

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

FORM S-1/A
(Amendment No. 2)

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
Non-accelerated filer

Accelerated filer
Smaller reporting company
Emerging growth company

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.

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 JANUARY 30, 2023

PRELIMINARY PROSPECTUS

ARCH THERAPEUTICS, INC.

**2,432,432 Units consisting of
2,432,432 Shares of Common Stock and
Investor Warrants to Purchase up to 2,432,432 Shares of Common Stock**

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 not less than 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.

Our Common Stock is currently quoted on the QB tier of the OTC Marketplace (“OTCQB”) under the symbol “ARTHD”. The last reported sale price of our Common Stock on January 27, 2023, was \$5.55 per share. The public offering price per Unit 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 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.

The final public offering price per Unit 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 effected a 1-for-200 reverse stock split of our Common Stock on January 17, 2023 and increased our authorized shares to 12,000,000. Unless otherwise indicated, and other than in the consolidated historical financial statements and related notes included in this prospectus, the share and per share information in this prospectus is adjusted to reflect the 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 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.

	<u>Per Unit</u>	<u>Total</u>
Public offering price ⁽¹⁾	\$	\$
Underwriting discounts and commissions ⁽²⁾	\$	\$
Proceeds, before expenses, to us	\$	\$

(1) Does not include additional compensation payable to the underwriters. We have agreed to reimburse the underwriters for certain expenses in connection with this offering. 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 9% of the number of Units 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.

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 364,865 shares of Common Stock at the public offering price and/or Investor Warrants to purchase up to 364,865 shares of Common Stock (equal to 15% of the shares of Common Stock and Investor Warrants underlying the Units 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 shares of Common Stock and Investor Warrants comprising the Units to the purchasers on or about , 2023.

Sole Book-Running Manager

Maxim Group LLC

The date of this prospectus is , 2023

TABLE OF CONTENTS

ABOUT THIS PROSPECTUS	1
CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS	2
PROSPECTUS SUMMARY	3
THE OFFERING	10
RISK FACTORS	13
USE OF PROCEEDS	39
MARKET PRICE OF AND DIVIDENDS ON COMMON STOCK AND RELATED MATTERS	40
CAPITALIZATION	41
DILUTION	43
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	45
OUR BUSINESS	58
DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE	76
EXECUTIVE COMPENSATION	80
CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE	85
SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT	86
SHARES ELIGIBLE FOR FUTURE SALE	88
DESCRIPTION OF SECURITIES	89
UNDERWRITING	97
LEGAL MATTERS	104
EXPERTS	104
WHERE YOU CAN FIND MORE INFORMATION	104
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS	F-1
REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM	F-2

ABOUT THIS PROSPECTUS

This prospectus relates to the primary offering and sale by Arch Therapeutics, Inc. of 2,432,432 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 218,919 shares (or 251,757 shares if the underwriters exercise their over-allotment option in full) of Common Stock issuable upon exercise of the Underwriter Warrants.

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 [104](#) 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 and the repayment of the 2022 Notes (as defined below) if this offering is successful;
- 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 13 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 stopping bleeding (hemostasis), controlling leaking (sealant) and managing wounds created during surgery, trauma or interventional care or from disease. We have only recently commenced commercial sales of our first product, AC5® Advanced Wound System, and have recently devoted substantially all of our operational effort to continue the ongoing commercialization and market adoption of 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. 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-VTM 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 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 connective tissue and self-assemble 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 other properties, regardless of the presence of antithrombotic agents, 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 additional applications in which there is a wound inside or on the body, and in which there is need for a hemostatic agent or sealant. 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.

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. If approved, we would expect a final decision from CMS in July 2023 with a go-live date of April 1, 2023. In the meantime, we have launched a temporary reimbursement support program in line with CMS guidance to support commercial use and adoption of AC5 Advanced Wound System while awaiting the decision by CMS on the unique product code. 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; 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:

- 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 December 28, 2022 is sufficient to meet our anticipated cash requirements into at least the second quarter of fiscal 2023. 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.

As a result of the private placement that we completed on July 6, 2022 (the “**First Closing**”) and January 18, 2023 (the “**Second Closing**”) and, together with the First Closing, the “**2022 Private Placement Financing**”), we have (i) Senior Secured Convertible Promissory Notes in the aggregate principal amount of \$4.23 million outstanding (the “**First Notes**”), (ii) Unsecured Promissory Notes in the aggregate principal amount of \$636,000 outstanding (the “**Second Notes**”) and, collectively with the First Notes and the Exchanged Notes, the “**2022 Notes**”), and (iii) Series 3B Convertible Promissory Notes in the aggregate principal amount of \$699,780.93 outstanding (the “**Exchanged Notes**”). The holders of the First Notes have been granted a security interest in substantially all of our assets pursuant to the terms of the Security Agreement (as defined below). 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.

Further, in connection with the 2022 Private Placement Financing, we are required to complete an uplisting of our Common Stock to the Nasdaq Capital Market or an Alternate Exchange by February 15, 2023 (an “**Uplist Transaction**”) under the terms of the 2022 Notes. This offering is intended to qualify as an Uplist Transaction. 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. Upon completion of our Uplist Transaction, the 2022 Note holders have the right to require us to immediately apply the proceeds to repay the outstanding balance of the 2022 Notes within two (2) days of receipt of such demand for repayment. See the section entitled “**Recent Developments – 2022 Private Placement Financing**” for more information.

Proposed Listing on the Nasdaq Capital Market or an Alternate Exchange

Our Common Stock is presently quoted on the OTCQB under the trading symbol “**ARTHD**.” 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 February 15, 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 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

We were incorporated under the laws of the State of Nevada on September 16, 2009, under the name Almah, Inc. to pursue the business of distributing automobile spare parts online. On May 10, 2013, we entered into an Agreement and Plan of Merger (the “**Merger Agreement**”) with Arch Biosurgery, Inc. (formerly known as Arch Therapeutics, Inc.), a Massachusetts corporation (“**ABS**”), and Arch Acquisition Corporation, our wholly owned subsidiary formed for the purpose of the transaction, pursuant to which Arch Acquisition Corporation merged with and into ABS and ABS thereby became our wholly owned subsidiary (the “**Merger**”). The Merger closed on June 26, 2013. In contemplation of the Merger, we changed our name from Almah, Inc. to Arch Therapeutics, Inc.

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, or that can be accessed through, on 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.

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., and on June 26, 2013, ABS changed its name from Arch Therapeutics, Inc. to Arch Biosurgery, Inc.

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. Upon the closing of the Merger, we abandoned our prior business plan and began pursuing, as our sole business, our current business as a biotechnology company.

Recent Developments

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 Centers 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.

Reverse Stock Split

On September 29, 2022, we held our annual meeting of stockholders (the "Annual Meeting"). At the Annual Meeting, the stockholders approved a proposal authorizing our Board of Directors (the "Board"), in its sole and absolute discretion, without further action by the stockholders, to amend the Company's amended and restated articles of incorporation (the "Charter") to (i) effect a reverse stock split of its issued and outstanding and authorized shares of Common Stock at a specific ratio, ranging from 1-for-100 to 1-for-200, at any time prior to September 29, 2023 (the "Reverse Stock Split"), with the exact ratio to be determined by our Board, and (ii) increase the number of authorized shares of Common Stock following consummation of the Reverse Stock Split by 300%. On January 6, 2023, the Board approved a reverse split ratio of 1-for-200 to be effective prior to the pricing of this offering. The Reverse Stock Split and authorized share increase were effected on January 17, 2023.

Convertible Promissory Notes and Warrants Private Placement Financing

First Closing

On July 6, 2022 (the "First Closing Date"), we entered into a Securities Purchase Agreement (the "SPA") with certain institutional and accredited individual investors providing for the issuance and sale of an aggregate of (i) 63,833 shares of Common Stock (the "First Inducement Shares"); (ii) First Notes in the aggregate principle amount of \$4.23 million that are convertible into 462,801 shares of Common Stock (the "First Conversion Shares"); (iii) warrants (the "First Warrants") to purchase up to 425,554 shares of Common Stock (the "First Warrant Shares") at an exercise price of \$9.94 per share; and (iv) Placement Agent Warrants (the "First Placement Agent Warrants") to purchase up to 31,510 shares of Common Stock at an exercise price of \$10.06 per share.

The First Notes become due and payable on January 6, 2024 (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 initial conversion price of \$9.14 (the "Conversion Price") through the later of (i) the Maturity Date and (ii) the date of payment of the Default Amount (as defined below); 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 (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 our Common Stock and/or a market and such loss is not cured during the specified cure periods; (iv) our failure to complete 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.

Upon an event of default, the First Notes shall become immediately due and payable and the Company shall pay to each First Note holder an amount equal to 125% (the “**Default Premium**”) multiplied by the sum of the outstanding principal amount of the First Notes plus any accrued and unpaid interest on the unpaid principal amount of the First Notes to the date of payment, plus any Default Interest and any other amounts owed to the Holder under the SPA (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 First Note holder, the Default Amount may be paid in cash or shares of Common Stock equal to the Default Amount divided by the Conversion Price at the time of payment.

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 Warrants if, as a result of the exercise of the First 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 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 an engagement agreement (the “**2022 Engagement Letter**”) that we entered into with Maxim Group LLC (“**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 to 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 months from the date of issuance. We also reimbursed Maxim approximately \$58,000 for non-accountable expenses, legal fees and other expenses.

In connection with the First Closing, we entered into a security agreement with certain investors on 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 to the investors. Upon an event of default under the First Notes, each investor may exercise its rights to the collateral pursuant to the terms of the Security Agreement.

In addition, on July 6, 2022, we issued to certain investors Exchanged Notes in the aggregate principal amount of \$699,780.93 issued in exchange (the “**Notes Exchange**”) for a portion of the Company’s unsecured 10% Series 1 Convertible Notes (the “**Series 1 Convertible Notes**”) and unsecured 10% Series 2 Convertible Notes (the “**Series 2 Convertible Notes**”) and, together with the Series 1 Convertible Notes, the “**Series Convertible Notes**”). The Exchanged Notes are convertible into 76,563 shares of Common Stock (the “**Exchanged Conversion Shares**”) at a conversion price of \$9.14. 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 prior 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 in respect of the First Notes. As of January 18, 2023, up to 76,563 Exchanged Conversion Shares may be acquired upon the conversion of the Exchanged Notes.

Second Closing

On January 18, 2023 (the “**Second Closing Date**”), we entered into an amendment to the SPA with certain institutional and accredited individual investors providing for the issuance and sale of an aggregate of (i) 9,598 shares of Common Stock (the “**Second Inducement Shares**” and, together with the First Inducement Shares, the “**Inducement Shares**”); (ii) Second Notes in the aggregate principle amount of \$636,000 that are convertible into 69,585 shares of Common Stock (the “**Second Conversion Shares**”); and (iii) warrants (the “**Second Warrants**” and, together with the First Warrants, the “**2022 Warrants**”) to purchase up to 127,968 shares of Common Stock (the “**Second Warrant Shares**” and, together with the First Warrant Shares, the “**2022 Warrant Shares**”) at an exercise price of \$9.94 per share. The terms of the Second Notes are substantially similar to those of the First Notes, 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 warrants to purchase up to 6,565 shares of Common Stock to Maxim pursuant to the 2022 Engagement Letter (the “**Second Placement Agent Warrants**”). The Second Placement Agent Warrants have substantially the same terms as the Second Warrants, except that the exercise price of the Second 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 Second 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 the Second Closing Date, we entered into an amended and restated registration rights agreement with certain investors (as amended and restated, the “**A&R Registration Rights Agreement**”), pursuant to which we are obligated, subject to certain conditions, to file with the SEC one or more registration statements (any such registration statement, a “**Resale Registration Statement**”) to register the Second Inducement Shares, the Second Conversion Shares and the Second Warrant Shares for resale under the Securities Act within the earlier of (i) the date that is 45 days following the Uplist Transaction, and (ii) the date that is 90 days following the Second Closing Date. Our failure to satisfy certain filing and effectiveness deadlines with respect to a Resale Registration Statement and certain other requirements set forth in the A&R Registration Rights Agreement may subject us to payment of monetary penalties.

The Offering

Units being offered	2,432,432 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.
Common Stock outstanding prior to the offering(1)	1,259,280
Common Stock to be outstanding after the offering(1)	3,691,712 shares (4,056,577 shares if the underwriters exercise their option to purchase additional shares in full, and assuming, in each case, no exercise of the Investor Warrants).
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 364,865 shares of Common Stock and/or Investor Warrants to purchase up to an additional 364,865 shares of Common Stock (equal to 15% of the shares of Common Stock and Investor Warrants underlying the Units 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>The Investor Warrants will have an exercise price per share of Common Stock equal to not less than 100% of the offering price of the Unit in this offering, 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 2,432,432 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 9% of the number of Units sold in this offering, including any shares sold in the over-allotment option, if any, at an exercise price equal to 110% of the public offering price of the Units (the “ Underwriter Warrants ”). The Underwriter Warrants shall be exercisable commencing six months after the closing of this offering and will expire five years after the commencement date of sales in this offering. This prospectus also registers up to 218,919 shares (or 251,757 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 \$ 11.5 million or approximately \$ 13.4 million if the underwriters exercise their over-allotment option in full, based upon an assumed public offering price of \$5.55 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, for general working capital purposes, and to repay the outstanding balances under the 2022 Notes upon completion of our Uplist Transaction. See “Use of Proceeds” beginning on page 39 of this prospectus for more information.</p>
Market for Common Stock	Our Common Stock is traded on the OTCQB under the symbol “ ARTH.D. ” On January 27, 2023, the closing price of our Common Stock was \$5.55 per share. The public offering price per Unit 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 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 “ ARTH.W. ” 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 13 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, and the holder of 5% or more of the outstanding shares of our Common Stock 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) Gives effect to the one-for-two hundred Reverse Stock Split of the outstanding Common Stock of the Company, resulting in 1,259,280 shares (post-split) outstanding immediately before this offering. 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 104,325 shares of Common Stock at exercise prices ranging from \$4.00 to \$130.00 per share and with a weighted average exercise price of \$ 39.06 per share; (ii) 730 shares of Common Stock issuable upon the exercise of outstanding warrants issued to the Massachusetts Life Sciences Center (“**MLSC**”), with an exercise price of \$54.80 per share (the “**MLSC Warrant**”); (iii) 34,013 shares of Common Stock issuable upon the exercise of our Series G Warrants (“**Series G Warrants**”) issued in our registered direct financing that closed on July 2, 2018 (the “**2018 Registered Direct Financing**”) at an exercise price of \$140.00 per share; (iv) 43,077 shares of Common Stock issuable upon the exercise of our Series H Warrants (“**Series H Warrants**”) issued in our registered direct financing that closed on May 14, 2019 (the “**May 2019 Registered Direct Financing**”) at an exercise price of \$80.00 per share; (v) 71,429 shares of Common Stock issuable upon the exercise of our Series I Warrants (“**Series I Warrants**”) that were issued in our registered direct financing that closed on October 18, 2019 (the “**October 2019 Registered Direct Financing**”) at an exercise price of \$44.00 per share; (vi) 5,358 shares of Common Stock issuable upon the exercise of the warrants granted to the placement agent that we engaged in the October 2019 Registered Direct Financing (the “**2019 Placement Agent Warrants**”) at an exercise price of \$43.75 per share; (vii) 161,719 shares of Common stock issuable upon the exercise of the Series K Warrants (“**Series K Warrants**”) issued in the private placement that closed on February 17, 2021 (the “**2021 Private Placement Financing**”) with an exercise price of \$34.00 per share; (viii) 16,172 shares of Common Stock issuable upon the exercise of the placement agent warrants issued in the 2021 Private Placement Financing with an exercise price of \$40.00 per share (the “**2021 Placement Agent Warrants**”); (ix) 21,302 shares of Common Stock issuable upon the conversion of our Series 1 Convertible Notes at a conversion price of \$54.00 per share; (x) 18,815 shares of Common Stock issuable upon conversion of our Series 2 Convertible Notes at a conversion price of \$50.00 per share; (xi) 462,801 First Conversion Shares issuable upon conversion of the First Notes; (xii) 425,554 First Warrant Shares issuable to selling stockholders upon exercise, at an exercise price of \$9.94 per share, of our First Warrants; (xiii) 31,510 shares of Common Stock issuable upon exercise of the First Placement Agent Warrants at an exercise price of \$10.06 per share; (xiv) 76,563 Exchanged Conversion Shares issued to certain holders in the Notes Exchange issuable upon the conversion of the Exchanged Notes with a conversion price of \$9.14 per share; (xv) 69,585 shares of Common Stock issuable upon conversion of the Second Notes; (xvi) 127,968 Second Conversion Shares issuable upon the exercise of the Second Warrants; (xvii) 6,565 shares of Common Stock issuable upon exercise of the Second Placement Agent Warrants at an exercise price of \$10.06 per share; (xviii) up to 2,432,432 shares of Common Stock issuable upon exercise of the Investor Warrants to be issued in this offering; and (xix) up to 218,919 shares 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 exercise of the underwriters’ option to purchase up to 364,865 additional shares of Common Stock and/or Investor Warrants to purchase up to 364,865 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 will only meet our anticipated cash requirements into the second quarter of fiscal 2023.
- 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.
- If we do not receive a dedicated HCPCS code for AC5 Advanced Wound System or if private or government insurers elect to not reimburse providers at all or at lower than anticipated rates, our ability to commercialize the product will be significantly impaired; receipt of the dedicated HCPCS code is not a guarantee of product coverage and reimbursement.
- 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 December 28, 2022 is sufficient to meet our anticipated cash requirements into at least the second quarter of fiscal 2023. Even if this offering is successful, we will need to secure additional resources to support our continued operations.

During the first and second quarters of fiscal 2021, the fourth quarter of fiscal 2022 and the second quarter of fiscal 2023, we obtained additional cash 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 Securities Purchase Agreement that we entered into on June 28, 2018 (the “**2018 SPA**”) in connection with the 2018 Registered Direct Financing and the SPA that we entered into in connection with the 2022 Private Placement Financing, in each case as described in greater detail in the risk factor entitled “*The terms of the 2018 Financing and 2022 Private Placement 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 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 2018 Financing and 2022 Private Placement Financing could impose additional challenges on our ability to raise funding in the future.

The 2018 SPA contains provisions that provide that until such time as the three lead investors in the 2018 Financing collectively own less than 20% of the Series G Warrants purchased by them pursuant to the 2018 SPA, the Company is prohibited from effecting or entering 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 below) including, but not limited to, an equity line of credit or “At-the-Market” financing facility .

As of January 18, 2023, none of the lead investors for the 2018 Financing have exercised or transferred any of their Series G Warrants. As defined in the 2018 SPA, “**Variable Rate Transaction**” means a transaction in which the Company (a) issues or sells any debt or equity securities that are convertible into, exchangeable or exercisable for, or include the right to receive additional shares of Common Stock either (A) at a conversion price, exercise price or exchange rate or other price that is based upon and/or varies with the trading prices of or quotations for the shares of Common Stock at any time after the initial issuance of such debt or equity securities, or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such debt or equity security or upon the occurrence of specified or contingent events directly or indirectly related to the business of the Company or the market for the Common Stock (excluding adjustments under customary anti-dilution provisions) or (b) enters into, or effects a transaction under, any agreement, including, but not limited to, an equity line of credit, whereby the Company may issue securities at a future determined price. These provisions could make our securities less attractive to investors and could limit our ability to obtain adequate financing on a timely basis or on acceptable terms in the future, which could have significant harmful effects on our financial condition and business and could include substantial limitations on our ability to continue to conduct operations.

The SPA, as amended, entered into in connection with the 2022 Private Placement Financing 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 any variable rate debt transactions that do not contain a floor price that is more than \$4.97 or \$ 3.20 , or 50% of the closing price of the Common Stock on the trading day immediately prior to the First Closing Date and Second Closing Date, respectively; in each instance without each applicable 2022 Note holder's prior written consent, which shall not be unreasonably withheld.

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 on or after six (6) months after the First Closing Date or the Second Closing date, as applicable; (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; (iv) our failure to complete an uplisting of our Common Stock ("**Uplist Transaction**") by February 15, 2023; and (v) upon completion of an Uplist Transaction, our failure to repay the outstanding balance of the 2022 Notes within two days of receipt of a 2022 Note holder's demand for repayment.

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.

If we fail to maintain 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 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. If we are unable to maintain 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 to 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 device 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 Massachusetts Institute of Technology and Versitech Limited ("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 (the "EPO") Board of Appeal (the "Appeal Board") 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 Appeal Board, 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 Appeal Board 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 Appeal Board'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 January 18, 2023, we either own or license from others several 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 a total of 22 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 patent term extension), as well as fifteen patents that have been either allowed, issued or granted in foreign jurisdictions.

The three 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 not before 2024 (absent patent term extension), as well as four patents that have been 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

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 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.

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 February 15, 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 recent Reverse Stock 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 September 29, 2022, the shareholders approved a reverse stock split between 1-for-100 and 1-for-200. Our Board of Directors set the reverse split ratio at 1-for-200 to be effective prior to pricing of this offering. The Reverse Stock Split was effected on January 17, 2023. Even if our recent Reverse Stock Split increased 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 Stock 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 Stock Split given the reduced number of shares outstanding following the Reverse Stock Split. In addition, the Reverse Stock Split may have increased 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.***" As of December 28, 2022, we believe that our current cash on hand will meet our anticipated cash requirements into the second quarter of fiscal 2023. 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, and the holder of 5% or more of the outstanding shares of our Common Stock 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 January 18, 2023, our articles of incorporation authorize the issuance of up to 12,000,000 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 January 18, 2023, there were issued and outstanding:

- Warrants exercisable for 924,095 shares of Common Stock with a weighted average exercise price of \$25.60 per share, consisting of:
 - Series G Warrants to purchase up to an aggregate of 34,013 shares of Common Stock at an exercise price of \$140.00 per share;
 - Series H Warrants to purchase up to an aggregate of 43,077 shares of Common Stock at an exercise price of \$80.00 per share;
 - Series I Warrants to purchase up to an aggregate of 71,429 shares of Common Stock at an exercise price of \$44.00 per share;
 - 2019 Placement Agent Warrants to purchase up to an aggregate of 5,358 shares of Common Stock at an exercise price of \$43.75 per share;
 - Series K Warrants to purchase up to an aggregate of 161,719 shares of Common Stock at an exercise price of \$34.00 per share;
 - 2021 Placement Agent Warrants to purchase up to an aggregate of 16,172 shares of Common Stock at an exercise price of \$40.00 per share;
 - MLSC Warrant to purchase up to an aggregate of 730 shares of our Common Stock at an exercise price of \$54.80 per share;
 - First Warrants to purchase up to an aggregate of 425,554 shares of our Common Stock at an exercise price of \$9.94 per share;
 - First Placement Agent Warrants to purchase up to an aggregate of 31,510 shares of our Common Stock at an exercise price of \$10.06 per share;
 - Second Warrants to purchase up to an aggregate of 127,968 shares of our Common Stock at an exercise price of \$9.94 per share;
 - Second Placement Agent Warrants to purchase up to an aggregate of 6,565 shares of our Common Stock at an exercise price of \$10.06 per share;
- Convertible notes convertible into 649,066 shares of Common Stock with a weighted average conversion price of \$11.80, consisting of:
 - Series 1 Convertible Notes convertible into 21,302 shares of Common Stock at a conversion price of \$54.00 per share;
 - Series 2 Convertible Notes convertible into 18,815 shares of Common Stock at a conversion price of \$50.00 per share;
 - First Notes convertible into up to 462,801 shares of our Common Stock at a conversion price of \$9.14 per share;
 - Exchanged Notes convertible into up to 76,563 shares of our Common Stock at a conversion price of \$9.14 per share; and
 - Second Notes convertible into up to 69,585 shares of our Common Stock at a conversion price of \$9.14 per share;
- Options granted to employees, directors and consultants under the 2013 Plan to purchase up to an aggregate of 104,325 shares of Common Stock at exercise prices ranging from \$4.00 to \$130.00 per share and with a weighted average exercise price of \$39.06 per share.

Additionally, the numbers issuable under the 2013 Plan will increase by up to 3 million shares on the first business day of each following fiscal year as set forth in the 2013 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. By way of example, on September 27, 2021, we issued 1,500 shares of restricted stock in connection with our entrance into a consulting agreement with Michael J. Parker, in consideration of the services to be provided under and in accordance with the terms of the consulting agreement. 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 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.

Certain of our directors and officers own a significant percentage of our capital stock and are able to exercise significant influence over the Company.

Certain of our directors and executive officers own a significant percentage of our outstanding capital stock. As of January 18, 2023, Dr. Terrence W. Norchi, our Chairman of the Board, President and Chief Executive Officer beneficially own (as determined under Section 13(d) of the Exchange Act and the rules and regulations thereunder) approximately 8% of our shares of Common Stock. Accordingly, this member of our Board and management team has substantial voting power to approve matters requiring stockholder approval, including without limitation the election of directors, and has significant influence over our affairs. This concentration of ownership could have the effect of delaying or preventing a change in control of our Company, even if such a change in control would be beneficial to our stockholders.

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 you purchase.

The public offering price of the Units being offered in this offering is substantially higher than the net tangible book deficit per share of our Common Stock prior to the offering. Investors purchasing Units in this offering may pay a 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 \$5.55 per Unit (the last reported sale price of our Common Stock on the OTCQB on January 27, 2023), if you purchase shares of our Common Stock in this offering, you will suffer immediate and substantial dilution of \$ 3.50 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.

USE OF PROCEEDS

We expect to receive net proceeds of approximately \$ 11.5 million from this offering (or approximately \$ 13.4 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 \$5.55 per Unit (the last reported sale price of our Common Stock on the OTCQB on January 27, 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, for general working capital purposes and to repay the outstanding balances under the 2022 Notes upon completion of our Uplist Transaction.

Upon completion of Uplist Transaction, the 2022 Note holders have the right to require us to immediately apply the proceeds to repay the outstanding balance of the 2022 Notes within two (2) days of receipt of such demand for repayment. The 2022 Notes are also convertible into an aggregate of 608,948 shares of Common Stock at the option of each holder of the 2022 Notes 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. Further, the 2022 Notes 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 2022 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.

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 \$0.50 increase (decrease) in the assumed public offering price of \$5.55 per Unit (the last reported sale price of our Common Stock on the OTCQB on January 27, 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 \$ 1.1 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 \$5.0 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 “**ARTHD**”. 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 “**ARTHW**”, 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.

Holdings

As of January 18, 2023, there were approximately 100 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 September 30, 2022:

- on an actual basis;
- on a pro forma basis to give effect to the Second Closing; and
- on a pro forma, as adjusted basis, to give effect to the issuance and sale by us of Units in this offering based on an assumed public offering price of \$5.55 per Unit, 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 financial statements and related notes thereto included elsewhere in this prospectus.

	As of September 30, 2022		Pro Forma As Adjusted (unaudited) (1)
	Actual (unaudited)	Pro Forma (unaudited)	
Cash	\$ 746,940	\$ 1,211,940	\$ 12,751,940
Stockholders’ 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	1,259
Additional paid-in capital	\$ 50,878,721	\$ 51,114,141	\$ 62,651,709
Accumulated deficit	\$ (55,072,773)	\$ (55,072,773)	\$ (55,072,773)
Total stockholders’ (deficit) equity	\$ (4,192,803)	\$ (3,957,373)	\$ 7,582,627
Total capitalization	\$ 2,603,739	\$ 3,068,739	\$ 14,608,739

(1) A \$0.50 increase or decrease in the assumed public offering price of \$5.55 per Unit (the last reported sale price of our Common Stock on the OTCQB on January 27, 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 \$ 1.1 million, assuming that the number of Units offered by us, as set forth on the cover page of this prospectus, remains the same 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, 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 \$5.0 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.

The total number of shares reflected in the discussion and tables above is based on 1,249,682 shares of our Common Stock outstanding as of September 30, 2022, and excludes, in each case:

- 806,437 shares of Common Stock issuable upon the exercise of outstanding warrants, having a weighted average exercise price of \$29.33 per share, consisting of:
 - Series G Warrants to purchase up to an aggregate of 34,013 shares of Common Stock at an exercise price of \$140.00 per share;
 - Series H Warrants to purchase up to an aggregate of 43,077 shares of Common Stock at an exercise price of \$80.00 per share;
 - Series I Warrants to purchase up to an aggregate of 71,429 shares of Common Stock at an exercise price of \$44.00 per share;
 - 2019 Placement Agent Warrants to purchase up to an aggregate of 5,358 shares of Common Stock at an exercise price of \$43.75 per share;
 - Series J Warrants to purchase up to an aggregate of 16,875 shares of Common Stock at an exercise price of \$50.00 per share (the **Series J Warrants**);
 - Series K Warrants to purchase up to an aggregate of 161,719 shares of Common Stock at an exercise price of \$34.00 per share;
 - 2021 Placement Agent Warrants to purchase up to an aggregate of 16,172 shares of Common Stock at an exercise price of \$40.00 per share;
 - MLSC Warrant to purchase up to an aggregate of 730 shares of our Common Stock at an exercise price of \$54.80 per share;
 - First Warrants to purchase up to an aggregate of 425,554 shares of our Common Stock at an exercise price of \$9.94 per share;
 - First Placement Agent Warrants to purchase up to an aggregate of 31,510 shares of our Common Stock at an exercise price of \$10.06 per share;
- 579,481 shares of Common Stock issuable upon the conversion of outstanding convertible notes, having a weighted average conversion price of \$12.12, consisting of
 - Series 1 Convertible Notes convertible into 21,302 shares of Common Stock at a conversion price of \$54.00 per share;
 - Series 2 Convertible Notes convertible into 18,815 shares of Common Stock at a conversion price of \$50.00 per share;
 - First Notes convertible into up to 462,801 shares of our Common Stock at a conversion price of \$9.14 per share;
 - Exchanged Notes convertible into up to 76,563 shares of our Common Stock at a conversion price of \$9.14 per share; and
- Options granted to employees, directors and consultants under the 2013 Plan to purchase up to an aggregate of 98,626 shares of Common Stock at exercise prices ranging from \$4.00 to \$130.00 per share and with a weighted average exercise price of \$52.00 per share;
- Up to 2,432,432 shares of Common Stock issuable upon the exercise of Investor Warrants to be issued in this offering; and
- Up to 218,919 shares of Common Stock issuable upon exercise of the Underwriter Warrants to be issued to the Representative, or its designees, upon the completion of this offering in an amount equal to 9% of the number of Units sold in this offering, as described in “**Underwriting**.”

Except as indicated otherwise, the discussion and table above assume no exercise of the underwriters’ option to purchase up to 364,865 additional shares of Common Stock and/or Investor Warrants to purchase up to 364,865 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 (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 deficit of our Common Stock as of September 30, 2022, was approximately \$4.2 million, or approximately \$3.36 per share of Common Stock. Net tangible book deficit 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 September 30, 2022.

Our pro forma net tangible book deficit as of September 30, 2022 was \$3,957,373, or \$3.14 per share of Common Stock. Pro forma net tangible book deficit represents the amount of our total tangible assets less our total liabilities, after giving effect to our receipt of an estimated \$465,000 in net proceeds from the issuance and sale of (i) the Second Notes in the aggregate principal amount of \$636,000 that are convertible into 69,585 shares of Common Stock; (ii) the Second Warrants that are exercisable into 127,968 shares of Common Stock. Pro forma net tangible book deficit per share represents the pro forma net tangible book deficit divided by the total number of shares outstanding as of September 30, 2022, after giving effect to the pro forma adjustment described above.

After giving further effect to the sale of shares of Common Stock included in the Units in this offering at a n assumed public offering price of \$5.55 per share of Common Stock included in each 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, our pro forma, as adjusted net tangible book value as of September 30, 2022 would have been approximately \$ 7.6 million, or approximately \$ 2.05 per share of Common Stock. This amount represents an immediate increase in actual book value of \$ 5.20 per share to our existing stockholders and immediate dilution of approximately \$ 3.50 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		\$	5.55
Net (deficit) tangible book deficit per share as of September 30, 2022	\$	3.36	
Pro forma net tangible book deficit per share after giving effect to the Second Closing		3.14	
Increase in pro forma net tangible book value per share after giving effect to this offering (excluding the Second Closing)		5.20	
Pro forma, as adjusted net tangible book value per share as of September 30, 2022 after giving effect to this offering and the Second Closing		2.05	
Dilution per share to new investors in this offering		3.50	

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 \$ 2.32 per share, the increase in pro forma net tangible book value per share would be approximately \$ 5.47 and dilution per share to new investors would be approximately \$ 3.23 per share.

Each \$0.50 increase (decrease) in the assumed public offering price of \$5.55 per Unit (the last reported sale price of our Common Stock on the OTCQB on January 27, 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 \$ 1.1 million, assuming that the number of Units offered by us, as set forth on the cover page of this prospectus, remains the same 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 \$5.0 million, assuming the public offering price stays the same and assuming no exercise of the Invest 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 1,249,682 shares of our Common Stock outstanding as of September 30, 2022, and excludes, in each case:

- 806,437 shares of Common Stock issuable upon the exercise of outstanding warrants, having a weighted average exercise price of \$29.33 per share, consisting of:
 - Series G Warrants to purchase up to an aggregate of 34,013 shares of Common Stock at an exercise price of \$140.00 per share;
 - Series H Warrants to purchase up to an aggregate of 43,077 shares of Common Stock at an exercise price of \$80.00 per share;
 - Series I Warrants to purchase up to an aggregate of 71,429 shares of Common Stock at an exercise price of \$44.00 per share;
 - 2019 Placement Agent Warrants to purchase up to an aggregate of 5,358 shares of Common Stock at an exercise price of \$43.75 per share;
 - Series J Warrants to purchase up to an aggregate of 16,875 shares of Common Stock at an exercise price of \$50.00 per share;
 - Series K Warrants to purchase up to an aggregate of 161,719 shares of Common Stock at an exercise price of \$34.00 per share;
 - 2021 Placement Agent Warrants to purchase up to an aggregate of 16,172 shares of Common Stock at an exercise price of \$40.00 per share;
 - MLSC Warrant to purchase up to an aggregate of 730 shares of our Common Stock at an exercise price of \$54.80 per share;
 - First Warrants to purchase up to an aggregate of 425,554 shares of our Common Stock at an exercise price of \$9.94 per share;
 - First Placement Agent Warrants to purchase up to an aggregate of 31,510 shares of our Common Stock at an exercise price of \$10.06 per share;
- 579,481 shares of Common Stock issuable upon the conversion of outstanding convertible notes, having a weighted average conversion price of \$12.12, consisting of:
 - Series 1 Convertible Notes convertible into 21,302 shares of Common Stock at a conversion price of \$54.00 per share;
 - Series 2 Convertible Notes convertible into 18,815 shares of Common Stock at a conversion price of \$50.00 per share;
 - First Notes convertible into up to 462,801 shares of our Common Stock at a conversion price of \$9.14 per share;
 - Exchanged Notes convertible into up to 76,563 shares of our Common Stock at a conversion price of \$9.14 per share.
- Options granted to employees, directors and consultants under the 2013 Plan to purchase up to an aggregate of 98,626 shares of Common Stock at exercise prices ranging from \$4.00 to \$130.00 per share and with a weighted average exercise price of \$52.00 per share;
- Up to 2,432,432 shares of Common Stock issuable upon the exercise of Investor Warrants to be issued in this offering; and
- Up to 218,919 shares of Common Stock issuable upon exercise of the Underwriter Warrants to be issued to the Representative, or its designees, upon the completion of this offering in an amount equal to 9% of the number of Units sold in this offering, as described in “Underwriting.”

Except as indicated otherwise, the discussion and table above assume no exercise of the underwriter’s option to purchase up to 364,865 additional shares of Common Stock and/or Investor Warrants to purchase up to 364,865 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") 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, or the Merger, with Arch Biosurgery, Inc. (formerly known as Arch Therapeutics, Inc.), a Massachusetts corporation, or ABS, and Arch Acquisition Corporation, or 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.

The Company only recently commenced commercial sales of our first product, AC5® Advanced Wound System, and has recently devoted substantially all of our operational effort to continue the ongoing commercialization and market adoption of the Company's 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 its potential 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 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. 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 at September 30, 2022 decreased by \$1,519,699 to \$746,940 compared to \$2,266,639 as of September 30, 2021.

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 stopping bleeding (hemostasis), controlling leaking (sealant) and managing wounds created during surgery, trauma or interventional care, or from disease. We have only recently commenced commercial sales of our first product, AC5® Advanced Wound System, and have recently devoted substantially all of our operational effort to continue the ongoing commercialization and market adoption of 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 management of complicated chronic wounds or acute surgical wounds. 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 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 connective tissue and self-assemble 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 other properties, regardless of the presence of antithrombotic agents, 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 in which there is a wound inside or on the body, and in which there is need for a hemostatic agent or sealant. 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 (TM). 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.

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. If approved, we would expect a final decision from CMS in February 2023 with a go-live date of April 1, 2023. In the meantime, we have launched a temporary reimbursement support program in line with CMS guidance to support commercial use and adoption of AC5 Advanced Wound System while awaiting the decision by CMS on the unique product code. 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; 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:

- 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 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.

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 December 28, 2022, we believe that our current cash on hand will meet our anticipated cash requirements into the second quarter of fiscal 2023. 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.

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 has 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 may present an opportunity for our new technology to address certain poorly met needs.

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.

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 has 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. We have observed the following effects, 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 may present an opportunity for our new technology to address certain poorly met needs.

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”. In connection with the Reverse Stock Split, the Company changed its ticker symbol to “ARTHD”.

Recent Developments

On July 6, 2022, or the First Closing Date, we entered into the 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, which included an aggregate \$0.705 million original issue discount in respect of the First Notes, convertible into 462,801 First Conversion Shares; (iii) First Warrants to purchase an aggregate of 425,554 First Warrant Shares; and (iv) First Placement Agent Warrants to purchase 31,510 shares of Common Stock. On January 18, 2023, or the Second Closing Date, we entered into an amendment to the SPA with certain investors providing for the issuance and sale of (i) 9,598 Second Inducement Shares; (ii) Second Notes in the aggregate principal amount of \$636,000, which included an aggregate \$106,000 original issue discount in respect of the Second Notes, convertible into 69,585 Second Conversion Shares; (iii) Second Warrants to purchase up to 127,968 shares of Common Stock; and (iv) Second Placement Agent Warrants to purchase 6,565 shares of Common Stock. In connection with the 2022 Private Placement Financing, we issued to certain investors Exchanged Notes convertible into 76,563 Exchanged Conversion Shares. We refer to the First Notes, Second Notes and Exchange Notes as the “2022 Notes”.

The 2022 Notes may be prepaid by the Company, in whole or in part, at any time with 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 2022 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 (as defined below). 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 terms of the Exchanged Notes and the Second Notes are substantially the same terms as the First Notes, except that the Second Notes are unsecured.

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) the Maturity Date and (ii) the date of payment of the Default Amount (as defined in the 2022 Notes); *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 after the First Closing Date or the Second Closing date, as applicable; (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 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 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 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). The Second Warrants have substantially the same terms as the First Warrants.

Pursuant to an engagement agreement that we entered into with Maxim Group LLC (the **2022 Placement Agent**™), we agreed, among other things, to (i) pay the 2022 Placement Agent 10% of the gross proceeds in the 2022 Placement Agent from certain institutional investors in the 2022 Private Placement Financing, or \$290,000, and (ii) issue the 2022 Placement Agent, or its designees, warrants to purchase up to 10% of the aggregate number of shares sold to the institutional investors in the 2022 Private Placement Financing, or First Placement Agent Warrants to purchase up to 31,510 shares of Common Stock and Second Placement Agent Warrants to purchase up to 6,565 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. The Second Placement Agent Warrants have substantially the same terms as the Second Warrants, except that the exercise price of the Second Placement Agent Warrants is \$10.06 per share and are not exercisable until six (6) months from the date of issuance. We also reimbursed the 2022 Placement Agent approximately \$58,000 for non-accountable banking fees, legal fees and other expenses.

On the Second Closing Date, the Company entered into the A&R Registration Rights Agreement, pursuant to which we are obligated, subject to certain conditions, to file with the SEC one or more Resale Registration Statements to register the Second Inducement Shares, the Second Conversion Shares and the Second Warrant Shares for resale under the Securities Act within the earlier of (i) the date that is 45 days following the Uplist Transaction, and (ii) the date that is 90 days following the Second Closing Date. Our failure to satisfy certain filing and effectiveness deadlines with respect to a Resale Registration Statement and certain other requirements set forth in the A&R Registration Rights Agreement may subject us to payment of monetary penalties.

On September 29, 2022, the Company held its Annual Meeting. At the Annual Meeting, the stockholders approved a proposal authorizing our Board, in its sole and absolute discretion, without further action by the stockholders, to amend the Company's Charter to (i) effect the Reverse Stock Split of our issued and outstanding and authorized shares of Common Stock at a specific ratio, ranging from 1-for-100 to 1-for-200, at any time prior to September 29, 2023, with the exact ratio to be determined by our Board, and (ii) increase the number of authorized shares of Common Stock following consummation of the Reverse Stock Split by 300%. On January 6, 2023, the Board approved a reverse split ratio of 1-for-200 to be effective prior to the pricing of this offering. The Reverse Stock Split and authorized share increase were effected on January 17, 2023.

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 Centers 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.

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.

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 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	\$ (722,299)	\$ 1,940,198

[Table of Contents](#)

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 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. As of December 28, 2022, we believe that our current cash on hand will meet our anticipated cash requirements into the second quarter of fiscal 2023. 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 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. 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 2018 SPA (See Note 6) and the 2022 SPA (See Note 10) restricting our ability to effect or enter into an agreement to effect any issuance by the Company or any of its subsidiaries 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) including, but not limited to, an equity line of credit or “At-the-Market” financing facility until the three lead investors in the 2018 Financing collectively own less than 20% of the Series G Warrants purchased by them pursuant to the 2018 SPA. These restrictions and provisions could make it more challenging for us to raise capital through the incurrence of debt or through equity issuances. 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.

Going Concern

We have commenced commercial sales of our first product, AC5® Advanced Wound System. From inception, we have had recurring losses from operations. While the Company anticipates that it will have cash on hand into the second quarter of fiscal 2023, the continuation of our business as a going concern is dependent upon raising additional capital and eventually attaining and maintaining profitable operations. As of September 30, 2022, 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. 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 Accounting Standards Code 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 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.

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**”) 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. Our 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.

The Company only recently commenced commercial sales of our first product, AC5® Advanced Wound System, and has recently devoted substantially all of our operational effort to the to continue the ongoing commercialization and market adoption of the Company’s 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 its potential 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 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 stopping bleeding (hemostasis), controlling leaking (sealant) and managing wounds created during surgery, trauma or interventional care or from disease. We have only recently commenced commercial sales of our first product, AC5® Advanced Wound System, and recently devoted substantially all of our operational effort to continue the ongoing commercialization and market adoption of 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 December 28, 2022, we believe that our cash on hand will meet our anticipated cash requirements into at least the second quarter of fiscal 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. 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. 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 AC5 platform contain a 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 connective tissue and self-assemble 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 other properties, regardless of the presence of antithrombotic agents, 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 additional applications in which there is a wound inside or on the body, and in which there is need for a hemostatic agent or sealant. 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.

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; 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:

- 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

Further, in connection with the 2022 Private Placement 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.

We believe that the Company has cash on hand is sufficient to meet its anticipated cash requirements into at least the second quarter of fiscal 2023. Notwithstanding this, depending upon additional input from EU and US regulatory authorities, we may need to raise additional capital before then. 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.

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 have completed two clinical studies to date. The first study, which met its primary and secondary endpoints, assessed the safety and performance of AC5® Advanced Wound System in 46 patients with bleeding skin wounds that resulted from excision of skin lesions and followed for 30 days. The second study assessed AC5® Advanced Wound System on skin, determining that it was neither an irritant nor a sensitizer, and no immunogenic response or serious or other adverse events attributable to this product were reported in any of the approximately 50 enrolled volunteers. AC5® Advanced Wound System subsequently received FDA marketing clearance in March 2020 and CE Mark in Europe in April 2020 for AC5 Topical Hemostat, as it is known in Europe. in the United States and AC5 Topical Hemostat in Europe.

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 Centers for Medicare and Medicaid Services ("**CMS**") for a dedicated Healthcare Common Procedure Coding System ("**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. A final decision, which we anticipate, but cannot guarantee, will be positive, is expected during the first calendar quarter of 2023 with a "go live" date of April 1, 2023. In the meantime, CMS has established a new and temporary coding option to facilitate the reimbursement of doctor's offices and wound clinics, and certain providers have begun to submit claims under this new code as we pursue a dedicated HCPCS code.

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 has 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. We have observed the following effects, 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 may present an opportunity for our new technology to address certain poorly met needs.

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 of 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, micromilieu, 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 through-put, 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.

As of January 18, 2023, we either own or license from others several of U.S. patents, U.S. patent applications, foreign patents and foreign patent applications.

Six patent portfolios assigned to Arch Biosurgery, Inc. include a total of 43 patents and pending applications in a total of nine jurisdictions, including twelve 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 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 patent term extension), as well as sixteen 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 a total of 22 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 patent term extension), as well as fifteen patents that have been either allowed, issued or granted in foreign jurisdictions.

The three 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 not before 2024 (absent patent term extension), as well as four 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

We presently have eight 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 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 April 18, 2023. 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. The SEC is seeking against Dr. Avtar Dhillon permanent injunctions, conduct-based injunctions, disgorgement of allegedly ill-gotten gains plus interest, civil penalties, penny stock bars, and an officer and director bar. 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 Cellanx 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 Securities Exchange Act of 1934, as amended (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, 2022, and September 30, 2021 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, <i>President and Chief Executive Officer</i>	2022	450,500	-	-	-	-	450,500
	2021	450,500	27,030	-	157,400	-	634,930
	2022	325,000	-	-	-	-	325,000
Michael S. Abrams, <i>Chief Financial Officer</i>	2021	135,417	-	-	66,895	-	202,312
	2022	316,667	-	-	9,075	-	325,742
Daniel Yrigoyen, <i>VP of Sales</i>	2021	64,299	-	13,500	27,545	-	105,344

(1) Represents the aggregate grant date fair values of awards granted during the fiscal year ended September 30, 2021 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, 2021 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, 2022:

Name	Option Awards				Stock Awards		Market Value of Shares or Units of Stock That Have Not Vested (\$)
	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 (#)	
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		
	4,688	771	(7)	45.84	12/19/2029		
	3,325	1,675	(8)	20.56	09/26/2031		
	1,667	3,334	(9)	20.56	09/26/2031		
Michael S. Abrams	1,250	1,250	(10)	26.58	05/02/2031		
	584	1,167	(11)	20.56	09/26/2031		
Daniel M. Yrigoyen	292	459	(12)	18.00	07/29/2031		
	334	667	(14)	20.56		750 (13)	19,500
	84	667	(15)	12.10	05/23/2032		

- (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 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.
- (11) 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.
- (12) 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.
- (13) 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.
- (14) 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.
- (15) 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.

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, 2022:

Director Compensation Table

	Fees Earned or Paid In Cash (\$)	Stock Awards (\$)	Option Awards (\$)	All other Compensation (\$)	Total (\$)
Punit Dhillon (1)	25,000	-	-	-	25,000
Laurence Hicks (2)	-	-	-	-	-
Guy L. Fish (3)	-	-	18,350	-	18,350

(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, 2022 held by Mr. Dhillon was 5,000.

(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, 2022 held by Mr. Hicks was 1,250.

(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, 2022 held by Dr. Fish was 1,250.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Related Party Transactions

During fiscal years 2022 and 2021, 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 January 18, 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.

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 1,259,280 shares of our Common Stock outstanding on January 18, 2023. Shares of our Common Stock subject to options, warrants, or other rights currently exercisable or exercisable within 60 days of January 18, 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)	Percentage of Shares Beneficially Owned after the Offering **
<i>5%+ Stockholders:</i>			
Michael A. Parker (2)	112,097	8.90%	3.0%
<i>Named Executive Officers and Directors:</i>			
Terrence Norchi (3)	102,226	7.90%	2.7%
Punit Dhillon (4)	4,235	*	*
Laurence Hicks (5)	10,254	*	*
Michael Abrams (6)	10,521	*	*
Daniel Yrigoyen (7)	1,876	*	*
Guy Fish (8)	660	*	*
Current Directors and Executive Officers as a Group (6 persons)	129,770	10.31%	3.5%
Maxim Partners LLC (9)	31,510	2.50%	*%

* 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 January 18, 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 (i) 47,443 shares of Common Stock owned individually by Ana Parker, Michael A. Parker's spouse; (ii) 38,155 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) 3,000 shares of Common Stock that may be acquired upon the exercise of Series G Warrants (which expire July 7, 2023); (b) any of the 6,154 shares of Common Stock that may be acquired upon the exercise of Series H Warrants (which expire May 14, 2024); (c) 103,559 First Conversion Shares; (d) 47,840 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 4.9% 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 January 18, 2023, neither Ms. Parker nor Mr. Parker have waived such limitation.
- (3) 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) 7,096 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 Warrant Shares; and (h) 363 First Inducement Shares; and (i) 29,028 shares subject to options exercisable within 60 days after January 18, 2023. Dr. Norchi disclaims beneficial ownership of the securities held by Twelve Pins Partners, LLC except to the extent of his pecuniary interest therein.
- (4) Represents 4,235 shares of Common Stock subject to options exercisable within 60 days after January 18, 2023.
- (5) Represents 2,014 shares of Common Stock subject to options exercisable within 60 days after January 18, 2023. Includes (i) 137 shares of Common Stock, (ii) 3,939 First Conversion Shares, (iii) 3,622 Warrant Shares, and (iv) 544 First Inducement Shares held by Drake Partners Equity LLC, in which Mr. Hicks has an ownership interest.
- (6) Represents (i) 3,939 First Conversion Shares; (ii) 3,622 Warrant Shares; (iii) 544 First Inducement Shares; and (iv) 2,417 shares of Common Stock subject to options exercisable within 60 days after January 18, 2023.
- (7) Represents 750 shares of restricted stock granted to Mr. Yrigoyen on July 30, 2021 and 1,126 shares of Common Stock subject to options exercisable within 60 days after January 18, 2023.
- (8) Represents 660 shares of Common Stock subject to options exercisable within 60 days after January 18, 2023.
- (9) Represents 31,510 shares of Common Stock issuable upon exercise of First Placement Agent Warrants exercisable within 60 days after January 18, 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 3,691,712 shares of Common Stock issued and outstanding, assuming no exercise of outstanding options or warrants (including the Investor Warrants included in the Units sold in this offering) and the underwriters do not exercise their over-allotment option. 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. Certain of the shares of Common Stock after the offering will be held by our existing shareholders. Upon consummation of the offering, approximately [●]% of our issued and outstanding Common Stock will be subject to lock-up agreements as described below.

Lock-Up Agreements

We, our directors and executive officers, and the holder of 5% or more of the outstanding shares of our Common Stock 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 Maxim. Maxim 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.

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 approximately 36,917 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, our authorized capital stock consists of 12,000,000 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, on January 17, 2023, we effected a one-for-two hundred reverse stock split pursuant to which every two hundred shares of our Common Stock were reclassified as one share of Common Stock.

Common Stock Issued and Outstanding; Common Stock Registered Hereby

As of January 18, 2023, there were issued and outstanding 1,259,280 shares of Common Stock. Of our issued and outstanding shares of Common Stock, we are registering under the registration statement of which this prospectus forms a part 2,432,432 shares of Common Stock.

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 "ARTHD". 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 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.

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 (not less than 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 \$ [] (not less than 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 218,919 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.

Warrants, Options and Convertible Notes Issued and Outstanding

As of January 18, 2023, there were issued and outstanding:

- Warrants exercisable for 924,095 shares of Common Stock with a weighted average exercise price of \$25.60 per share, consisting of:
 - Series G Warrants to purchase up to an aggregate of 34,013 shares of Common Stock at an exercise price of \$140.00 per share;
 - Series H Warrants to purchase up to an aggregate of 43,077 shares of Common Stock at an exercise price of \$80.00 per share;
 - Series I Warrants to purchase up to an aggregate of 71,429 shares of Common Stock at an exercise price of \$44.00 per share;
 - 2019 Placement Agent Warrants to purchase up to an aggregate of 5,358 shares of Common Stock at an exercise price of \$43.75 per share;
 - Series K Warrants to purchase up to an aggregate of 161,719 shares of Common Stock at an exercise price of \$34.00 per share;
 - 2021 Placement Agent Warrants to purchase up to an aggregate of 16,172 shares of Common Stock at an exercise price of \$40.00 per share;
 - MLSC Warrant to purchase up to an aggregate of 730.00 shares of our Common Stock at an exercise price of \$54.80 per share;
 - First Warrants to purchase up to an aggregate of 425,554 shares of our Common Stock at an exercise price of \$9.94 per share;
 - First Placement Agent Warrants to purchase up to an aggregate of 31,510 shares of our Common Stock at an exercise price of \$10.06 per share;
 - Second Warrants to purchase up to an aggregate of 127,968 shares of our Common Stock at an exercise price of \$9.94 per share;
 - Second Placement Agent Warrants to purchase up to an aggregate of 6,565 shares of our Common Stock at an exercise price of \$10.06 per share;
- Convertible notes convertible into 649,066 shares of Common Stock with a weighted average conversion price of \$11.80, consisting of:
 - Series 1 Convertible Notes convertible into 21,302 shares of Common Stock at a conversion price of \$54.00 per share;
 - Series 2 Convertible Notes convertible into 18,815 shares of Common Stock at a conversion price of \$50.00 per share;
 - First Notes convertible into up to 462,801 shares of our Common Stock at a conversion price of \$9.14 per share;
 - Exchanged Notes convertible into up to 76,563 shares of our Common Stock at a conversion price of \$9.14 per share; and
 - Second Notes convertible into up to 69,585 shares of our Common Stock at a conversion price of \$9.14 per share;
- Options granted to employees, directors and consultants under the 2013 Plan to purchase up to an aggregate of 104,325 shares of Common Stock at exercise prices ranging from \$4.00 to \$130.00 per share and with a weighted average exercise price of \$39.06 per share.

First Warrants

The First Warrants had an initial exercise price of \$9.94 per share, were exercisable immediately upon their issuance and have a term of exercise equal to 5 years after their issuance date. The number of shares of our 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). In addition, the First Warrants are not exercisable to the extent that the exercise thereof would result in the First Warrant holder, together with any person whose beneficial ownership would be aggregated with the holder, beneficially owning more than the Ownership Limitation; *provided however*, the holder may increase such ownership limitation to 9.99% of the outstanding shares of our Common Stock, in which case the ownership limitation increase will become effective 61 days after the holder requests such increase. In addition, if there is no effective registration statement registering the resale of the Warrant Shares as of certain time periods (as provided in the First Warrants), the First Warrant holders may choose to exercise such First Warrants on a “cashless exercise” (or “net exercise”) basis.

Second Warrants

The Second Warrants have substantially the same terms as the First Warrants.

Placement Agent Warrants

Pursuant to the 2022 Engagement Letter that we entered into with Maxim, we agreed, among other things, to issue Maxim, or its designees, warrants to purchase up to 10% of the aggregate number of shares sold to certain 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 (i) the exercise price of the First Placement Agent Warrants is \$10.06 per share and (ii) are not exercisable until six (6) months from the date of issuance.

In connection with the Second Closing, we (i) agreed to pay Maxim 10% of the gross proceeds in the Second Closing from the institutional investors, or \$50,000, and (ii) we issued Second Placement Agent Warrants to purchase up to 6,565 shares of Common Stock to Maxim pursuant to the 2022 Engagement Letter. The Second Placement Agent Warrants have substantially the same terms as the Second Warrants, except that the exercise price of the Second Placement Agent Warrants is \$10.06 per share and are not exercisable until six (6) months from the date of issuance.

First Notes

In addition to the aforementioned First Warrants, in July 2022 we issued the First Notes. The First Notes become due and payable on January 6, 2024, 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 July 6, 2022 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 through the later of (i) the Maturity Date and (ii) the date of payment of the Default Amount; *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 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 our Common Stock and/or a market and such loss is not cured during the specified cure periods; (iv) our failure to complete an Uplist Transaction by February 15, 2023; 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.

Upon an event of default, the First Notes shall become immediately due and payable and the Company shall pay to each First Note holder an amount equal to 125%, or the Default Premium, multiplied by the sum of the outstanding principal amount of the First Notes plus any accrued and unpaid interest on the unpaid principal amount of the First 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 entered to an additional 5% to the Default Premium for each subsequent event of default. At the election of each First Note holder, the Default Amount may be paid in cash or shares of Common Stock equal to the Default Amount divided by the Conversion Price at the time of payment.

In connection with the issuance of the First Notes, the Company entered into the Security Agreement with certain investors on July 6, 2022, pursuant to which we provided a security interest in, and a lien on, substantially all of our assets as collateral to the investors. Upon an event of default under the First Notes, each investor may exercise its rights to the collateral pursuant to the terms of the Security Agreement.

Notes Exchange and Exchanged Notes

In connection with the Notes Exchange, we issued certain investors Exchanged Notes in the aggregate principal amount of \$699,780.93. The Exchanged Notes are convertible into 76,563 shares of Common Stock at a conversion price of \$9.14 in exchange for a portion of the Company’s Series Convertible Notes. 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 prior 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. As of January 18, 2023, up to 76,563 Exchanged Conversion Shares may be acquired upon the conversion of the Exchanged Notes.

Second Notes

The Second Notes have substantially the same terms as the First Notes, except that the Second Notes are unsecured.

Series K Warrants and 2021 Placement Agent Warrants

Each of the investors participating in the 2021 Private Placement Financing was issued a Series K Warrant to purchase up to a number of shares of our Common Stock equal to 75% of the shares of Common Stock purchased by such investor in such financing. The Series K Warrants had an initial exercise price of \$34.00 per share, were exercisable immediately upon their issuance and have a term of exercise equal to 5.5 years after their issuance date. The number of shares of our 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). In addition, certain of the Series K Warrants provide that they shall not be exercisable in the event and to the extent that the exercise thereof would result in the holder of the Series K Warrant, together with any person whose beneficial ownership would be aggregated with the holder, beneficially owning more than 4.99% of the outstanding shares of our Common Stock; *provided however*, the holder may increase such ownership limitation to 9.99% of the outstanding shares of our Common Stock, in which case the ownership limitation increase will become effective 61 days after the holder requests such increase. In addition, if there is no effective registration statement registering the resale of the shares of Common Stock underlying the Series K Warrants as of certain time periods (as provided in the Series K Warrants), the Series K Warrant holders may choose to exercise such Series K Warrants on a “cashless exercise” or “net exercise” basis.

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.

Series I Warrants and 2019 Placement Agent Warrants

Each of the investors participating in the October 2019 Registered Direct Financing was issued a Series I Warrant to purchase up to a number of shares of our Common Stock equal to 100% of the shares of Common Stock purchased by such investor in such financing. The Series I Warrants had an initial exercise price of \$44.00 per share, were exercisable immediately upon their issuance and have a term of exercise equal to five years after their issuance date. The number of shares of our Common Stock into which each of the Series I Warrants is exercisable and the exercise price therefor 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). In addition, the Series I Warrants provide that they shall not be exercisable in the event and to the extent that the exercise thereof would result in the holder of the Series I Warrant, together with any person whose beneficial ownership would be aggregated with the holder, beneficially owning more than 4.99% of the outstanding shares of our Common Stock; *provided however*, the holder may increase such ownership limitation to 9.99% of the outstanding shares of our Common Stock, in which case the ownership limitation increase will become effective 61 days after the holder requests such increase. In addition, if there is no effective registration statement registering the resale of the shares of Common Stock underlying the Series I Warrants as of certain time periods (as provided in the Series I Warrants), the Series I Warrant holders may choose to exercise such Series I Warrants on a “cashless exercise” or “net exercise” basis.

The 2019 Placement Agent Warrants have substantially the same terms as the Series I Warrants, except that the exercise price of the 2019 Placement Agent Warrants is \$43.75 per share and the term of the 2019 Placement Agent Warrants is five years from October 16, 2019.

Series H Warrants

Each of the investors participating in the May 2019 Registered Direct Financing was issued a Series H Warrant to purchase up to a number of shares of our Common Stock equal to 100% of the shares of Common Stock purchased by such investor in such financing. The Series H Warrants had an initial exercise price of \$80.00 per share, were exercisable immediately upon their issuance and have a term of exercise equal to five years after their issuance date. The number of shares of our Common Stock into which each of the Series H Warrants is exercisable and the exercise price therefor are subject to adjustment as set forth in the Series H Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise). In addition, the Series H Warrants provide that they shall not be exercisable in the event and to the extent that the exercise thereof would result in the holder of the Series H Warrant, together with any person whose beneficial ownership would be aggregated with the holder, beneficially owning more than 4.99% of the outstanding shares of our Common Stock; *provided however*, the holder may increase such ownership limitation to 9.99% of the outstanding shares of our Common Stock, in which case the ownership limitation increase will become effective 61 days after the holder requests such increase. In addition, if (i) there is no effective registration statement registering the resale of the shares of Common Stock underlying the Series H Warrants as of certain time periods (as provided in the Series H Warrants), the Series H Warrant holders may choose to exercise such Series H Warrants on a “cashless exercise” or “net exercise” basis; and (ii) we undergo a change of control or are involved in a similar transaction, the holder may cause us or any successor entity to purchase its Series H Warrants for an amount of cash equal to \$10.66 for each share of Common Stock underlying the Series H Warrants.

Series G Warrants

Each of the investors participating in the 2018 Registered Direct Financing was issued a Series G Warrant to purchase up to a number of shares of our Common Stock equal to 75% of the shares of Common Stock purchased by such investor in such financing. The Series G Warrants had an initial exercise price of \$140.00 per share, were exercisable immediately upon their issuance and have a term of exercise equal to five years after their issuance date. The number of shares of our Common Stock into which each of the Series G Warrants is exercisable and the exercise price therefor are subject to adjustment as set forth in the Series G Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise). In addition, the Series G Warrants provide that they shall not be exercisable in the event and to the extent that the exercise thereof would result in the holder of the Series G Warrant, together with any person whose beneficial ownership would be aggregated with the holder, beneficially owning more than 4.99% of the outstanding shares of our Common Stock; *provided however*, the holder may increase such ownership limitation to 9.99% of the outstanding shares of our Common Stock, in which case the ownership limitation increase will become effective 61 days after the holder requests such increase. In addition, if (i) there is no effective registration statement registering the resale of the shares of Common Stock underlying the Series G Warrants as of certain time periods (as provided in the Series G Warrants), the Series G Warrant holders may choose to exercise such Series G Warrants on a “cashless exercise” or “net exercise” basis; and (ii) we undergo a change of control or are involved in a similar transaction, the holder may cause us or any successor entity to purchase its Series G Warrants for an amount of cash equal to \$22.00 for each share of Common Stock underlying the Series G Warrants.

MLSC Warrants

In connection with and as a condition to receiving the \$1,000,000 unsecured subordinated loan that MLSC (such agreement, the **“MLSC Loan Agreement”**) issued to us on September 30, 2013, we issued to MLSC the MLSC Warrant on September 30, 2013 to purchase 730 shares of our Common Stock at an exercise price of \$54.80 per share. The MLSC Warrant is exercisable immediately upon its issuance and expires on the earlier of September 30, 2023 and the completion of a sale of substantially all of our assets or a change-of-control transaction.

Series 1 Convertible Notes and Series 2 Convertible Notes

In addition to the aforementioned warrants, in June 2020 and November 2020, we issued \$550,000 and \$1,050,000 in aggregate principal amount of our Series 1 Convertible Notes and Series 2 Convertible Notes, respectively. The Series 1 Convertible Notes and Series 2 Convertible Notes (i) have a three year term; (ii) accrue interest on the unpaid principal balance at a rate equal to ten percent (10.0%), and (iii) can be converted into 21,302 shares and 18,815 shares of our Common Stock, respectively, at a conversion price of \$54.00 per share and \$50.00 per share, respectively. At maturity, at our sole option, we may convert the principal and accrued interest under the Series Convertible Notes (the **“Note Obligations”**) into shares of our Common Stock at the applicable conversion price in lieu of repaying the Convertible Notes; provided, however, in the event we exercise this option, the Note Obligations will be deemed to equal the product of 1.35 (which was subsequently increased to 1.60 in connection with the July 2022 financing as holders of the Series Convertible Notes were required to execute subordination agreements as a condition to the July 2022 financing) and the outstanding Note Obligations.

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 _____, 2023 with Maxim Group LLC as the representative of the several underwriters named below (“Maxim” or the “Representative”), in connection with this offering. Maxim 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 set forth opposite their respective names below.

Underwriters	Number of Units
Maxim Group LLC	
Total	

The underwriters are committed to purchase all the 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, 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 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 Investor Warrants underlying the Units 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 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 through one or more of their affiliates or selling agents. If all the 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 9% of the gross proceeds of this offering, 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	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 \$125,000.

We estimate that the total expenses of the offering payable by us, excluding the total underwriting discount and non-accountable expense allowance, will be approximately \$[●].

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 Maxim (or its permitted designees) warrants to purchase up to a number of shares of our Common Stock equal to 9% of the number of Units 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 110% 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 Maxim Group LLC 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 Maxim Group LLC 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, and the holder of 5% or more of the outstanding shares of our Common Stock 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 Maxim. Maxim 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 agreed that until February 15, 2023 (the “**Engagement Period**”), Maxim 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 Maxim 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 Maxim 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 Maxim.

Right of First Refusal

We have granted a right of first refusal to Maxim 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 for which the Company retains the service of an underwriter, agent, advisor, finder or other person or entity in connection with such offering 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

Maxim previously served as our placement agent for the 2022 Private Placement Financing. 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, 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.

In connection with the Second Closing, we agreed, among other things, to (i) pay Maxim 10% of the gross proceeds in the Second Closing from certain institutional investors, and (ii) issue to Maxim, or its designees, warrants to purchase up to 6,565 shares of Common Stock pursuant to the 2022 Engagement Letter. The Second Placement Agent Warrants have substantially the same terms as the Second Warrants, except that the exercise price of the Second Placement Agent Warrants is \$10.06 per share and are not exercisable until six (6) months from the date of issuance. See “**Description of Securities – Warrants, Options and Convertible Notes Issued and Outstanding – Placement Agent Warrants**” for a discussion of the warrants we issued to Maxim in the 2022 Private Placement Financing.

In connection with the 2022 Private Placement Financing, the total fees paid to Maxim was \$290,000 and the total expenses reimbursed was \$57,540.

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 “**ARTHD**” 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. Loeb & Loeb LLP, New York, New York, 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.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of September 30, 2022 and 2021	F-4
Consolidated Statements of Operations for the Years Ended September 30, 2022 and 2021	F-5
Consolidated Statements of Changes in Stockholders' Deficit for the Years Ended September 30, 2022 and 2021	F-6
Consolidated Statements of Cash Flows for the Years Ended September 30, 2022 and 2021	F-7
Notes to Consolidated Financial Statements	F-8

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	\$ 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.

[Table of Contents](#)

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.

[Table of Contents](#)

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.

[Table of Contents](#)

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
		<u>33,756</u>	<u>33,756</u>
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”).

[Table of Contents](#)

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	\$ —	\$ 748,275	\$ 459,200

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	\$ 1,000,000	\$ 748,275	\$ 459,200

[Table of Contents](#)

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).

[Table of Contents](#)

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.

[Table of Contents](#)

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, \$699,780 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.

[Table of Contents](#)

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.

[Table of Contents](#)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.

2,432,432 Units

**Each Unit Consisting of One Share of Common Stock and
One Warrant to Purchase One Share of Common Stock**

ARCH THERAPEUTICS, INC.

PRELIMINARY PROSPECTUS

Sole Book-Running Manager

Maxim Group LLC

, 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.

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	\$ 125,000
Legal fees and expenses	\$ 400,000
Accounting fees and expenses	\$ 54,500
Printing and engraving expenses	\$ 100,000
Miscellaneous expenses	\$ 5,619
	<u>\$ 745,000</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.

On July 6, 2022, we entered into a Securities Purchase Agreement, or the 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 First 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 February 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 Group LLC, or 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.

[Table of Contents](#)

In the Notes Exchange, we issued certain investors Exchanged Notes in the aggregate principal amount of \$699,780.93. 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 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 in respect of the First Notes.

On January 18, 2023, we entered into an amendment to the SPA with certain institutional and accredited individual investors 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 convertible into 69,584 Second Conversion Shares; and (iii) Second Warrants to purchase up to 127,968 shares of Common Stock at an exercise price of \$9.94 per share. The terms of the Second Notes are substantially similar to those of the First Notes, 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 Second Placement Agent Warrants to purchase up to 6,565 shares of Common Stock to Maxim pursuant to the 2022 Engagement Letter. The Second Placement Agent Warrants have substantially the same terms as the Second Warrants, except that the exercise price of the Second 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 Second 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 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 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 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.

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, have a term of exercise equal to one year after their issuance date; *provided, however*, on November 6, 2020, a 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 is exercisable and the exercise price therefor are 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 provide that they shall not be exercisable in the event and to the extent that the exercise thereof would result in the holder of the Series J Warrant, together with any person whose beneficial ownership would be aggregated with the holder, beneficially owning more than 4.99% of the outstanding shares of our Common Stock; provided however, the holder may increase such ownership limitation to 9.99% of the outstanding shares of our Common Stock, in which case the ownership limitation increase will become effective 61 days after the holder requests such increase. In addition, each Series J Warrant provides 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.

[Table of Contents](#)

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.

Item 16. Exhibits and Financial Statement Schedules

Exhibits

See the Exhibit Index immediately following the signature page hereto, which is incorporated into this Item 16 by reference.

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 January 30 , 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>	January 30 , 2023
<u>/s/ Michael S. Abrams</u> Michael S. Abrams	Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	January 30 , 2023
<u>*</u> Punit Dhillon	Director	January 30 , 2023
<u>*</u> Guy Fish, MD	Director	January 30 , 2023
<u>*</u> Laurence Hicks	Director	January 30 , 2023

*By: */s/ Terrence W. Norchi, Attorney-in-Fact*

EXHIBIT INDEX

Exhibit No.	Exhibit Title	Filed Herewith	Incorporated By Reference			
			Form	Exhibit No.	File No.	Filing Date
1.1 **	Form of Underwriting Agreement		S-1/A	1.1	333-268008	01/23/2023
1.2	Form of Warrant Agent 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
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		S-1/A	4.3	333-268008	01/23/2023
5.1	Opinion of McDonald Carano LLP	X				
5.2	Opinion of Lowenstein Sandler LLP	X				
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

Table of Contents

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	9/9/2013
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	9/29/2016
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	8/7/2015
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

[Table of Contents](#)

10.16#	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	8-K	10.4	000-54986	07/20/2018
10.17	May 2019 Securities Purchase Agreement	8-K	10.1	000-54986	05/13/2019
10.18	Form of Series H Warrants	8-K	10.2	000-54986	05/13/2019
10.19	Form of October 2019 Securities Purchase Agreement	8-K	10.1	000-54986	10/18/2019
10.20	Form of Series I Warrants	8-K	10.2	000-54986	10/18/2019
10.21	2019 Engagement Agreement	8-K	10.3	000-54986	10/18/2019
10.22	Form of 2019 Placement Agent Warrant	8-K	10.4	000-54986	10/18/2019
10.23	Form of Amendment to Series D Warrants to Purchase Common Stock	8-K	10.1	000-54986	06/05/2020
10.24	Form of Series J Warrant	8-K	10.2	000-54986	06/05/2020
10.25	Form of Series 1 Convertible Notes	8-K	10.3	000-54986	06/05/2020
10.26	Amendment to Series J Warrant to Purchase Common Stock	8-K	10.1	000-54986	11/10/2020
10.27	Form of Series 2 Convertible Notes	8-K	10.2	000-54986	11/10/2020
10.28	Form of 2021 Securities Purchase Agreement	8-K	10.1	000-54986	2/12/2021
10.29	Form of Series K Warrant	8-K	10.2	000-54986	2/12/2021
10.30	2021 Engagement Agreement	8-K	10.3	000-54986	2/12/2021
10.31	Form of 2021 Placement Agent Warrant	8-K	10.4	000-54986	2/12/2021
10.32	Form of Registration Rights Agreement	8-K	10.5	000-54986	2/12/2021

[Table of Contents](#)

10.33	Executive Employment Agreement, effective May 3, 2021, by and between Arch Therapeutics, Inc. and Michael S. Abrams		8-K	10.2	000-54986	5/3/2021
10.34	Employment Agreement, effective June 30, 2021, by and between Arch Therapeutics, Inc. and Dan M. Yrigoyen		8-K	10.1	000-54986	8/11/2021
10.35	First Amendment to Employment Agreement, effective August 9, 2021, by and between Arch Therapeutics, Inc. and Dan M. Yrigoyen		8-K	10.2	000-54986	8/11/2021
10.36	Form of Securities Purchase Agreement, dated July 6, 2022, by and among the Company and the signatories thereto		8-K	10.1	000-54986	7/8/2022
10.37	Form of First Notes		8-K	10.2	000-54986	7/8/2022
10.38	Form of First Warrant		8-K	10.3	000-54986	7/8/2022
10.39	Form of Registration Rights Agreement, dated July 6, 2022, by and among the Company and the signatories thereto		8-K	10.4	000-54986	7/8/2022
10.40 [^]	Form of Security Agreement, dated July 6, 2022, by and among the Company and the signatories thereto		8-K	10.5	000-54986	7/8/2022
10.41	Form of Second Note		8-K	10.2	000-54986	1/20/2023
10.42	Form of Second Warrant		8-K	10.3	000-54986	1/20/2023
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	1/20/2023
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	1/20/2023
21.1	List of Subsidiaries		8-K	21.1	333-178883	6/26/2013
23.1	Consent of Independent Registered Public Accounting Firm	X				
23.2	Consent of McDonald Carano LLP (included in Exhibit 5.1)	X				
23.3	Consent of Lowenstein Sandler LLP (included in Exhibit 5.2)	X				
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		S-1/A	107	333-268008	01/23/2023

* 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.

WARRANT AGENT AGREEMENT

This WARRANT AGENT AGREEMENT (this “Warrant Agreement”) dated as of [], 2023 (the “Issuance Date”) is between **Arch Therapeutics, Inc.** a Nevada corporation (the “Company”), and **Empire Stock Transfer Inc.**, a Nevada corporation (the “Warrant Agent”).

WHEREAS, pursuant to the terms of that certain Underwriting Agreement (“Underwriting Agreement”), dated [], 2023, by and among the Company and Maxim Group LLC, as the representative (the “Representative”) of the underwriters set forth therein, the Company is engaged in a public offering of (i) units consisting of (A) [●] shares (the “Offered Shares”) of common stock, par value \$0.001 per share (“Common Stock”) and (B) warrants exercisable for [●] shares of Common Stock (each, an “Offered Warrant”), and (ii) [●] shares of Common Stock (the “Option Shares”) and, together with the Offered Shares, the “Shares”) and/or warrants exercisable for [●] shares of Common Stock (the “Option Warrants”) and, together with the Offered Warrants, the “Warrants”) that may be sold pursuant to the over-allotment option granted by the Company;

WHEREAS, the Company has filed with the Securities and Exchange Commission (the “Commission”) a Registration Statement on Form S-1 (File No. 333-268008) (as the same may be amended from time to time, the “Registration Statement”), for the registration under the Securities Act of 1933, as amended (the “Securities Act”), of the sale of the Shares, Warrants, shares underlying the Warrants, Representative’s Warrants (as defined therein), and shares underlying the Representatives’ Warrants, and such Registration Statement was declared effective on [], 2023; and

WHEREAS, the Company desires the Warrant Agent to act on behalf of the Company, and the Warrant Agent is willing to so act, in accordance with the terms set forth in this Warrant Agreement in connection with the issuance, registration, transfer, exchange and exercise of the Warrants;

WHEREAS, the Company desires to provide for the provisions of the Warrants, the terms upon which they shall be issued and exercised, and the respective rights, limitation of rights, and immunities of the Company, the Warrant Agent, and the holders of the Warrants; and

WHEREAS, all acts and things have been done and performed which are necessary to make the Warrants the valid, binding and legal obligations of the Company, and to authorize the execution and delivery of this Warrant Agreement.

NOW, THEREFORE, in consideration of the mutual agreements herein contained, the parties hereto agree as follows:

1. Appointment of Warrant Agent. The Company hereby appoints the Warrant Agent to act as agent for the Company with respect to the Warrants, and the Warrant Agent hereby accepts such appointment and agrees to perform the same in accordance with the express terms and conditions set forth in this Warrant Agreement (and no implied terms or conditions).

2. Warrants.

2.1. Form of Warrants. The Warrants shall be registered securities and shall be evidenced by a global warrant (“Global Warrant”) in the form of Exhibit A to this Warrant Agreement, which shall be deposited on behalf of the Company with a custodian for The Depository Trust Company (“DTC”) and registered in the name of Cede & Co., as nominee of DTC. The terms of the Global Warrant are incorporated herein by reference. If DTC subsequently ceases to make its book-entry settlement system available for the Warrants, the Company may instruct the Warrant Agent regarding making other arrangements for book-entry settlement. In the event that the Warrants are not eligible for, or it is no longer necessary to have the Warrants available in, book-entry form, the Company may instruct the Warrant Agent to provide written instructions to DTC to deliver to the Warrant Agent for cancellation the Global Warrant, and the Company shall instruct the Warrant Agent to deliver to each holder of the Warrants separate certificates evidencing Warrants (“Definitive Certificates”) and, together with the Global Warrant, “Warrant Certificates”) registered as requested through the DTC system. In the event Definitive Certificates are delivered to the Holders, the transfer, exchange or exercise of the Warrants shall be conducted in accordance with the customary procedures of the Warrant Agent.

2.2. Issuance and Registration of Warrants.

2.2.1. Warrant Register. Upon the receipt of all relevant information from the Company or its agents, the Warrant Agent shall maintain books ("Warrant Register") for the registration of original issuance and the registration of transfer of the Warrants.

2.2.2. Issuance of Warrants. Upon the initial issuance of the Warrants, the Warrant Agent shall issue the Global Warrant and deliver the Warrants in the DTC book-entry settlement system in accordance with written instructions delivered to the Warrant Agent by the Company. Ownership of security entitlements in the Warrants shall be shown on, and the transfer of such ownership shall be effected through, records maintained (i) by DTC and (ii) by institutions that have accounts with DTC (each, a "Participant").

2.2.3. Beneficial Owner; Holder. Prior to due presentment for registration of transfer of any Warrant, the Company and the Warrant Agent may deem and treat the Person (as such term is defined in the Global Warrant) in whose name that Warrant shall be registered on the Warrant Register (the "Holder", which shall include, if the Warrants are held in "street name", a Participant or a designee appointed by such Participant) as the absolute owner of such Warrant for purposes of any exercise thereof, and for all other purposes, and neither the Company nor the Warrant Agent shall be affected by any notice to the contrary. Notwithstanding the foregoing, nothing herein shall prevent the Company, the Warrant Agent or any agent of the Company or the Warrant Agent from giving effect to any written certification, proxy or other authorization furnished by DTC governing the exercise of the rights of a holder of a beneficial interest in any Warrant. The rights of beneficial owners in a Warrant evidenced by the Global Warrant shall be exercised by the Holder or a Participant through the DTC system, except to the extent set forth herein or in the Global Warrant.

2.2.4. Delivery of Warrant Certificate. 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 Warrants, which request shall be in the form attached hereto as Exhibit B (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 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 Warrants in the name set forth in the Warrant Certificate Request Notice. Such Warrant Certificate shall be dated the date of issuance of the Warrant Certificate, shall include the initial exercise date of the Warrants, shall be executed by an authorized signatory of the Company and shall be reasonably acceptable in all respects to such Holder. 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 (as defined in the Global Warrant) of the Warrant Certificate Request Notice pursuant to the delivery instructions in the Warrant Certificate Request Notice ("Warrant Certificate Delivery Date"). The Warrant Agent shall have no liability for the Company's failure to deliver to the Holders the Warrant Certificate as set forth in this Section 2.2.4. 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 Warrants evidenced by such Warrant Certificate and the terms of this Warrant Agreement.

2.2.5. Execution. The Warrant Certificates shall be executed on behalf of the Company by any authorized officer of the Company (an "Authorized Officer"), which need not be the same authorized signatory for all of the Warrant Certificates, either manually or by facsimile signature. The Warrant Certificates shall be countersigned by an authorized signatory of the Warrant Agent, either by manual, electronic or facsimile signature, which need not be the same signatory for all of the Warrant Certificates, and no Warrant Certificate shall be valid for any purpose unless so countersigned. In case any Authorized Officer of the Company that signed any of the Warrant Certificates ceases to be an Authorized Officer of the Company before countersignature by the Warrant Agent and issuance and delivery by the Company, such Warrant Certificates, nevertheless, may be countersigned by the Warrant Agent, issued and delivered with the same force and effect as though the person who signed such Warrant Certificates had not ceased to be such officer of the Company; and any Warrant Certificate may be signed on behalf of the Company by any person who, at the actual date of the execution of such Warrant Certificate, shall be an Authorized Officer of the Company authorized to sign such Warrant Certificate, although at the date of the execution of this Warrant Agreement any such person was not such an Authorized Officer.

2.2.6. Registration of Transfer. At any time at or prior to the Expiration Date (as defined below), a transfer of any Warrants may be registered and any Warrant Certificate or Warrant Certificates may be split up, combined or exchanged for another Warrant Certificate or Warrant Certificates evidencing the same number of Warrants as the Warrant Certificate or Warrant Certificates surrendered. Any Holder desiring to register the transfer of Warrants or to split up, combine or exchange any Warrant Certificate shall make such request in writing delivered to the Warrant Agent, and shall surrender to the Warrant Agent the Warrant Certificate or Warrant Certificates evidencing the Warrants the transfer of which is to be registered or that is or are to be split up, combined or exchanged and, in the case of registration of transfer, shall provide a signature guarantee by an “eligible guarantor institution” that is a member or participant in the Securities Transfer Agents Medallion Program or other comparable “signature guarantee program”. Thereupon, the Warrant Agent shall countersign and deliver to the Person entitled thereto a Warrant Certificate or Warrant Certificates, as the case may be, as so requested. The Company and the Warrant Agent may require payment, by the Holder requesting a registration of transfer of Warrants or a split-up, combination or exchange of a Warrant Certificate (but, for purposes of clarity, not upon the exercise of the Warrants and issuance of shares of Common Stock issuable upon exercise of the Warrants (the “Warrant Shares”) to the Holder), of a sum sufficient to cover any tax or governmental charge that may be imposed in connection with such registration of transfer, split-up, combination or exchange, together with reimbursement to the Company and the Warrant Agent of all reasonable expenses incidental thereto.

2.2.7. Loss, Theft and Mutilation of Warrant Certificates. Upon receipt by the Company and the Warrant Agent of evidence reasonably satisfactory to them of the loss, theft, destruction or mutilation of a Warrant Certificate, and, in case of loss, theft or destruction, of indemnity or security reasonably acceptable to the Warrant Agent and the Company, 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 Warrant Agent shall, on behalf of the Company, countersign and deliver a new Warrant Certificate of like tenor to the Holder in lieu of the Warrant Certificate so lost, stolen, destroyed or mutilated. The Warrant Agent may charge the Holder an administrative fee for processing the replacement of lost Warrant Certificates, The Warrant Agent may receive compensation from the surety companies or surety agents for administrative services provided to them.

2.2.8. Proxies. The Holder of a Warrant may grant proxies or otherwise authorize any Person, including the Participants and beneficial holders that may own interests through the Participants, to take any action that a Holder is entitled to take under this Warrant Agreement or the Warrants; provided, however, that at all times that Warrants are evidenced by a Global Warrant, exercise of those Warrants shall be effected on their behalf by Participants through DTC in accordance with the procedures administered by DTC.

3. Terms and Exercise of Warrants.

3.1. Exercise Price. Each Warrant shall entitle the Holder, subject to the provisions of the applicable Warrant Certificate and of this Warrant Agreement, to purchase from the Company the number of shares of Common Stock stated therein, at the price of \$[] per whole share, subject to the subsequent adjustments provided in the Global Warrant. The term “Exercise Price” as used in this Warrant Agreement refers to the price per share at which shares of Common Stock may be purchased at the time a Warrant is exercised.

3.2. Duration of Warrants. A Warrant may be exercised only during the period (“Exercise Period”) commencing on the date of issuance and ending on the Termination Date. For purposes of this Warrant Agreement, the “Termination Date” shall have the meaning set forth in the Global Warrant. Each Warrant not exercised on or before the Termination Date shall become void, and all rights thereunder and all rights in respect thereof under this Warrant Agreement shall cease at the close of business on the Termination Date.

3.3. Exercise of Warrants.

3.3.1. Exercise. Subject to the provisions of the Global Warrant and in accordance with the procedures of DTC, a Holder (or a Participant or a designee of a Participant acting on behalf of a Holder) may exercise Warrants by delivering to the Warrant Agent, (i) not later than 5:00 P.M., Eastern Time, on any Business Day during the Exercise Period a notice of exercise of the Warrants to be exercised (A) in the form attached as Annex A to the Global Warrant or (B) via an electronic warrant exercise through the DTC system (each, an “Election to Purchase”), (ii) within one (1) Trading Day following the delivery of the Election to Purchase, Warrants to be exercised by (A) surrender of the Warrant Certificate evidencing the Warrants to the Warrant Agent at its office designated for such purpose or (B) delivery of the Warrants to an account of the Warrant Agent at DTC designated for such purpose in writing by the Warrant Agent to DTC from time to time, and (iii) within the earlier of (A) two (2) Trading Days and (B) the number of Trading Days comprising the Standard Settlement Period (as defined in the Global Warrant) following the date of exercise as aforesaid, the Exercise Price for each Warrant to be exercised (and, if applicable, any taxes or charges due in connection with the exercise of such Warrants), in lawful money of the United States of America by (A) certified or official bank check or wire transfer from a United States bank payable to the Warrant Agent or (B) payment to the Warrant Agent through the DTC system, unless cashless exercise is applicable. Partial exercises of a Warrant resulting in purchases of a portion of the total number of Warrant Shares available thereunder 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. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender the Global Warrant to the Warrant Agent until the Holder has purchased all of the Warrant Shares available hereunder and the Global Warrant has been exercised in full, in which case, the Holder shall surrender the Global Warrant to the Company for cancellation within three (3) Trading Days of the date on which the final Election to Purchase is delivered to the Company. **The Holder and any assignee, by acceptance of a 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 thereof.**

3.3.2. The Warrant Agent shall, by 5:00 p.m., New York City time, on the Trading Day following the Exercise Date of any Warrant, advise the Company, the transfer agent and registrar for the Company’s Common Stock, in respect of (i) the number of Warrant Shares indicated on the Election to Purchase as issuable upon such exercise with respect to such exercised Warrants, (ii) the instructions of the Holder or Participant, as the case may be, provided to the Warrant Agent with respect to the delivery of the Warrant Shares and the number of Warrants that remain outstanding after such exercise and (iii) such other information as the Company or such transfer agent and registrar shall reasonably request. The Company shall issue the Warrant Shares in compliance with the terms of the Warrant. The term “Exercise Date” shall mean the date on which the Election to Purchase is delivered to the Warrant Agent.

3.3.3. Valid Issuance. All Warrant Shares issued by the Company upon the proper exercise of a Warrant in conformity with this Warrant Agreement shall be validly issued, fully paid and non-assessable.

3.3.4. No Fractional Exercise. Notwithstanding any provision contained in this Warrant Agreement to the contrary, no fractional shares or scrip representing fractional shares shall be issued upon the exercise of the 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.

3.3.5. Charges, Taxes, and Expenses. Issuance of Warrant Shares shall be made without charge to a 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 a Holder or in such name or names as may be directed by a Holder; provided, however, that in the event that Warrant Shares are to be issued in a name other than the name of a Holder, the Warrant, when surrendered for exercise, shall be accompanied by the Assignment Form attached to the Warrant 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 DTC (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

3.3.6. Date of Issuance. The Company will treat an exercising Holder as a beneficial owner of the Warrant Shares as of the Exercise Date, and for purposes of Regulation SHO, a holder whose interest in this Warrant is a beneficial interest in certificate(s) representing this Warrant held in book-entry form through DTC shall be deemed to have exercised its interest in this Warrant upon instructing its broker that is a DTC participant to exercise its interest in this Warrant, except that, if the Exercise Date is a date when the stock transfer books of the Company are closed, such Person shall be deemed to have become the holder of such shares at the open of business on the next succeeding date on which the stock transfer books are open.

4. Adjustments. Upon every adjustment of the Exercise Price or the number of Warrant Shares issuable upon exercise of a Warrant or any other adjustment pursuant to the terms of the Warrants, the Company shall give written notice thereof to the Warrant Agent, which notice shall state the Exercise Price resulting from such adjustment and the increase or decrease, if any, in the number of Warrant Shares purchasable at such price upon the exercise of a Warrant, setting forth in reasonable detail the method of calculation and the facts upon which such calculation is based. Failure to give such notice, or any defect therein, shall not affect the legality or validity of such event. The Warrant Agent shall be entitled to rely conclusively on, and shall be fully protected in relying on, any certificate, notice or instructions provided by the Company with respect to any adjustment of the Exercise Price or the number of shares issuable upon exercise of a Warrant, or any related matter, and the Warrant Agent shall not be liable for any action taken, suffered or omitted to be taken by it in accordance with any such certificate, notice or instructions or pursuant to this Warrant Agreement.

5. Restrictive Legends; Fractional Warrants. In the event that a Warrant Certificate surrendered for transfer bears a restrictive legend, the Warrant Agent shall not register that transfer until the Warrant Agent has received an opinion of counsel for the Company stating that such transfer may be made and indicating whether the Warrants must also bear a restrictive legend upon that transfer. The Warrant Agent shall not be required to effect any registration of transfer or exchange which will result in the transfer of or delivery of a Warrant Certificate for a fraction of a Warrant.

6. Other Provisions Relating to Rights of Holders of Warrants.

6.1. No Rights as Stockholder. Except as otherwise specifically provided herein, a Holder, solely in its capacity as a Holder of Warrants, shall not be entitled to vote or receive dividends or be deemed the holder of share capital of the Company for any purpose, nor shall anything contained in this Warrant Agreement be construed to confer upon a Holder, solely in its capacity as the registered holder of Warrants, any of the rights of a stockholder of the Company or any right to vote, give or withhold consent to any corporate action (whether any reorganization, issue of stock, reclassification of share capital, consolidation, merger, conveyance or otherwise), receive notice of meetings, receive dividends or subscription rights or rights to participate in new issues of shares, or otherwise, prior to the issuance to the Holder of the Warrant Shares which it is then entitled to receive upon the due exercise of Warrants.

6.2. Reservation of Common Stock. The Company shall at all times reserve and keep available a number of its authorized but unissued shares of Common Stock that will be sufficient to permit the exercise in full of all outstanding Warrants issued pursuant to this Warrant Agreement.

7. Concerning the Warrant Agent and Other Matters.

7.1. Any instructions given to the Warrant Agent orally, as permitted by any provision of this Warrant Agreement, shall be confirmed in writing by the Company as soon as practicable. The Warrant Agent shall not be liable or responsible and shall be fully authorized and protected for acting, or failing to act, in accordance with any oral instructions which do not conform with the written confirmation received in accordance with this Section 7.1.

7.2. Whether or not any Warrants are exercised, for the Warrant Agent's services as agent for the Company hereunder, the Company shall pay to the Warrant Agent such fees as may be separately agreed between the Company and Warrant Agent and the Warrant Agent's out of pocket expenses in connection with this Warrant Agreement, including, without limitation, the reasonable fees and expenses of the Warrant Agent's counsel. No provision of this Warrant Agreement shall require Warrant Agent to expend or risk its own funds or otherwise incur any financial liability in the performance of any of its duties under this Warrant Agreement or in the exercise of its rights.

7.3. As agent for the Company hereunder the Warrant Agent: (a) shall have no duties or obligations other than those specifically set forth herein or as may subsequently be agreed to in writing by the Warrant Agent and the Company; (b) shall be regarded as making no representations and having no responsibilities as to the validity, sufficiency, value, or genuineness of the Warrants or any Warrant Shares; (c) shall not be obligated to take any legal action hereunder; if, however, the Warrant Agent determines to take any legal action hereunder, and where the taking of such action might, in its judgment, subject or expose it to any expense or liability it shall not be required to act unless it has been furnished with an indemnity reasonably satisfactory to it; (d) may rely on and shall be fully authorized and protected in acting or failing to act upon any certificate, instrument, opinion, notice, letter, telegram, telex, email, facsimile transmission or other document or security delivered to the Warrant Agent and believed by it to be genuine and to have been signed by the proper party or parties; (e) shall not be liable or responsible for any recital or statement contained in the Registration Statement or any other documents relating thereto, this Warrant Agreement or any Warrant Certificate except as to its countersignature thereof, 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; (f) shall not be liable or responsible for any failure on the part of the Company to comply with any of its covenants and obligations relating to the Warrants, including without limitation obligations under this Warrant Agreement or applicable securities laws; (g) may rely on and shall be fully authorized and protected in acting or failing to act upon the written, telephonic or oral instructions with respect to any matter relating to its duties as Warrant Agent covered by this Warrant Agreement (or supplementing or qualifying any such actions) of officers of the Company, and is hereby authorized and directed to accept instructions with respect to the performance of its duties hereunder from the Company or counsel to the Company, and may apply to the Company, for advice or instructions in connection with the Warrant Agent's duties hereunder, and the Warrant Agent shall not be liable for any delay in acting while waiting for those instructions; any applications by the Warrant Agent for written instructions from the Company may, at the option of the Warrant Agent, set forth in writing any action proposed to be taken or omitted by the Warrant Agent under this Warrant Agreement and the date on or after which such action shall be taken or such omission shall be effective; the Warrant Agent shall not be liable for any action taken by, or omission of, the Warrant Agent in accordance with a proposal included in such application on or after the date specified in such application (which date shall not be less than five (5) Business Days after the date such application is sent to the Company, unless the Company shall have consented in writing to any earlier date) unless prior to taking any such action, the Warrant Agent shall have received written instructions in response to such application specifying the action to be taken or omitted; (h) may consult with counsel satisfactory to the Warrant Agent, including its in-house counsel, and the 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 the absence of bad faith and in accordance with the advice of such counsel; (i) may perform any of its duties hereunder either directly or by or through nominees, correspondents, designees, or subagents, and it shall not be liable or responsible for any act, omission, default, misconduct or negligence on the part of any nominee, correspondent, designee, or subagent absent gross negligence or willful misconduct in the selection and continued employment thereof (which gross negligence or willful misconduct must be determined by a final, non-appealable judgment of a court of competent jurisdiction); (j) is not authorized, and shall have no obligation, to pay any brokers, dealers, or soliciting fees to any Person; and (k) shall not be required hereunder to comply with the laws or regulations of any country other than the United States of America or any political subdivision thereof.

7.4. (a) In the absence of gross negligence or willful misconduct on its part (which gross negligence or willful misconduct must be determined by a final, non-appealable judgment of a court of competent jurisdiction), the Warrant Agent shall not be liable for any action taken, suffered, or omitted by it or for any error of judgment made by it in the performance of its duties under this Warrant Agreement. Anything in this Warrant Agreement to the contrary notwithstanding, in no event shall Warrant Agent be liable for special, indirect, incidental, consequential or punitive losses or damages of any kind whatsoever (including but not limited to lost profits), even if the Warrant Agent has been advised of the possibility of such losses or damages and regardless of the form of action. Any liability of the Warrant Agent will be limited in the aggregate to the amount of fees (but not reimbursed costs, charges or expenses) paid by the Company hereunder for the twelve (12) months preceding the event for which recovery from the Warrant Agent is being sought. The Warrant Agent shall not be liable for any failures, delays or losses, arising directly or indirectly out of conditions beyond its reasonable control including, but not limited to, acts of government, exchange or market ruling, suspension of trading, work stoppages or labor disputes, fires, civil disobedience, riots, rebellions, storms, electrical or mechanical failure, computer hardware or software failure, communications facilities failures including telephone failure, war, terrorism, insurrection, earthquakes, floods, epidemics, pandemics, acts of God or similar occurrences. (b) In the event any question or dispute arises with respect to the proper interpretation of the Warrants or the Warrant Agent's duties under this Warrant Agreement or the rights of the Company or of any Holder, the Warrant Agent shall not be required to act and shall not be held liable or responsible for its refusal to act until the question or dispute has been judicially settled (and, if appropriate, it may file a suit in interpleader or for a declaratory judgment for such purpose) by final judgment rendered by a court of competent jurisdiction, binding on all Persons interested in the matter which is no longer subject to review or appeal, or settled by a written document in form and substance satisfactory to Warrant Agent and executed by the Company and each such Holder. In addition, the Warrant Agent may require for such purpose, but shall not be obligated to require, the execution of such written settlement by all the Holders and all other Persons that may have an interest in the settlement.

7.5. The Company covenants to indemnify the Warrant Agent and hold it harmless from and against any loss, liability, damage, judgment, fine, penalty, claim, demand, settlement, cost or expense (including, without limitation, the reasonable fees and expenses of legal counsel) (“Loss”) arising out of or in connection with the Warrant Agent’s duties under this Warrant Agreement, including the costs and expenses of defending itself against any Loss, unless such Loss shall have been determined by a court of competent jurisdiction pursuant to a final, non-appealable judgment to be a result of the Warrant Agent’s gross negligence or willful misconduct.

7.6. Unless terminated earlier by the parties hereto, this Warrant Agreement shall terminate 90 days after the earlier of the Expiration Date and the date on which no Warrants remain outstanding (the “Agreement Termination Date”). On the Business Day following the Agreement Termination Date, the Warrant Agent shall deliver to the Company any entitlements, if any, held by the Warrant Agent under this Warrant Agreement. The Warrant Agent’s rights under this Section 7 shall survive the expiration or termination of this Warrant Agreement and the resignation, removal or replacement of the Warrant Agent.

7.7. If any provision of this Warrant Agreement shall be held illegal, invalid, or unenforceable by any court, this Warrant Agreement shall be construed and enforced as if such provision had not been contained herein and shall be deemed an Agreement among the parties to it to the full extent permitted by applicable law; provided, however, that if such excluded provision shall adversely affect the rights, immunities, liabilities, duties or obligations of the Warrant Agent, the Warrant Agent shall be entitled to resign immediately upon written notice to the Company.

7.8. The Company represents and warrants that: (a) it is duly incorporated and validly existing under the laws of its jurisdiction of incorporation; (b) the offer and sale of the Warrants and the execution, delivery and performance of all transactions contemplated thereby (including this Warrant Agreement) have been duly authorized by all necessary corporate action and will not result in a breach of or constitute a default under the articles of association, bylaws or any similar document of the Company or any indenture, agreement or instrument to which it is a party or is bound; (c) this Warrant Agreement has been duly executed and delivered by the Company and constitutes the legal, valid, binding and enforceable obligation of the Company; (d) the Warrants will comply in all material respects with all applicable requirements of law; and (e) to the best of its knowledge, there is no litigation pending or threatened as of the date hereof in connection with the offering of the Warrants.

7.9. [Reserved].

7.10. Set forth in Exhibit C hereto is a list of the names and specimen signatures of the persons authorized to act for the Company under this Warrant Agreement (the “Authorized Representatives”). The Company shall, from time to time, certify to you the names and signatures of any other persons authorized to act for the Company under this Warrant Agreement. The Warrant Agent shall be fully authorized and protected in relying upon the advice or instructions received from any such Authorized Representatives.

7.11. Except as expressly set forth elsewhere in this Warrant Agreement, all notices, instructions and communications under this Warrant Agreement shall be in writing, by overnight delivery service, first-class mail, postage prepaid, properly addressed and shall be effective upon receipt and shall be addressed, if to the Company, to its address set forth beneath its signature to this Warrant Agreement, or, if to the Warrant Agent, to:

Empire Stock Transfer Inc.
1859 Whitney Mesa Dr.
Henderson, NV 89014
Attn: [●]

or to such other address of which a party hereto has notified the other party.

7.12. (a) This Warrant Agreement shall be governed by and construed in accordance with the internal laws of the State of New York applicable to contracts made in that state, without giving effect to any choice of law or conflict of law provision or rule that would cause the application of the laws of any jurisdiction other than the State of New York. All actions and proceedings relating to or arising from, directly or indirectly, this Warrant Agreement may be litigated in courts located within the Borough of Manhattan in the City and State of New York. The Company hereby submits to the personal jurisdiction of such courts and consents that any service of process may be made by certified or registered mail, return receipt requested, directed to the Company at its address last specified for notices hereunder. Each of the parties hereto hereby waives the right to a trial by jury in any action or proceeding arising out of or relating to this Warrant Agreement. No provision of this Warrant Agreement shall be construed as a waiver by the Holder of any rights that the Holder may have under U.S. federal securities laws and the rules and regulation of the Commission thereunder. (b) This Warrant Agreement shall inure to the benefit of and be binding upon the successors and assigns of the parties hereto. This Warrant Agreement may not be assigned, or otherwise transferred, in whole or in part, by either party without the prior written consent of the other party, which the other party will not unreasonably withhold, condition or delay; except that (i) consent is not required for an assignment or delegation of duties by Warrant Agent to any affiliate of Warrant Agent and (ii) any reorganization, merger, consolidation, sale of assets or other form of business combination by Warrant Agent or the Company shall not be deemed to constitute an assignment of this Warrant Agreement. (c) No provision of this Warrant Agreement may be amended, modified or waived, except in a written document signed by the Company and the Warrant Agent. The Company and the Warrant Agent may amend or supplement this Warrant Agreement without the consent of any Holder for the purpose of curing any ambiguity, or curing, correcting or supplementing any defective provision contained herein or adding or changing any other provisions with respect to matters or questions arising under this Warrant Agreement as the parties may deem necessary or desirable and that the parties determine, in good faith, shall not adversely affect the interest of the Holders in any material respect. All other amendments and supplements shall require the vote or written consent of Holders of at least 50.1% of the then outstanding Warrants, provided that adjustments may be made to the Warrant terms and rights in accordance with Section 4 without the consent of the Holders. As a condition precedent to the Warrant Agent executing any amendment or supplement, the Company shall deliver a certificate from an Authorized Representative which states that the proposed supplement or amendment is in compliance with the terms of this Section 7.12(c). Notwithstanding anything in this Warrant Agreement to the contrary, the Warrant Agent shall not be required to execute any supplement or amendment to this Warrant Agreement that it has determined would adversely affect its own rights, duties, obligations or immunities under this Warrant Agreement.

7.13. Payment of Taxes. The Company will from time to time promptly pay all taxes and charges that may be imposed upon the Company or the Warrant Agent in respect of the issuance or delivery of Warrant Shares upon the exercise of Warrants, but the Company may require the Holders to pay any transfer taxes in respect of the Warrants or such shares. The Warrant Agent may refrain from registering any transfer of Warrants or any delivery of any Warrant Shares unless or until the Persons requesting the registration or issuance shall have paid to the Warrant Agent for the account of the Company the amount of such tax or charge, if any, or shall have established to the reasonable satisfaction of the Company and the Warrant Agent that such tax or charge, if any, has been paid.

7.14. Resignation of Warrant Agent.

7.14.1. Appointment of Successor Warrant Agent. The Warrant Agent, or any successor to it hereafter appointed, may resign its duties and be discharged from all further duties and liabilities hereunder after giving thirty (30) days' notice in writing to the Company, or such shorter period of time agreed to by the Company. The Company may terminate the services of the Warrant Agent, or any successor Warrant Agent, after giving thirty (30) days' notice in writing to the Warrant Agent or successor Warrant Agent, or such shorter period of time as agreed. In the event any transfer agency relationship in effect between the Company and the Warrant Agent terminates, the Warrant Agent will be deemed to have resigned automatically and be discharged from its duties under this Warrant Agreement as of the effective date of such termination. If the office of the Warrant Agent becomes vacant by resignation, termination or incapacity to act or otherwise, the Company shall appoint in writing a successor Warrant Agent in place of the Warrant Agent. If the Company shall fail to make such appointment within a period of 30 days after it has been notified in writing of such resignation or incapacity by the Warrant Agent, then the Warrant Agent or any Holder may apply to any court of competent jurisdiction for the appointment of a successor Warrant Agent at the Company's cost. Pending appointment of a successor to such Warrant Agent, either by the Company or by such a court, the duties of the Warrant Agent shall be carried out by the Company. Any successor Warrant Agent (but not including the initial Warrant Agent), whether appointed by the Company or by such court, shall be a Person organized and existing under the laws of any state of the United States of America, in good standing, and authorized under such laws to exercise corporate trust powers and subject to supervision or examination by federal or state authority. After appointment, any successor Warrant Agent shall be vested with all the authority, powers, rights, immunities, duties, and obligations of its predecessor Warrant Agent with like effect as if originally named as Warrant Agent hereunder, without any further act or deed, and except for executing and delivering documents as provided in the sentence that follows, the predecessor Warrant Agent shall have no further duties, obligations, responsibilities or liabilities hereunder, but shall be entitled to all rights that survive the termination of this Warrant Agreement and the resignation or removal of the Warrant Agent, including but not limited to its right to indemnity hereunder. If for any reason it becomes necessary or appropriate or at the request of the Company, the predecessor Warrant Agent shall execute and deliver, at the expense of the Company, an instrument transferring to such successor Warrant Agent all the authority, powers, and rights of such predecessor Warrant Agent hereunder; and upon request of any successor Warrant Agent the Company shall make, execute, acknowledge, and deliver at the expense of the Company any and all instruments in writing for more fully and effectually vesting in and confirming to such successor Warrant Agent all such authority, powers, rights, immunities, duties, and obligations.

7.14.2. Notice of Successor Warrant Agent. In the event a successor Warrant Agent shall be appointed, the Company shall give notice thereof to the predecessor Warrant Agent and the transfer agent for the Common Stock not later than the effective date of any such appointment.

7.14.3. Merger or Consolidation of Warrant Agent. Any Person into which the Warrant Agent may be merged or converted or with which it may be consolidated or any Person resulting from any merger, conversion or consolidation to which the Warrant Agent shall be a party or any Person succeeding to the shareowner services business of the Warrant Agent or any successor Warrant Agent shall be the successor Warrant Agent under this Warrant Agreement, without any further act or deed.

8. Miscellaneous Provisions.

8.1. Persons Having Rights under this Warrant Agreement. Nothing in this Warrant Agreement expressed and nothing that may be implied from any of the provisions hereof is intended, or shall be construed, to confer upon, or give to, any Person other than the parties hereto any right, remedy, or claim under or by reason of this Warrant Agreement or of any covenant, condition, stipulation, promise, or agreement hereof. The terms of this Agreement are to be read in conjunction with the applicable terms of the Warrant Certificates. Notwithstanding anything to the contrary contained herein, to the extent any provision of a Warrant Certificate conflicts with any provision of this Warrant Agreement, the provision of the Warrant Certificate shall govern and be controlling, provided, however, that all provisions with respect to the rights, duties, protections and liability of the Warrant Agent shall be determined and interpreted solely by the provisions of this Warrant Agreement.

8.2. Examination of the Warrant Agreement. A copy of this Warrant Agreement shall be available at all reasonable times at the office of the Warrant Agent designated for such purpose for inspection by any Holder. Prior to such inspection, the Warrant Agent may require any such holder to provide reasonable evidence of its interest in the Warrants.

8.3. Counterparts. This Warrant Agreement may be executed in any number of original, facsimile or electronic 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.

8.4. Effect of Headings. The Section headings herein are for convenience only and are not part of this Warrant Agreement and shall not affect the interpretation thereof.

8.5 Further Assurance. The Company 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 or requested by the Warrant Agent for the carrying out or performing by the Warrant Agent of the provisions of this Warrant Agreement.

9. Certain Definitions. As used herein, the following terms shall have the following meanings:

- (a) “Trading Day” means a day on which the Common Stock is traded on a Trading Market.
- (b) “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, the New York Stock Exchange, OTCQB or OTCQX (or any successors to any of the foregoing).

IN WITNESS WHEREOF, this Warrant Agent Agreement has been duly executed by the parties hereto as of the day and year first above written.

ARCH THERAPEUTICS, INC.

By: _____
Name: Terrence W. Norchi
Title: Chief Executive Officer

**EMPIRE STOCK TRANSFER INC., as
Warrant Agent**

By: _____
Name: _____
Title: _____

EXHIBIT A

COMMON STOCK PURCHASE WARRANT
ARCH THERAPEUTICS, INC.

EXHIBIT B

**WARRANT CERTIFICATE REQUEST
NOTICE**

To: Empire Stock Transfer Inc., 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 C

AUTHORIZED REPRESENTATIVES

Name	Title	Signature
Terrence W. Norchi	Chief Executive Officer	
Michael S. Abrams	Chief Financial Officer	

COMMON STOCK PURCHASE WARRANT

ARCH THERAPEUTICS, INC.

Warrant Shares: _____

Initial Exercise Date: _____, 2023

THIS COMMON STOCK PURCHASE WARRANT (the "Warrant") certifies that, for value received, _____ 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 _____, 2028 (the "Termination Date") but not thereafter, to subscribe for and purchase from Arch Therapeutics, Inc., a Nevada corporation (the "Company"), up to _____ shares of Common Stock (as subject to adjustment hereunder, the "Warrant Shares"). 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. ("Bloomberg") (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 the 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 on 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 other than Saturday, Sunday or other day on which commercial banks in The City of New York are authorized or required by law to remain closed; 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, as amended (File No. 333-268008).

“Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“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, the New York Stock Exchange, OTCQB or OTCQX (or any successors to any of the foregoing).

“Transfer Agent” means Empire Stock Transfer Inc., the current transfer agent of the Company, with a mailing address of 1859 Whitney Mesa Dr., Henderson, NV 89014, and any successor transfer agent of the Company.

“Underwriting Agreement” means the underwriting agreement, dated as of [], 2023 between the Company and Maxim Group LLC as representative of the underwriters named therein, as amended, modified or supplemented from time to time in accordance with its terms.

“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 per share 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 the Common Stock is then listed or quoted on the OTCQB or OTCQX, the volume weighted average price per share 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 on 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 Empire Stock Transfer Inc., the current transfer agent of the Company, with a mailing address of 1859 Whitney Mesa Dr., Henderson, NV 89014, and any successor transfer agent of the Company, 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. Subject to the provisions of Section 2(e) herein, 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 (with a copy to the Company 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”-), and, unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise, delivery of the aggregate Exercise Price of the Warrant Shares specified in the applicable Notice of Exercise as specified in this Section 2(a). 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 Warrant Shares specified in the applicable Notice of Exercise by wire transfer of immediately available funds 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 Company and the Warrant Agent 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. The Company shall use commercially reasonable best efforts to cause the Registration Statement to remain effective with a current prospectus and to maintain the registration of the shares of Common Stock under the Exchange Act for as long as this Warrant remains outstanding. 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 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)(68) 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). Upon receipt of an Election to Purchase for a cashless exercise, the Warrant Agent will promptly deliver a copy of the Election to Purchase to the Company to confirm the number of Warrant Shares issuable in connection with the cashless exercise. The Company shall calculate and transmit to the Warrant Agent in a written notice, and the Warrant Agent shall have no duty, responsibility or obligation under this section to calculate, the number of Warrant Shares issuable in connection with any cashless exercise. The Warrant Agent shall be entitled to rely conclusively on any such written notice provided by the Company, and the Warrant Agent shall not be liable for any action taken, suffered or omitted to be taken by it in accordance with such written instructions or pursuant to the Warrant Agency Agreement.

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 by the Holder 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. 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.

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; provided, however, that the Holder shall be required to return any Warrant Shares or Common Stock subject to any such rescinded exercise notice concurrently with the return to Holder of the aggregate Exercise Price paid to the Company for such Warrant Shares and the restoration of Holder's right to acquire such Warrant Shares pursuant to this Warrant (including, issuance of a replacement warrant certificate evidencing such restored right).

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 to the extent such issuance would exceed such limitation. 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 neither the Company nor the Warrant Agent shall have any obligation to verify or confirm the accuracy of such determination and neither of them shall have any liability for any error made by the Holder or any other Person. 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 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, 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).

c) Pro Rata Distribution. 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, other than cash (including, without limitation, any distribution of 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).

d) 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 (and all of its Subsidiaries, taken as a whole), 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, (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 (other than as a result of a subdivision, combination or reclassification of shares of Common Stock covered by Section 3(a) above), 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 more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (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/or 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. 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(d) pursuant to written agreements in form and substance reasonably satisfactory to the Warrant Agent and 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 succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant with the same effect as if such Successor Entity had been named as the Company herein.

e) Calculations. All calculations under this Section 3 shall be made by the Company 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.

f) 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 Warrant Agent pursuant to Section 4 of the Warrant Agency Agreement and 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 (and all of its Subsidiaries, taken as a whole) is a party, any sale or transfer of all or substantially all of the assets of the Company, 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 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 (or otherwise disclose the material terms of such information) 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.

g) 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, subject to the prior written consent of the Holder, reduce the then current Exercise Price to any amount and for any period of time deemed appropriate by the Board of Directors.

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; *provided*, however, if the Warrant is in definitive form, and the transfer is not among beneficial holders through the facilities of DTC, such transfer shall be accompanied by a signature guarantee from an “eligible guarantor institution” that is a member or participant in the Securities Transfer Agents Medallion Program or other instrument satisfactory to the Warrant Agent. 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. Reserved.

Section 6. 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 any Warrant held in book entry form through DTC, 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.

i. 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).

ii. 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 articles 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 (it being understood that this Warrant shall not in any case prevent the Company from effecting any such amendment, reorganization, transfer, consolidation, merger, dissolution, issuance or sale). 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.

iii. 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. This Warrant shall be deemed to have been executed and delivered in New York and both this Warrant and the transactions contemplated hereby shall be governed as to validity, interpretation, construction, effect, and in all other respects by the laws of the State of New York applicable to agreements wholly performed within the borders of such state and without regard to the conflicts of laws principals thereof (other than Section 5-1401 of The New York General Obligations Law). Each of the Holder and the Company: (a) agrees that any legal suit, action or proceeding arising out of or relating to this Warrant and/or the transactions contemplated hereby shall be instituted exclusively in the Supreme Court of the State of New York, New York County, or in the United States District Court for the Southern District of New York, (b) waives any objection which it may have or hereafter to the venue of any such suit, action or proceeding, and (c) irrevocably consents to the jurisdiction of Supreme Court of the State of New York, New York County, or in the United States District Court for the Southern District of New York in any such suit, action or proceeding. Each of the Holder and the Company further agrees to accept and acknowledge service of any and all process which may be served in any such suit, action or proceeding in the Supreme Court of the State of New York, New York County, or in the United States District Court for the Southern District of New York and agrees that service of process upon the Company mailed by certified mail to the Company's address or delivered by Federal Express via overnight delivery shall be deemed in every respect effective service of process upon the Company, in any such suit, action or proceeding, and service of process upon the Holder mailed by certified mail to the Holder's address or delivered by Federal Express via overnight delivery shall be deemed in every respect effective service process upon the Holder, in any such suit, action or proceeding. THE HOLDER (ON BEHALF OF ITSELF, ITS SUBSIDIARIES AND, TO THE FULLEST EXTENT PERMITTED BY LAW, ON BEHALF OF ITS RESPECTIVE EQUITY HOLDERS AND CREDITORS) HEREBY WAIVES ANY RIGHT HOLDER MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY CLAIM BASED UPON, ARISING OUT OF OR IN CONNECTION WITH THIS WARRANT AND THE TRANSACTIONS CONTEMPLATED BY THIS WARRANT.

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 to the Warrant Agent including, without limitation, any Notice of Exercise, shall be in writing and delivered personally, or sent by a nationally recognized overnight courier service, first-class mail, postage prepaid, addressed to the Warrant Agent, at Empire Stock Transfer Inc., the current transfer agent of the Company, with a mailing address of 1859 Whitney Mesa Dr., Henderson, NV 89014, Attention: [●] or such other facsimile number, email address or address as the Company may specify for such purposes by notice to the Holders and the Company. Any and all notices or other communications or deliveries to be provided to the Company shall be in writing and delivered personally, or e-mail, or sent by a nationally recognized overnight courier service, at 235 Walnut St., Suite 6 Framingham, MA 01702, Attention: Michael S. Abrams, email address: mabrams@archtherapeutics.com, or such other facsimile number, email address or address as the Company may specify for such purposes by notice to the Warrant Agent 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 Warrant Agent. 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 in accordance with 7.12(c) of the Warrant Agency Agreement.

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 depositary), 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 with respect to the rights and obligations between the Holders and the Company, provided that, with respect to the rights, duties, obligations, protections, immunities and liability of the Warrant Agent, the Warrant Agency Agreement shall govern and control.

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: Terrence W. Norchi
Title: Chief Executive Officer

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: _____

McDONALD CARANO

January 30, 2023

Board of Directors
Arch Therapeutics, Inc.
235 Walnut Street, Suite 6
Framingham, MA 01702

Ladies and Gentlemen:

We have acted as special Nevada counsel to Arch Therapeutics, Inc., a Nevada corporation (the “Company”), in connection with the filing by the Company of a Registration Statement on Form S-1 (File No. 333-268008), as amended by Amendment No. 1 and Amendment No. 2 to the Registration Statement (including any preliminary prospectus and prospectus which is a part thereof, and as amended, the “Registration Statement”), with the Securities and Exchange Commission (the “Commission”), under the Securities Act of 1933, as amended (the “Act”), in connection with the offering of (i) units consisting of (a) up to 2,432,432 shares (the “Offered Shares”), of the Company’s common stock, par value \$0.001 per share (the “Common Stock”), and (b) Warrants, as hereinafter defined, to purchase up to 2,432,432 shares of Common Stock (the shares of Common Stock issuable upon exercise of the Warrants are referred to as the “Warrant Shares”), (ii) Underwriter Warrants, as hereinafter defined, to purchase up to 251,757 shares of Common Stock (the shares of Common Stock issuable upon exercise of the Underwriter Warrants are referred to as the “Underwriter Warrant Shares”); and (iii) up to 364,865 shares (the “Option Shares”) of Common Stock and/or warrants to purchase up to 364,865 shares of Common Stock, in the same form as the Warrants (the “Option Warrants”) to be sold upon exercise of the option granted to the underwriters (the shares of Common Stock issuable upon exercise of the Option Warrants are referred to as the “Option Warrant Shares”). The Offered Shares, the Warrants, the Underwriter Warrants, the Option Shares and the Option Warrants will be sold pursuant to an Underwriting Agreement in the form attached to the Registration Statement (the “Agreement”), between the Company and Maxim Group LLC (“Maxim”). The Offered Shares, the Option Shares, the Warrants, the Warrant Shares, the Underwriter Warrants, the Underwriter Warrant Shares, the Option Warrants and the Option Warrant Shares are referred to herein as the “Securities.”

In connection with this opinion, we have examined originals or copies, certified or otherwise identified to our satisfaction, of: (i) the Articles of Incorporation of the Company, as amended through the date hereof (the “Articles of Incorporation”); (ii) the Bylaws of the Company, as amended through the date hereof (the “Bylaws”); (iii) the form of the warrants to be issued, as a unit, in connection with the Offered Shares (the “Warrants”), (iv) the form of the warrants to be issued to Maxim (the “Underwriter Warrants”), (v) certain resolutions of the Board of Directors of the Company or a duly constituted and acting committee thereof (such Board of Directors or committee thereof being hereinafter collectively referred to as, the “Board”), relating to the issuance, sale and registration of the Securities (each, a “Resolution” and collectively, the “Resolutions”); (vi) the form of Agreement; and (vii) the Registration Statement. In addition, we have examined and relied upon originals or copies, certified or otherwise identified to our satisfaction, of certain other corporate records, documents, instruments and certificates of public officials and of the Company, and we have made such inquiries of officers of the Company and public officials and considered such questions of law as we have deemed necessary for purposes of rendering the opinions set forth herein. We have also relied upon the representations and warranties of the Company contained in the Agreement and those certain documents included as exhibits to the Registration Statement. In rendering our opinion, we have made the assumptions that are customary in opinion letters of this kind. We have not verified these assumptions.

mcdonaldcarano.com

100 West Liberty Street • Tenth Floor • Reno, Nevada 89501 • P: 775.788.2000
2300 West Sahara Avenue • Suite 1200 • Las Vegas, Nevada 89102 • P: 702.873.4100



In connection with this opinion, we have assumed the genuineness of all signatures, the legal capacity of natural persons, and the authenticity of all items submitted to us as originals and the conformity with originals of all items submitted to us as copies. In making our examination of documents executed by parties other than the Company, we have assumed that each other party has the power and authority to execute and deliver, and to perform and observe the provisions of, such documents and has duly authorized, executed and delivered such documents, and that such documents constitute the legal, valid and binding obligations of each such party. With respect to certain factual matters, we have relied upon certificates of officers of the Company.

We have further assumed that prior to issuance of the Offered Shares, the Option Shares, the Warrants, the Underwriter Warrants and the Option Warrants, the Board has approved, in conformity with the Articles of Incorporation and Bylaws, (a) the pricing of each Offered Share, Warrant, Option Share, Option Warrant, and Underwriter Warrant; (b) the terms of the Agreement, the Warrants, the Option Warrants, and the Underwriter Warrants; and (c) the number of Offered Shares and Option Shares to be issued, the number of Warrant Shares to be issued pursuant to the Warrants, the number of Option Warrant Shares to be issued pursuant to the Option Warrants; and the number of Underwriter Warrant Shares to be issued pursuant to the Underwriter Warrants. We note that, based solely upon a review of the Resolutions, the Company has reserved, and assume it will continue to maintain reserved, a sufficient number of shares of its duly authorized, but unissued, Common Stock as is necessary to provide for the issuance of the Warrant Shares, the Option Warrant Shares, and the Underwriter Warrant Shares.

We have also assumed that the Agreement, the Warrants, the Option Warrants, and the Underwriter Warrants, and the issuance and sale of the Securities by the Company will not, in each case, violate or constitute a default or breach under: (i) any agreement or instrument to which the Company or its properties is subject; (ii) any law, rule or regulation to which the Company is subject; (iii) any judicial or regulatory order or decree of any governmental authority; or (iv) any consent, approval, license, authorization or validation of, or filing, recording or registration with any governmental authority.

Finally, we have assumed that: (i) the Registration Statement and any amendments thereto will have become effective under the Act and comply with all applicable laws at the time the Securities are offered or issued as contemplated by the Registration Statement; (ii) an appropriate prospectus supplement, free writing prospectus or term sheet relating to the Securities offered thereby will be prepared and filed with the Commission in compliance with the Act and will comply with all applicable laws at the time the Securities are offered or issued as contemplated by the Registration Statement; and (iii) all Securities will be issued and sold in compliance with the applicable provisions of the Act and the securities or blue sky laws of various states and in the manner stated in the Registration Statement and the applicable prospectus supplement, free writing prospectus or term sheet.

Based upon, subject to and limited by the foregoing and the qualifications set forth in subsequent portions of this opinion letter, as of the date hereof, we are of the opinion that:

1. When issued and paid for in accordance with the terms of the Registration Statement, the applicable Resolution, and the Agreement, and when stock certificates or book entry positions representing shares of the Common Stock constituting the Offered Shares and the Option Shares have been duly executed, registered in the books and records of the Company, or delivered, as applicable, the Offered Shares and the Option Shares will be validly issued, fully paid and nonassessable.

2. When issued and paid for in accordance with the terms of the Registration Statement, the applicable Resolution, and the Agreement, the Warrants, the Underwriter Warrants and the Option Warrants will be validly issued.

3. When issued and paid for in accordance with the terms of the applicable Resolution and the Warrants, and when stock certificates or book entry positions representing the Warrant Shares have been duly executed, registered in the books and records of the Company, or delivered, as applicable, the Warrant Shares will be validly issued, fully paid and nonassessable.

4. When issued and paid for in accordance with the terms of the applicable Resolution and the Underwriter Warrants, and when stock certificates or book entry positions representing the Underwriter Warrant Shares have been duly executed, registered in the books and records of the Company, or delivered, as applicable, the Underwriter Warrant Shares will be validly issued, fully paid and nonassessable.

5. When issued and paid for in accordance with the terms of the applicable Resolution and the Option Warrants, and when stock certificates or book entry positions representing the Option Warrant Shares have been duly executed, registered in the books and records of the Company, or delivered, as applicable, the Option Warrant Shares will be validly issued, fully paid and nonassessable.

We are qualified to practice law in the State of Nevada. The opinions set forth herein are expressly limited to and based exclusively on the general corporate laws of the State of Nevada, and we do not purport to be experts on, or to express any opinion with respect to the applicability or effect of, the laws of any other jurisdiction. We express no opinion herein concerning, and we assume no responsibility as to the laws or judicial decisions related to, or any orders, consents or other authorizations or approvals as may be required by, any federal laws, rules or regulations, including, without limitation, any federal securities or bankruptcy laws, rules or regulations, any state securities or “blue sky” laws, rules or regulations or any state laws regarding fraudulent transfers. Our opinion is rendered as of the date hereof, and we assume no obligation to advise you of changes in law or fact (or the effect thereof on the opinions expressed herein) that hereafter may come to our attention.

This opinion is issued in the State of Nevada. By issuing this opinion, McDonald Carano LLP (i) shall not be deemed to be transacting business in any other state or jurisdiction other than the State of Nevada and (ii) does not consent to the jurisdiction of any state other than the State of Nevada. Any claim or cause of action arising out of the opinions expressed herein must be brought in the State of Nevada. Your acceptance of this opinion shall constitute your agreement to the foregoing.

We hereby consent to the filing of this opinion as part of the Registration Statement and to the reference to our firm therein under the caption “Legal Matters.” In giving this consent, we do not admit that we are within the category of persons whose consent is required by Section 7 of the Act or the rules and regulations of the Commission promulgated thereunder.

Sincerely,

/S/ MCDONALD CARANO LLP

MCDONALD CARANO LLP

January 30, 2023

Arch Therapeutics, Inc.
235 Walnut St., Suite 6
Framingham, MA 01702

Ladies and Gentlemen:

We have acted as counsel to Arch Therapeutics, Inc., a Nevada corporation (the “**Company**”), in connection with the proposed sale and issuance of (i) units consisting of (a) 2,432,432 shares (the “**Offered Shares**”), of the Company’s common stock, par value \$0.001 per share (the “**Common Stock**”), and (b) warrants (the “**Investor Warrants**”) to purchase up to 2,432,432 shares of Common Stock (the shares of Common Stock issuable upon exercise of the Warrants are referred to as the “**Investor Warrant Shares**”), (ii) underwriter warrants (“**Underwriter Warrants**”) to purchase up to 251,757 shares of Common Stock (the shares of Common Stock issuable upon exercise of the Underwriter Warrants are referred to as the “**Underwriter Warrant Shares**”); and (iii) up to 364,865 shares (the “**Option Shares**”) of Common Stock and/or warrants to purchase up to 364,865 shares of Common Stock, in the same form as the Investor Warrants (the “**Option Warrants**”) to be sold upon exercise of the option granted to the underwriters (the shares of Common Stock issuable upon exercise of the Option Warrants are referred to as the “**Option Warrant Shares**”), pursuant to the Registration Statement on Form S-1 (File No. 333-268008), as amended by Amendment No. 1 and Amendment No. 2 to the Registration Statement (as amended, the “**Registration Statement**”), filed by the Company with the Securities and Exchange Commission (the “**Commission**”) under the Securities Act of 1933, as amended (the “**Securities Act**”), and the rules and regulations promulgated thereunder, together with the prospectus contained therein (the “**Prospectus**”). The Offered Shares, the Investor Warrants, the Underwriter Warrants, the Option Shares and the Option Warrants are to be sold pursuant to an Underwriting Agreement (the “**Agreement**”) between the Company and Maxim Group LLC (the “**Underwriter**”).

As counsel to the Company in connection with the proposed sale and issuance of the above-referenced Offered Shares, the Option Shares, the Investor Warrants, the Investor Warrant Shares, the Underwriter Warrants, the Underwriter Warrant Shares, the Option Warrants and the Option Warrant Shares, we have reviewed the Registration Statement, Prospectus and the respective exhibits thereto (including the Form of Underwriting Agreement, Form of Investor Warrant, and the Form of Underwriter Warrant). We have also reviewed such corporate documents and records of the Company, such certificates of public officials and officers of the Company and such other matters as we have deemed necessary or appropriate for purposes of this opinion. In our examination, we have assumed: (i) the authenticity of original documents and the genuineness of all signatures; (ii) the conformity to the originals of all documents submitted to us as copies; (iii) the truth, accuracy and completeness of the information, representations and warranties contained in the instruments, documents, certificates and records we have reviewed; (iv) that, as set forth in a separate opinion delivered to the Company on the date hereof by McDonald Carano LLP, special Nevada counsel to the Company, the Investor Warrants, the Underwriter Warrants and the Option Warrants have been duly authorized and validly issued; and (v) the legal capacity for all purposes relevant hereto of all natural persons and, with respect to all parties to agreements or instruments relevant hereto other than the Company, that such parties had the requisite power and authority (corporate or otherwise) to execute, deliver and perform such agreements or instruments, that such agreements or instruments have been duly authorized by all requisite action (corporate or otherwise), executed and delivered by such parties and that such agreements or instruments are the valid, binding and enforceable obligations of such parties. As to any facts material to the opinions expressed herein that were not independently established or verified, we have relied upon oral or written statements and representations of officers and other representatives of the Company.

Based on the foregoing, and subject to the assumptions, limitations and qualifications set forth herein, we are of the opinion that when the Investor Warrants, Underwriter Warrants and Option Warrants are duly executed and delivered by the Company pursuant to the Agreement, such Investor Warrants, Underwriter Warrants and Option Warrants will constitute the legal, valid and binding obligation of the Company, enforceable against the Company in accordance with their terms, subject to bankruptcy, insolvency or other similar laws affecting creditors’ rights and to general equitable principles.

The opinion set forth above is subject to the following exceptions, limitations and qualifications: (i) the effect of bankruptcy, insolvency, reorganization, fraudulent conveyance, moratorium or other similar laws now or hereafter in effect relating to or affecting the rights and remedies of creditors; (ii) the effect of general principles of equity, including without limitation, concepts of materiality, reasonableness, good faith and fair dealing and the possible unavailability of specific performance or injunctive relief, regardless of whether enforcement is considered in a proceeding in equity or at law, and the discretion of the court before which any proceeding therefor may be brought; and (iii) the unenforceability under certain circumstances under law or court decisions of provisions providing for the indemnification of, or contribution to, a party with respect to liability where such indemnification or contribution is contrary to public policy. We express no opinion concerning the enforceability of any waiver of rights or defenses with respect to stay, extension or usury laws.

Our opinion is limited to the laws of New York. We express no opinion as to the effect of the law of any other jurisdiction. Our opinion is rendered as of the date hereof, and we assume no obligation to advise you of changes in law or fact (or the effect thereof on the opinions expressed herein) that hereafter may come to our attention. We advise you that matters of Nevada law are covered in the opinion of McDonald Carano LLP, special Nevada counsel for the Company, in Exhibit 5.1 to the Registration Statement.

We hereby consent to the inclusion of this opinion as Exhibit 5.2 to the Registration Statement and to the references to our firm therein and in the Prospectus under the caption "Legal Matters." In giving our consent, we do not admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations thereunder.

Very truly yours,

/s/ Lowenstein Sandler LLP

Lowenstein Sandler LLP

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the use in this Amendment No. 2 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

January 30, 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	0.0001102	\$1,710.86
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	Common Stock issuable upon exercise of the Investor Warrants(3)(5)	Rule 457(o)	—	—	\$15,525,000	0.0001102	\$1,710.86
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	0.0001102	\$153.98
Fees Previously Paid	—	—	—	—	—	—	—	\$3,972.99
Carry Forward Securities	—	—	—	—	—	—	—	—
Total Offering Amounts						\$32,447,250		\$3,575.75
Total Fees Previously Paid								\$3,972.99
Total Fee Offsets								\$0.00
Net Fee Due								\$0.00

- (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 Maxim Group LLC (or its designees), the representative of the underwriters, warrants (the “**Underwriter Warrants**”) to purchase the number of shares equal to nine percent (9%) of the shares 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 110% of the price per Unit in this offering.