value \$0.001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

“Common Stock Equivalents” means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

“Exchange Act” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

“Person” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“Registration Statement” means the Company’s registration statement on Form S-1 (File No. 333-268008).

“Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“Subsidiary” means any subsidiary of the Company and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

“Trading Day” means a day on which the Common Stock is traded on a Trading Market.

“Trading Market” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the Nasdaq Capital Market, the NYSE American, the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange (or any successors to any of the foregoing).

“Transfer Agent” means Empire Stock Transfer, the current transfer agent of the Company, with a mailing address of [1859 Whitney Mesa Drive, Henderson, Nevada 89014], an email address of [____], and a facsimile number of (____) [____], and any successor transfer agent of the Company.

“VWAP” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

“Warrant Agency Agreement” means that certain warrant agency agreement, dated on or about the Initial Exercise Date, between the Company and the Warrant Agent.

“Warrant Agent” means the Transfer Agent and any successor warrant agent of the Company.

“Warrants” means this Warrant and other Common Stock purchase warrants issued by the Company pursuant to the Registration Statement.

Section 2. Exercise.

a) Exercise of Warrant. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Warrant Agent of a duly executed facsimile copy or PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form annexed hereto (the “Notice of Exercise”). Within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the shares specified in the applicable Notice of Exercise by wire transfer or cashier’s check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Warrant Agent until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Warrant Agent for cancellation within three (3) Trading Days of the date on which the final Notice of Exercise is delivered to the Warrant Agent. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Business Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

Notwithstanding the foregoing in this Section 2(a), a holder whose interest in this Warrant is a beneficial interest in certificate(s) representing this Warrant held in book-entry form through DTC (or another established clearing corporation performing similar functions), shall effect exercises made pursuant to this Section 2(a) by delivering to DTC (or such other clearing corporation, as applicable) the appropriate instruction form for exercise, complying with the procedures to effect exercise that are required by DTC (or such other clearing corporation, as applicable), subject to a Holder’s right to elect to receive a Warrant in certificated form pursuant to the terms of the Warrant Agency Agreement, in which case this sentence shall not apply.

b) Exercise Price. The exercise price per share of Common Stock under this Warrant shall be \$[___], subject to adjustment hereunder (the “Exercise Price”).

c) Cashless Exercise. If at the time of exercise hereof there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of the Warrant Shares to the Holder, then this Warrant may be exercised, in whole or in part, at such time by means of a “cashless exercise” in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of “regular trading hours” (as defined in Rule 600(b) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the Bid Price of the Common Stock on the principal Trading Market as reported by Bloomberg L.P. as of the time of the Holder’s execution of the applicable Notice of Exercise if such Notice of Exercise is executed during “regular trading hours” on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of “regular trading hours” on a Trading Day) pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of “regular trading hours” on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised. The Company agrees not to take any position contrary to this Section 2(c).

Notwithstanding anything herein to the contrary, on the Termination Date this Warrant shall be automatically exercised via cashless exercise pursuant to this Section 2(c).

d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by Holder or (B) this Warrant is being exercised via cashless exercise, and otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earliest of (i) two (2) Trading Days after the delivery to the Company of the Notice of Exercise, (ii) one (1) Trading Day after delivery of the aggregate Exercise Price to the Company and (iii) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company of the Notice of Exercise (such date, the "Warrant Share Delivery Date"). Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period following delivery of the Notice of Exercise. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each \$1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), \$10 per Trading Day (increasing to \$20 per Trading Day on the third Trading Day after the Warrant Share Delivery Date) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Exercise. Notwithstanding the foregoing, with respect to any Notice(s) of Exercise delivered on or prior to 12:00 p.m. (New York City time) on the Initial Exercise Date, which may be delivered at any time after the time of execution of the Placement Agency Agreement, the Company agrees to deliver the Warrant Shares subject to such notice(s) by 4:00 p.m. (New York City time) on the Initial Exercise Date and the Initial Exercise Date shall be the Warrant Share Delivery Date for purposes hereunder, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received by such Warrant Share Delivery Date.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of \$11,000 to cover a Buy-In with respect to an attempted exercise of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of \$10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder \$1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) **Holder's Exercise Limitations.** The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within one Trading Day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% (or, upon election by a Holder prior to the issuance of any Warrants, 9.99%) of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

Section 3. Certain Adjustments.

a) **Stock Dividends and Splits.** If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) Subsequent Equity Sales. If the Company or any Subsidiary thereof, as applicable, at any time while this Warrant is outstanding, shall sell, enter into an agreement to sell, or grant any option to purchase, or sell, enter into an agreement to sell, or grant any right to reprice, or otherwise dispose of or issue (or announce any offer, sale, grant or any option to purchase or other disposition) any Common Stock or Common Stock Equivalents, at an effective price per share less than the Exercise Price then in effect (such lower price, the “Base Share Price” and such issuances collectively, a “Dilutive Issuance”) (it being understood and agreed that if the holder of the Common Stock or Common Stock Equivalents so issued shall at any time, whether by operation of purchase price adjustments, reset provisions, floating conversion, exercise or exchange prices or otherwise, or due to warrants, options or rights per share which are issued in connection with such issuance, be entitled to receive shares of Common Stock at an effective price per share that is less than the Exercise Price, such issuance shall be deemed to have occurred for less than the Exercise Price on such date of the Dilutive Issuance at such effective price), then simultaneously with the consummation (or, if earlier, the announcement) of each Dilutive Issuance the Exercise Price shall be reduced and only reduced to equal the Base Share Price and the number of Warrant Shares issuable hereunder shall be increased such that the aggregate Exercise Price payable hereunder, after taking into account the decrease in the Exercise Price, shall be equal to the aggregate Exercise Price prior to such adjustment. Notwithstanding the foregoing, no adjustments shall be made, paid or issued under this Section 3(b) in respect of an Exempt Issuance. The Company shall notify the Holder, in writing, no later than the Trading Day following the issuance or deemed issuance of any Common Stock or Common Stock Equivalents subject to this Section 3(b), indicating therein the applicable issuance price, or applicable, reset price, exchange price, conversion price and other pricing terms (such notice, the “Dilutive Issuance Notice”). For purposes of clarification, whether or not the Company provides a Dilutive Issuance Notice pursuant to this Section 3(b), upon the occurrence of any Dilutive Issuance, the Holder is entitled to receive a number of Warrant Shares based upon the Base Share Price regardless of whether the Holder accurately refers to the Base Share Price in the Notice of Exercise. If the Company enters into a Variable Rate Transaction, the Company shall be deemed to have issued Common Stock or Common Stock Equivalents at the lowest possible price, conversion price or exercise price at which such securities may be issued, converted or exercised.

c) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the “Purchase Rights”), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, that, to the extent that the Holder’s right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

d) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a “Distribution”), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, that, to the extent that the Holder’s right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

e) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company or any Subsidiary, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock or 50% or more of the voting power of the common equity of the Company, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, merger or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires 50% or more of the outstanding shares of Common Stock or 50% or more of the voting power of the common equity of the Company (each a “Fundamental Transaction”), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the “Alternate Consideration”) receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. Notwithstanding anything to the contrary, in the event of a Fundamental Transaction, the Company or any Successor Entity (as defined below) shall, at the Holder’s option, exercisable at any time concurrently with, or within 30 days after, the consummation of the Fundamental Transaction (or, if later, the date of the public announcement of the applicable Fundamental Transaction), purchase this Warrant from the Holder by paying to the Holder an amount of cash equal to the Black Scholes Value (as defined below) of the remaining unexercised portion of this Warrant on the date of the consummation of such Fundamental Transaction; provided, however, that, if the Fundamental Transaction is not within the Company’s control, including not approved by the Company’s Board of Directors, the Holder shall only be entitled to receive from the Company or any Successor Entity the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of this Warrant, that is being offered and paid to the holders of Common Stock of the Company in connection with the Fundamental Transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of Common Stock are given the choice to receive from among alternative forms of consideration in connection with the Fundamental Transaction; provided, further, that if holders of Common Stock of the Company are not offered or paid any consideration in such Fundamental Transaction, such holders of Common Stock will be deemed to have received common stock of the Successor Entity (which Entity may be the Company following such Fundamental Transaction) in such Fundamental Transaction. “Black Scholes Value” means the value of this Warrant based on the Black-Scholes Option Pricing Model obtained from the “OV” function on Bloomberg, L.P. (“Bloomberg”) determined as of the day of consummation of the applicable Fundamental Transaction for pricing purposes and reflecting (A) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the time between the date of the public announcement of the applicable contemplated Fundamental Transaction and the Termination Date, (B) an expected volatility equal to the greater of (1) the 30 day volatility, (2) the 100 day volatility or (3) the 365 day volatility, each of clauses (1)-(3) as obtained from the HVT function on Bloomberg (determined utilizing a 365 day annualization factor) as of the Trading Day immediately following the public announcement of the applicable contemplated Fundamental Transaction, (C) the underlying price per share used in such calculation shall be the highest VWAP during the period beginning on the Trading Day immediately preceding the public announcement of the applicable contemplated Fundamental Transaction (or the consummation of the applicable Fundamental Transaction, if earlier) and ending on the Trading Day of the Holder’s request pursuant to this Section 3(e) and (D) a remaining option time equal to the time between the date of the public announcement of the applicable contemplated Fundamental Transaction and the Termination Date, and (E) a zero cost of borrow. The payment of the Black Scholes Value will be made by wire transfer of immediately available funds (or such other consideration) within the later of (i) five Business Days of the Holder’s election and (ii) the date of consummation of the Fundamental Transaction. The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the “Successor Entity”) to assume in writing all of the obligations of the Company under this Warrant in accordance with the provisions of this Section 3(e) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall be added to the term “Company” under this Warrant (so that from and after the occurrence or consummation of such Fundamental Transaction, each and every provision of this Warrant and the other Transaction Documents referring to the “Company” shall refer instead to each of the Company and the Successor Entity or Successor Entities, jointly and severally, may exercise every right and power of the Company prior thereto and the Successor Entity or Successor Entities shall assume all of the obligations of the Company prior thereto under this Warrant with the same effect as if the Company and such Successor Entity or Successor Entities, jointly and severally, had been named as the Company herein. For the avoidance of doubt, the Holder shall be entitled to the benefits of the provisions of this Section 3(e) regardless of (i) whether the Company has sufficient authorized shares of Common Stock for the issuance of Warrant Shares and/or (ii) whether a Fundamental Transaction occurs prior to the Initial Exercise Date.

f) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

g) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by facsimile or email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company (or any of its Subsidiaries) is a party, any sale or transfer of all or substantially all of its assets, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by facsimile or email to the Holder at its last facsimile number or email address as it shall appear upon the Warrant Register of the Company, at least 20 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

h) Voluntary Adjustment By Company. Subject to the rules and regulations of the Trading Market, the Company may at any time during the term of this Warrant reduce the then current Exercise Price to any amount and for any period of time deemed appropriate by the board of directors of the Company.

Section 4. Transfer of Warrant.

a) Transferability. This Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers an assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. If this Warrant is not held in global form through DTC (or any successor depository), this Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Warrant Agent shall register this Warrant, upon records to be maintained by the Warrant Agent for that purpose (the “Warrant Register”), in the name of the record Holder hereof from time to time. The Company and the Warrant Agent may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 5. Miscellaneous.

a) No Rights as Stockholder Until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting any rights of a Holder to receive Warrant Shares on a “cashless exercise” pursuant to Section 2(c) or to receive cash payments pursuant to Section 2(d)(i) and Section 2(d)(iv) herein, in no event shall the Company be required to net cash settle an exercise of this Warrant.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then, such action may be taken or such right may be exercised on the next succeeding Business Day.

d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Warrant (whether brought against a party hereto or their respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Warrant and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action, suit or proceeding to enforce any provisions of this Warrant, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for their reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. Without limiting any other provision of this Warrant, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) Notices. Any and all notices or other communications or deliveries to be provided by the Holders hereunder including, without limitation, any Notice of Exercise, shall be in writing and delivered personally, by facsimile or e-mail, or sent by a nationally recognized overnight courier service, addressed to the Company, at Arch Therapeutics, Inc., 235 Walnut Street, Suite 6, Framingham, MA 01702, Attention: CEO, or such other facsimile number, email address or address as the Company may specify for such purposes by notice to the Holders. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by facsimile or e-mail, or sent by a nationally recognized overnight courier service addressed to each Holder at the facsimile number, e-mail address or address of such Holder appearing on the books of the Company. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number or via e-mail at the e-mail address set forth in this Section prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number or via e-mail at the e-mail address set forth in this Section on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company, on the one hand, and the Holder or the beneficial owner of this Warrant, on the other hand.

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

o) Warrant Agency Agreement. If this Warrant is held in global form through DTC (or any successor depository), this Warrant is issued subject to the Warrant Agency Agreement. To the extent any provision of this Warrant conflicts with the express provisions of the Warrant Agency Agreement, the provisions of this Warrant shall govern and be controlling.

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

ARCH THERAPEUTICS, INC.

By: _____
Name:
Title:

NOTICE OF EXERCISE

TO: ARCH THERAPEUTICS, INC.

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

[] in lawful money of the United States; or

[] if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

The Warrant Shares shall be delivered to the following DWAC Account Number:

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____

Signature of Authorized Signatory of Investing Entity: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Date: _____

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name:	<div></div> <div>(Please Print)</div>
Address:	<div></div> <div>(Please Print)</div>
Phone Number:	<div></div>
Email Address:	<div></div>
Dated: _____, _____	
Holder's Signature: _____	
Holder's Address: _____	

THE REGISTERED HOLDER OF THIS PURCHASE WARRANT BY ITS ACCEPTANCE HEREOF, AGREES THAT IT WILL NOT SELL, TRANSFER OR ASSIGN THIS PURCHASE WARRANT EXCEPT AS HEREIN PROVIDED AND THE REGISTERED HOLDER OF THIS PURCHASE WARRANT AGREES THAT IT WILL NOT SELL, TRANSFER, ASSIGN, PLEDGE OR HYPOTHECATE THIS PURCHASE WARRANT FOR A PERIOD OF ONE HUNDRED EIGHTY DAYS FOLLOWING [●], 2023, WHICH IS THE COMMENCEMENT DATE OF SALES IN THE OFFERING (THE “EFFECTIVE DATE”) TO ANYONE OTHER THAN (I) DAWSON JAMES SECURITIES, INC., OR A SELECTED DEALER IN CONNECTION WITH THE OFFERING FOR WHICH THIS PURCHASE WARRANT WAS ISSUED TO THE UNDERWRITER AS CONSIDERATION (THE “OFFERING”), OR (II) THE OFFICERS OR PARTNERS, REGISTERED PERSONS OR AFFILIATES OF DAWSON JAMES SECURITIES, INC.

THIS PURCHASE WARRANT IS NOT EXERCISABLE PRIOR TO [●], 2023. VOID AFTER 5:00 P.M., EASTERN TIME, [●], 2028.

COMMON STOCK PURCHASE WARRANT

For the Purchase of [●] Shares of Common Stock
of
Arch Therapeutics, Inc.

1. Purchase Warrant. THIS CERTIFIES THAT, in consideration of funds duly paid by or on behalf of [●] (“Holder”), as registered owner of this Purchase Warrant, to Arch Therapeutics, Inc., a Nevada corporation (the “Company”), Holder is entitled, at any time or from time to time beginning [●], 2024 (the “Commencement Date”), and at or before 5:00 p.m., Eastern time, [●], 2028 (the “Expiration Date”), but not thereafter, to subscribe for, purchase and receive, in whole or in part, up to [●] shares of common stock of the Company, par value \$0.001 per share (the “Shares”), subject to adjustment as provided in Section 6 hereof. If the Expiration Date is a day on which banking institutions are authorized by law to close, then this Purchase Warrant may be exercised on the next succeeding day which is not such a day in accordance with the terms herein. During the period ending on the Expiration Date, the Company agrees not to take any action that would terminate this Purchase Warrant. This Purchase Warrant is initially exercisable at \$[●] per Share; provided, however, that upon the occurrence of any of the events specified in Section 6 hereof, the rights granted by this Purchase Warrant, including the exercise price per Share and the number of Shares to be received upon such exercise, shall be adjusted as therein specified. The term “Exercise Price” shall mean the initial exercise price or the adjusted exercise price, depending on the context.

2. Exercise.

2.1 Exercise Form. In order to exercise this Purchase Warrant, the exercise form attached hereto must be duly executed and completed and delivered to the Company, together with this Purchase Warrant and payment of the Exercise Price for the Shares being purchased payable in cash by wire transfer of immediately available funds to an account designated by the Company or by certified check or official bank check. If the subscription rights represented hereby shall not be exercised at or before 5:00 p.m., Eastern time, on the Expiration Date, this Purchase Warrant shall become and be void without further force or effect, and all rights represented hereby shall cease and expire. Each exercise hereof shall be irrevocable.

2.2 Cashless Exercise. If at the time of exercise hereof there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of the Warrant Shares to the Holder, then this Warrant may also be exercised, in whole or in part, at such time by means of a “cashless exercise” in which the Holder shall be entitled to receive a number of Warrant Shares according to the following formula:

$X = [(A-B)(Y)] / (A)$, where:

(X) = the number of Warrants Shares to be issued to Holder;

(A) = the last VWAP immediately preceding the time of delivery of the Notice of Exercise giving rise to the applicable “cashless exercise”, as set forth in the applicable Notice of Exercise (to clarify, the “last VWAP” will be the last VWAP as calculated over an entire Trading Day such that, in the event that this Warrant is exercised at a time that the Trading Market is open, the prior Trading Day’s VWAP shall be used in this calculation);

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(Y) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised. The Company agrees not to take any position contrary to this Section 2(c), except as permitted or required by law.

“VWAP” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the “Pink Sheets” published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date), or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holder and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

“Trading Day” means a day on which the New York Stock Exchange is open for trading.

“Trading Market” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, or the New York Stock Exchange (or any successors to any of the foregoing).

3. Transfer.

3.1 General Restrictions. The registered Holder of this Purchase Warrant agrees by his, her or its acceptance hereof, that such Holder will not: (a) sell, transfer, assign, pledge or hypothecate this Purchase Warrant for a period of one hundred eighty (180) days following the Effective Date to anyone other than: (i) Dawson James Securities, Inc. (“Dawson”) or an underwriter or a selected dealer participating in the Offering, or (ii) the officers or partners, registered persons or affiliates of Dawson or of any such underwriter or selected dealer, in each case in accordance with FINRA Conduct Rule 5110(e), and (b) cause this Purchase Warrant or the securities issuable hereunder to be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of this Purchase Warrant or the securities hereunder, except as provided for in FINRA Rule 5110(e)(2). After 180 days after the Effective Date, transfers to others may be made subject to compliance with or exemptions from applicable securities laws. In order to make any permitted assignment, the Holder must deliver to the Company the assignment form attached hereto duly executed and completed, together with the Purchase Warrant and payment of all transfer taxes, if any, payable in connection therewith. The Company shall within five (5) Business Days transfer this Purchase Warrant on the books of the Company and shall execute and deliver a new Purchase Warrant or Purchase Warrants of like tenor to the appropriate assignee(s) expressly evidencing the right to purchase the aggregate number of Shares purchasable hereunder or such portion of such number as shall be contemplated by any such assignment.

3 . 2 Restrictions Imposed by the Act. The securities evidenced by this Purchase Warrant shall not be transferred unless and until: (i) if required by applicable law, the Company has received the opinion of counsel for the Company that the securities may be transferred pursuant to an exemption from registration under the Act and applicable state securities laws, or (ii) a registration statement or a post-effective amendment to the Registration Statement relating to the offer and sale of such securities has been filed by the Company and declared effective by the U.S. Securities and Exchange Commission (the "**Commission**") and compliance with applicable state securities law has been established.

4. Reserved.

5. New Purchase Warrants to be Issued.

5 . 1 Partial Exercise or Transfer. Subject to the restrictions in Section 3 hereof, this Purchase Warrant may be exercised or assigned in whole or in part. In the event of the exercise or assignment hereof in part only, upon surrender of this Purchase Warrant for cancellation, together with the duly executed exercise or assignment form, the Company shall cause to be delivered to the Holder without charge a new Purchase Warrant of like tenor to this Purchase Warrant in the name of the Holder evidencing the right of the Holder to purchase the number of Shares purchasable hereunder as to which this Purchase Warrant has not been exercised or assigned.

5 . 2 Lost Certificate. Upon receipt by the Company of evidence satisfactory to it of the loss, theft, destruction or mutilation of this Purchase Warrant and of reasonably satisfactory indemnification or the posting of a bond, determined in the sole discretion of the Company, the Company shall execute and deliver a new Purchase Warrant of like tenor and date. Any such new Purchase Warrant executed and delivered as a result of such loss, theft, mutilation or destruction shall constitute a substitute contractual obligation on the part of the Company.

6. Adjustments.

6 . 1 Adjustments to Exercise Price and Number of Securities. The Exercise Price and the number of Shares underlying the Purchase Warrant shall be subject to adjustment from time to time as hereinafter set forth:

6 . 1 . 1 Share Dividends; Split Ups. If, after the date hereof, and subject to the provisions of Section 6.3 below, the number of outstanding Shares is increased by a stock dividend payable in Shares or by a split up of Shares or other similar event, then, on the effective day thereof, the number of Shares purchasable hereunder shall be increased in proportion to such increase in outstanding Shares, and the Exercise Price shall be proportionately decreased.

6.1.2 Aggregation of Shares. If, after the date hereof, and subject to the provisions of Section 6.3 below, the number of outstanding Shares is decreased by a consolidation, combination or reclassification of Shares or other similar event, then, on the effective date thereof, the number of Shares purchasable hereunder shall be decreased in proportion to such decrease in outstanding Shares, and the Exercise Price shall be proportionately increased.

6 . 1 . 3 Replacement of Securities upon Reorganization, etc. In case of any reclassification or reorganization of the outstanding Shares other than a change covered by Section 6.1.1 or 6.1.2 hereof or that solely affects the par value of such Shares, or in the case of any share reconstruction or amalgamation or consolidation or merger of the Company with or into another corporation (other than a consolidation or share reconstruction or amalgamation or merger in which the Company is the continuing corporation and that does not result in any reclassification or reorganization of the outstanding Shares), or in the case of any sale or conveyance to another corporation or entity of the property of the Company as an entirety or substantially as an entirety in connection with which the Company is dissolved, the Holder of this Purchase Warrant shall have the right thereafter (until the expiration of the right of exercise of this Purchase Warrant) to receive upon the exercise hereof, for the same aggregate Exercise Price payable hereunder immediately prior to such event, the kind and amount of shares of stock or other securities or property (including cash) receivable upon such reclassification, reorganization, share reconstruction or amalgamation, or consolidation, or upon a dissolution following any such sale or transfer, by a Holder of the number of Shares of the Company obtainable upon exercise of this Purchase Warrant immediately prior to such event; and if any reclassification also results in a change in Shares covered by Section 6.1.1 or 6.1.2, then such adjustment shall be made pursuant to Sections 6.1.1, 6.1.2 and this Section 6.1.3. The provisions of this Section 6.1.3 shall similarly apply to successive reclassifications, reorganizations, share reconstructions or amalgamations, or consolidations, sales or other transfers.

6.1.4 Changes in Form of Purchase Warrant. This form of Purchase Warrant need not be changed because of any change pursuant to this Section 6.1, and Purchase Warrants issued after such change may state the same Exercise Price and the same number of Shares as are stated in the Purchase Warrants initially issued pursuant to this Agreement. The acceptance by any Holder of the issuance of new Purchase Warrants reflecting a required or permissive change shall not be deemed to waive any rights to an adjustment occurring after the Commencement Date or the computation thereof.

6.2 Substitute Purchase Warrant. In case of any consolidation of the Company with, or share reconstruction or amalgamation or merger of the Company with or into, another corporation (other than a consolidation or share reconstruction or amalgamation or merger which does not result in any reclassification or change of the outstanding Shares), the corporation formed by such consolidation or share reconstruction or amalgamation shall execute and deliver to the Holder a supplemental Purchase Warrant providing that the holder of each Purchase Warrant then outstanding or to be outstanding shall have the right thereafter (until the stated expiration of such Purchase Warrant) to receive, upon exercise of such Purchase Warrant, the kind and amount of shares of stock and other securities and property receivable upon such consolidation or share reconstruction or amalgamation, by a holder of the number of Shares of the Company for which such Purchase Warrant might have been exercised immediately prior to such consolidation, share reconstruction or amalgamation or merger, sale or transfer. Such supplemental Purchase Warrant shall provide for adjustments which shall be identical to the adjustments provided for in this Section 6. The above provision of this Section shall similarly apply to successive consolidations or share reconstructions or amalgamations or mergers.

6.3 Elimination of Fractional Interests. The Company shall not be required to issue certificates representing fractions of Shares upon the exercise of the Purchase Warrant, nor shall it be required to issue scrip or pay cash in lieu of any fractional interests, it being the intent of the parties that all fractional interests shall be eliminated by rounding any fraction up or down, as the case may be, to the nearest whole number of Shares or other securities, properties or rights.

7. Reservation. The Company shall at all times reserve and keep available out of its authorized Shares, solely for the purpose of issuance upon exercise of the Purchase Warrants, such number of Shares or other securities, properties or rights as shall be issuable upon the exercise thereof. The Company covenants and agrees that, upon exercise of the Purchase Warrants and payment of the Exercise Price therefor, in accordance with the terms hereby, all Shares and other securities issuable upon such exercise shall be duly and validly issued, fully paid and non-assessable and not subject to preemptive rights of any shareholder.

8. Certain Notice Requirements.

8.1 Holder's Right to Receive Notice. Nothing herein shall be construed as conferring upon the Holders the right to vote or consent or to receive notice as a shareholder for the election of directors or any other matter, or as having any rights whatsoever as a shareholder of the Company. If, however, at any time prior to the expiration of the Purchase Warrants and their exercise, any of the events described in Section 8.2 shall occur, then, in one or more of said events, the Company shall deliver to each Holder a copy of each notice relating to such events given to the other shareholders of the Company at the same time and in the same manner that such notice is given to the shareholders.

8.2 Events Requiring Notice. The Company shall be required to give the notice described in this Section 8 upon one or more of the following events: (i) if the Company shall take a record of the holders of its Shares for the purpose of entitling them to receive a dividend or distribution payable otherwise than in cash, or a cash dividend or distribution payable otherwise than out of retained earnings, as indicated by the accounting treatment of such dividend or distribution on the books of the Company, or (ii) the Company shall offer to all the holders of its Shares any additional shares of capital stock of the Company or securities convertible into or exchangeable for shares of capital stock of the Company, or any option, right or warrant to subscribe therefor.

8.3 Notice of Change in Exercise Price. The Company shall, promptly after an event requiring a change in the Exercise Price pursuant to Section 6 hereof, send notice to the Holders of such event and change ("**Price Notice**"). The Price Notice shall describe the event causing the change and the method of calculating same.

8.4 Transmittal of Notices. All notices, requests, consents and other communications under this Purchase Warrant shall be in writing and shall be deemed to have been duly made when hand delivered, or mailed by express mail or private courier service: (i) if to the registered Holder of the Purchase Warrant, to the address of such Holder as shown on the books of the Company, or (ii) if to the Company, to following address or to such other address as the Company may designate by notice to the Holders:

If to the Holder:

Dawson James Securities, Inc.
101 N. Federal Highway, Suite 600
Newport Beach, CA 92660
Attention: []

with a copy (which shall not constitute notice) to:

ArentFox Schiff LLP
1717 K Street NW
Washington, DC 20006
Attn: Ralph DeMartino, Esq.

If to the Company:

Arch Therapeutics, Inc.
235 Walnut St., Suite 6
Framingham, MA 01702
Attention: Terrence W. Norchi

With copies to *(which shall not constitute notice)*:

Lowenstein Sandler LLP
One Lowenstein Drive
Roseland, NJ 07068

9. Miscellaneous.

9.1 Amendments. The Company and Dawson may from time to time supplement or amend this Purchase Warrant without the approval of any of the Holders in order to cure any ambiguity, to correct or supplement any provision contained herein that may be defective or inconsistent with any other provisions herein, or to make any other provisions in regard to matters or questions arising hereunder that the Company and Dawson may deem necessary or desirable and that the Company and Dawson deem shall not adversely affect the interest of the Holders. All other modifications or amendments shall require the written consent of and be signed by (i) the Company and (ii) the Holder(s) of Purchase Warrants then-exercisable for at least a majority of the Shares then-exercisable pursuant to all then-outstanding Purchase Warrants.

9.2 Headings. The headings contained herein are for the sole purpose of convenience of reference, and shall not in any way limit or affect the meaning or interpretation of any of the terms or provisions of this Purchase Warrant.

9.3. Entire Agreement. This Purchase Warrant (together with the other agreements and documents being delivered pursuant to or in connection with this Purchase Warrant) constitutes the entire agreement of the parties hereto with respect to the subject matter hereof, and supersedes all prior agreements and understandings of the parties, oral and written, with respect to the subject matter hereof.

9.4. Binding Effect. This Purchase Warrant shall inure solely to the benefit of and shall be binding upon, the Holder and the Company and their permitted assignees, respective successors, legal representative and assigns, and no other person shall have or be construed to have any legal or equitable right, remedy or claim under or in respect of or by virtue of this Purchase Warrant or any provisions herein contained.

9.5. Governing Law; Submission to Jurisdiction; Trial by Jury. This Purchase Warrant shall be governed by and construed and enforced in accordance with the laws of the State of New York, without giving effect to conflict of laws principles thereof. The Company hereby agrees that any action, proceeding or claim against it arising out of, or relating in any way to this Purchase Warrant shall be brought and enforced in the courts located in New York, New York, or in the United States District Court located in New York, New York, and irrevocably submits to such jurisdiction, which jurisdiction shall be exclusive. The Company hereby waives any objection to such exclusive jurisdiction and that such courts represent an inconvenient forum. Any process or summons to be served upon the Company may be served by transmitting a copy thereof by registered or certified mail, return receipt requested, postage prepaid, addressed to it at the address set forth in Section 8 hereof. Such mailing shall be deemed personal service and shall be legal and binding upon the Company in any action, proceeding or claim. The Company and the Holder agree that the prevailing party(ies) in any such action shall be entitled to recover from the other party(ies) all of its reasonable attorneys' fees and expenses relating to such action or proceeding and/or incurred in connection with the preparation therefor. The Company (on its behalf and, to the extent permitted by applicable law, on behalf of its stockholders and affiliates) and the Holder hereby irrevocably waive, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

9.6. Waiver, etc. The failure of the Company or the Holder to at any time enforce any of the provisions of this Purchase Warrant shall not be deemed or construed to be a waiver of any such provision, nor to in any way affect the validity of this Purchase Warrant or any provision hereof or the right of the Company or any Holder to thereafter enforce each and every provision of this Purchase Warrant. No waiver of any breach, non-compliance or non-fulfillment of any of the provisions of this Purchase Warrant shall be effective unless set forth in a written instrument executed by the party or parties against whom or which enforcement of such waiver is sought; and no waiver of any such breach, non-compliance or non-fulfillment shall be construed or deemed to be a waiver of any other or subsequent breach, non-compliance or non-fulfillment.

9.7. Exchange Agreement. As a condition of the Holder's receipt and acceptance of this Purchase Warrant, Holder agrees that, at any time prior to the complete exercise of this Purchase Warrant by Holder, if the Company and Dawson enter into an agreement ("**Exchange Agreement**") pursuant to which they agree that all outstanding Purchase Warrants will be exchanged for securities or cash or a combination of both, then Holder shall agree to such exchange and become a party to the Exchange Agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, the Company has caused this Purchase Warrant to be signed by its duly authorized officer as of the [●] day of [●], 2023.

Arch Therapeutics, Inc.

By: _____
Name:
Title:

[Form to be used to exercise Purchase Warrant]

Date: _____, 20__

The undersigned hereby elects irrevocably to exercise the Purchase Warrant for _____ shares of common stock, par value \$0.001 per share (the “**Shares**”), of Arch Therapeutics, Inc., a Nevada corporation (the “**Company**”), and hereby makes payment of \$_____ (at the rate of \$_____ per Share) in payment of the Exercise Price pursuant thereto. Please issue the Shares as to which this Purchase Warrant is exercised in accordance with the instructions given below and, if applicable, a new Purchase Warrant representing the number of Shares for which this Purchase Warrant has not been exercised.

or

The undersigned hereby elects irrevocably to convert its right to purchase ____ Shares of the Company under the Purchase Warrant for _____ Shares, as determined in accordance with the following formula:

$$X = \frac{Y(A-B)}{A}$$

Where,

- X = The number of Shares to be issued to Holder;
- Y = The number of Shares for which the Purchase Warrant is being exercised;
- A = The fair market value of one Share which is equal to \$_____; and
- B = The Exercise Price which is equal to \$_____ per share

The undersigned agrees and acknowledges that the calculation set forth above is subject to confirmation by the Company and any disagreement with respect to the calculation shall be resolved by the Company in its sole discretion.

Please issue the Shares as to which this Purchase Warrant is exercised in accordance with the instructions given below and, if applicable, a new Purchase Warrant representing the number of Shares for which this Purchase Warrant has not been converted.

Signature _____

Signature Guaranteed _____

INSTRUCTIONS FOR REGISTRATION OF SECURITIES

Name: _____
(Print in Block Letters)

Address: _____

NOTICE: The signature to this form must correspond with the name as written upon the face of the Purchase Warrant without alteration or enlargement or any change whatsoever, and must be guaranteed by a bank, other than a savings bank, or by a trust company or by a firm having membership on a registered national securities exchange.

ASSIGNMENT

(To be executed by the registered Holder to effect a transfer of the within Purchase Warrant):

FOR VALUE RECEIVED, _____ does hereby sell, assign and transfer unto the right to purchase shares of Common Stock, par value \$0.001 per share, of Arch Therapeutics, Inc., a Nevada corporation (the “**Company**”), evidenced by the Purchase Warrant and does hereby authorize the Company to transfer such right on the books of the Company.

Dated: _____, 2023

Signature _____

Signature Guaranteed _____

NOTICE: The signature to this form must correspond with the name as written upon the face of the within Purchase Warrant without alteration or enlargement or any change whatsoever, and must be guaranteed by a bank, other than a savings bank, or by a trust company or by a firm having membership on a registered national securities exchange.

**PRE-FUNDED COMMON STOCK PURCHASE WARRANT
ARCH THERAPEUTICS, INC.**

Warrant Shares: _____

Initial Exercise Date: September [], 2023
CUSIP:

THIS PRE-FUNDED COMMON STOCK PURCHASE WARRANT (the “Warrant”) certifies that, for value received, CEDE & CO. or its assigns (the “Holder”) is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the date hereof (the “Initial Exercise Date”) and until this Warrant is exercised in full (the “Termination Date”) but not thereafter, to subscribe for and purchase from Arch Therapeutics, Inc., a Nevada corporation (the “Company”), up to _____ shares (as subject to adjustment hereunder, the “Warrant Shares”) of Common Stock. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b). This Warrant shall initially be issued and maintained in the form of a security held in book-entry form and the Depository Trust Company or its nominee (“DTC”) shall initially be the sole registered holder of this Warrant, subject to a Holder’s right to elect to receive a Warrant in certificated form pursuant to the terms of the Warrant Agency Agreement, in which case this sentence shall not apply.

Section 1. Definitions. In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated in this Section 1:

“Affiliate” means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

“Bid Price” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the bid price of the Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

“Board of Directors” means the board of directors of the Company.

“Business Day” means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the City of New York are authorized or required by law or other governmental action to close; provided, however, for clarification, commercial banks shall not be deemed to be authorized or required by law to remain closed due to “stay at home”, “shelter-in-place”, “non-essential employee” or any other similar orders or restrictions or the closure of any physical branch locations at the direction of any governmental authority so long as the electronic funds transfer systems (including for wire transfers) of commercial banks in The City of New York generally are open for use by customers on such day.

“Commission” means the United States Securities and Exchange Commission.

“Common Stock” means the common stock of the Company, par value \$0.001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

“Common Stock Equivalents” means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

“Exchange Act” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

“Person” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“Registration Statement” means the Company’s registration statement on Form S-1 (File No. 333-268008).

“Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“Subsidiary” means any subsidiary of the Company and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

“Trading Day” means a day on which the Common Stock is traded on a Trading Market.

“Trading Market” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange, QTCQB or QTCQX (or any successors to any of the foregoing).

“Transfer Agent” means Empire Stock Transfer, the current transfer agent of the Company, with a mailing address of [1859 Whitney Mesa Drive, Henderson, Nevada 89014], an email address of [____], and a facsimile number of (____) [____], and any successor transfer agent of the Company.

“VWAP” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

“Warrant Agency Agreement” means that certain warrant agency agreement, dated on or about the Initial Exercise Date, between the Company and the Warrant Agent.

“Warrant Agent” means the Transfer Agent and any successor warrant agent of the Company.

“Warrants” means this Warrant and other Common Stock purchase warrants issued by the Company pursuant to the Registration Statement.

Section 2. Exercise.

a) Exercise of Warrant. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Warrant Agent of a duly executed facsimile copy or PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form annexed hereto (the “Notice of Exercise”). Within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the shares specified in the applicable Notice of Exercise by wire transfer or cashier’s check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Warrant Agent until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Warrant Agent for cancellation within three (3) Trading Days of the date on which the final Notice of Exercise is delivered to the Warrant Agent. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Business Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

Notwithstanding the foregoing in this Section 2(a), a holder whose interest in this Warrant is a beneficial interest in certificate(s) representing this Warrant held in book-entry form through DTC (or another established clearing corporation performing similar functions), shall effect exercises made pursuant to this Section 2(a) by delivering to DTC (or such other clearing corporation, as applicable) the appropriate instruction form for exercise, complying with the procedures to effect exercise that are required by DTC (or such other clearing corporation, as applicable), subject to a Holder’s right to elect to receive a Warrant in certificated form pursuant to the terms of the Warrant Agency Agreement, in which case this sentence shall not apply.

b) Exercise Price. The aggregate exercise price of this Warrant, except for a nominal exercise price of \$0.0001 per Warrant Share, was pre-funded to the Company on or prior to the Issue Date and, consequently, no additional consideration (other than the nominal exercise price of \$0.0001 per Warrant Share) shall be required to be paid by the Holder to any Person to effect any exercise of this Warrant. The Holder shall not be entitled to the return or refund of all, or any portion, of such pre-paid aggregate exercise price under any circumstance or for any reason whatsoever, including in the event this Warrant shall not have been exercised prior to the Termination Date. The remaining unpaid exercise price per share of Common Stock under this Warrant shall be \$0.0001, subject to adjustment hereunder (the “Exercise Price”).

c) Cashless Exercise. This Warrant may also be exercised, in whole or in part, at such time by means of a “cashless exercise” in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing $[(A-B) (X)]$ by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of “regular trading hours” (as defined in Rule 600(b) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the Bid Price of the Common Stock on the principal Trading Market as reported by Bloomberg L.P. as of the time of the Holder’s execution of the applicable Notice of Exercise if such Notice of Exercise is executed during “regular trading hours” on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of “regular trading hours” on a Trading Day) pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of “regular trading hours” on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised. The Company agrees not to take any position contrary to this Section 2(c).

Notwithstanding anything herein to the contrary, on the Termination Date this Warrant shall be automatically exercised via cashless exercise pursuant to this Section 2(c).

d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by Holder or (B) this Warrant is being exercised via cashless exercise, and otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earliest of (i) two (2) Trading Days after the delivery to the Company of the Notice of Exercise, (ii) one (1) Trading Day after delivery of the aggregate Exercise Price to the Company and (iii) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company of the Notice of Exercise (such date, the "Warrant Share Delivery Date"). Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period following delivery of the Notice of Exercise. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each \$1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), \$10 per Trading Day (increasing to \$20 per Trading Day on the third Trading Day after the Warrant Share Delivery Date) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Exercise. Notwithstanding the foregoing, with respect to any Notice(s) of Exercise delivered on or prior to 12:00 p.m. (New York City time) on the Initial Exercise Date, which may be delivered at any time after the time of execution of the Placement Agency Agreement, the Company agrees to deliver the Warrant Shares subject to such notice(s) by 4:00 p.m. (New York City time) on the Initial Exercise Date and the Initial Exercise Date shall be the Warrant Share Delivery Date for purposes hereunder, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received by such Warrant Share Delivery Date.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of \$11,000 to cover a Buy-In with respect to an attempted exercise of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of \$10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder \$1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) **Holder's Exercise Limitations.** The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within one Trading Day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% (or, upon election by a Holder prior to the issuance of any Warrants, 9.99%) of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

Section 3. Certain Adjustments.

a) **Stock Dividends and Splits.** If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) Subsequent Equity Sales. If the Company or any Subsidiary thereof, as applicable, at any time while this Warrant is outstanding, shall sell, enter into an agreement to sell, or grant any option to purchase, or sell, enter into an agreement to sell, or grant any right to reprice, or otherwise dispose of or issue (or announce any offer, sale, grant or any option to purchase or other disposition) any Common Stock or Common Stock Equivalents, at an effective price per share less than the Exercise Price then in effect (such lower price, the “Base Share Price” and such issuances collectively, a “Dilutive Issuance”) (it being understood and agreed that if the holder of the Common Stock or Common Stock Equivalents so issued shall at any time, whether by operation of purchase price adjustments, reset provisions, floating conversion, exercise or exchange prices or otherwise, or due to warrants, options or rights per share which are issued in connection with such issuance, be entitled to receive shares of Common Stock at an effective price per share that is less than the Exercise Price, such issuance shall be deemed to have occurred for less than the Exercise Price on such date of the Dilutive Issuance at such effective price), then simultaneously with the consummation (or, if earlier, the announcement) of each Dilutive Issuance the Exercise Price shall be reduced and only reduced to equal the Base Share Price and the number of Warrant Shares issuable hereunder shall be increased such that the aggregate Exercise Price payable hereunder, after taking into account the decrease in the Exercise Price, shall be equal to the aggregate Exercise Price prior to such adjustment. Notwithstanding the foregoing, no adjustments shall be made, paid or issued under this Section 3(b) in respect of an Exempt Issuance. The Company shall notify the Holder, in writing, no later than the Trading Day following the issuance or deemed issuance of any Common Stock or Common Stock Equivalents subject to this Section 3(b), indicating therein the applicable issuance price, or applicable, reset price, exchange price, conversion price and other pricing terms (such notice, the “Dilutive Issuance Notice”). For purposes of clarification, whether or not the Company provides a Dilutive Issuance Notice pursuant to this Section 3(b), upon the occurrence of any Dilutive Issuance, the Holder is entitled to receive a number of Warrant Shares based upon the Base Share Price regardless of whether the Holder accurately refers to the Base Share Price in the Notice of Exercise. If the Company enters into a Variable Rate Transaction, the Company shall be deemed to have issued Common Stock or Common Stock Equivalents at the lowest possible price, conversion price or exercise price at which such securities may be issued, converted or exercised.

c) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the “Purchase Rights”), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, that, to the extent that the Holder’s right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

d) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a “Distribution”), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, that, to the extent that the Holder’s right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

e) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company or any Subsidiary, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock or 50% or more of the voting power of the common equity of the Company, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, merger or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires 50% or more of the outstanding shares of Common Stock or 50% or more of the voting power of the common equity of the Company (each a “Fundamental Transaction”), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the “Alternate Consideration”) receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. Notwithstanding anything to the contrary, in the event of a Fundamental Transaction, the Company or any Successor Entity (as defined below) shall, at the Holder’s option, exercisable at any time concurrently with, or within 30 days after, the consummation of the Fundamental Transaction (or, if later, the date of the public announcement of the applicable Fundamental Transaction), purchase this Warrant from the Holder by paying to the Holder an amount of cash equal to the Black Scholes Value (as defined below) of the remaining unexercised portion of this Warrant on the date of the consummation of such Fundamental Transaction; provided, however, that, if the Fundamental Transaction is not within the Company’s control, including not approved by the Company’s Board of Directors, the Holder shall only be entitled to receive from the Company or any Successor Entity the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of this Warrant, that is being offered and paid to the holders of Common Stock of the Company in connection with the Fundamental Transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of Common Stock are given the choice to receive from among alternative forms of consideration in connection with the Fundamental Transaction; provided, further, that if holders of Common Stock of the Company are not offered or paid any consideration in such Fundamental Transaction, such holders of Common Stock will be deemed to have received common stock of the Successor Entity (which Entity may be the Company following such Fundamental Transaction) in such Fundamental Transaction. “Black Scholes Value” means the value of this Warrant based on the Black-Scholes Option Pricing Model obtained from the “OV” function on Bloomberg, L.P. (“Bloomberg”) determined as of the day of consummation of the applicable Fundamental Transaction for pricing purposes and reflecting (A) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the time between the date of the public announcement of the applicable contemplated Fundamental Transaction and the Termination Date, (B) an expected volatility equal to the greater of (1) the 30 day volatility, (2) the 100 day volatility or (3) the 365 day volatility, each of clauses (1)-(3) as obtained from the HVT function on Bloomberg (determined utilizing a 365 day annualization factor) as of the Trading Day immediately following the public announcement of the applicable contemplated Fundamental Transaction, (C) the underlying price per share used in such calculation shall be the highest VWAP during the period beginning on the Trading Day immediately preceding the public announcement of the applicable contemplated Fundamental Transaction (or the consummation of the applicable Fundamental Transaction, if earlier) and ending on the Trading Day of the Holder’s request pursuant to this Section 3(e) and (D) a remaining option time equal to the time between the date of the public announcement of the applicable contemplated Fundamental Transaction and the Termination Date, and (E) a zero cost of borrow. The payment of the Black Scholes Value will be made by wire transfer of immediately available funds (or such other consideration) within the later of (i) five Business Days of the Holder’s election and (ii) the date of consummation of the Fundamental Transaction. The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the “Successor Entity”) to assume in writing all of the obligations of the Company under this Warrant in accordance with the provisions of this Section 3(e) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall be added to the term “Company” under this Warrant (so that from and after the occurrence or consummation of such Fundamental Transaction, each and every provision of this Warrant and the other Transaction Documents referring to the “Company” shall refer instead to each of the Company and the Successor Entity or Successor Entities, jointly and severally, may exercise every right and power of the Company prior thereto and the Successor Entity or Successor Entities shall assume all of the obligations of the Company prior thereto under this Warrant with the same effect as if the Company and such Successor Entity or Successor Entities, jointly and severally, had been named as the Company herein. For the avoidance of doubt, the Holder shall be entitled to the benefits of the provisions of this Section 3(e) regardless of (i) whether the Company has sufficient authorized shares of Common Stock for the issuance of Warrant Shares and/or (ii) whether a Fundamental Transaction occurs prior to the Initial Exercise Date.

f) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

g) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by facsimile or email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company (or any of its Subsidiaries) is a party, any sale or transfer of all or substantially all of its assets, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by facsimile or email to the Holder at its last facsimile number or email address as it shall appear upon the Warrant Register of the Company, at least 20 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

h) Voluntary Adjustment By Company. Subject to the rules and regulations of the Trading Market, the Company may at any time during the term of this Warrant reduce the then current Exercise Price to any amount and for any period of time deemed appropriate by the board of directors of the Company.

Section 4. Transfer of Warrant.

a) Transferability. This Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers an assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. If this Warrant is not held in global form through DTC (or any successor depository), this Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Warrant Agent shall register this Warrant, upon records to be maintained by the Warrant Agent for that purpose (the “Warrant Register”), in the name of the record Holder hereof from time to time. The Company and the Warrant Agent may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 5. Miscellaneous.

a) No Rights as Stockholder Until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting any rights of a Holder to receive Warrant Shares on a “cashless exercise” pursuant to Section 2(c) or to receive cash payments pursuant to Section 2(d)(i) and Section 2(d)(iv) herein, in no event shall the Company be required to net cash settle an exercise of this Warrant.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then, such action may be taken or such right may be exercised on the next succeeding Business Day.

d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Warrant (whether brought against a party hereto or their respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Warrant and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action, suit or proceeding to enforce any provisions of this Warrant, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for their reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. Without limiting any other provision of this Warrant, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) Notices. Any and all notices or other communications or deliveries to be provided by the Holders hereunder including, without limitation, any Notice of Exercise, shall be in writing and delivered personally, by facsimile or e-mail, or sent by a nationally recognized overnight courier service, addressed to the Company, at Arch Therapeutics, Inc., 235 Walnut Street, Suite 6, Framingham, MA 01702, Attention: CEO, or such other facsimile number, email address or address as the Company may specify for such purposes by notice to the Holders. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by facsimile or e-mail, or sent by a nationally recognized overnight courier service addressed to each Holder at the facsimile number, e-mail address or address of such Holder appearing on the books of the Company. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number or via e-mail at the e-mail address set forth in this Section prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number or via e-mail at the e-mail address set forth in this Section on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company, on the one hand, and the Holder or the beneficial owner of this Warrant, on the other hand.

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

o) Warrant Agency Agreement. If this Warrant is held in global form through DTC (or any successor depository), this Warrant is issued subject to the Warrant Agency Agreement. To the extent any provision of this Warrant conflicts with the express provisions of the Warrant Agency Agreement, the provisions of this Warrant shall govern and be controlling.

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

ARCH THERAPEUTICS, INC.

By: _____

Name:

Title:

NOTICE OF EXERCISE

TO: ARCH THERAPEUTICS, INC.

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

[] in lawful money of the United States; or

[] if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

The Warrant Shares shall be delivered to the following DWAC Account Number:

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____

Signature of Authorized Signatory of Investing Entity: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Date: _____

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name:

(Please Print)

Address:

(Please Print)

Phone Number:

Email Address:

Dated: ,

Holder's Signature:

Holder's Address:

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the use in this Amendment No. 3 to Registration Statement on Form S-1/A for Arch Therapeutics, Inc. and Subsidiary (collectively, the “Company”) of our report dated December 28, 2022 (except for the effects of the reverse stock split described in Note 2 as to which the date is January 23, 2023), relating to the consolidated financial statements of the Company as of and for the years ended September 30, 2022 and 2021. Our report contains an explanatory paragraph regarding the Company’s ability to continue as a going concern.

We also consent to the reference to us under the heading “Experts” in such Registration Statement.

/s/ Baker Tilly US, LLP

Tewksbury, Massachusetts

October 5, 2023

Calculation of Filing Fee Tables

Form S-1
(Form Type)Arch Therapeutics, Inc.
(Exact Name of Registrant as Specified in its Charter)

	Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered (1)	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price(1)(2)	Fee Rate	Amount of Registration Fee
Fees to Be Paid	Equity	Units consisting of:(3)	Rule 457(o)	—	—	\$15,525,000.00	0.0001476	\$2,291.49
Fees to Be Paid	Equity	(i) Common Stock, par value \$0.001 per share(4)	—	—	—	—	—	—
Fees to Be Paid	Equity	(ii) one Investor Warrant to purchase one share of Common Stock(4)	—	—	—	—	—	—
Fees to Be Paid	Equity	Pre-Funded Units consisting of: (3)(7)	Rule 457(o)	—	—	—	0.0001476	—
Fees to Be Paid	Equity	(i) one Pre-Funded Warrant to purchase one share of Common Stock(4)	—	—	—	—	—	—
Fees to Be Paid	Equity	(i) one Investor Warrant to purchase one share of Common Stock(4)	—	—	—	—	—	—
Fees to Be Paid	Equity	Common Stock issuable upon exercise of Pre-Funded Warrants (3)(5)	Rule 457(o)	—	—	—	0.0001476	—
Fees to Be Paid	Equity	Common Stock issuable upon exercise of the Investor Warrants(3)(5)	Rule 457(o)	—	—	\$15,525,000.00	0.0001476	\$2,291.49
Fees to Be Paid	Equity	Underwriter Warrants to purchase Common Stock(6)	Rule 457(g)	—	—	—	—	—
Fees to Be Paid	Equity	Common Stock issuable upon exercise of the Underwriter Warrants(3)	Rule 457(g)	—	—	\$1,397,250.00	0.0001476	\$206.23
Fees to Be Paid	Equity	Shares of Common Stock offered by the Selling Stockholders in the Resale Prospectus(8)	Rule 457(c)	94,567,245	\$1.30	\$122,937,418.50	0.0001476	\$18,145.57
Fees Previously Paid	—	—	—	—	—	—	—	\$3,972.99
Carry Forward Securities	—	—	—	—	—	—	—	—
Total Offering Amounts						\$139,859,668.50		\$22,934.78
Total Fees Previously Paid								\$3,972.99
Total Fee Offsets								\$0.00
Net Fee Due								\$18,961.79

- (1) Pursuant to Rule 416 under the Securities Act of 1933, as amended (the “**Securities Act**”), there is also being registered hereby such indeterminate number of additional shares of common stock, par value \$0.001 per share (the “**Common Stock**”), of Arch Therapeutics, Inc. (the “**Company**”), as may be issued or issuable because of stock splits, stock dividends stock distributions, and similar transactions.
- (2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act.
- (3) Includes any additional shares of Common Stock and/or warrants to purchase shares of Common Stock (the “**Investor Warrants**”) that may be issued upon exercise of the option granted to the underwriters to cover over-allotments, if any.
- (4) No separate registration fee is payable pursuant to Rule 457(g) under the Securities Act.
- (5) The Investor Warrants are exercisable at a per share price of 100% of the price per Unit in this offering.
- (6) We have agreed to issue to Dawson James Securities, Inc.(or its designees), the representative of the underwriters, warrants (the “**Underwriter Warrants**”) to purchase the number of shares equal to five percent (5%) of the total number of shares of Common Stock and Pre-Funded Warrants sold in this offering, including any additional shares of Common Stock that may be issued upon exercise of the option granted to the underwriters to cover over-allotments, if any. The Underwriter Warrants are exercisable at a price per share equal to 125% of the price per Unit in this offering.
- (7) The proposed maximum aggregate offering price of the Units will be reduced on a dollar-for-dollar basis based on the offering price of any Pre-Funded Units issued in the offering, and the proposed maximum aggregate offering price of the Pre-Funded Units to be issued in the offering will be reduced on a dollar-for-dollar basis based on the offering price of any Units issued in the offering. Accordingly, the proposed maximum aggregate offering price of the Units and Pre-Funded Units, if any, is \$15,525,000
- (8) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act based on a per share price of \$1.30, the average of the high and low reported sales prices of the registrant’s common stock on the OTCQB on October 2, 2023