As filed with the U.S. Securities and Exchange Commission on January 23, 2023

Registration No. 333-268008

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

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

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

ARCH THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Nevada	**3841**	**46-0524102**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(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)

Terrence W. Norchi
President and Chief Executive Officer
235 Walnut St., Suite 6
Framingham, MA 01702
(617) 431-2313
(Name, address, including zip code, and telephone number, including area code, of agent for service)

With Copies to:

Michael J. Lerner **Alan Wovsaniker** **Lowenstein Sandler LLP** **One Lowenstein Drive** **Roseland, NJ 07068** **(973) 597-2500**	**Mitchell S. Nussbaum** **David J. Levine** **Loeb & Loeb LLP** **345 Park Avenue** **New York, NY 10154** **(212) 407-4159**

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 □	Accelerated filer □
Non-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 23, 2023

PRELIMINARY PROSPECTUS

ARCH THERAPEUTICS, INC.

[●] Units consisting of
[●] Shares of Common Stock and
Investor Warrants to Purchase up to [●] 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 [●], 2023, was $[●] per share. 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 "ARTH.W," 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.

	Per Unit	Total
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 [●] shares of Common Stock at the public offering price and/or Investor Warrants to purchase up to [●] 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

This prospectus relates to the primary offering and sale by Arch Therapeutics, Inc. of [●] Units, each consisting of one share of Common Stock and one Investor Warrant to purchase one share of Common Stock. This prospectus also registers the [●] shares (or [●] 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 "ARTH.W," 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	[●] 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)	[●] shares ([●] 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 [●] 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.
Description of Investor Warrants	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. This prospectus also registers the 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.

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 the shares (or shares if the underwriters exercise their over-allotment option in full) of Common Stock issuable upon exercise of the Underwriter Warrants.
Use of proceeds	We estimate that we will receive net proceeds from this offering of approximately $[●], or approximately $[●] if the underwriters exercise their over-allotment option in full, based upon an assumed public offering price of per Unit and after deducting the underwriting discounts and commissions and estimating offering expenses payable by us. 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.
Market for Common Stock	Our Common Stock is traded on the OTCQB under the symbol "**ARTHD**." On January [●], 2023, the closing price of our Common Stock was $[●] per share. 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) [●] shares of Common Stock issuable upon exercise of the Investor Warrants to be issued in this offering; and (xix) [●] 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 additional shares of Common Stock and/or Investor Warrants.

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.

 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 concer*n**," 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 technolJogies 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 $[●], 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 world increase, and the probability of successfully commercializing a product would decrease. Any or all of those circumstances would materially adversely affect our business.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to our Intellectual Property

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

Our success will depend in large part on our ability to obtain and maintain protection in the U.S. and other countries for the intellectual property rights covering or incorporated into our technology and products. The ability to obtain patents covering technology in the field of medical devices generally is highly uncertain and involves complex legal, technical, scientific and factual questions. We may not be able to obtain and maintain patent protection relating to our technology or products. Many of our owned or licensed patent applications are pending. Even if issued, patents issued or licensed to us may be challenged, narrowed, invalidated, held to be unenforceable or circumvented, or determined not to cover our product candidates or our competitors' products, which could limit our ability to stop competitors from marketing identical or similar products. Because our patent portfolio includes certain patents and applications that are in-licensed on a non-exclusive basis, other parties may be able to develop, manufacture, market and sell products with similar features covered by the same patent rights and technologies, which in turn could significantly undercut the value of any of our product candidates and adversely affect our business. Our licensed 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 "ARTH.W," 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 deficit 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. 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 $[●] per share (the last reported sale price of our Common Stock on the OTCQB on January [●], 2023), if you purchase shares of our Common Stock, you will suffer immediate and substantial dilution of $[●] per share with respect to the net tangible book deficit 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 $[●] million from this offering (or approximately $[●] 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 $[●] per Unit (the last reported sale price of our Common Stock on the OTCQB on January [●], 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 $0.01 increase (decrease) in the assumed public offering price of $[●] per Unit (the last reported sale price of our Common Stock on the OTCQB on January [●], 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 $[●], 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 $[●], 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 "ARTH.W", respectively. There is no assurance that our listing application will be approved by the Nasdaq Capital Market, or, if successful, that an active trading market for our Common Stock or Investor Warrants will develop or be sustained. If we are unable to list our Common Stock on the Nasdaq Capital Market or an Alternate Exchange, we will not consummate this offering.

Dividends

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

Holders

As of 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 the public offering price of $[●] 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		
	Actual	Pro Forma	Pro Forma As Adjusted
	(unaudited)	(unaudited)	(unaudited) (1)
Cash	$ [●]	$ [●]	$ [●]
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	[●]		
Additional paid-in capital	$ [●]	$ [●]	$ [●]
Accumulated deficit	$ [●]	$ [●]	$ [●]
Total stockholders' (deficit) equity	$ [●]	$ [●]	$ [●]
Total capitalization	$ [●]	$ [●]	$ [●]

(1) A $0.01 increase or decrease in the assumed public offering price of $[●] per Unit (the last reported sale price of our Common Stock on the OTCQB on January [●], 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 $[●] 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 $[●], 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;
- [●] shares of Common Stock issuable upon the exercise of Investor Warrants to be issued in this offering; and
- [●] 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, including any shares sold in the over-allotment option, if any, as described in "**Underwriting**."

Except as indicated otherwise, the discussion and table above assume no exercise of the underwriters' option to purchase additional shares of Common Stock and/or Investor Warrants.

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 deficit per share of our Common Stock after this offering. We calculate net tangible book deficit per share by dividing the net tangible book deficit (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 $[●], or approximately $[●] 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 $[●], or $[●] 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 public offering price of $[●] 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 deficit as of September 30, 2022 would have been approximately $[●] million, or approximately $[●] per share of Common Stock. This amount represents an immediate increase in actual book deficit of $[●] per share to our existing stockholders and immediate dilution of approximately $[●] 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 deficit 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		$ [●]
Net (deficit) tangible book deficit per share as of September 30, 2022	$ [●]	
Pro forma net tangible book deficit per share after giving effect to the Second Closing	[●]	
Increase in pro forma net tangible book deficit per share after giving effect to this offering (excluding the Second Closing)	[●]	
Pro forma, as adjusted net tangible book deficit per share as of September 30, 2022 after giving effect to this offering and the Second Closing	[●]	
Dilution per share to new investors in this offering	[●]	

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

Each $0.01 increase (decrease) in the assumed public offering price of $[●] per Unit (the last reported sale price of our Common Stock on the OTCQB on January [●], 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 $[●], 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 $, 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;
- [●] shares of Common Stock issuable upon the exercise of Investor Warrants to be issued in this offering; and
- [●] 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, including any shares sold in the over-allotment option, if any, as described in “Underwriting.”

Except as indicated otherwise, the discussion and table above assume no exercise of the underwriter’s option to purchase additional shares of Common Stock and/or Investor Warrants.

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 principle 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 warrants 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.

O*ther 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

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.

Ca*sh 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 or our self-assembling peptide technology and our product safety and performance specifications. Those features, which include, among others, that they possess barrier properties and can create an environment permissive to healing, can deliver a benefit in the treatment of external and internal wounds that are open, exposed, bleeding, leaking, and/or at risk for excessive inflammation or contamination.

Dermal Sciences

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

Wounds can vary widely in terms of degree of bleeding and oozing, chronicity, acuity, complications, anatomic location, biochemistry, 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 addition 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, Universality 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 scares 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 Cellanyx 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 will consist 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, *President and Chief Executive Officer*	2022	450,500	-	-	-	-	450,500
	2021	450,500	27,030	-	157,400	-	634,930
Michael S. Abrams, *Chief Financial Officer*	2022	325,000	-	-	-		325,000
	2021	135,417	-	-	66,895	-	202,312
Daniel Yrigoyen, *VP of Sales*	2022	316,667	-	-	9,075		325,742
	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:

	Option Awards					Stock Awards	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable		Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)
Dr. Terrence W. Norchi	2,500	-	(1)	70.00	03/23/2024		
	2,000	-	(2)	38.00	01/21/2025		
	1,775	-	(3)	56.00	08/17/2025		
	6,250	-	(4)	78.00	05/02/2026		
	3,250	-	(5)	130.00	02/02/2027		
	1,800	-	(6)	85.00	07/18/2028		
	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**
5%+ Stockholders:			
Michael A. Parker (2)	112,097	8.90%	1%
Named Executive Officers and Directors:			
Terrence Norchi (3)	102,226	7.90%	1%
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%	1%
Maxim Partners LLC (9)	31,510	2.50%	1%

* Less than 1%.

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 [●] 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 underwriter does not exercise its 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 [●] 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 [●] 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 "ARTH.W." 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 [●] shares of Common Stock issuable upon exercise of the Underwriter Warrants. 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 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 its name below.

Underwriter	Number of Units
Maxim Group LLC	[●]
Total	[●]

The underwriter is committed to purchase all the Units offered by us if they buy any of them. However, the underwriter is not obligated to purchase the shares and Investor Warrants covered by the underwriter's over-allotment option described below. The underwriter is 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 underwriter to purchase the Units included in this offering are subject to approval of legal matters by their counsel and to other conditions. The underwriter reserves 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 underwriter 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 underwriter 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 underwriter 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 underwriter proposes 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 underwriter 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 underwriter 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 underwriter's 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 underwriter of its over-allotment option:

		Total	
	Per Unit	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 underwriter against certain liabilities, including liabilities under the Securities Act, or to contribute to payments that the underwriter 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 "ARTH.W," 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 underwriter 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 underwriter's 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 underwriter 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

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	2,598,195	3,667,745
Long-term assets:		
Property and equipment, net	2,044	5,240
Other assets	3,500	3,500
Total long-term assets	5,544	8,740
Total assets	$ 2,603,739	$ 3,676,485
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	3,320,494	1,727,547
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	3,476,048	2,974,612
Total liabilities	6,796,542	4,702,159
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	(4,192,803)	(1,025,674)
Total liabilities and stockholders' deficit	$ 2,603,739	$ 3,676,485

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

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

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

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

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

Fiscal Year Ended September 30, 2022	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
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	1,249,432	$ 1,249	$ 50,878,721	$ (55,072,773)	$ (4,192,803)

Fiscal Year Ended September 30, 2021	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
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	1,183,599	$ 1,184	$ 48,770,061	$ (49,796,919)	$ (1,025,674)

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.

Cash and Cash Equivalents

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

Inventories

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

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist primarily of cash. The Company maintains its cash in bank deposits accounts, which, at times, may exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk on cash.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful life of the related asset. Upon sale or retirement, the cost and accumulated depreciation are eliminated from their respective accounts, and the resulting gain or loss is included in income or loss for the period. Repair and maintenance expenditures are charged to expense as incurred.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment when circumstances indicate the carrying value of an asset may not be recoverable in accordance with FASB ASC Topic 360, *Property, Plant and Equipment*. For assets that are to be held and used, impairment is recognized when the estimated undiscounted cash flows associated with the asset or group of assets is less than their carrying value. If impairment exists, an adjustment is made to write the asset down to its fair value, and a loss is recorded as the difference between the carrying value and fair value. Fair values are determined based on quoted market values, discounted cash flows or internal and external appraisals, as applicable. Assets to be disposed of are carried at the lower of carrying value or estimated net realizable value. For the years ended September 30, 2022 and 2021 there has not been any impairment of long-lived assets.

Leases

The Company determines if an arrangement is a lease at its inception. Operating lease right-of-use ("*ROU*") assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As our lease does not provide an implicit interest rate, the Company used an incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Income Taxes

In accordance with FASB ASC Topic 740, *Income Taxes* ("*ASC 740*"), the Company recognizes deferred tax assets and liabilities for the expected future tax consequences or events that have been included in our consolidated financial statements and/or tax returns. Deferred tax assets and liabilities are based upon the differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities and for loss and credit carryforwards using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

The Company provides reserves for potential payments of tax to various tax authorities related to uncertain tax positions when management determines that it is more likely than not that a loss will be incurred related to these matters and the amount of the loss is reasonably determinable.

Revenue

In accordance with FASB ASC Topic 606, *Revenue Recognition*, the Company recognizes revenue through a five-step process: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) a performance obligation is satisfied.

The Company's source of revenue is product sales. Contracts with customers contain a single performance obligation and the Company recognizes revenue from product sales when the Company has satisfied our performance obligation by transferring control of the product to the customers. Control of the product transfers to the customer upon shipment from the Company's third-party warehouse. The Company launched a reimbursement support program in September 2022. Under the terms of the program, the invoice amount may be adjusted through full or partial write-offs based on actual reimbursement amounts paid by for Medicare and Medicaid Services ("CMS") for AC5 units applied and billed by doctors. As such, revenue, if any, for the units shipped in connection with the Company's reimbursement support program will be booked in future periods when all conditions have been satisfied.

Cost of Revenues

Cost of revenues includes product costs, warehousing, overhead allocation and royalty expenses.

Research and Development

The Company expenses internal and external research and development costs, including costs of funded research and development arrangements, in the period incurred.

Accounting for Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with the guidance of FASB ASC Topic 718, *Compensation-Stock Compensation* ("*ASC 718*"), which requires all share-based payments be recognized in the consolidated financial statements based on their fair values. In accordance with ASC 718, the Company has elected to use the Black-Scholes option pricing model to determine the fair value of options granted and recognizes the compensation cost of share-based awards on a straight-line basis over the vesting period of the award.

The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by the fair value of the common stock and a number of other assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. The expected life for awards uses the simplified method for all "plain vanilla" options, as defined in ASC 718-10-S99, and the contractual term for all other employee and non-employee awards. The risk-free interest rate assumption is based on observed interest rates appropriate for the terms of our awards. The dividend yield assumption is based on history and the expectation of paying no dividends. Stock-based compensation expense, when recognized in the consolidated financial statements, is based on awards that are ultimately expected to vest.

Fair Value Measurements

The Company measures both financial and nonfinancial assets and liabilities in accordance with FASB ASC Topic 820, *Fair Value Measurements and Disclosures*, including those that are recognized or disclosed in the consolidated financial statements at fair value on a recurring basis. The standard created a fair value hierarchy which prioritizes the inputs to valuation techniques used to measure fair value into three broad levels as follows: Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities; Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and Level 3 inputs are unobservable inputs that reflect the Company's own views about the assumptions market participants would use in pricing the asset or liability.

At September 30, 2022 and 2021, the carrying amounts of cash, accounts payables and accrued expenses and other liabilities approximate fair value because of their short-term nature. The carrying amounts for the Convertible Notes (See Notes 11 and 12) approximate fair value because borrowing rates and the terms are similar to comparable market participants. The carrying amounts of the Derivative Liabilities (See Note 7) are valued using Level 3 inputs and are recognized in the consolidated financial statements at fair value.

Derivative Liabilities

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

Complex Financial Instruments

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

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

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

Financial Statement Reclassification

Certain balances in the prior year consolidated financial statements have been reclassified for comparison purposes to conform to the presentation in the current year consolidated financial statements. These reclassifications had no effect on the reported results of operations or financial position.

Subsequent Events

The Company evaluated all events or transactions through December 28, 2022, the date which these consolidated financial statements were issued. Please note the following matters deemed to be subsequent events.

CMS HCPCS Code Status

On December 5, 2022, the Company announced that the Centers for Medicare and Medicaid Services ("CMS") made a preliminary recommendation to establish a dedicated Healthcare Common Procedure Coding System ("HCPCS") Level II billing code specific to AC5® Advanced Wound System ("AC5"). The preliminary recommendation was discussed at CMS' First Biannual 2022 HCPCS Public Meeting, which was held on November 30, 2022. The HCPCS code would better enable providers to bill third party payors for AC5® Advanced Wound System that is used in doctors' offices. Although the establishment of a dedicated HCPCS code does not guarantee coverage or reimbursement, a HCPCS code specific to AC5® Advanced Wound System would also enhance the Company's ability to work directly with payors and expand access in outpatient settings.

Going Concern Basis of Accounting

As reflected in the consolidated financial statements, the Company has an accumulated deficit as of September 30, 2022, has suffered significant net losses and negative cash flows from operations, only recently commenced generating limited operating revenues, and has limited working capital. The continuation of the Company's business as a going concern is dependent upon raising additional capital, the ability to successfully market and sell its product and eventually attaining and maintaining profitable operations. In particular, as of September 30, 2022, the Company will be required to raise additional capital, obtain alternative means of financial support, or both, in order to continue to fund operations, and therefore there is substantial doubt about the Company's ability to continue as a going concern. The Company expects to incur substantial expenses into the foreseeable future for the research, development and commercialization of its current and potential products. In addition, the Company will require additional financing in order to seek to license or acquire new assets, research and develop any potential patents and the related compounds, and obtain any further intellectual property that the Company may seek to acquire. Finally, some of our product candidates or the materials contained therein (such as the Active Pharmaceutical Ingredients for our AC5® product line), are manufactured from facilities in areas impacted by the outbreak of the COVID-19, which could result in shortages due to ongoing efforts to address the outbreak. Historically, the Company has principally funded operations through debt borrowings, the issuance of convertible debt, and the issuance of units consisting of common stock and warrants. Provisions in the Securities Purchase Agreements that the Company entered into on June 28, 2018 ("*2018 SPA*"), and July 6, 2022 ("*2022 SPA*") restrict the Company's ability to effect or enter into an agreement to effect any issuance by the Company or its subsidiary of Common Stock or securities convertible, exercisable or exchangeable for Common Stock (or a combination of units thereof) involving a Variable Rate Transaction (as defined in the 2018 SPA and 2022 SPA) including, but not limited to, an equity line of credit or "At-the-Market" financing facility until the institutional investors in the 2018 SPA collectively own less than 20% of the Series F Warrants and the Series G Warrants purchased by them pursuant to the and 2018 SPA, respectively and for a period of six months pursuant to the 2022 SPA. In addition, under the 2022 SPA, we are required to complete an uplist to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American by February 15, 2023. See Note 6 for more information on the 2018 Financing, including the terms of the Series F Warrants and Series G Warrants. and Note 10 for more information on the 2022 Note Financing, including the terms of the 2022 Warrants and 2022 Placement Agent Warrants.

The 2021 SPA contains certain restrictions on our ability to conduct subsequent sales of our equity securities (See Note 9). The continued spread of COVID-19 and uncertain market conditions may also limit the Company's ability to access capital. If the Company is unable to obtain adequate capital, the Company may be required to reduce the scope, delay, or eliminate some or all of its planned activities. These conditions, in the aggregate, raise substantial doubt as to the Company's ability to continue as a going concern.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The consolidated financial statements do not include any adjustments that might result from this uncertainty.

3. PROPERTY AND EQUIPMENT

At September 30, 2022 and 2021, property and equipment consisted of:

	Estimated Useful Life (in years)	September 30, 2022	September 30, 2021
Furniture and fixtures	5	$ 9,357	$ 9,357
Leasehold improvements	Life of Lease	8,983	8,983
Computer equipment	3	14,416	14,416
Lab equipment	5	1,000	1,000
		33,756	33,756
Less – accumulated depreciation		31,712	28,516
Property and equipment, net		$ 2,044	$ 5,240

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	$ 1,414,848	$ 1,093,765

The Company capitalizes inventory that has been produced for commercial sale and has been determined to have a probable future economic benefit. The determination of whether or not the inventory has a future economic benefit requires estimates by management, to the extent that inventory is expected to expire prior to being sold or used for research and development or used for samples, the Company will write down the value of inventory. In evaluating the net realizable value of the inventory, appropriate consideration is given to obsolescence, excessive levels, deterioration, and other factors.

5. INSURANCE PREMIUM FINANCING

In July 2022, the Company entered into a finance agreement with First Insurance Funding in order to fund a portion of its insurance policies. The amount financed is approximately $354,000 and incurs interest at a rate of 2.99%. The Company is required to make monthly payments of approximately $35,000 through April 2023. The outstanding balance as of September 30, 2022 was approximately $248,000.

6. REGISTERED DIRECT OFFERINGS

On September 30, 2016, the Company filed a registration statement with the SEC utilizing a “shelf” registration process, which was subsequently declared effective by the SEC on October 20, 2016 (such registration statement, the “*Shelf Registration Statement*”). Under the Shelf Registration Statement, the Company may offer and sell any combination of its Common Stock, warrants, debt securities, subscription rights, and/or units comprised of the foregoing to raise up to $50,000,000 in gross proceeds.

On February 20, 2017, the Company entered into a Securities Purchase Agreement (the “2017 SPA”) with six accredited investors (collectively, the "2017 “ Investors”) providing for the issuance and sale by the Company to the 2017 Investors of an aggregate of 50,833 units at a purchase price of $120.00 per unit in a registered offering (the “2017 Financing”). The securities comprising the units sold in the 2017 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant equal to 55% of the shares of Common Stock at an exercise price of $150.00 per share (“Series F Warrant”) at any time prior to the fifth anniversary of the issuance date of the Series F Warrant subject to certain restrictions on exercise (the "2017“ Warrants”) and the shares issuable upon exercise of the 2017 Warrants (the "2017“ Warrant Shares”).

On June 28, 2018, the Company entered into a Securities Purchase Agreement (“2018 SPA”) with eight accredited investors (collectively, the “2018 Investors”) providing for the issuance and sale by the Company to the 2018 Investors of an aggregate of 45,350 units at a purchase price of $100.00 per unit in a registered offering (“2018 Financing”). The securities comprising the units sold in the 2018 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant to purchase up to a number of shares of the Company’s Common Stock equal to 75% of the shares of Common Stock at an exercise price of $140.00 per share (“*Series G Warrant*”) at any time prior to the fifth anniversary of the issuance date of the Series G Warrant subject to certain restrictions on exercise (the “*2018 Warrants*”) and the shares issuable upon exercise of the 2018 Warrants (the “*2018 Warrant Shares*”).

On May 12, 2019, the Company entered into a Securities Purchase Agreement ("*2019 SPA*") with five accredited investors (collectively, the "*2019 Investors*") providing for the issuance and sale by the Company to the 2019 Investors of an aggregate of 43,077 units at a purchase price of $65.00 per unit in a registered offering ("*2019 Financing*"). The securities comprising the units sold in the 2019 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant to purchase one share of Common Stock at an exercise price of $80.00 per share ("*Series H Warrant*") at any time prior to the fifth anniversary of the issuance date of the Series H Warrant subject to certain restrictions on exercise (the "*2019 Warrants*") and the shares issuable upon exercise of the *2019* Warrants (the "*2019 Warrant Shares*").

During the years ended September 30, 2022 and 2021, no Series F, Series G or Series H Warrants had been exercised. As of September 30, 2022, up to 34,013 and 43,077 shares may be acquired upon the exercise of the Series G and Series H Warrants, respectively.

During the year ended September 30, 2022, all 27,958 remaining Series F Warrants expired.

7. Derivative Liabilities

The Company accounted for the Series F Warrants, Series G Warrants and the Series H Warrants in accordance with ASC 815-10. Since the Company may be required to purchase its Series F Warrants, Series G Warrants and Series H Warrants for an amount of cash equal to $36.00, $22.00 and $10.66, respectively, for each share of Common Stock ("Minimum") they are recorded as liabilities at the greater of the Minimum or fair value. They are marked to market each reporting period through the Consolidated Statement of Operations. During the year ended September 30, 2022, the Company recognized income of $1,000,000 for the expiration of the Series F Warrants.

On the respective closing dates, the derivative liabilities related to the Series G Warrants and Series H Warrants were recorded at an aggregate fair value of $1,628,113. Given that the fair value of the derivative liabilities was less than the net proceeds, the remaining proceeds were allocated to Common Stock and additional-paid-in-capital. For the fiscal year ended September 30, 2021, the Company recorded income of $108,944 in connection with the decrease in the fair value of the derivative liability.

Fair Value Measurements Using Significant Unobservable Inputs - Year Ended September 30, 2022
(Level 3)

	Series F	Series G	Series H
Beginning balance at September 30, 2021	$ 1,000,000	$ 748,275	$ 459,200
Issuances	—	—	—
Adjustments for the expiration of warrant	(1,000,000)	—	—
Ending balance at September 30, 2022	$ —	$ 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

The derivative liabilities are recorded as liabilities at September 30, 2022 using the greater of the minimum value or the Black Scholes Model with the following assumptions. As of September 30, 2022, the derivative liabilities are recorded at their minimum value.

	Series G	Series H
Closing price per share of Common Stock		
Exercise price per share	$ 140.00	$ 80.00
Expected volatility	132.97%	122.50%
Risk-free interest rate	4.05%	4.14%
Dividend yield	—	—
Remaining expected term of underlying securities (years)	0.69	1.57

During the year ended September 30, 2022, the Series F Warrants expired.

The derivative liabilities are recorded as liabilities at September 30, 2021 using the greater of the minimum value or the Black Scholes Model with the following assumptions. As of September 30, 2021, the derivative liabilities are recorded at their minimum value.

	Series F	Series G	Series H
Closing price per share of Common Stock	$ 0.12	$ 0.12	$ 0.12
Exercise price per share	$ 150.00	$ 140.00	$ 80.00
Expected volatility	90.28%	87.40%	86.59%
Risk-free interest rate	0.04%	0.19%	0.41%
Dividend yield	—	—	—
Remaining expected term of underlying securities (years)	0.34	1.70	2.58

8. OCTOBER 2019 REGISTERED DIRECT OFFERING

On October 16, 2019, the Company entered into a Securities Purchase Agreement (the "*October 2019 SPA*") with seven accredited investors (collectively, the "*October 2019 Investors*") providing for the issuance and sale by the Company to the 2019 Investors of an aggregate of 71,429 units at a purchase price of $35.00 per unit in a registered offering ("*October 2019 Financing*"). The securities comprising the units sold in the October 2019 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant to purchase one share of Common Stock at an exercise price of $44.00 per share ("*Series I Warrant*") at any time prior to the fifth anniversary of the issuance date of the Series I Warrant subject to certain restrictions on exercise and the shares issuable upon exercise of the Series I Warrants (collectively, the " *October 2019 Warrant Shares*"). As of October 18, 2019, the Company recorded the 71,429 shares as Common Stock. Pursuant to the Engagement Agreement (as defined below), the Company also agreed to issue to the Placement Agent, or its designees, warrants to purchase up to 5,358 shares (the "*Placement Agent Warrants*"). The 2019 Placement Agent Warrants have substantially the same terms as the Series I Warrants, except that the exercise price of the Placement Agent Warrants is $43.75 per share and the term of the Placement Agent Warrants is five years.

The gross proceeds to the Company from the October 2019 Financing, which were received as of October 18, 2019, were approximately $2.5 million before deducting financing costs of approximately $333,000 which includes approximately $158,000 of placement fees. The number of shares of the Company's Common Stock into which each of the Series I Warrants is exercisable and the exercise price therefore are subject to adjustment, as set forth in the Series I Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise).

The Company engaged H.C. Wainwright as its exclusive institutional investor placement agent (the "*Placement Agent*") in connection with the October 2019 SPA pursuant to an engagement agreement dated as of October 10, 2019 (the "*2019 Engagement Agreement*"). In consideration for the services provided by the Placement Agent, the Placement Agent was entitled to receive cash fees ranging from 6.0% to 8.2% of the gross proceeds received by the Company, as well as reimbursement for all reasonable expenses incurred by it in connection with its engagement. The Company received gross proceeds of approximately $2.5 million in the aggregate, resulting in a fee of approximately $158,000.

During the year ended September 30, 2022, no Series I Warrants or Placement Agent Warrants have been exercised. As of September 30, 2022, up to 71,429 and 5,358 shares may be acquired upon the exercise of the Series I Warrants and Placement Agent Warrants, respectively.

Common Stock

At October 18, 2019 the Closing Date of the October 2019 Financing, the Company issued 71,429 shares of Common Stock.

Equity Value of Warrants

The Company accounted for the Series I Warrants and the Placement Agent Warrants relating to the aforementioned October 2019 Registered Direct Offering in accordance with ASC 815-40. Because the Series I Warrants and the Placement Agent Warrants are indexed to the Company's stock, they are classified within stockholders' equity (deficit) in the accompanying consolidated financial statements.

9. 2021 REGISTERED DIRECT OFFERING

On February 11, 2021, the Company entered into a Securities Purchase Agreement (the "*2021 SPA*") with certain institutional and accredited investors (collectively, "*2021 Investors*") providing for the issuance and sale by the Company to the 2021 Investors of an aggregate of 215,625 shares (the "Shares") of the Company's Common Stock, and warrants (the "*Series K Warrants*") to purchase an aggregate of 161,719 shares (the "*Warrant Shares*") of Common Stock, at a combined offering price of $32.00 per share (the "*2021 Financing*"). The Series K Warrants have an exercise price of $34.00 per share and are exercisable for a period of 5.5 years. The aggregate gross proceeds for the sale of the Shares and Series K Warrants were approximately $6.9 million, before deducting the Placement Agent's fees and expenses and other offering expenses payable by the Company, of approximately $700,000. Pursuant to an engagement agreement dated as of February 8, 2021 (the "*2021 Engagement Agreement*"), by and between the Company and the Placement Agent, the Company agreed to pay the Placement Agent cash fees equal to (i) 7.5% of the gross proceeds received by the Company from certain investors in the 2021 Financing, and (ii) 6.0% of the gross proceeds received by the Company from certain investors that had pre-existing relationships with the Company. In addition, the Placement Agent received a one-time non-accountable expense fee of $10,000, up to $50,000 for fees and expenses of legal counsel and other out-of-pocket expenses and $10,000 for clearing expenses. Pursuant to the 2021 Engagement Agreement, the Company also agreed to issue to the Placement Agent, or its designees, warrants to purchase up to 7.5% of the aggregate number of Shares sold to the 2021 Investors, or warrants to purchase up to 16,172 shares (the "2021 *Placement Agent Warrants*") of the Company's Common Stock. The 2021 Placement Agent 2 Warrants have substantially the same terms as the Series K Warrants, except that the exercise price of the 2021 Placement Agent Warrants is $40.00 per share. The 2021 Engagement Agreement contained indemnity and other customary provisions for transactions of this nature.

The 2021 SPA contained certain restrictions on the Company's ability to conduct subsequent sales of the Company's equity securities. In particular, we were prohibited from entering into or effecting a Variable Rate Transaction (as defined in the 2021 SPA) until February 11, 2022; provided, however, the Company may enter into and effect an at-the-market offering facility with the Placement Agent.

The number of shares of the Company's Common Stock into which each of the Series K Warrants is exercisable and the exercise price therefore are subject to adjustment, as set forth in the Series K Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise). During the fiscal year ended September 30, 2022, no Series K Warrants or 2021 Placement Agent Warrants had been exercised. As of September 30, 2022, up to 161,719 and 16,172 shares may be acquired upon the exercise of the Series K Warrants and Placement Agent Warrants, respectively.

Common Stock

On February 17, 2021 the Closing Date of the 2021 Financing, the Company issued 215,625 shares of Common Stock.

Equity Value of Warrants

The Company accounted for the Series K Warrants and the Placement Agent 2 Warrants relating to the aforementioned February 2021 Registered Direct Offering in accordance with ASC 815-40, *Derivatives and Hedging*. Because the Series K Warrants and the Placement Agent 2 Warrants are indexed to the Company's stock, they are classified within stockholders' equity (deficit) in the accompanying consolidated financial statements.

10. 2022 CONVERTIBLE NOTE OFFERING

On July 7, 2022, the Company announced that it had entered into a Securities Purchase Agreement (the "2022 *SPA*") with certain institutional and accredited individual investors (collectively, the "*2022 Investors*") providing for the issuance and sale by the Company to the 2022 Investors of (i) Senior Secured Convertible Promissory Notes (each a "*2022 Note*" and collectively, the "*2022 Notes*") in the aggregate principal amount of $4.23 million, which includes an aggregate $0.705 million original issue discount in respect of the 2022 Notes; (ii) Warrants (the "*2022 Warrants*"), to purchase an aggregate of 425,554 shares (the "*2022 Warrant Shares*") of Common Stock; and (iii) 63,833 shares of Common Stock (the "*2022 Inducement Shares*") equal to 15% of the principal amount of the 2022 Notes divided by the closing price of the Common Stock immediately prior to the Closing Date (as defined below). The 2022 Notes, 2022 Warrants and 2022 Inducement Shares were issued as part of a convertible note offering authorized by the Company's board of directors (the "*2022 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 outstanding shares of our Common Stock; and (ii) any increase in the Ownership Limitation will not become effective until the 61st day after delivery of such waiver notice. The number of shares of Common Stock into which each of the 2022 Warrants is exercisable and the exercise price therefor are subject to adjustment as set forth in the 2022 Warrants, including standard antidilution provisions, and adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise). In the event of a Fundamental Transaction (as defined in the 2022 Warrants) holders of the 2022 Warrants would be entitled to receive alternate consideration in connection with such Fundamental Transaction, but only to the extent that holders of our Common Stock were entitled to receive the same. Moreover, as long as the 2022 Notes and 2022 Warrants remaining outstanding, upon the issuance of any security in connection with any potential future financing activity on terms more favorable than the existing terms, the Company has an obligation to notify the holders of the 2022 Notes and 2022 Warrants of such more favorable terms and to use best efforts to effect such terms in the 2022 Notes and 2022 Warrants. Finally, because of the Company's net loss position, the shares underlying the 2022 Notes on an as converted basis are excluded from the calculation of basic and fully diluted earnings per share. Similarly, because of the Company's net loss position, there was no impact on the calculation of basic and fully diluted earnings per share related to the classification of the 2022 Warrants as participating securities.

The Company retained a placement agent in connection with the private placement of $2.4 million of the 2022 Notes to the institutional investors. The Company paid the 2022 Placement Agent 10% of the gross proceeds in the 2022 Placement Agent from certain institutional investors, or $240,000 and we also reimbursed the 2022 Placement Agent approximately $58,000 for non-accountable banking fees, legal fees and other expenses. In addition, we issued 2022 Placement Agent Warrants to purchase an aggregate of 31,510 shares of Common Stock. An additional $1.1 million was raised in connection with the placement of the private placement notes, which included certain accredited investors some of which were Board members and executive officers of the Company. Board member, Laurence Hicks, and executive officers, Terrence W. Norchi and Michael S. Abrams, invested in the 2022 Senior Secured Convertible Notes. The investment made in the 2022 Senior Secured Convertible Notes made by the Board member and executive officers totaled $80,000.

In addition, as a part of the 2022 Convertible Notes Offering, certain holders (the "*Series Holders*") of the Company's 10% Series 2 Convertible Notes (the "*Series Notes*") agreed to exchange their Series 2 Notes for promissory notes of the Company on substantially similar terms to those of the 2022 Notes (the "*Subordinated*"). 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*") 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%
Increase/(Decrease) due to:		
State income taxes – net of federal benefit	3.65%	5.80%
Permanent Differences:		
Key man life insurance	---%	(0.01)%
Stock Based Compensation	(18.10)%	---%
R&D, taken as a credit	(0.23)%	(0.29)%
Adjustment to fair value of derivative	3.98%	0.37%
PPP Loan Forgiveness	---%	0.60%
Other	(1.14)%	(1.41)%
Change in Valuation Allowance	(9.16)%	(26.06)%
Total Income Tax Provision / (Benefit)	---%	---%

As of September 30, 2022 and 2021, the Company had federal net operating loss carryforwards totaling approximately $42,695,000 and $37,018,000, respectively, which may be available to offset future taxable income. The pre-2018 federal net operating loss carryforwards total approximately $21,750,000, and begin to expire in 2026. Due to the CARES Act, federal net operating losses generated in tax years beginning after December 31, 2017 can be carried forward indefinitely. As of September 30, 2022 and 2021, the Company has federal net operating loss carryforwards with an indefinite life of $20,945,000 and $15,268,000. As of September 30, 2022 and 2021, the Company had federal research and experimentation credit carryforwards of $626,000 and $643,000, respectively, which may be available to offset future income tax liabilities and which would begin to expire in 2028.

As of September 30, 2022 and 2021, the Company had state net operating loss carryforwards of approximately $40,367,000 and $36,033,000, respectively, which may be available to offset future taxable income and which would begin to expire in 2030. As of September 30, 2022 and 2021, the Company had state research and development credit carryforwards of $406,000 and $384,000, respectively, which may be able to offset future income tax liabilities and which would begin to expire in 2023.

As the Company has not yet achieved profitable operations, management believes the tax benefits as of September 30, 2022 and 2021 did not satisfy the realization criteria set forth in FASB ASC Topic 740, *Income Taxes*, and therefore has recorded a valuation allowance for the entire deferred tax asset. The valuation allowance increased in 2022 by approximately $483,000 and increased in 2021 by approximately $1,626,000. The Company’s effective income tax rate differed from the federal statutory rate due to state taxes and the Company’s full valuation allowance and stock based compensation, the latter of which reduced the Company’s effective federal income tax rate to zero.

The Company experienced an ownership change as a result of the Merger described in Note 1, causing a limitation on the annual use of the net operating loss carryforwards, which are subject to a substantial annual limitation due to the ownership change limitations set forth in Internal Revenue Code Section 382 and similar state provisions. A formal Section 382 study has not been performed.

As of September 30, 2022, the Company is open to examination in the U.S. federal and certain state jurisdictions for tax years ended September 30, 2022, 2021, 2010 and 2019. In addition, any loss years remain open to the extent that losses are available for carryover to future years. Therefore, the tax years ended 2006 through 2022 remain open for examination by the IRS.

The Coronavirus Aid, Relief and Economic Security (CARES) Act was enacted on March 27, 2020. The CARES Act affected items such as carryback periods for net operating losses, modifications to the net interest deduction limitations and changes to tax depreciation methods. The company has taken the CARES Act into consideration for the tax year ended September 30, 2022 and continues to evaluate the impact of the CARES act on the business.

13. PAYROLL PROTECTION PROGRAM LOAN

On April 25, 2020, the Company executed a promissory note (the "*PPP Note*") evidencing an unsecured loan in the amount of $176,300 under the Paycheck Protection Program (the "*PPP Loan*"). The Paycheck Protection Program (or "*PPP*") was established under the Cares Act and is administered by the U.S. Small Business Administration ("*SBA*"). The Loan has been made through First Republic Bank (the "*Lender*").

The PPP Loan had a two-year term and bears interest at a rate of 1.00% per annum. Monthly principal and interest payments are deferred until the SBA makes a decision on our loan forgiveness application. Unless the PPP Loan is forgiven, the Company would have been required to make monthly payments of principal and interest of approximately $20,000 to the Lender.

The PPP Note contains customary events of default relating to, among other things, payment defaults, providing materially false and misleading representations to the SBA or Lender, or breaching the terms of the PPP Loan documents. The occurrence of an event of default may result in the immediate repayment of all amounts outstanding, collection of all amounts owing from the Company, or filing suit and obtaining judgment.

Under the terms of the CARES Act, PPP Loan recipients can apply for and be granted forgiveness for all or a portion of the loan granted under the PPP. Such forgiveness will be determined, subject to limitations, based on the use of loan proceeds for payment of payroll costs and any payments of mortgage interest, rent, and utilities. However, no assurance is provided that forgiveness for any portion of the PPP Loan will be obtained. During November 2020, the Company applied for forgiveness of the PPP Loan. On May 28, 2021, the Company received notice that the SBA completed review and all principal and interest has been forgiven. For the fiscal year ended September 30, 2021, approximately $178,000 was recorded to Gain on forgiveness of loan in Other Income in the consolidated statements of operations.

14. STOCK-BASED COMPENSATION

2013 Stock Incentive Plan

On June 18, 2013, the Company established the 2013 Stock Incentive Plan (the "*2013 Plan*"). Under the 2013 Plan, during the fiscal year ended September 30, 2021, a maximum number of 155,571 shares of the Company's authorized and available common stock could be issued in the form of options, stock appreciation rights, sales or bonuses of restricted stock, restricted stock units or dividend equivalent rights, and an award may consist of one such security or benefit, or two or more of them in any combination or alternative. The 2013 Plan provides that on the first business day of each fiscal year commencing with fiscal year 2014, the number of shares of our common stock reserved for issuance under the 2013 Plan for all awards except for incentive stock option awards will be subject to increase by an amount equal to the lesser of (A) 15,000 Shares, (B) four (4) percent of the number of shares outstanding on the last day of the immediately preceding fiscal year of the Company, or (C) such lesser number of shares as determined by the Company's Board of Directors (the "*Board*"). The exercise price of each option shall be the fair value as determined in good faith by the Board at the time each option is granted. On October 1, 2021, the aggregate number of authorized shares under the Plan was further increased by 15,000 shares to a total of 170,571 shares.

The exercise price of each option is equal to the closing price of a share of our common stock on the date of grant.

Share-based awards

During the year ended September 30, 2022, the Company granted 2,375 options to employees and directors and 4,250 options to consultants to purchase shares of common stock under the 2013 Plan**.**

Share-based compensation expense for awards granted during the year ended September 30, 2022 was based on the grant date fair value estimated using the Black-Scholes Option Pricing Model. The following assumptions were used to calculate the fair value of share-based compensation for the year ended September 30, 2022; expected volatility, 79.44% - 119.44%, risk-free interest rate, 0.13% - 2.85%, expected dividend yield, 0%, expected term, 5.6 years.

Common Stock Options

Stock compensation activity under the 2013 Plan for the year ended September 30, 2022 follows:

	Option Shares Outstanding	Weighted Average Exercise Price	Average Remaining Contractual Term (years)	Weighted Aggregate Intrinsic Value
Outstanding at September 30, 2021	124,495	$ 58.00	1.83	$ 140,151
Awarded	6,625	$ 6.00		
Forfeited/Cancelled	(32,494)	$ 70.00		
Outstanding at September 30, 2022	98,626	$ 52.00	1.46	$ 16,900
Vested at September 30, 2022	82,522	$ 58.00	1.52	$ —
Vested and expected to vest at September 30, 2022	98,626	$ 52.00	1.46	$ 16,900

As of September 30, 2022, 41,366 shares are available for future grants under the 2013 Plan. Share-based compensation expense recorded in the Company's Consolidated Statements of Operations for the year ended September 30, 2022 and 2021 resulting from stock options awarded to the Company's employees, directors and consultants was approximately $459,000 and $391,000, respectively. Of this amount during the years ended September 30, 2022 and 2021, $148,000 and $124,000, respectively, were recorded as research and development expenses, and $311,000 and $267,000, respectively were recorded as general and administrative expenses in the Company's Consolidated Statements of Operations.

During the years ended September 30, 2022 and 2021, no stock options awarded under the 2013 Stock Incentive Plan were exercised for cash. During the years ended September 30, 2022 and 2021, no stock options awarded under the 2013 Stock Incentive Plan were exercised on a cashless basis.

As of September 30, 2022, there is approximately $181,000 of unrecognized compensation expense related to unvested stock-based compensation arrangements granted under the 2013 Plan. That cost is expected to be recognized over a weighted average period of 2.47 years.

Restricted Stock

On October 14, 2020, the Company awarded 250 shares of Restricted Stock to a consultant. The shares subject to this grant were awarded under the 2013 Plan and vested 90 days from the date of the award.

On January 27, 2021, the Company awarded 2,500 shares of Restricted Stock to a consultant. The shares subject to this grant were awarded under the 2013 Plan and vested immediately.

On July 30, 2021, the Company awarded 750 shares of Restricted Stock to an employee. The shares subject to this grant were awarded under the 2013 Plan and 250 shares vest on each of the following dates: January 12, 2022, July 12, 2022 and January 12, 2023.

On September 27, 2021, the Company awarded 1,500 shares of Restricted Stock to a consultant. The shares subject to this grant were awarded under the 2013 Plan and 1/12 of the shares will vest on each of the next twelve monthly anniversaries.

Restricted stock activity in shares under the 2013 Plan for the years ended September 30, 2022 and 2021 follows:

	2022	2021
Non Vested at September 30, 2021 and 2020	2,250	
Awarded	—	5,000
Vested	(2,000)	(2,750)
Forfeited	—	—
Non Vested at September 30, 2022 and 2021	250	2,250

The weighted average restricted stock award date fair value information for the years ended September 30, 2022 and 2019 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.

[●] 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	[●]
Nasdaq listing and filing fees	[●]
Reimbursement to underwriters for expenses	$ 125,000
Legal fees and expenses	$ 400,000
Accounting fees and expenses	[●]
Printing and engraving expenses	$ 100,000
Miscellaneous expenses	[●]
Total offering expenses	[●]

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 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.

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 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 principle 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 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.

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 23, 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.

SIGNATURE	TITLE	DATE
/s/ Terrence W. Norchi, MD Terrence W. Norchi, MD	President, Chief Executive Officer and Director (*Principal Executive Officer*)	January 23, 2023
/s/ Michael S. Abrams Michael S. Abrams	Chief Financial Officer (*Principal Financial and Accounting Officer*)	January 23, 2023
* Punit Dhillon	Director	January 23, 2023
* Guy Fish, MD	Director	January 23, 2023
* Laurence Hicks	Director	January 23, 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	X				
1.2*	Form of Warrant Agent Agreement					
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					
4.3	Form of Underwriter Warrant	X				
5.1*	Opinion of McDonald Carano LLP					
5.2*	Opinion of Lowenstein Sandler LLP					
10.1#	Executive Employment Agreement dated June 26, 2013 between Arch Therapeutics, Inc. and Terrence W. Norchi		8-K	10.8	333-178883	6/26/2013
10.2#	First Amendment to Executive Employment Agreement, dated March 23, 2014, by and between Arch Therapeutics, Inc. and Terrence W. Norchi Stock		8-K	10.1	000-54986	3/27/2014
10.3#	Arch Therapeutics, Inc. 2013 Stock Incentive Plan		8-K	10.1	333-178883	6/24/2013

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

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

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)					
23.3*	Consent of Lowenstein Sandler LLP (included in Exhibit 5.2)					
24.1**	Power of Attorney (included in the signature page to this registration statement)		S-1	24.1	333-268008	10/26/2022
101.INS	Inline XBRLInstance Document					
101.SCH	Inline XBRL Taxonomy Extension Schema Document					
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document and included in Exhibit 101)					
107	Filing fee table	X				

* To be filed by amendment.

** Previously filed.

^ Pursuant to Item 601(b)(10) of Regulation S-K, certain identified information has been excluded from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed. Further, the schedules and exhibits to this agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission upon request.

† Confidential treatment has been granted as to certain portions of these Exhibits.

Management contract or compensatory plan or arrangement.

Exhibit 1.1

[●] UNITS
EACH UNIT CONSISTING OF
ONE SHARE OF COMMON STOCK
AND
ONE WARRANT TO PURCHASE ONE SHARE OF COMMON STOCK

ARCH THERAPEUTICS, INC.

UNDERWRITING AGREEMENT

[●], 2023

Maxim Group LLC
300 Park Avenue, 16th Floor
New York, New York 10022

As Representative of the S*everal Underwriters, if any, named in Schedule I hereto*

Ladies and Gentlemen:

The undersigned, Arch Therapeutics, Inc., a Nevada corporation (collectively with its subsidiaries and affiliates, including, without limitation, all entities disclosed or described in the Registration Statement (as defined below) as being subsidiaries or affiliates of Arch Therapeutics, Inc., if any, the "Company"), hereby confirms its agreement (this "Agreement") with the several underwriters (such underwriters, including the Representative (as defined below), the "Underwriters" and each an "Underwriter") named in Schedule I hereto for which Maxim Group LLC ("Maxim") is acting as representative to the several Underwriters (in such capacity, the "Representative" and if there are no Underwriters under than the Representative, references to multiple Underwriters shall be disregarded and the term Representative as used herein shall have the same meaning as Underwriter) on the terms and conditions set forth herein.

It is understood that the several Underwriters are to make a public offering of the Public Securities (as defined below) as soon as the Representative deems it advisable to do so. The Public Securities are to be initially offered to the public at the public offering price set forth in the Prospectus (as defined below). The Representative may from time to time thereafter change the public offering price and other selling terms.

It is further understood that Maxim will act as the Representative for the Underwriters in the offering and sale of the Closing Securities (as defined below) and, if any, the Option Securities (as defined below) in accordance with this Agreement.

ARTICLE I.
DEFINITIONS

1.1 Definitions. In addition to the terms defined elsewhere in this Agreement, for all purposes of this Agreement, the following terms have the meanings set forth in this Section 1.1:

"Action" shall have the meaning ascribed to such term in Section 3.1(k).

"Affiliate" means with respect to any Person, any other Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with such Person as such terms are used in and construed under Rule 405 under the Securities Act.

"Alternate Exchange" means The Nasdaq Global Market, NYSE or NYSE American (or any successors to any of the foregoing).

"Authorizations" means all requisite power and authority, and all necessary consents, approvals, authorizations, orders, registrations, qualifications, licenses, filings and permits of, with and from all governmental, judicial, regulatory or administrative agency, body or court, domestic or foreign, having jurisdiction over the Company or any of its assets or business and all third parties, foreign and domestic.

"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.

"Closing" means the closing of the purchase and sale of the Closing Securities pursuant to Section 2.1.

"Closing Date" means the hour and the date on the Trading Day on which all conditions precedent to (i) the Underwriters' obligations to pay the Closing Purchase Price and (ii) the Company's obligations to deliver the Closing Securities, in each case, have been satisfied or waived, but in no event later than 10:00 a.m. (New York City time) on the second (2nd) Trading Day following the date hereof or at such earlier time as shall be agreed upon by the Representative and the Company.

"Closing Purchase Price" shall have the meaning ascribed to such term in Section 2.1(b), which aggregate purchase price shall be net of underwriting discounts and commissions.

"Closing Securities" shall have the meaning ascribed to such term in Section 2.1(a)(iii).

"Closing Shares" shall have the meaning ascribed to such term in Section 2.1(a)(ii).

"Closing Units" shall have the meaning ascribed to such term in Section 2.1(a)(i).

"Closing Warrants" shall have the meaning ascribed to such term in Section 2.1(a)(iii).

"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.

"Company Auditor" means Baker Tilly US, LLP, with offices located at 1 Highwood Drive, Tewksbury, MA 01876.

"Company Counsel" means Lowenstein Sandler LLP, with offices located at One Lowenstein Drive, Roseland, NJ 07068.

"EDGAR" shall have the meaning ascribed to such term in Section 3.1(f).

"Environmental Laws" shall have the meaning ascribed to such term in Section 3.1(n).

"Effective Date" means the date and time as of which the Registration Statement, or the most recent post-effective amendment thereto, became effective, or is deemed to have become effective by the Commission, in accordance with the rules and regulations under the Securities Act.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"Execution Date" shall mean the date on which the parties execute and enter into this Agreement.

"Exempt Issuance" means the issuance of (a) shares of Common Stock, restricted stock, restricted stock units or options to employees, consultants, advisors, officers or directors of the Company pursuant to any stock or option plan duly adopted for such purpose, by a majority of the non-employee members of the Board of Directors or a majority of the members of a committee of non-employee directors established for such purpose, for services rendered to the Company, (b) securities upon the exercise or exchange of or conversion of any Securities issued hereunder and/or other securities exercisable or exchangeable for or convertible into shares of Common Stock issued and outstanding on the date of this Agreement, provided that such securities have not been amended since the date of this Agreement to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities (other than in connection with automatic price resets, stock splits, adjustments or combinations as set forth in such securities) or to extend the term of such securities and (c) securities issued pursuant to acquisitions or strategic transactions approved by a majority of the disinterested directors of the Company, provided that such securities are issued as "restricted securities" (as defined in Rule 144) and carry no registration rights that require or permit the filing of any registration statement in connection therewith during the prohibition period in Section 4.22(a) herein, and provided that any such issuance shall only be to a Person (or to the equityholders of a Person) which is, itself or through its subsidiaries, an operating company or an owner of an asset in a business synergistic with the business of the Company and shall provide to the Company additional benefits in addition to the investment of funds, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities.

"FCPA" means the Foreign Corrupt Practices Act of 1977, as amended.

"FINRA" means the Financial Industry Regulatory Authority.

"GAAP" shall have the meaning ascribed to such term in Section 3.1(i).

"General Disclosure Package" shall have the meaning ascribed to such term in Section 3.1(f).

"Hazardous Materials" shall have the meaning ascribed to such term in Section 3.1(n).

"Indebtedness" means (a) any liabilities for borrowed money or amounts owed in excess of $50,000 (other than trade accounts payable incurred in the ordinary course of business), (b) all guaranties, endorsements and other contingent obligations in respect of indebtedness of others, whether or not the same are or should be reflected in the Company's consolidated balance sheet (or the notes thereto), except guaranties by endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business; and (c) the present value of any lease payments in excess of $50,000 due under leases required to be capitalized in accordance with GAAP.

"Intellectual Property Rights" shall have the meaning ascribed to such term in Section 3.1(q).

"Liens" means a lien, charge, pledge, security interest, encumbrance, right of first refusal, preemptive right or other restriction.

"Lock-Up Agreements" means the lock-up agreements that are delivered on the date hereof by each of the Company's officers and directors and each holder of Common Stock or Common Stock Equivalents holding, on a fully-diluted basis, more than 5% of the Company's issued and outstanding Common Stock, in the form of Exhibit A attached hereto.

"Material Adverse Effect" shall have the meaning assigned to such term in Section 3.1(b).

"Material Permit" shall have the meaning ascribed to such term in Section 3.1(ff).

"Offering" shall have the meaning ascribed to such term in Section 2.1(c).

"Option Closing Date" shall have the meaning ascribed to such term in Section 2.2(c).

"Option Closing Purchase Price" shall have the meaning ascribed to such term in Section 2.2(b), which aggregate purchase price shall be net of the underwriting discounts and commissions.

"Option Securities" shall have the meaning ascribed to such term in Section 2.2(a).

"Option Shares" shall have the meaning ascribed to such term in Section 2.2(a).

"Option Warrants" shall have the meaning ascribed to such term in Section 2.2(a).

"Over-Allotment Option" shall have the meaning ascribed to such term in Section 2.2(a).

"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.

"Preliminary Prospectus" shall have the meaning ascribed to such term in Section 3.1(f).

"Privacy and Data Security Laws" shall have the meaning ascribed to such term in Section 3.1(o).

"Proceeding" means an action, claim, suit, investigation or proceeding (including, without limitation, an informal investigation or partial proceeding, such as a deposition), whether commenced or threatened.

"Prospectus" shall have the meaning ascribed to such term in Section 3.1(f).

"Prospectus Supplement" means, if any, any supplement to the Prospectus complying with Rule 424(b) of the Securities Act that is filed with the Commission.

"Public Securities" means, collectively, the Closing Securities and, if any, the Option Securities.

"Registration Statement" shall have the meaning ascribed to such term in Section 3.1(f).

"Representative Counsel" means Loeb & Loeb LLP, counsel to the Underwriters, with offices located at 345 Park Avenue, New York, New York 10154, who are acting as counsel to Maxim, or any replacement legal counsel to Maxim.

"Representative Warrants" shall have the meaning ascribed to such term in Section 4.6(e).

"Required Approvals" shall have the meaning ascribed to such term in Section 3.1(e).

"Rule 144" means Rule 144 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.

"Rule 424" means Rule 424 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.

"SEC Reports" shall have the meaning ascribed to such term in Section 3.1(i).

"Securities" means the Closing Securities, the Option Securities, the Warrant Shares, the Warrants and the Representative Warrants.

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

"Share Purchase Price" shall have the meaning ascribed to such term in Section 2.1(b).

"Shares" means, collectively, the shares of Common Stock delivered to the Underwriters in accordance with Section 2.1(a)(ii) and Section 2.2(a).

"Subsidiary" means any subsidiary of the Company and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

"Trading Day" means a day on which the principal Trading Market is open for trading.

"Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: The Nasdaq Capital Market, The Nasdaq Global Market, NYSE or NYSE American (or any successors to any of the foregoing).

"Transaction Documents" means this Agreement and all exhibits and schedules hereto, the Warrants, the Representative Warrants, the Warrant Agreement, the Lock-Up Agreements, and any other documents or agreements executed in connection with the transactions contemplated hereunder.

"Transfer Agent" means Empire Stock Transfer, the transfer agent of the Company, with a mailing address of 1859 Whitney Mesa Drive, Henderson, Nevada 89014, and any successor transfer agent of the Company.

"Underwriters' Information" shall have the meaning ascribed to such term in Section 6.1.

"Units" shall have the meaning ascribed to such term in Section 2.1(a)(i).

"Warrant Agent" means the Transfer Agent.

"Warrant Agreement" means the warrant agreement by and between the Company and Empire Stock Transfer, as warrant agent, dated on or before the Closing Date, for the purpose of administering the Warrants, in the form of Exhibit G attached hereto.

"Warrant Purchase Price" shall have the meaning ascribed to such term in Section 2.1(b).

"Warrant Shares" means the shares of Common Stock issuable upon exercise of the Warrants and the Representative Warrants.

"Warrants" means, collectively, the Common Stock purchase warrants delivered to the Underwriters in accordance with Section 2.1(a)(iii) and Section 2.2, which Warrants shall be exercisable immediately and have a term of exercise equal to five (5) years, in the form of Exhibit E attached hereto.

ARTICLE II.
PURCHASE AND SALE

2.1 Closing.

(a) Upon the terms and subject to the conditions set forth herein, the Company agrees to sell in the aggregate (i) [●] units (the "Units"), with each Unit consisting of one share of Common Stock and one Warrant to purchase one share of Common Stock, subject to the terms and conditions stated herein, and each Underwriter agrees to purchase, severally and not jointly, at the Closing, the following securities of the Company:

(i) the number of Units (the "Closing Units") set forth opposite the name of such Underwriter on Schedule I hereof; and

(ii) the number of shares of Common Stock (the "Closing Shares") set forth opposite the name of such Underwriter on Schedule I hereof included in the Closing Units; and

(iii) the number of Warrants to purchase shares of Common Stock set forth opposite the name of such Underwriter on Schedule I hereof included in the Closing Units (the "Closing Warrants" and collectively with the Closing Shares, the "Closing Securities"), which Warrants shall have an exercise price of $[●] (subject to adjustment as provided therein).

The Units have no stand-alone rights or obligations and will not be certificated or issued as stand-alone securities. The shares of Common Stock and the Warrants comprising the Units are immediately separable and will be issued separately at the Closing.

(b) The Underwriters, severally and not jointly, agree to purchase from the Company the number of Closing Securities set forth opposite their respective names on Schedule I attached hereto and made a part hereof at a purchase price of $[●] per Unit, or 91% of the public offering price of each Unit (the "Closing Purchase Price"). The combined purchase price of each Closing Unit shall be allocated as follows: $[●] per Closing Share (the "Share Purchase Price") and $[●] per Closing Warrant (the "Warrant Purchase Price").

(c) On the Closing Date, each Underwriter shall deliver or cause to be delivered to the Company, via wire transfer, immediately available funds equal to such Underwriter's Closing Purchase Price and the Company shall deliver to, or as directed by, such Underwriter its respective Closing Securities and the Company shall deliver the other items required pursuant to Section 2.3 deliverable at the Closing. Upon satisfaction of the covenants and conditions set forth in Sections 2.3 and 2.4, the Closing shall occur at the offices of Loeb & Loeb LLP or such other location (including remotely by facsimile or other electronic transmission) as the Company and Representative shall mutually agree. The Public Securities are to be offered initially to the public at the offering price set forth on the cover page of the Prospectus (the "Offering").

2.2 Over-Allotment Option.

(a) For the purposes of covering any over-allotments in connection with the distribution and sale of the Closing Securities, the Representative is hereby granted an option (the "Over-Allotment Option") to purchase, in the aggregate, up to [●] shares of Common Stock, representing fifteen percent (15%) of the Closing Shares sold as part of the Closing Units sold in the Offering (the "Option Shares"), and/or Warrants to purchase, in the aggregate, up to [●] shares of Common Stock, representing fifteen percent (15%) of the Closing Warrants sold as part of the Closing Units sold in the Offering (the "Option Warrants" and, collectively with the Option Shares, the "Option Securities"), which may be purchased in any combination of Option Shares and/or Option Warrants at the Share Purchase Price and/or Warrant Purchase Price, respectively.

(b) In connection with an exercise of the Over-Allotment Option, (a) the purchase price to be paid for any Option Shares is equal to the product of the Share Purchase Price multiplied by the number of Option Shares to be purchased and (b) the purchase price to be paid for any Option Warrants is equal to the product of the Warrant Purchase Price multiplied by the number of Option Warrants to be purchased (the aggregate purchase price to be paid on an Option Closing Date, the "Option Closing Purchase Price").

(c) The Over-Allotment Option granted pursuant to this Section 2.2 may be exercised by the Representative as to all (at any time) or any part (from time to time) of the Option Shares and/or Option Warrants in any combination thereof within 45 days after the Execution Date. An Underwriter will not be under any obligation to purchase any Option Securities prior to the exercise of the Over-Allotment Option by the Representative. The Over-Allotment Option granted hereby may be exercised by the giving of oral notice to the Company from the Representative, which must be confirmed in writing by overnight mail or facsimile or other electronic transmission setting forth the number of Option Shares and/or Option Warrants to be purchased and the date and time for delivery of and payment for the Option Securities (each, an "Option Closing Date"), which will not be later than the earlier of (i) 45 days after the Execution Date and (ii) two (2) full Business Days after the date of the notice or such other time as shall be agreed upon by the Company and the Representative, at the offices of Loeb & Loeb LLP or at such other place (including remotely by facsimile or other electronic transmission) as shall be agreed upon by the Company and the Representative. If such delivery and payment for the Option Securities does not occur on the Closing Date, each Option Closing Date will be as set forth in the notice. Upon exercise of the Over-Allotment Option, the Company will become obligated to convey to the Underwriters, and, subject to the terms and conditions set forth herein, the Underwriters will become obligated to purchase, the number of Option Shares and/or Option Warrants specified in such notice. The Representative may cancel the Over-Allotment Option at any time prior to the expiration of the Over-Allotment Option by written notice to the Company.

2.3 Deliveries. The Company shall deliver or cause to be delivered to each Underwriter (if applicable) the following:

(a) At the Closing Date, the Closing Shares included in the Closing Units and, as to each Option Closing Date, if any, the applicable Option Shares, which shares shall be delivered via The Depository Trust Company's Deposit or Withdrawal at Custodian system for the accounts of the several Underwriters;

(b) At the Closing Date, the Closing Warrants included in the Closing Units and, as to each Option Closing Date, if any, the applicable Option Warrants, which Warrants shall be delivered via The Depository Trust Company's Deposit or Withdrawal at Custodian system for the accounts of the several Underwriters;

(c) At the Closing Date and at each Option Closing Date, if any, the applicable Representative Warrants, which Representative Warrants shall be issued in the name or names and in such authorized denominations as the Representative may request;

(d) At the Closing Date, the Warrant Agreement duly executed by the parties thereto;

(e) At the Closing Date, the legal opinions of Company Counsel (including, without limitation, a negative assurance letter or statement) addressed to the Underwriters, dated as of the Closing Date and as to each Option Closing Date, if any, bring-down opinions and negative assurances from Company Counsel addressed to the Underwriters, in each case in form and substance reasonably satisfactory to the Representative Counsel;

(f) Contemporaneously with the execution hereof, a cold comfort letter, addressed to the Underwriters and in form and substance reasonably satisfactory to the Representative and Representative Counsel from the Company Auditor dated, respectively, as of the date of this Agreement and a bring-down comfort letter dated as of the Closing Date and each Option Closing Date, if any;

(g) On the Closing Date and on each Option Closing Date, if any, the duly executed and delivered Officers' Certificate, substantially in the form required by Exhibit B attached hereto;

(h) On the Closing Date and on each Option Closing Date, if any, the duly executed and delivered Secretary's Certificate, substantially in the form required by Exhibit C attached hereto;

(i) On the Closing Date and on each Option Closing Date, if any, a duly executed and delivered Chief Financial Officer's Certificate, substantially in the form required by Exhibit D attached hereto, addressed to the Underwriters; and

(j) Contemporaneously herewith, the duly executed and delivered Lock-Up Agreements.

2.4 Closing Conditions. The respective obligations of each Underwriter hereunder in connection with the Closing and each Option Closing Date are subject to the following conditions being met:

(a) the accuracy in all material respects when made and on the date in question (other than representations and warranties of the Company already qualified by materiality, which shall be true and correct in all respects) of the representations and warranties of the Company contained herein (unless as of a specific date therein);

(b) all obligations, covenants and agreements of the Company required to be performed at or prior to the date in question shall have been performed or such performance shall have been waived by the Representative;

(c) the delivery by the Company of the items set forth in Section 2.3 of this Agreement;

(d) the Registration Statement shall be effective on the date of this Agreement or such later date and time as shall be consented to in writing by the Representative and at each of the Closing Date and each Option Closing Date, if any, no stop order suspending the effectiveness of the Registration Statement shall have been issued and no proceedings for that purpose shall have been instituted or shall be pending or contemplated by the Commission and any request on the part of the Commission for additional information shall have been complied with to the reasonable satisfaction of the Representative;

(e) by the Execution Date, if required by FINRA, the Underwriters shall have received a notice of no objections from FINRA as to the amount of compensation allowable or payable to and the terms and arrangements for acting as the Underwriters as described in the Registration Statement;

(f) the shares of Common Stock, including the Closing Shares, the Option Shares and the Warrant Shares, and the Warrants have been approved for listing on The Nasdaq Capital Market or an Alternate Exchange;

(g) the Company has filed with the Commission a Form 8-A (File No. [●]) providing for the registration pursuant to Section 12(b) under the Exchange Act of the shares of Common Stock and the Warrants; and such Form 8-A has become effective under the Exchange Act. The Company has taken no action designed to, or likely to have the effect of, terminating the registration of the shares of Common Stock or the Warrants under the Exchange Act, nor has the Company received any notification that the Commission is contemplating terminating such registration; and

(h) prior to and on each of the Closing Date and each Option Closing Date, if any: (i) there shall have been no material adverse change or development involving a prospective material adverse change in the condition or prospects or the business activities, financial or otherwise, of the Company and its Subsidiaries, taken as a whole, from the latest dates as of which such condition is set forth in the Registration Statement, the General Disclosure Package and Prospectus; (ii) no action suit or proceeding, at law or in equity, shall have been pending or threatened against the Company or any Affiliate of the Company before or by any court or federal or state commission, board or other administrative agency wherein an unfavorable decision, ruling or finding may materially adversely affect the business, operations, prospects or financial condition or income of the Company, except as set forth in the Registration Statement, the General Disclosure Package and Prospectus; (iii) no stop order applicable to the Company shall have been issued under the Securities Act and no proceedings therefor shall have been initiated or threatened by the Commission; (iv) the Company has not incurred any material liabilities or obligations, direct or contingent, nor has it entered into any material transactions not in the ordinary course of business, other than pursuant to this Agreement and the transactions referred to herein; (v) the Company has not paid or declared any dividends or other distributions of any kind on any class of its capital stock; (vi) the Company has not altered its method of accounting; and (vii) the Registration Statement, the General Disclosure Package and the Prospectus and any amendments or supplements thereto shall contain all material statements which are required to be stated therein in accordance with the Securities Act and the rules and regulations thereunder and shall conform in all material respects to the requirements of the Securities Act and the rules and regulations thereunder, and neither the Registration Statement, the General Disclosure Package nor the Prospectus nor any amendment or supplement thereto shall contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

If any of the conditions specified in this Section 2.4 shall not have been fulfilled when and as required by this Agreement, or if any of the certificates, opinions, written statements or letters furnished to the Representative or to the Representative Counsel pursuant to this Section 2.4 shall not be reasonably satisfactory in form and substance to the Representative and to the Representative Counsel, all obligations of the Underwriters hereunder may be cancelled by the Representative at, or at any time prior to, the consummation of the Closing. Notice of such cancellation shall be given to the Company in writing or orally. Any such oral notice shall be confirmed promptly thereafter in writing.

ARTICLE III.
REPRESENTATIONS AND WARRANTIES

3.1 Representations and Warranties of the Company. The Company represents and warrants to the Underwriters as of the Execution Date, as of the Closing Date and as of each Option Closing Date, if any, as follows:

(a) Subsidiaries. All of the Subsidiaries of the Company are set forth in the Registration Statement, the General Disclosure Package and Prospectus. Except as indicated in the Registration Statement, the General Disclosure Package and Prospectus, the Company owns, directly or indirectly, all of the capital stock or other equity interests of each Subsidiary free and clear of any Liens, and all of the issued and outstanding shares of capital stock of each Subsidiary are validly issued and are fully paid, non-assessable and free of preemptive and similar rights to subscribe for or purchase securities. If the Company has no Subsidiaries, all other references to the Subsidiaries or any of them in the Transaction Documents shall be disregarded.

(b) Organization and Qualification. The Company and each of the Subsidiaries is an entity duly incorporated or otherwise organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization, with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted. Neither the Company nor any Subsidiary is in violation nor default of any of the provisions of its respective certificate or articles of incorporation, bylaws or other organizational or charter documents. Each of the Company and the Subsidiaries is duly qualified to conduct business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, would not have or reasonably be expected to result in: (i) a material adverse effect on the legality, validity or enforceability of any Transaction Document, (ii) a material adverse effect on the results of operations, assets, business, prospects or condition (financial or otherwise) of the Company and the Subsidiaries, taken as a whole, or (iii) a material adverse effect on the Company's ability to perform on a timely basis its obligations under any Transaction Document (any of (i), (ii) or (iii), a "Material Adverse Effect") and no Proceeding has been instituted in any such jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification. The Company's articles of incorporation and other constitutive or organizational documents of the Company comply with the requirements of applicable Nevada law and are in full force and effect.

(c) Authorization; Enforcement. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement and each of the other Transaction Documents to which it is a party and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of this Agreement and each of the other Transaction Documents by the Company and the consummation by it of the transactions contemplated hereby and thereby have been duly authorized by all necessary action on the part of the Company and no further action is required by the Company, the Board of Directors or the Company's stockholders in connection herewith or therewith other than in connection with the Required Approvals. This Agreement and each other Transaction Document to which the Company is a party has been (or upon delivery will have been) duly executed by the Company and, when delivered in accordance with the terms hereof and thereof, will constitute the valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(d) No Conflicts. The execution, delivery and performance by the Company of this Agreement and the other Transaction Documents to which it is a party, the issuance and sale of the Securities and the consummation by it of the transactions contemplated hereby and thereby do not and will not (i) conflict with or violate any provision of the Company's or any Subsidiary's certificate or articles of incorporation, bylaws or other organizational or charter documents, (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any Lien upon any of the properties or assets of the Company or any Subsidiary, or give to others any rights of termination, amendment, acceleration or cancellation (with or without notice, lapse of time or both) or anti-dilution or similar adjustments of, any agreement, credit facility, debt or other instrument (evidencing a Company or Subsidiary debt or otherwise) or other understanding to which the Company or any Subsidiary is a party or by which any property or asset of the Company or any Subsidiary is bound or affected, or (iii) subject to the Required Approvals, conflict with or result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority to which the Company or a Subsidiary is subject (including federal and state securities laws and regulations), or by which any property or asset of the Company or a Subsidiary is bound or affected; except in the case of each of clauses (ii) and (iii), such as would not have or reasonably be expected to result in a Material Adverse Effect.

(e) Filings, Consents and Approvals. The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any court or other federal, state, local or other governmental authority or other Person in connection with the execution, delivery and performance by the Company of the Transaction Documents, other than: (i) the filing with the Commission of the Prospectus or any Prospectus Supplement, (ii) such filings as are required to be made under applicable state securities laws and the rules and regulations of FINRA, and (iii) application(s) to each applicable Trading Market for the listing of the Shares and Warrants for trading thereon in the time and manner required thereby (collectively, the "Required Approvals").

(f) Registration Statement. The Company has filed with the Commission the Registration Statement, including any related Preliminary Prospectus or Prospectuses, for the registration of the Securities under the Securities Act, which Registration Statement has been prepared by the Company in all material respects in conformity with the requirements of the Securities Act and the rules and regulations of the Commission under the Securities Act. The registration of the shares of Common Stock and the Warrants (which are included in the Units) under the Exchange Act has been declared effective by the Commission on the date hereof. Copies of such Registration Statement and of each amendment thereto, if any, including the related Preliminary Prospectuses, heretofore filed by the Company with the Commission have been delivered to the Underwriters. The term "Registration Statement" means such registration statement on Form S-1 (File No. 333-268008), as amended, as of the relevant Effective Date, including financial statements, all exhibits and any information deemed to be included or incorporated by reference therein, including any information deemed to be included pursuant to Rule 430A or Rule 430B of the Securities Act and the rules and regulations thereunder, as applicable. If the Company files a registration statement to register a portion of the Securities and relies on Rule 462(b) of the Securities Act and the rules and regulations thereunder for such registration statement to become effective upon filing with the Commission (the "Rule 462 Registration Statement"), then any reference to the "Registration Statement" shall be deemed to include the Rule 462 Registration Statement, as amended from time to time. The term "Preliminary Prospectus" as used herein means a preliminary prospectus as contemplated by Rule 430 or Rule 430A of the Securities Act and the rules and regulations thereunder as included at any time as part of, or deemed to be part of or included in, the Registration Statement. The term "Prospectus" means the final prospectus in connection with this Offering as first filed with the Commission pursuant to Rule 424(b) of the Securities Act and the rules and regulations thereunder or, if no such filing is required, the form of final prospectus included in the Registration Statement at the Effective Date, except that if any revised prospectus or prospectus supplement shall be provided to the Representative by the Company for use in connection with the Securities which differs from the Prospectus (whether or not such revised prospectus or prospectus supplement is required to be filed by the Company pursuant to Rule 424(b)), the term "Prospectus" shall also refer to such revised prospectus or prospectus supplement, as the case may be, from and after the time it is first provided to the Representative for such use or filed on EDGAR as defined below. Any reference herein to the terms "amend," "amendment" or "supplement" with respect to the Registration Statement, any Preliminary Prospectus or the Prospectus shall be deemed to refer to and include: (i) the filing of any document under the Exchange Act after the Effective Date, the date of such Preliminary Prospectus or the date of the Prospectus, as the case may be, which is incorporated therein by reference, and (ii) any such document so filed. All references in this Agreement to the Registration Statement, a Preliminary Prospectus and the Prospectus, or any amendments or supplements to any of the foregoing shall be deemed to include any copy thereof filed with the Commission pursuant to its Electronic Data Gathering, Analysis and Retrieval System ("EDGAR"). The term "General Disclosure Package" means, collectively, the Permitted Free Writing Prospectus(es) (as defined below) included on Schedule II hereto, the most recent preliminary prospectus related to this Offering, and the information included on Schedule I hereto.

(g) Issuance of Securities. The Securities are duly authorized and, when issued and paid for in accordance with the applicable Transaction Documents, will be duly and validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company. The Warrant Shares are duly authorized and, when issued in accordance with the terms of the Warrants and the Representative Warrants, will be validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company. The Company has reserved from its duly authorized capital stock the maximum number of shares of Common Stock issuable pursuant to this Agreement, the Warrants and the Representative Warrants. The Securities are not and will not be subject to the preemptive rights of any holders of any security of the Company or similar contractual rights granted by the Company. All corporate action required to be taken for the authorization, issuance and sale of the Securities has been duly and validly taken. The Securities conform in all material respects to all statements with respect thereto contained in the Registration Statement, the General Disclosure Package and the Prospectus. When issued, the Warrants and Representative Warrants will constitute valid and binding obligations of the Company to issue and sell, upon exercise thereof and payment of the exercise price therefor, the number and type of securities of the Company called for thereby in accordance with the terms thereof and the Warrants and Representative Warrants are enforceable against the Company in accordance with their terms; provided, however, that the enforceability thereof may be limited by bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar laws relating to or affecting creditors' rights generally and by general principles of equity (regardless of whether such enforceability is considered a proceeding in equity or at law).

(h) Capitalization. The capitalization of the Company as of the date hereof is as set forth in the Registration Statement. Except as set forth in the Registration Statement, the General Disclosure Package and Prospectus, the Company has not issued any capital stock since its most recently filed periodic report under the Exchange Act, other than pursuant to the exercise of employee stock options under the Company's stock option plans, the issuance of shares of Common Stock to employees pursuant to the Company's employee stock purchase plans and pursuant to the conversion and/or exercise of Common Stock Equivalents outstanding as of the date of the most recently filed periodic report under the Exchange Act. No Person other than the Representative has any right of first refusal, preemptive right, right of participation, or any similar right to participate in the transactions contemplated by the Transaction Documents, except such rights which have been waived prior to the date hereof. Except as a result of the purchase and sale of the Securities or as set forth in the Registration Statement, the General Disclosure Package and Prospectus, there are no outstanding options, warrants, scrip rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire, any shares of Common Stock or the capital stock of any Subsidiary, or contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to issue additional shares of Common Stock or Common Stock Equivalents or the capital stock of any Subsidiary. Except as set except as set forth in the Registration Statement, the General Disclosure Package and Prospectus, there are no outstanding securities or instruments of the Company or any Subsidiary with any provision that adjusts the exercise, conversion, exchange or reset price of such security or instrument upon an issuance of securities by the Company or any Subsidiary. The issuance and sale of the Securities will not obligate the Company or any Subsidiary to issue shares of Common Stock or other securities to any Person (other than the Underwriters). There are no outstanding securities or instruments of the Company or any Subsidiary that contain any redemption or similar provisions, and there are no contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to redeem a security of the Company or such Subsidiary. The Company does not have any stock appreciation rights or "phantom stock" plans or agreements or any similar plan or agreement. All of the outstanding shares of capital stock of the Company are duly authorized, validly issued, fully paid and nonassessable, have been issued in compliance with all federal and state securities and other applicable laws, and none of such outstanding shares was issued in violation of any preemptive rights or similar rights to subscribe for or purchase securities. The authorized shares of the Company conform in all material respects to all statements relating thereto contained in the Registration Statement, the General Disclosure Package and the Prospectus and any Prospectus Supplement. The offers and sales of the Company's securities were at all relevant times either registered under the Securities Act and the applicable state securities or Blue Sky laws or, based in part on the representations and warranties of the purchasers, exempt from such registration requirements. No further approval or authorization of any stockholder, the Board of Directors or others is required for the issuance and sale of the Securities. There are no stockholders agreements, voting agreements or other similar agreements with respect to the Company's capital stock to which the Company is a party or, to the knowledge of the Company, between or among any of the Company's stockholders.

(i) SEC Reports. (i) The Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the two (2) years preceding the date hereof (or such shorter period as the Company was required by law or regulation to file such material) (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, together with the Prospectus, being collectively referred to herein as the "SEC Reports") on a timely basis or has received a valid extension of such time of filing and has filed any such SEC Reports prior to the expiration of any such extension. As of their respective dates, the SEC Reports complied in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable, and none of the SEC Reports, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(ii) Financial Statements. The financial statements of the Company, including the notes thereto and supporting schedules, included in the Registration Statement, the Preliminary Prospectus, the General Disclosure Package, the Prospectus and the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. The selected financial data set forth under the caption "Selected Historical Consolidated Financial Data" fairly present, on the basis stated in the Registration Statement, the Preliminary Prospectus and the Prospectus, the information included therein. Such financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved ("GAAP"), except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company and its consolidated Subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments.

(iii) Material Agreements. The agreements and documents described in the Registration Statement, the Preliminary Prospectus, the General Disclosure Package, the Prospectus, and the SEC Reports conform in all material respects to the descriptions thereof contained therein and there are no agreements or other documents required by the Securities Act and the rules and regulations thereunder to be described in the Registration Statement, the Preliminary Prospectus, the General Disclosure Package, the Prospectus or the SEC Reports or to be filed with the Commission as exhibits to the Registration Statement, that have not been so described or filed. Each agreement or other instrument (however characterized or described) to which the Company is a party or by which it is or may be bound or affected and (i) that is referred to in or filed as an exhibit to the Registration Statement, the General Disclosure Package, the Prospectus, any Prospectus Supplement or the SEC Reports, or (ii) is material to the Company's business, has been duly authorized and validly executed by the Company (each, a "Material Agreement"), is in full force and effect in all material respects and is enforceable against the Company and, to the Company's knowledge, the other parties thereto, in accordance with its terms, except (x) as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting creditors' rights generally, (y) as enforceability of any indemnification or contribution provision may be limited under the federal and state securities laws, and (z) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefore may be brought. No such Material Agreement has been assigned by the Company, and neither the Company nor, to the Company's knowledge, any other party is in default thereunder and, to the Company's knowledge, no event has occurred that, with the lapse of time or the giving of notice, or both, would constitute a default thereunder. Performance by the Company of the material provisions of the Material Agreements will not result in a violation of any existing applicable law, rule, regulation, judgment, order or decree of any governmental agency or court, domestic or foreign, having jurisdiction over the Company or any of its assets or businesses, including, without limitation, those relating to environmental laws and regulations, except for violations which would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect.

(j) Material Changes; Undisclosed Events, Liabilities or Developments. Since the date of the latest audited financial statements included within the Registration Statement, except as specifically disclosed in the Registration Statement, the Preliminary Prospectus, the General Disclosure Package, or the Prospectus, (i) there has been no event, occurrence or development that has had or that would reasonably be expected to result in a Material Adverse Effect, (ii) the Company has not incurred any liabilities (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company's financial statements pursuant to GAAP or disclosed in filings made with the Commission, (iii) the Company has not altered its method of accounting, (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock and (v) the Company has not issued any equity securities to any officer, director or Affiliate, except pursuant to existing Company stock option plans and the issuance of Common Stock Equivalents as disclosed in the Registration Statement. The Company does not have pending before the Commission any request for confidential treatment of information. Except for the issuance of the Securities contemplated by this Agreement, no event, liability, fact, circumstance, occurrence or development has occurred or exists or is reasonably expected to occur or exist with respect to the Company or its Subsidiaries or their respective businesses, prospects, properties, operations, assets or financial condition that would be required to be disclosed by the Company under applicable securities laws at the time this representation is made or deemed made that has not been publicly disclosed at least one (1) Trading Day prior to the date that this representation is made. Unless otherwise disclosed in the Registration Statement, the Company has not: (i) issued any securities or incurred any liability or obligation, direct or contingent, for borrowed money; or (ii) declared or paid any dividend or made any other distribution on or in respect to its capital stock.

(k) Litigation. There has not been, and to the knowledge of the Company there is not pending or contemplated, any action, suit, inquiry, notice of violation, proceeding or investigation pending or, to the knowledge of the Company, threatened against or affecting the Company, any Subsidiary or any of their respective properties before or by any court, arbitrator, governmental or administrative agency or regulatory authority (federal, state, county, local or foreign) (collectively, an "Action") which (i) adversely affects or challenges the legality, validity or enforceability of any of the Transaction Documents or the Securities or (ii) would, if there were an unfavorable decision, have or reasonably be expected to result in a Material Adverse Effect. Neither the Company nor any Subsidiary, nor any director or officer thereof, is or has been the subject of any Action involving a claim of violation of or liability under federal or state securities laws or a claim of breach of fiduciary duty. Except as set forth in the Registration Statement, the General Disclosure Package, the Prospectus and the SEC Reports, there has not been and, to the knowledge of the Company, there is not pending or contemplated, any investigation by the Commission involving the Company or any current or former director or officer of the Company. The Commission has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company or any Subsidiary under the Exchange Act or the Securities Act.

(l) Labor Relations. No labor dispute exists or, to the knowledge of the Company, is imminent with respect to any of the employees of the Company, which would reasonably be expected to result in a Material Adverse Effect. None of the Company's or its Subsidiaries' employees is a member of a union that relates to such employee's relationship with the Company or such Subsidiary, and neither the Company nor any of its Subsidiaries is a party to a collective bargaining agreement, and the Company and its Subsidiaries believe that their relationships with their employees are good. No executive officer of the Company or any Subsidiary, is, or is now expected to be, in violation of any material term of any employment contract, confidentiality, disclosure or proprietary information agreement or non-competition agreement, or any other contract or agreement or any restrictive covenant in favor of any third party, and the continued employment of each such executive officer does not subject the Company or any of the Subsidiaries to any liability with respect to any of the foregoing matters that would reasonably be expected to have a Material Adverse Effect. The Company and its Subsidiaries are in compliance with all applicable U.S. federal, state, local and foreign laws and regulations relating to employment and employment practices, terms and conditions of employment and wages and hours, except where the failure to be in compliance would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(m) Compliance. Neither the Company nor any Subsidiary: (i) is in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by the Company or any Subsidiary under), nor has the Company or any Subsidiary received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived), (ii) is in violation of any judgment, decree or order of any court, arbitrator or other governmental authority or (iii) is or has been in violation of any statute, rule, ordinance or regulation of any governmental authority, including without limitation all foreign, federal, state and local laws, except in each case as would not have or reasonably be expected to result in a Material Adverse Effect.

(n) Environmental Laws. The Company and its Subsidiaries (i) are in compliance with all applicable federal, state, local and foreign laws relating to pollution or protection of human health or the environment (including ambient air, surface water, groundwater, land surface or subsurface strata), including laws relating to emissions, discharges, releases or threatened releases of chemicals, pollutants, contaminants, or toxic or hazardous substances or wastes (collectively, "Hazardous Materials") into the environment, or otherwise relating to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials, as well as all authorizations, codes, decrees, demands, or demand letters, injunctions, judgments, licenses, notices or notice letters, orders, permits, plans or regulations, issued, entered, promulgated or approved thereunder ("Environmental Laws"); (ii) have received all permits licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses; and (iii) are in compliance with all terms and conditions of any such permit, license or approval where in each clause (i), (ii) and (iii), the failure to so comply would be reasonably expected to have, individually or in the aggregate, a Material Adverse Effect.

(o) Privacy and Data Security Laws and Regulations. The Company and its Subsidiaries have (A) operated and currently operate their respective businesses in a manner compliant with all applicable foreign, federal, state and local laws and regulations, all contractual obligations and all Company policies (internal and posted) related to privacy and data security applicable to the Company's and the Subsidiaries' collection, use, handling, transfer, transmission, storage, disclosure and/or disposal of the data of their respective customers, employees and other third parties (the "Privacy and Data Security Laws"), and (B) implemented, monitored and have been and are in compliance with, applicable administrative, technical and physical safeguards and policies and procedures designed to ensure compliance with Privacy and Data Security Laws, except as would not be reasonably expected to have, individually or in the aggregate, a Material Adverse Effect. Except as described in the Registration Statement, the General Disclosure Package or the Prospectus, there has been no loss or unauthorized access, use, modification or breach of security of customer, employee or third party data maintained by or on behalf of the Company and its Subsidiaries, and neither the Company nor any of the Subsidiaries has notified, nor has the current intention to notify, any customer, governmental entity or the media of any such event with regard to any material data breach.

(p) Title to Assets. Except as set forth in the Registration Statement, the General Disclosure Package and Prospectus, the Company and its Subsidiaries have good and marketable title in fee simple or have valid and marketable rights to lease or otherwise use all real property and personal property used by them that is material to the business of the Company and its Subsidiaries, in each case free and clear of all Liens, except for (i) Liens as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and its Subsidiaries and (ii) Liens for the payment of federal, state or other taxes, for which appropriate reserves have been made therefor in accordance with GAAP and, the payment of which is neither delinquent nor subject to penalties. Any real property and facilities held under lease by the Company and its Subsidiaries are held by them under valid, subsisting and enforceable leases with which the Company and its Subsidiaries are in material compliance.

(q) Intellectual Property. The Company and the Subsidiaries have, or have rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other intellectual property rights and similar rights necessary or required for use in connection with their respective businesses as described in the Registration Statement, the General Disclosure Package or the Prospectus and which the failure to so have would have a Material Adverse Effect (collectively, the "Intellectual Property Rights"). To the knowledge of the Company, the Company is not now infringing, and upon commercialization, will not infringe, any valid claim of any issued patents, copyrights or trademarks of others. Neither the Company nor any Subsidiary has received a notice (written or otherwise) that any of the Intellectual Property Rights has expired, terminated or been abandoned, or is expected to expire or terminate or be abandoned, within two (2) years from the date of this Agreement. Neither the Company nor any Subsidiary has received, since the date of the latest audited financial statements included within the Registration Statement, the General Disclosure Package, the Prospectus or the SEC Reports, a written notice of a claim or otherwise has any knowledge that the Company's business or planned business as described in the Registration Statement, the General Disclosure Package or the Prospectus violates or infringes upon the rights of any Person. All such Intellectual Property Rights are enforceable, or would be enforceable if issued as of the date hereof, and to the knowledge of the Company, there is no existing infringement by another Person of any of the Intellectual Property Rights that would be material to the business of the Company and its Subsidiaries taken as a whole. The Company and the Subsidiaries have taken reasonable security measures to protect the secrecy, confidentiality and value of all of their intellectual properties, except where failure to do so would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(r) Insurance. The Company and the Subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are prudent and customary in the businesses in which the Company and the Subsidiaries are engaged, including, but not limited to, directors and officers insurance coverage. Neither the Company nor any Subsidiary has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business without a significant increase in cost. The Company carries (or will carry at the Closing Date) and is entitled to the benefits of directors and officers insurance coverage at least equal to $3,000,000. There are no material claims by the Company under any such policy or instrument as to which any insurance company is denying liability or defending under a reservation of rights clause.

(s) Transactions with Affiliates and Employees. Except as set forth in the Registration Statement, General Disclosure Package or Prospectus, none of the officers or directors of the Company or any Subsidiary and, to the knowledge of the Company, none of the employees of the Company or any Subsidiary is presently a party to any transaction with the Company or any Subsidiary (other than for services as employees, officers and directors), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from, providing for the borrowing of money from or lending of money to or otherwise requiring payments to or from, any officer, director or such employee or, to the knowledge of the Company, any entity in which any officer, director, or any such employee has a substantial interest or is an officer, director, trustee, stockholder, member or partner, in each case in excess of $120,000 other than for (i) payment of salary or consulting fees for services rendered, (ii) reimbursement for expenses incurred on behalf of the Company and (iii) other employee benefits, including stock option agreements under any stock option plan of the Company.

(t) Accounting Controls. Except as described in the Registration Statement, the General Disclosure Package or the Prospectus, the Company's disclosure controls and procedures and internal controls are effective. Except as described in the Registration Statement, the General Disclosure Package or the Prospectus, the Company and the Subsidiaries are in material compliance with any and all applicable requirements of the Sarbanes-Oxley Act of 2002 that are effective as of the date hereof, and any and all applicable rules and regulations promulgated by the Commission thereunder that are effective as of the date hereof and as of the Closing Date. The Company and the Subsidiaries maintain a system of internal accounting controls designed to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization, and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Except as set forth in the Registration Statement, the Prospectus or the Prospectus Supplement, if any, the Company and the Subsidiaries have established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and the Subsidiaries designed to record, process, summarize and report the information required to be disclosed by the Company in the reports it files or submits under the Exchange Act within the time periods specified in the Commission's rules and forms. The Company's certifying officers have evaluated the effectiveness of the disclosure controls and procedures of the Company and the Subsidiaries as of the end of the period covered by the most recently filed periodic report under the Exchange Act (such date, the "Evaluation Date"). The Company presented in its most recently filed periodic report under the Exchange Act the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no changes in the internal control over financial reporting (as such term is defined in the Exchange Act) of the Company and the Subsidiaries that have materially affected, or is reasonably likely to materially affect, the internal control over financial reporting of the Company and the Subsidiaries.

(u) Certain Fees. Except as set forth in the Registration Statement, the General Disclosure Package and Prospectus or any Prospectus Supplement, no brokerage or finder's fees or commissions are or will be payable by the Company, any Subsidiary or Affiliate of the Company to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by the Transaction Documents. There are no other arrangements, agreements or understandings of the Company or, to the Company's knowledge, any of its stockholders that may affect the Underwriters' compensation, as determined by FINRA. Other than payments to the Underwriters for this Offering, the Company has not made and has no agreements, arrangements or understanding to make any direct or indirect payments (in cash, securities or otherwise) to: (i) any person, as a finder's fee, consulting fee or otherwise, in consideration of such person raising capital for the Company or introducing to the Company persons who raised or provided capital to the Company; (ii) any FINRA member; or (iii) any person or entity that has any direct or indirect affiliation or association with any FINRA member, within the 180-day period preceding the initial filing of the Registration Statement through the 90-day period after the Effective Date. None of the net proceeds of the Offering will be paid by the Company to any participating FINRA member or its affiliates, except as specifically authorized herein.

(v) Investment Company. The Company is not, and is not an Affiliate of, and immediately after receipt of payment for the Securities will not be or be an Affiliate of, an "investment company" within the meaning of the Investment Company Act of 1940, as amended. The Company shall conduct its business in a manner so that it will not become an "investment company" subject to registration under the Investment Company Act of 1940, as amended.

(w) Registration Rights. No Person has any right to cause the Company or any Subsidiary to effect the registration under the Securities Act of any securities of the Company or any Subsidiary.

(x) Compliance with Exchange Act. (i) The Company has filed with the Commission a Form 8-A (File No. [●]) providing for the registration of the shares of Common Stock and the Warrants pursuant to Section 12(b) under the Exchange Act. The registration of the Common Stock and Warrants under the Exchange Act has been declared effective by the Commission on or prior to the date hereof. The Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the shares of Common Stock and the Warrants under the Exchange Act nor has the Company received any notification that the Commission is contemplating terminating such registration. The Company has not, in the 12 months preceding the date hereof, received notice from any Trading Market on which the Common Stock is or has been listed or quoted to the effect that the Company is not in compliance with the listing or maintenance requirements of such Trading Market. The Common Stock and Warrants are currently eligible for electronic transfer through The Depository Trust Company or another established clearing corporation and the Company is current in payment of the fees of The Depository Trust Company (or such other established clearing corporation) in connection with such electronic transfer. The shares of Common Stock, including the Closing Shares, the Option Shares and the Warrant Shares, and the Warrants have been approved for listing on The Nasdaq Capital Market or an Alternate Exchange, subject to official notice of issuance. The Company is, and has no reason to believe that it will not in the foreseeable future continue to be, in compliance with all such applicable listing and maintenance requirements of The Nasdaq Capital Market or an Alternate Exchange, as applicable.

(ii) Compliance with Continued Listing Requirements. The Company has taken all necessary actions to ensure that, upon such time as The Nasdaq Capital Market or an Alternate Exchange shall have approved the shares of Common Stock and Warrants for listing, it will be in compliance with all applicable corporate governance requirements set forth in the rules of The Nasdaq Capital Market or an Alternate Exchange, as applicable, that are in effect.

(y) Application of Takeover Protections. The Company and the Board of Directors have taken all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Company's articles of incorporation (or similar charter documents) or the laws of its state of incorporation that is or would become applicable as a result of the Underwriters and the Company fulfilling their obligations or exercising their rights under the Transaction Documents.

(z) Disclosure; 10b-5. The Registration Statement (and any further documents to be filed with the Commission in connection with the Offering) contains all exhibits and schedules as required by the Securities Act. Each of the Registration Statement and any post-effective amendment thereto, if any, at the time it became effective, complied in all material respects with the Securities Act and the Exchange Act and the applicable rules and regulations thereunder and did not and, as amended or supplemented, if applicable, will not, contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. The Preliminary Prospectus and the Prospectus, each as of its respective date, comply in all material respects with the Securities Act and the Exchange Act and the applicable rules and regulations thereunder. The Prospectus, as amended or supplemented, did not and will not contain as of the date thereof any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading; provided, however, that this representation and warranty shall not apply to the Underwriters' Information. As of its date and the date hereof, the General Disclosure Package did not and does not include any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The SEC Reports, when they were filed with the Commission, conformed in all material respects to the requirements of the Securities Act and the Exchange Act, as applicable, and the applicable rules and regulations thereunder, and none of such documents, when they were filed with the Commission, contained any untrue statement of a material fact or omitted to state a material fact necessary to make the statements therein (with respect to the SEC Reports incorporated by reference in the Prospectus), in light of the circumstances under which they were made, not misleading; and any further documents so filed and incorporated by reference in the Prospectus, when such documents are filed with the Commission, will conform in all material respects to the requirements of the Securities Act and the Exchange Act and the applicable rules and regulations thereunder, and will not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading. No post-effective amendment to the Registration Statement reflecting any facts or events arising after the date thereof which represent, individually or in the aggregate, a fundamental change in the information set forth therein is required to be filed with the Commission. There are no documents required to be filed with the Commission in connection with the transactions contemplated in the Transaction Documents that (x) have not been filed as required pursuant to the Securities Act or (y) will not be filed within the requisite time period. There are no contracts or other documents required to be described in the Preliminary Prospectus or Prospectus or Prospectus Supplement, or to be filed as exhibits or schedules to the Registration Statement, which have not been described or filed as required. The statistical and market-related data included in each of the General Disclosure Package, the Prospectus and any Prospectus Supplement are based on or derived from sources that the Company reasonably and in good faith believes are reliable and accurate or represent the Company's good faith estimates that are made on the basis of data derived from such sources. The Company has obtained all consents required for the inclusion of such statistical and market-related data in each of the General Disclosure Package, the Prospectus and any Prospectus Supplement. No forward-looking statement (within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act) contained in the General Disclosure Package, the Prospectus or any Prospectus Supplement has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith. The press releases disseminated by the Company during the twelve months preceding the date of this Agreement do not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made and when made, not misleading.

(aa) No Integrated Offering. Neither the Company, nor any of its Affiliates, nor any Person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause this Offering of the Securities to be integrated with prior offerings by the Company for purposes of any applicable shareholder approval provisions of any Trading Market on which any of the securities of the Company are listed or designated.

(bb) Solvency. Based on the consolidated financial condition of the Company as of the Closing Date, after giving effect to the receipt by the Company of the proceeds from the sale of the Securities hereunder, (i) the fair saleable value of the Company's assets exceeds the amount that will be required to be paid on or in respect of the Company's existing debts and other liabilities (including known contingent liabilities) as they mature, (ii) the Company's assets do not constitute unreasonably small capital to carry on its business as now conducted and as proposed to be conducted including its capital needs taking into account the particular capital requirements of the business conducted by the Company, consolidated and projected capital requirements and capital availability thereof, and (iii) the current cash flow of the Company, together with the proceeds the Company would receive, were it to liquidate all of its assets, after taking into account all anticipated uses of the cash, would be sufficient to pay all amounts on or in respect of its liabilities when such amounts are required to be paid. The Company does not intend to incur debts beyond its ability to pay such debts as they mature (taking into account the timing and amounts of cash to be payable on or in respect of its debt). The Company has no knowledge of any facts or circumstances which lead it to believe that it will file for reorganization or liquidation under the bankruptcy or reorganization laws of any jurisdiction within one year from the Closing Date. The Registration Statement, the General Disclosure Package and Prospectus set forth as of the date hereof all outstanding secured and unsecured Indebtedness of the Company or any Subsidiary, or for which the Company or any Subsidiary has commitments. Neither the Company nor any Subsidiary is in default with respect to any Indebtedness.

(cc) Tax Status. Except for matters that would not, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect, the Company and the Subsidiaries each (i) has made or filed all United States federal, state and local income and all foreign income and franchise tax returns, reports and declarations required by any jurisdiction to which it is subject, (ii) has paid all taxes and other governmental assessments and charges that are shown or determined to be due on such returns, reports and declarations (other than any amounts being contested by the Company in good faith) and (iii) has set aside on its books provision reasonably adequate for the payment of all taxes for periods subsequent to the periods to which such returns, reports or declarations apply. There are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction (other than any amounts being contested by the Company in good faith), and the officers of the Company or of any Subsidiary know of no basis for any such claim. The provisions for taxes payable, if any, shown on the financial statements filed with or as part of the Registration Statement are sufficient for all accrued and unpaid taxes, whether or not disputed, and for all periods to and including the dates of such consolidated financial statements, except as would not, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect. The term "taxes" mean all federal, state, local, foreign, and other net income, gross income, gross receipts, sales, use, ad valorem, transfer, franchise, profits, license, lease, service, service use, withholding, payroll, employment, excise, severance, stamp, occupation, premium, property, windfall profits, customs, duties or other taxes, fees, assessments, or charges of any kind whatsoever, together with any interest and any penalties, additions to tax, or additional amounts with respect thereto. The term "returns" means all returns, declarations, reports, statements, and other documents required to be filed in respect to taxes.

(dd) Foreign Corrupt Practices. Neither the Company nor any Subsidiary, nor to the knowledge of the Company or any Subsidiary, any employee or other person acting on behalf of the Company or any Subsidiary, has (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company or any Subsidiary (or made by any person acting on its behalf of which the Company is aware) which is in violation of law, or (iv) violated in any material respect any provision of FCPA. The Company has taken reasonable steps to ensure that its accounting controls and procedures are designed to cause the Company to comply in all material respects with the FCPA.

(ee) Accountants. The Company Auditor, whose report is filed with the Commission as part of the Registration Statement, (i) is an independent registered public accounting firm as required by the Exchange Act and (ii) has expressed its opinion with respect to the financial statements included in the Company's Annual Reports for the fiscal years ended September 30, 2022 and 2021. The Company Auditor has not, during the periods covered by the financial statements included in the Company's Annual Reports for the fiscal years ended September 30, 2022 and 2021, provided to the Company any non-audit services, as such term is used in Section 10A(g) of the Exchange Act.

(ff) Regulatory Permits. The Company and the Subsidiaries possess all certificates, authorizations, approvals, orders, licenses and permits issued by the appropriate federal, state, local or foreign governmental or regulatory authorities, including, without limitation, those administered by the U.S. Food and Drug Administration ("FDA") of the U.S. Department of Health and Human Services, or by any foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA, necessary to conduct their respective businesses as described in the Registration Statement, the General Disclosure Package or the Prospectus, except where the failure to possess such permits would not reasonably be expected to result in a Material Adverse Effect (each, a "Material Permit"), and neither the Company nor any Subsidiary has received any notice of proceedings relating to the revocation or modification of any Material Permit. The disclosures in the Registration Statement concerning the effects of federal, state, local and all foreign regulation on the Company's business as currently contemplated are correct in all material respects.

(gg) Regulatory. All preclinical and clinical studies conducted by or on behalf of the Company, taken as a whole, are or have been adequately described in the Registration Statement in all material respects. The clinical and preclinical studies conducted by or on behalf of the Company that are described in the Registration Statement or the results of which are referred to in the Registration Statement were and, if still ongoing, are being conducted in material compliance with all laws and regulations applicable thereto in the jurisdictions in which they are being conducted. The descriptions in the Registration Statement of the results of such studies are accurate and complete in all material respects and fairly present the data derived from such studies, and the Company has no knowledge of, or reason to believe that, any clinical study the aggregate results of which are inconsistent with or otherwise call into question the results of any clinical study conducted by or on behalf of the Company and its Subsidiaries that are described in the Registration Statement or the results of which are referred to in the Registration Statement. Except as disclosed in the Registration Statement, the Company has not received any written notices or statements from the FDA or any other governmental agency or authority requiring, requesting or suggesting termination, suspension or material modification for or of any clinical or preclinical studies that are described in the Registration Statement or the results of which are referred to in the Registration Statement. Except as disclosed in the Registration Statement, the Company has not received any written notices or statements from any governmental agency, and otherwise has no knowledge of, or reason to believe that any license, approval, permit or authorization to conduct any clinical trial of any potential product of the Company has been, will be or may be suspended, revoked, modified or limited.

(hh) Stock Option Plans. Each stock option granted by the Company under the Company's stock option plan was granted (i) in accordance with the terms of the Company's stock option plan and (ii) with an exercise price at least equal to the fair market value of the Common Stock on the date such stock option would be considered granted under GAAP and applicable law. No stock option granted under the Company's stock option plan has been backdated. The Company has not granted, and there is no and has been no Company policy or practice to grant, stock options prior to, or otherwise coordinate the grant of stock options with, the release or other public announcement of material information regarding the Company or its Subsidiaries or their financial results or prospects.

(ii) Office of Foreign Assets Control. Neither the Company nor any Subsidiary nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company or any Subsidiary is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department.

(jj) U.S. Real Property Holding Corporation; PFIC. The Company is not and has never been a U.S. real property holding corporation within the meaning of Section 897 of the Internal Revenue Code of 1986, as amended (including the applicable rules and regulations promulgated thereunder, the "Code"). Based on the Company's current income and assets and projections as to the value of its assets and the market value of its Common Stock, including the current and anticipated valuation of its assets, the Company does not believe it was a Passive Foreign Investment Company ("PFIC") within the meaning of Section 1297 of the Code, for its most recent taxable year, and does not expect to become a PFIC for its current taxable year or in the foreseeable future.

(kk) Bank Holding Company Act. Neither the Company nor any of its Subsidiaries or Affiliates is subject to the Bank Holding Company Act of 1956, as amended (the "BHCA"), or to regulation by the Board of Governors of the Federal Reserve System (the "Federal Reserve"). Neither the Company nor any of its Subsidiaries or Affiliates owns or controls, directly or indirectly, five percent (5%) or more of the outstanding shares of any class of voting securities or twenty-five percent (25%) or more of the total equity of a bank or any entity that is subject to the BHCA or to regulation by the Federal Reserve. Neither the Company nor any of its Subsidiaries or Affiliates exercises a controlling influence over the management or policies of a bank or any entity that is subject to the BHCA or to regulation by the Federal Reserve.

(ll) Money Laundering. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial record-keeping and reporting requirements and money laundering statutes of the United States and, to the Company's knowledge, all other jurisdictions to which the Company and its Subsidiaries are subject, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any applicable governmental agency, including of the Currency and Foreign Transactions Reporting Act of 1970, as amended (collectively, the "Money Laundering Laws"), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any Subsidiary with respect to the Money Laundering Laws is pending or, to the knowledge of the Company or any Subsidiary, threatened.

(mm) D&O Questionnaires. All information contained in the questionnaires most recently completed by each of the Company's directors and officers and, to the Company's knowledge, beneficial owner of 5% or more of the Company's Common Stock or Common Stock Equivalents is true and correct in all material respects and the Company has not become aware of any information which would cause the information disclosed in such questionnaires to become inaccurate and incorrect in any material respect.

(nn) FINRA Affiliation. No officer, director or any beneficial owner of 10% or more of the Company's shares of Common Stock or Common Stock Equivalents has any direct or indirect affiliation or association with any FINRA member (as determined in accordance with the rules and regulations of FINRA) that is participating in the Offering. Except for securities purchased on the open market, no Company Affiliate is an owner of stock or other securities of any member of FINRA. No Company Affiliate has made a subordinated loan to any member of FINRA. No proceeds from the sale of the Securities (excluding underwriting compensation as disclosed in the Registration Statement, the Prospectus and any Prospectus Supplement) will be paid to any FINRA member, any persons associated with a FINRA member or an affiliate of a FINRA member. Except as disclosed in the Prospectus and any Prospectus Supplement, the Company has not issued any warrants or other securities or granted any options, directly or indirectly, to the Representative or any of the Underwriters named on Schedule I hereto within the 180-day period prior to the initial filing date of the Prospectus. Except as disclosed in the Registration Statement and except for securities issued to the Representative as disclosed in the Prospectus and any Prospectus Supplement, and securities sold by the Representative on behalf of the Company, no person to whom securities of the Company have been privately issued within the 180-day period prior to the initial filing date of the Prospectus is a FINRA member, is a person associated with a FINRA member or is an affiliate of a FINRA member. No FINRA member participating in the Offering has a conflict of interest with the Company. For this purpose, a "conflict of interest" exists when a FINRA member, the parent or affiliate of a FINRA member or any person associated with a FINRA member in the aggregate beneficially own 5% or more of the Company's outstanding subordinated debt or common equity, or 5% or more of the Company's preferred equity. "FINRA member participating in the Offering" includes any associated person of a FINRA member that is participating in the Offering, any member of such associated person's immediate family and any affiliate of a FINRA member that is participating in the Offering. "Any person associated with a FINRA member" means (1) a natural person who is registered or has applied for registration under the rules of FINRA and (2) a sole proprietor, partner, officer, director, or branch manager of a FINRA member, or other natural person occupying a similar status or performing similar functions, or a natural person engaged in the investment banking or securities business who is directly or indirectly controlling or controlled by a FINRA member. When used in this Section 3.1(mm) the term "affiliate of a FINRA member" or "affiliated with a FINRA member" means an entity that controls, is controlled by or is under common control with a FINRA member. The Company will advise the Representative and the Representative Counsel if it learns that any officer, director or owner of 10% or more of the Company's outstanding shares of Common Stock or Common Stock Equivalents is or becomes an affiliate or associated person of a FINRA member firm.

(oo) Officers' Certificate. Any certificate signed by any duly authorized officer of the Company and delivered to the Representative or the Representative Counsel shall be deemed a representation and warranty by the Company to the Underwriters as to the matters covered thereby.

(pp) Board of Directors. The Board of Directors is comprised of the persons set forth under the heading of the Prospectus captioned "Management." The qualifications of the persons serving as board members and the overall composition of the Board of Directors comply with the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder applicable to the Company and the rules of the Trading Market. At least one member of the Board of Directors qualifies as a "financial expert" as such term is defined under the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder and the rules of the Trading Market. In addition, at least a majority of the persons serving on the Board of Directors qualify as "independent" as defined under the rules of the Trading Market.

(qq) ERISA. The Company is not a party to an "employee benefit plan," as defined in Section 3(3) of the Employee Retirement Income Security Act of 1974, as amended ("ERISA"), which: (i) is subject to any provision of ERISA and (ii) is or was at any time maintained, administered or contributed to by the Company or any of its ERISA Affiliates (as defined hereafter). These plans are referred to collectively herein as the "Employee Plans." An "ERISA Affiliate" of any person or entity means any other person or entity which, together with that person or entity, could be treated as a single employer under Section 414(b), (c), (m) or (o) of the Code. Each Employee Plan has been maintained in material compliance with its terms and the requirements of applicable law. No Employee Plan is subject to Title IV of ERISA. The Registration Statement, Preliminary Prospectus, the Prospectus and any Prospectus Supplement identify each employment, severance or other similar agreement, arrangement or policy and each material plan or arrangement required to be disclosed pursuant to the Rules and Regulations providing for insurance coverage (including any self-insured arrangements), workers' compensation, disability benefits, severance benefits, supplemental unemployment benefits, vacation benefits or retirement benefits, or deferred compensation, profit-sharing, bonuses, stock options, stock appreciation rights or other forms of incentive compensation, or post-retirement insurance, compensation or benefits, which: (i) is not an Employee Plan; (ii) is entered into, maintained or contributed to, as the case may be, by the Company or any of its ERISA Affiliates; and (iii) covers any officer or director or former officer or director of the Company or any of its ERISA Affiliates. These agreements, arrangements, policies or plans are referred to collectively as "Benefit Arrangements." Each Benefit Arrangement has been maintained in material compliance with its terms and with the requirements of applicable law. Except as disclosed in the Registration Statement, Preliminary Prospectus, the Prospectus and any Prospectus Supplement, there is no liability in respect of post-retirement health and medical benefits for retired employees of the Company or any of its ERISA Affiliates, other than medical benefits required to be continued under applicable law. No "prohibited transaction" (as defined in either Section 406 of ERISA or Section 4975 of the Code) has occurred with respect to any Employee Plan; and each Employee Plan that is intended to be qualified under Section 401(a) of the Code is so qualified, and nothing has occurred, whether by action or by failure to act, which would cause the loss of such qualification.

(rr) COVID-19. Since the onset of the COVID-19 pandemic, the Company has complied and is in compliance, in all material respects, with all statutes, rules, or regulations applicable to the Company's business and operation relating to COVID-19, including those relating to (A) shelter-in-place, quarantine and other similar orders, (B) the maintenance of safe and acceptable working conditions, and (C) employee benefits, privacy or labor and employment, including with respect to the furlough or termination of employees, the reduction or modification of compensation or employee benefits or the administration of employee leaves of absence.

(ss) Authorizations. The Company has filed and received approval of all Authorizations issued by, and has made all declarations and filings with all federal, state, local or foreign governmental or regulatory authority that are necessary for the ownership or lease of its properties or the conduct of its business as described in the Registration Statement, the General Disclosure Package and the Prospectus. The Company is in compliance with and is not in violation of, or in default under, any such Authorization. To the knowledge of the Company, no event has occurred which allows, or after notice or lapse of time would allow, revocation, termination or modification of any Authorization or result in any other material impairment of the rights of the holder of any Authorization and the Company does not have any reason to believe that any Authorization will not be renewed in the ordinary course.

(tt) Ineligible Issuer Status. At the time of filing the Registration Statement and at the date hereof, the Company was not and is not an "ineligible issuer," as defined under Rule 405 under the Securities Act.

ARTICLE IV.
OTHER AGREEMENTS OF THE PARTIES

4.1 Amendments to Registration Statement. The Company has delivered, or will as promptly as practicable deliver, to the Underwriters complete conformed copies of the Registration Statement and of each consent and certificate of experts, as applicable, filed as a part thereof, and conformed copies of the Registration Statement (without exhibits), the Prospectus, as amended or supplemented, and the General Disclosure Package in such quantities and at such places as an Underwriter reasonably requests. Neither the Company nor any of its directors and officers has distributed and none of them will distribute, prior to the Closing Date, any offering material in connection with the offering and sale of the Securities other than the Prospectus, the General Disclosure Package, the Prospectus Supplement, if any, and the Registration Statement, and copies of the documents incorporated by reference therein. The Company shall not file any such amendment or supplement to which the Representative shall reasonably object in writing.

4.2 Federal Securities Laws.

(a) Compliance. During the time when a Prospectus is required to be delivered under the Securities Act, the Company will use its best efforts to comply with all requirements imposed upon it by the Securities Act and the rules and regulations thereunder and the Exchange Act and the rules and regulations thereunder, as from time to time in force, so far as necessary to permit the continuance of sales of or dealings in the Securities in accordance with the provisions hereof and the Prospectus. If at any time when a Prospectus relating to the Securities is required to be delivered under the Securities Act, any event shall have occurred as a result of which, in the opinion of counsel for the Company or the Representative Counsel, the Prospectus, as then amended or supplemented, includes an untrue statement of a material fact or omits to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, or if it is necessary at any time to amend the Prospectus to comply with the Securities Act, the Company will notify the Underwriters promptly and prepare and file with the Commission, subject to Section 4.1 hereof, an appropriate amendment or supplement in accordance with Section 10 of the Securities Act.

(b) Filing of Final Prospectus. The Company will file the Prospectus (in form and substance satisfactory to the Representative and the Representative Counsel) with the Commission pursuant to the requirements of Rule 424.

(c) Exchange Act Registration. For a period of two (2) years from the Execution Date, subject to any requirements under applicable law, the Company will use its best efforts to maintain the registration of the Common Stock and the Warrants under the Exchange Act. The Company will not deregister the Common Stock and the Warrants under the Exchange Act without the prior written consent of the Representative.

(d) Free Writing Prospectuses. The Company represents and agrees that it has not made and will not make any offer relating to the Securities that would constitute an issuer free writing prospectus, as defined in Rule 433 of the rules and regulations under the Securities Act, without the prior written consent of the Representative. Any such free writing prospectus consented to by the Representative is herein referred to as a "Permitted Free Writing Prospectus." The Company represents that it will treat each Permitted Free Writing Prospectus as an "issuer free writing prospectus" as defined in the rules and regulations under the Securities Act, and has complied and will comply with the applicable requirements of Rule 433 of the Securities Act, including timely Commission filing where required, legending and record keeping.

4.3 Delivery to the Underwriters of Prospectuses. The Company will deliver to the Underwriters, without charge, from time to time during the period when the Prospectus is required to be delivered under the Securities Act or the Exchange Act such number of copies of each Prospectus as the Underwriters may reasonably request and, as soon as the Registration Statement or any amendment or supplement thereto becomes effective, deliver to the Representative two original executed Registration Statements, including exhibits, and all post-effective amendments thereto and copies of all exhibits filed therewith or incorporated therein by reference and all original executed consents of certified experts.

4.4 Effectiveness and Events Requiring Notice to the Underwriters. The Company will use its best efforts to cause the Registration Statement to remain effective with a current prospectus until the later of nine (9) months from the Execution Date and the date on which the Warrants and the Representative Warrants are no longer outstanding, and will notify the Underwriters and holders of the Warrants and the Representative Warrants immediately and confirm the notice in writing: (i) of the cessation of the effectiveness of the Registration Statement and any amendment thereto; (ii) of the issuance by the Commission of any stop order or of the initiation, or the threatening, of any proceeding for that purpose; (iii) of the issuance by any state securities commission of any proceedings for the suspension of the qualification of the Securities for offering or sale in any jurisdiction or of the initiation, or the threatening, of any proceeding for that purpose; (iv) of the mailing and delivery to the Commission for filing of any amendment or supplement to the Registration Statement or Prospectus; (v) of the receipt of any comments or request for any additional information from the Commission; and (vi) of the happening of any event during the period described in this Section 4.4 that, in the judgment of the Company, makes any statement of a material fact made in the Registration Statement, the General Disclosure Package or the Prospectus untrue or that requires the making of any changes in the Registration Statement, the General Disclosure Package or the Prospectus in order to make the statements therein, in light of the circumstances under which they were made, not misleading. If the Commission or any state securities commission shall enter a stop order or suspend such qualification at any time, the Company will make every reasonable effort to obtain promptly the lifting of such order.

4.5 Review of Financial Statements. For a period of three (3) years from the Execution Date, the Company shall file with the SEC all reports required to be filed pursuant to the Exchange Act and, at its expense, shall cause its regularly engaged independent registered public accounting firm to review (but not audit except as required by law) the Company's financial statements included in such reports.

4.6 Reports to the Underwriters; Expenses of the Offering.

(a) Periodic Reports, etc. For a period of two (2) years from the Execution Date, the Company will furnish or make available to the Underwriters copies of such financial statements and other periodic and special reports as the Company from time to time furnishes generally to holders of any class of its securities and also promptly furnish or make available to the Underwriters: (i) a copy of each periodic report the Company shall be required to file with the Commission; (ii) a copy of every press release and every news item and article with respect to the Company or its affairs which was released by the Company; (iii) a copy of each Form 8-K prepared and filed by the Company; (iv) a copy of each registration statement filed by the Company under the Securities Act; (v) such additional documents and information with respect to the Company and the affairs of any future Subsidiaries of the Company as any Representative may from time to time reasonably request; provided that the Underwriters shall each sign, if requested by the Company, a Regulation FD compliant confidentiality agreement which is reasonably acceptable to the Representative in connection with such Underwriter's receipt of such information. Documents filed with the Commission pursuant to its EDGAR system shall be deemed to have been delivered to the Underwriters pursuant to this Section.

(b) Transfer Sheets. For a period of three (3) years from the Execution Date, the Company shall retain the Transfer Agent or a transfer and registrar agent reasonably acceptable to the Representative and will furnish to the Underwriters at the Company's sole cost and expense such transfer sheets of the Company's securities as an Underwriter may reasonably request, including the daily and monthly consolidated transfer sheets of the Transfer Agent and the DTC.

(c) Trading Reports. During such time as the Common Stock or the Warrants are listed on a Trading Market, the Company shall provide to the Underwriters, at the Company's expense, such reports published by the Trading Market relating to price and trading of such securities, as the Underwriters shall reasonably request.

(d) General Expenses Related to the Offering. The Company hereby agrees to pay on each of the Closing Date and each Option Closing Date, if any, to the extent not paid at the Closing Date, all expenses incident to the performance of the obligations of the Company under this Agreement, including, but not limited to: (a) all filing fees and communication expenses relating to the registration of the Securities to be sold in the Offering (including the Option Securities) with the Commission; (b) all FINRA Public Offering Filing System fees associated with the review of the Offering by FINRA; all fees and expenses relating to the listing of the Common Stock and the Warrants on the Trading Market and such other stock exchanges as the Company and the Representative together determine; (c) the costs of all mailing and printing of the underwriting documents (including, without limitation, the Underwriting Agreement, any Blue Sky Surveys and, if appropriate, any Agreement Among Underwriters, any agreements with Selected Dealers, Underwriters' Questionnaire and Power of Attorney), Registration Statements, Prospectuses, Prospectus Supplements and all amendments, supplements and exhibits thereto and as many preliminary and final Prospectuses as the Representative may reasonably deem necessary; (d) the costs and expenses of the public relations firm referred to in Section 4.25; (e) the costs of preparing, printing and delivering the Securities; (f) fees and expenses of the Transfer Agent for the Securities (including, without limitation, any fees required for same-day processing of any instruction letter delivered by the Company); (g) stock transfer and/or stamp taxes, if any, payable upon the transfer of securities from the Company to the Underwriters; (h) the fees and expenses of the Company's accountants; (i) the fees and expenses of the Company's legal counsel and other agents and representatives; (j) the Underwriters' costs of mailing prospectuses to prospective investors; (k) all reasonable fees, expenses and disbursements relating to background checks of the Company's officers and directors; (l) all fees, expenses and disbursements relating to the registration or qualification of such Securities under the "blue sky" securities laws of such states and other jurisdictions as the Representative may reasonably designate (including, without limitation, all filing and registration fees, and the fees and disbursements of counsel of the Representative for such counsel's participation in the "blue sky' and stock exchange listing process); (m) the fees and expenses associated with the Underwriters' use of i-Deal's book-building, prospectus tracking and compliance software (or other similar software) for the Offering; and (n) the Company's actual "road show" expenses for the Offering. The Underwriters may also deduct from the net proceeds of the Offering payable to the Company on the Closing Date, or each Option Closing Date, if any, all out-of-pocket fees, expenses and disbursements (including legal fees and expenses) of the Underwriters incurred as a result of providing services related to the Offering to be paid by the Company to the Underwriters; provided, however, that all such costs and expenses pursuant to this Section 4.6(d), including those referenced in clauses (k) and (m) above and legal expenses of counsel to the Underwriters and otherwise, which are incurred by the Underwriters and for which the Company shall be responsible shall not exceed $125,000 in the aggregate in the event of a Closing of the Offering ($10,000 of which has been paid as an advance (the "Advance") prior to the Execution Date). In the event the offering is terminated, the Advance received against reasonable out-of-pocket expenses incurred in connection with the offering will be returned to the Company to the extent not actually incurred in accordance with FINRA Rule 5110(f)(2)(C). Upon any Representative's request, the Company shall provide funds to pay all such costs and expenses pursuant to this Section 4.6(d) in advance.

(e) Representative Warrants. On the Closing Date and each Option Closing Date, if any, the Company shall issue to the Representative (and/or its designees) warrants to purchase a number of shares of Common Stock equal to nine percent (9%) of the aggregate number of Shares sold in the Offering, including any Option Shares sold in the Over-Allotment Option, if any (the "Representative Warrants"). The Representative Warrants, in the form attached hereto as Exhibit F, shall be exercisable at an initial exercise price per share of Common Stock equal to 110% of the public offering price of each Unit and expire five (5) years from the Effective Date. The Representative understands and agrees that there are significant restrictions pursuant to FINRA Rule 5110 against transferring the Representative Warrants and the Warrant Shares issuable upon exercise of the Representative Warrants during the one hundred eighty (180) days after the Effective Date and by its acceptance thereof the Representative shall agree that it will not sell, transfer, assign, pledge or hypothecate the Representative Warrants, or any portion thereof, or the Warrant Shares, or any portion thereof, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of such securities for a period of one hundred eighty (180) days following the Effective Date to anyone other than (i) an Underwriter or a selected dealer in connection with the Offering (or any successor of the Representative or of any such Underwriter or selected dealer), or (ii) a bona fide officer, manager, partner or member of the Representative or of any such Underwriter or selected dealer (or any officer, manager, partner or member of any such successor); and only if any such transferee agrees to the foregoing lock-up restrictions. Delivery of the applicable Representative Warrants shall be made on the Closing Date and each Option Closing Date, if any, and shall be issued in the name or names and in such authorized denominations as the Representative may request.

4.7 [Reserved].

4.8 Application of Net Proceeds. The Company will apply the net proceeds from the Offering received by it in a manner consistent with the application described under the caption "Use of Proceeds" in the Prospectus and any Prospectus Supplement.

4.9 Delivery of Earnings Statements to Security Holders. The Company will make generally available to its security holders as soon as practicable, but not later than the first day of the fifteenth full calendar month following the Execution Date, an earnings statement (which need not be certified by an independent registered public accounting firm unless required by the Securities Act or the rules and regulations thereunder, but which shall satisfy the provisions of Rule 158(a) under Section 11(a) of the Securities Act) covering a period of at least twelve consecutive months beginning after the Execution Date.

4.10 Stabilization. Neither the Company nor any of its employees, directors or, to its knowledge, stockholders (without the consent of the Representative) has taken or will take, directly or indirectly, any action designed to or that has constituted or that might reasonably be expected to cause or result in, under the Exchange Act, or otherwise, stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities.

4.11 Internal Controls. The Company will implement and maintain a system of internal accounting controls designed to provide reasonable assurances that: (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary in order to permit preparation of financial statements in accordance with GAAP and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

4.12 Accountants. For a period of three (3) years from the Effective Date, the Company shall continue to retain a nationally recognized, independent PCAOB registered public accounting firm. The Underwriters acknowledge that the Company Auditor is acceptable to the Underwriters.

4.13 FINRA. The Company shall advise the Underwriters (who shall make an appropriate filing with FINRA) if it is aware that any officer, director, 5% or greater shareholder of the Company or Person that received the Company's unregistered equity securities in the past 180 days is or becomes an affiliate or associated person of a FINRA member firm prior to the earlier of the termination of this Agreement or the conclusion of the distribution of the Offering.

4.14 No Fiduciary Duties. The Company acknowledges and agrees that the Underwriters' responsibility to the Company is solely contractual and commercial in nature, based on arms-length negotiations and that neither the Underwriters nor their affiliates or any selected dealer shall be deemed to be acting in a fiduciary capacity, or otherwise owes any fiduciary duty to the Company or any of its affiliates in connection with the Offering and the other transactions contemplated by this Agreement. Notwithstanding anything in this Agreement to the contrary, the Company acknowledges that the Underwriters may have financial interests in the success of the Offering that are not limited to the difference between the price to the public and the purchase price paid to the Company by the Underwriters for the shares and the Underwriters have no obligation to disclose, or account to the Company for, any of such additional financial interests. The Company hereby waives and releases, to the fullest extent permitted by law, any claims that the Company may have against the Underwriters with respect to any breach or alleged breach of any fiduciary or similar duty to the Company in connection with the transactions contemplated by this Agreement or any matters leading up to such transactions.

4.15 Warrant Shares. If all or any portion of a Warrant or a Representative Warrant is exercised at a time when there is an effective registration statement to cover the issuance of the Warrant Shares or if the Warrant or Representative Warrant is exercised via cashless exercise, the Warrant Shares issued pursuant to any such exercise shall be issued free of all restrictive legends. If at any time following the date hereof the Registration Statement (or any subsequent registration statement registering the sale or resale of the Warrant Shares) is not effective or is not otherwise available for the sale of the Warrant Shares, the Company shall immediately notify the holders of the Warrants or the Representative Warrants in writing that such registration statement is not then effective and thereafter shall promptly notify such holders when the registration statement is effective again and available for the sale of the Warrant Shares (it being understood and agreed that the foregoing shall not limit the ability of the Company to issue, or any holder thereof to sell, any of the Warrant Shares in compliance with applicable federal and state securities laws).

4.16 Board Composition and Board Designations. The Company shall ensure that: (i) qualifications of the persons serving as board members of the Company and the overall composition of the Board of Directors comply with the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder and with the listing requirements of the Trading Market and (ii) if applicable, at least one member of the Board of Directors qualifies as a "financial expert" as such term is defined under the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder.

4.17 Securities Laws Disclosure; Publicity. At the request of the Representative, by 9:00 a.m. (New York City time) on the date hereof, the Company shall issue a press release disclosing the material terms of the Offering. The Company and the Representative shall consult with each other in issuing any press releases with respect to the Offering, and neither the Company nor any Underwriter shall issue any such press release nor otherwise make any such public statement without the prior consent of the Company, with respect to any other press release of such Underwriter, or without the prior consent of such Underwriter, with respect to any press release of the Company, which consent shall not unreasonably be withheld or delayed, except if such disclosure is required by law, in which case the disclosing party shall promptly provide the other party with prior notice of such public statement or communication. The Company will not issue press releases or engage in any other publicity, without the Representative's prior written consent for a period ending at 5:00 p.m. (New York City time) on the first business day following the 45th day following the Closing Date, other than normal and customary releases issued in the ordinary course of the Company's business.

4.18 Shareholder Rights Plan. No claim will be made or enforced by the Company or, with the consent of the Company, any other Person, that any Underwriter of the Securities is an "Acquiring Person" under any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or similar anti-takeover plan or arrangement in effect or hereafter adopted by the Company, or that any Underwriter of Securities could be deemed to trigger the provisions of any such plan or arrangement, by virtue of receiving Securities.

4.19 Reservation of Common Stock. As of the date hereof, the Company has reserved and the Company shall continue to reserve and keep available at all times, free of preemptive rights, a sufficient number of shares of Common Stock for the purpose of enabling the Company to issue Option Shares pursuant to the Over-Allotment Option, and Warrant Shares pursuant to any exercise of the Warrants and the Representative Warrants.

4.20 Listing of Common Stock and Warrants. The Common Stock and the Warrants have been approved for trading on The Nasdaq Capital Market or an Alternate Exchange. The Company agrees to use its commercially reasonable best efforts to effect and maintain the trading of the Common Stock and the Warrants on The Nasdaq Capital Market or an Alternate Exchange for at least three (3) years after the Closing Date. The Company further agrees, if the Company applies to have the shares of Common Stock or Warrants traded on any other Trading Market, it will then include in such application all of the Closing Shares, Option Shares and Warrant Shares and all of the Warrants, and will take such other action as is necessary to cause all of the Closing Shares, Option Shares and Warrant Shares and all of the Warrants to be listed or quoted on such other Trading Market as promptly as possible. The Company will then take all action reasonably necessary to continue the listing and trading of the shares of Common Stock and the Warrants on a Trading Market and will comply in all respects with the Company's reporting, filing and other obligations under the bylaws or rules of the Trading Market. The Company agrees to maintain the eligibility of the shares of Common Stock and the Warrants for electronic transfer through The Depository Trust Company or another established clearing corporation, including, without limitation, by timely payment of fees to The Depository Trust Company or such other established clearing corporation in connection with such electronic transfer.

4.21 Right of First Refusal. The Company grants Maxim the right of first refusal (the "Right of First Refusal") for a period of twelve (12) months from the Closing Date to act as a 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 (each, a "Subject Transaction"), at Maxim's sole and exclusive discretion. The Company shall provide written notice Maxim of its intention to pursue a Subject Transaction, including the material terms thereof, and if Maxim fails to exercise its Right of First Refusal with respect to such Subject Transaction within ten (10) Business Days after receipt of such written notice, then Maxim shall have no further claim or right with respect to such Subject Transaction. The Company shall not offer to retain any entity or person in connection with any such Subject Transaction on terms more favorable than terms on which it offers to retain Maxim. Maxim may elect, in its sole and absolute discretion, not to exercise its Right of First Refusal with respect to any Subject Transaction; provided that any such election by Maxim shall not adversely affect its Right of First Refusal with respect to any other Subject Transaction during the twelve (12) month period agreed to above. For the avoidance of any doubt, the Company shall not retain, engage or solicit any additional investment banker, book-runner, financial advisor, underwriter and/or placement agent in a Subject Transaction without the express written consent of Maxim.

4.22 Subsequent Equity Sales.

(a) From the date hereof until one hundred eighty (180) days after the Closing Date, neither the Company nor any Subsidiary shall issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of Common Stock or Common Stock Equivalents, without the prior written approval of the Representative and subject to Section 4.21.

(b) Notwithstanding the foregoing, this Section 4.22 shall not apply in respect of an Exempt Issuance.

4.23 Capital Changes. As of the Execution Date, the Company has effected the Reverse Stock Split as described in the Registration Statement. Until one hundred eighty (180) days after the Closing Date and except for the Reverse Stock Split as described in the Registration Statement, the Company shall not undertake a reverse or forward stock split or reclassification of the Common Stock without the prior written consent of the Representative.

4.24 Post-Offering Investments. Notwithstanding any other provision of this Agreement, including, but not limited to, Section 4.21, if within twelve (12) months following the Closing of the Offering, the Company completes any financing of equity, equity-linked or debt or other capital raising activity (other than the exercise by any Person of any options, warrants or other convertible securities) with, or receives any proceeds from, any of the investors contacted or introduced by Maxim, then the Company shall pay Maxim upon the closing of such financing or receipt of such proceeds the compensation equivalent received by Maxim for this Offering.

4.25 Financial Public Relations Firm. As of the Execution Date, the Company has retained a financial public relations firm reasonably acceptable to the Representative and the Company, which shall initially be [_____], which firm is experienced in assisting issuers in public offerings of securities and in their relations with their security holders, and shall retain such firm or another firm reasonably acceptable to the Representative for a period of not less than two (2) years after the Execution Date.

4.26 Research Independence. The Company acknowledges that each Underwriter's research analysts and research departments, if any, are required to be independent from their respective investment banking divisions and are subject to certain regulations and internal policies, and that such Underwriter's research analysts may hold and make statements or investment recommendations and/or publish research reports with respect to the Company and/or the Offering that differ from the views of its investment bankers. The Company hereby waives and releases, to the fullest extent permitted by law, any claims that the Company may have against such Underwriter with respect to any conflict of interest that may arise from the fact that the views expressed by their independent research analysts and research departments may be different from or inconsistent with the views or advice communicated to the Company by such Underwriter's investment banking divisions. The Company acknowledges that the Representative is a full service securities firm and as such from time to time, subject to applicable securities laws, may effect transactions for its own account or the account of its customers and hold long or short position in debt or equity securities of the Company.

ARTICLE V.
DEFAULT BY UNDERWRITERS

If on the Closing Date or any Option Closing Date, if any, any Underwriter shall fail to purchase and pay for the portion of the Closing Securities or Option Securities, as the case may be, which such Underwriter has agreed to purchase and pay for on such date (otherwise than by reason of any default on the part of the Company), the Representative, or if the Representative is the defaulting Underwriter, the non-defaulting Underwriters, shall use their commercially reasonable efforts to procure within 36 hours thereafter one or more of the other Underwriters, or any others, to purchase from the Company such amounts as may be agreed upon and upon the terms set forth herein, the Closing Securities or Option Securities, as the case may be, which the defaulting Underwriter or Underwriters failed to purchase. If during such 36 hours the Representative shall not have procured such other Underwriters, or any others, to purchase the Closing Securities or Option Securities, as the case may be, agreed to be purchased by the defaulting Underwriter or Underwriters, then (a) if the aggregate number of Closing Securities or Option Securities, as the case may be, with respect to which such default shall occur does not exceed 10% of the Closing Securities or Option Securities, as the case may be, covered hereby, the other Underwriters shall be obligated, severally, in proportion to the respective numbers of Closing Securities or Option Securities, as the case may be, which they are obligated to purchase hereunder, to purchase the Closing Securities or Option Securities, as the case may be, which such defaulting Underwriter or Underwriters failed to purchase, or (b) if the aggregate number of Closing Securities or Option Securities, as the case may be, with respect to which such default shall occur exceeds 10% of the Closing Securities or Option Securities, as the case may be, covered hereby, the Company or the Representative will have the right to terminate this Agreement without liability on the part of the non-defaulting Underwriters or of the Company except to the extent provided in Article VI hereof. In the event that the Closing Securities or Option Securities to which the default relates are to be purchased by the non-defaulting Underwriters, or are to be purchased by another party or parties as aforesaid, the non-defaulting Representative or the Company shall have the right to postpone the Closing Date or Option Closing Date for a reasonable period, but not in any event exceeding seven (7) Business Days, in order that the required changes in the Prospectus or in any other documents or arrangements may be effected. The term "Underwriter" includes any person substituted for a defaulting Underwriter. Any action taken under this Article shall not relieve any defaulting Underwriter from liability in respect of any default of such Underwriter under this Agreement.

ARTICLE VI.
INDEMNIFICATION

6.1 Indemnification of the Underwriters. The Company shall indemnify and hold harmless each Underwriter, its affiliates, the directors, officers, employees and agents of such Underwriter and each person, if any, who controls such Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act (collectively, the "Underwriter Indemnified Parties," and each, an "Underwriter Indemnified Party") from and against any and all losses, claims, liabilities, expenses and damages (including any and all investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding between any of the indemnified parties and any indemnifying parties or between any indemnified party and any third party, or otherwise, or any claim asserted), to which they, or any of them, may become subject under the Securities Act, the Exchange Act or other federal or state statutory law or regulation, at common law or otherwise, insofar as such losses, claims, liabilities, expenses or damages arise out of or are based on (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement (or any amendment thereto), including the information deemed to be a part of the Registration Statement at the time of effectiveness and at any subsequent time pursuant to Rules 430A and 430B of the Securities Act and the rules and regulations thereunder, as applicable, or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading or (ii) any untrue statement or alleged untrue statement of a material fact contained in any preliminary prospectus, any preliminary prospectus supplement, any Permitted Free Writing Prospectus or the Prospectus (or any amendment or supplement to any of the foregoing) or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading or (iii) any untrue statement or alleged untrue statement of a material fact contained in any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the Offering of the Securities, including any roadshow or investor presentations made to investors by the Company (whether in person or electronically) or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading or (iv) in whole or in part any inaccuracy in any material respect in the representations and warranties of the Company contained herein; provided, however, that the Company shall not be liable to the extent that such loss, claim, liability, expense or damage is based on any untrue statement or omission or alleged untrue statement or omission made in reliance on and in conformity with written information furnished to the Company in writing with respect to the Underwriters by the Representative expressly for use in the Registration Statement, the Pricing Prospectus or the Prospectus or any amendment thereof or supplement thereto, which information shall consist solely of the following: the information set forth in the Prospectus in the "Price Stabilization, Short Positions" and "Electronic Distribution" sections under the caption "Underwriting" (the "Underwriters' Information"). This indemnity agreement will be in addition to any liability that the Company might otherwise have.

6.2 Indemnification of the Company. Each Underwriter, severally and not jointly, agrees to indemnify and hold harmless the Company, its affiliates, the directors, officers, employees and agents of the Company and each other person or entity, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, against any losses, liabilities, claims, damages and expenses whatsoever, as incurred (including but not limited to reasonable attorneys' fees and any and all reasonable expenses whatsoever, incurred in investigating, preparing or defending against any litigation, commenced or threatened, or any claim whatsoever, and any and all amounts paid in settlement of any claim or litigation), joint or several, to which they or any of them may become subject under the Securities Act, the Exchange Act or otherwise, insofar as such losses, liabilities, claims, damages or expenses (or actions in respect thereof) arise out of or are based upon an untrue statement or alleged untrue statement of a material fact contained in the Registration Statement at the time of effectiveness and at any subsequent time pursuant to Rules 430A and 430B of the Securities Act and the rules and regulations thereunder, any Preliminary Prospectus, the Prospectus, or any amendment or supplement to any of them, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, in each case to the extent, but only to the extent, that any such loss, liability, claim, damage or expense (or action in respect thereof) arises out of or is based upon any such untrue statement or alleged untrue statement or omission or alleged omission made therein in reliance upon the Underwriters' Information; provided, however, that in no case shall any Underwriter (or any related Underwriter Indemnified Party) be liable or responsible for any amount in excess of the underwriting discounts and commissions applicable to the Securities purchased by such Underwriter hereunder.

6.3 Indemnification Procedures. Any party that proposes to assert the right to be indemnified under this Section 6 shall, promptly after receipt of notice of commencement of any action against such party in respect of which a claim is to be made against an indemnifying party or parties under this Section 6, notify each such indemnifying party of the commencement of such action, enclosing a copy of all papers served, but the omission so to notify such indemnifying party shall not relieve the indemnifying party from any liability that it may have to any indemnified party under the foregoing provisions of this Section 6 unless, and only to the extent that, such omission results in the forfeiture of substantive rights or defenses by the indemnifying party. If any such action is brought against any indemnified party and it notifies the indemnifying party of its commencement, the indemnifying party will be entitled to participate in and, to the extent that it elects by delivering written notice to the indemnified party promptly after receiving notice of the commencement of the action from the indemnified party, jointly with any other indemnifying party similarly notified, to assume the defense of the action, with counsel satisfactory to the indemnified party, and after notice from the indemnifying party to the indemnified party of its election to assume the defense, the indemnifying party will not be liable to the indemnified party for any legal or other expenses except as provided below and except for the reasonable out-of-pocket costs of investigation subsequently incurred by the indemnified party in connection with the defense. The indemnified party will have the right to employ its own counsel in any such action, but the fees, expenses and other charges of such counsel will be at the expense of such indemnified party unless (i) the employment of counsel by the indemnified party has been authorized in writing by one of the indemnifying parties in connection with the defense of such action, (ii) the indemnified party has reasonably concluded (based on advice of counsel) that there may be legal defenses available to it or other indemnified parties that are different from or in addition to those available to the indemnifying party, (iii) the indemnified party has reasonably concluded that a conflict or potential conflict exists (based on advice of counsel to the indemnified party) between the indemnified party and the indemnifying party (in which case the indemnifying party shall not have the right to direct the defense of such action on behalf of the indemnified party), (iv) the indemnifying party does not diligently defend the action after assumption of the defense, or (v) the indemnifying party has not in fact employed counsel satisfactory to the indemnified party to assume the defense of such action within a reasonable time after receiving notice of the commencement of the action, in each of which cases the reasonable fees, disbursements and other charges of counsel shall be at the expense of the indemnifying party or parties. It is understood that the indemnifying party or parties shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees, disbursements and other charges of more than one separate firm admitted to practice in such jurisdiction at any one time for all such indemnified party or parties. All such fees, disbursements and other charges shall be reimbursed by the indemnifying party promptly as they are incurred. An indemnifying party shall not be liable for any settlement of any action or claim effected without its written consent (which consent will not be unreasonably withheld or delayed). No indemnifying party shall, without the prior written consent of each indemnified party, settle or compromise or consent to the entry of any judgment in any pending or threatened claim, action or proceeding relating to the matters contemplated by this Section 6 (whether or not any indemnified party is a party thereto), unless (x) such settlement, compromise or consent (i) includes an unconditional release of each indemnified party from all liability arising or that may arise out of such claim, action or proceeding and (ii) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party, and (y) the indemnifying party confirms in writing its indemnification obligations hereunder with respect to such settlement, compromise or judgment. Notwithstanding the foregoing, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel, such indemnifying party agrees that it shall be liable for any settlement of the nature contemplated by Section 6.1 effected without its written consent if (A) such settlement is entered into more than 45 days after receipt by such indemnifying party of the aforesaid request, (B) such indemnifying party shall have received notice of the terms of such settlement at least 30 days prior to such settlement being entered into and (iii) such indemnifying party shall not have reimbursed such indemnified party in accordance with such request prior to the date of such settlement.

6.4 Contribution. In order to provide for just and equitable contribution in circumstances in which the indemnification provided for in the foregoing paragraphs of this Section 6 is applicable in accordance with its terms but for any reason is held to be unavailable, the Company and the Underwriters shall contribute to the total losses, claims, liabilities, expenses and damages (including any investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted, but after deducting any contribution received by the Company from persons other than the Underwriters, such as persons who control the Company within the meaning of the Securities Act, officers of the Company who signed the Registration Statement and directors of the Company, who may also be liable for contribution), to which the Company and the Underwriter may be subject in such proportion as shall be appropriate to reflect the relative benefits received by the Company on the one hand and the Underwriters on the other from the Offering of the Securities pursuant to this Agreement. The relative benefits received by the Company and the Underwriters shall be deemed to be in the same proportion as (x) the total proceeds from the Offering (net of underwriting discounts and commissions but before deducting expenses) received by the Company bears to (y) the underwriting discounts and commissions received by the Underwriters, in each case as set forth in the table on the cover page of the Prospectus. If, but only if, the allocation provided by the foregoing sentence is not permitted by applicable law, the allocation of contribution shall be made in such proportion as is appropriate to reflect not only the relative benefits referred to in the foregoing sentence but also the relative fault of the Company, on the one hand, and the Underwriters, on the other, with respect to the statements or omissions which resulted in such loss, claim, liability, expense or damage, or action in respect thereof, as well as any other relevant equitable considerations with respect to such offering. Such relative fault shall be determined by reference to whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or the Underwriters, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and the Underwriters agree that it would not be just and equitable if contributions pursuant to this Section 6.4 were to be determined by pro rata allocation or by any other method of allocation (even if the Underwriters were treated as one entity for such purpose) which does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, liability, expense or damage, or action in respect thereof, referred to above in this Section 6.4 shall be deemed to include, for purpose of this Section 6.4, any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this Section 6.4, no Underwriter shall be required to contribute any amount in excess of the underwriting discounts and commissions received by it. No person found guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 6.4, any person who controls a party to this Agreement within the meaning of the Securities Act will have the same rights to contribution as that party, and each officer of the Company who signed the Registration Statement will have the same rights to contribution as the Company, and each director, officer, employee, counsel or agent of an Underwriter will have the same rights to contribution as such Underwriter, subject in each case to the provisions hereof. Any party entitled to contribution, promptly after receipt of notice of commencement of any action against such party in respect of which a claim for contribution may be made under this Section 6.4, will notify any such party or parties from whom contribution may be sought, but the omission so to notify will not relieve the party or parties from whom contribution may be sought from any other obligation it or they may have under this Section 6.4. The obligations of the Underwriters to contribute pursuant to this Section 6.4 are several in proportion to the respective number of Securities to be purchased by each of the Underwriters hereunder and not joint. No party will be liable for contribution with respect to any action or claim settled without its written consent (which consent will not be unreasonably withheld).

6.5 Contribution Procedure. Within fifteen days after receipt by any party to this Agreement (or its representative) of notice of the commencement of any action, suit or proceeding, such party will, if a claim for contribution in respect thereof is to be made against another party ("contributing party"), notify the contributing party of the commencement thereof, but the failure to so notify the contributing party will not relieve it from any liability which it may have to any other party other than for contribution hereunder. In case any such action, suit or proceeding is brought against any party, and such party notifies a contributing party or its representative of the commencement thereof within the aforesaid fifteen days, the contributing party will be entitled to participate therein with the notifying party and any other contributing party similarly notified. Any such contributing party shall not be liable to any party seeking contribution on account of any settlement of any claim, action or proceeding affected by such party seeking contribution on account of any settlement of any claim, action or proceeding affected by such party seeking contribution without the written consent of such contributing party. The contribution provisions contained in this Section 6.5 are intended to supersede, to the extent permitted by law, any right to contribution under the Securities Act, the Exchange Act or otherwise available.

6.6 Survival. The indemnity and contribution agreements contained in this Section 6 and the representations and warranties of the Company contained in this Agreement shall remain operative and in full force and effect regardless of (i) any investigation made by or on behalf of any Underwriter or any controlling Person thereof, (ii) acceptance of any of the Securities and payment therefor or (iii) any termination of this Agreement.

ARTICLE VII.
MISCELLANEOUS

7.1 Termination.

(a) Termination Right. The Representative shall have the right to terminate this Agreement at any time prior to any Closing Date, (i) if any domestic or international event or act or occurrence has materially disrupted, or in its opinion will in the immediate future materially disrupt, general securities markets in the United States, or (ii) if trading on any Trading Market shall have been suspended or materially limited, or minimum or maximum prices for trading shall have been fixed, or maximum ranges for prices for securities shall have been required by FINRA or by order of the Commission or any other government authority having jurisdiction, or (iii) if the United States shall have become involved in a new war or an increase in major hostilities, or (iv) if a banking moratorium has been declared by a New York State or federal authority, or (v) if a moratorium on foreign exchange trading has been declared which materially adversely impacts the United States securities markets, or (vi) if the Company shall have sustained a material loss by fire, flood, accident, hurricane, earthquake, theft, sabotage or other calamity or malicious act which, whether or not such loss shall have been insured, will, in the Representative's opinion, make it inadvisable to proceed with the delivery of the Securities, or (vii) if the Company is in material breach of any of its representations, warranties or covenants hereunder, or (viii) if the Representative shall have become aware after the date hereof of such a material adverse change in the conditions or prospects of the Company, or such adverse material change in general market conditions as in the Representative's judgment would make it impracticable to proceed with the Offering, sale and/or delivery of the Securities or to enforce contracts made by the Underwriters for the sale of the Securities.

(b) Expenses. In the event this Agreement shall be terminated pursuant to Section 7.1(a), within the time specified herein or any extensions thereof pursuant to the terms herein, the Company shall be obligated to pay to Maxim its actual and accountable out of pocket expenses related to the transactions contemplated herein then due and payable up to $50,000 (inclusive of the Advance paid prior to the Execution Date) (provided, however, that such expense cap in no way limits or impairs the indemnification and contribution provisions of this Agreement). Notwithstanding the foregoing, any advance received by the Representative will be reimbursed to the Company to the extent not actually incurred in compliance with FINRA Rule 5110(f)(2)(C).

(c) Indemnification. Notwithstanding any contrary provision contained in this Agreement, any election hereunder or any termination of this Agreement, and whether or not this Agreement is otherwise carried out, the provisions of Article VI shall not be in any way effected by such election or termination or failure to carry out the terms of this Agreement or any part hereof.

7.2 Entire Agreement. The Transaction Documents, together with the exhibits and schedules thereto, any Preliminary Prospectus and the Prospectus, contain the entire understanding of the parties with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, oral or written, with respect to such matters, which the parties acknowledge have been merged into such documents, exhibits and schedules. Notwithstanding anything herein to the contrary, the Engagement Agreement, dated October 5, 2022, as amended from time to time ("Engagement Agreement"), by and between the Company and Maxim, shall continue to be effective and the terms therein, including, without limitation, Section 14 thereof with respect to any future offerings, shall continue to survive and be enforceable by Maxim in accordance with its terms, provided that, in the event of a conflict between the terms of the Engagement Agreement and this Agreement, the terms of this Agreement shall prevail.

7.3 Notices. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be in writing and shall be deemed given and effective on the earliest of: (a) the time of transmission, if such notice or communication is delivered via facsimile at the facsimile number (if any) or e-mail attachment at the e-mail address set forth on the signature pages attached hereto at or prior to 5:30 p.m. (New York City time) on a Trading Day, (b) the next Trading Day after the time of transmission, if such notice or communication is delivered via facsimile at the facsimile number or e-mail attachment at the e-mail address as set forth on the signature pages attached hereto on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (c) the second (2nd) Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service or (d) upon actual receipt by the party to whom such notice is required to be given. The address for such notices and communications shall be as set forth on the signature pages attached hereto.

7.4 Amendments; Waivers. No provision of this Agreement may be waived, modified, supplemented or amended except in a written instrument signed, in the case of an amendment, by the Company and the Representative. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right.

7.5 Headings. The headings herein are for convenience only, do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof.

7.6 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties and their successors and permitted assigns.

7.7 Governing Law; Agent for Service of Process. All questions concerning the construction, validity, enforcement and interpretation of the Transaction Documents shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that it hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in The City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents) that is brought against a party hereto (or its respective affiliates, directors, officers, shareholders, partners, members, employees or agents), and hereby irrevocably waives, and agrees not to assert in any action, suit or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action or proceeding to enforce any provisions of the Transaction Documents, then, in addition to the obligations of the Company under Article VI, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for its reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding. The Company irrevocably appoints Company Counsel as its authorized agent (the "Authorized Agent") upon which process may be served in any suit or proceeding arising out of the Transaction Documents, and agrees that service of process in any manner permitted by applicable law upon the Authorized Agent shall be deemed in every respect effective service of process in any manner permitted by applicable law upon the Company in any such suit or proceeding. The Company further agrees to take any and all action as may be necessary to maintain such designation and appointment of the Authorized Agent or a substitute authorized agent in full force and effect for a period of three (3) years from the date of this Agreement.

7.8 Survival. The representations and warranties contained herein shall survive the Closing and the Option Closing, if any, and the delivery of the Securities.

7.9 Execution. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to each other party, it being understood that the parties need not sign the same counterpart. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof.

7.10 Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their commercially reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

7.11 Remedies. In addition to being entitled to exercise all rights provided herein or granted by law, including recovery of damages, the Underwriters and the Company will be entitled to specific performance under the Transaction Documents. The parties agree that monetary damages may not be adequate compensation for any loss incurred by reason of any breach of obligations contained in the Transaction Documents and hereby agree to waive and not to assert in any action for specific performance of any such obligation the defense that a remedy at law would be adequate.

7.12 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.

7.13 Construction. The parties agree that each of them and/or their respective counsel have reviewed and had an opportunity to revise the Transaction Documents and, therefore, the normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of the Transaction Documents or any amendments thereto. In addition, each and every reference to share prices and shares of Common Stock in any Transaction Document shall be subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement.

7.14 **WAIVER OF JURY TRIAL. IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY ANY PARTY AGAINST ANY OTHER PARTY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY, THE PARTIES EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVE FOREVER ANY RIGHT TO TRIAL BY JURY.**

7.15 No Third Party Beneficiaries. This Agreement shall inure solely to the benefit of and shall be binding upon the Company, the Representative, the Underwriters and the directors, officers and controlling Persons referred to in Section 6 hereof, and their respective successors, legal representatives and assigns, and no other Person shall have or be construed to have any legal or equitable right, remedy or claim under or in respect of or by virtue of this Agreement or any provisions herein contained. The term "successors and assigns" shall not include a purchaser, in its capacity as such, of securities from the Underwriters.

(Signature Pages Follow)

If the foregoing correctly sets forth the understanding between the Underwriters and the Company, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement among the Company and the several Underwriters in accordance with its terms.

Very truly yours,

ARCH THERAPEUTICS, INC.

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

Address for Notice

If to the Company:

Arch Therapeutics, Inc.
235 Walnut St., Suite 6
Framingham, MA 01702
Attn: Terrence W. Norchi, President and Chief Executive Officer
Michael S. Abrams, Chief Financial Officer
E-mail: tnorchi@archtherapeutics.com; mabrams@archtherapeutics.com

with a copy (which shall not constitute notice) to:

Lowenstein Sandler LLP
One Lowenstein Drive
Roseland, NJ 07068
Attn: Michael J. Lerner; Alan Wovsaniker
E-mail: mlerner@lowenstein.com; awovsaniker@lowenstein.com
Fax: (973) 597-2400

Accepted by the Representative, acting for itself and as
Representative of the Underwriters named on Schedule I hereto,
as of the date first above written:

MAXIM GROUP LLC

By: _____
Name:
Title:

Address for Notice:

Maxim Group LLC
300 Park Avenue – 16th Floor
New York, New York 10022
Attention:
E-mail:
Fax:

with a copy (which shall not constitute notice) to:

Loeb & Loeb LLP
345 Park Avenue
New York, NY 10154
Attn: Mitchell Nussbaum, Esq.; David J. Levine, Esq.
E-mail: mnussbaum@loeb.com; dlevine@loeb.com
Fax: (212) 407-4990

SCHEDULE I

SCHEDULE OF UNDERWRITERS

Underwriters	Closing Units	Closing Shares	Closing Warrants	Closing Purchase Price
Maxim Group LLC				
Total				

SCHEDULE II

PERMITTED FREE WRITING PROSPECTUS

EXHIBIT A

FORM OF LOCK-UP AGREEMENT

[attached hereto]

EXHIBIT B

OFFICERS' CERTIFICATE

[attached hereto]

EXHIBIT C

SECRETARY'S CERTIFICATE

[attached hereto]

EXHIBIT D

CHIEF FINANCIAL OFFICER'S CERTIFICATE

[attached hereto]

EXHIBIT E

FORM OF WARRANT

See Exhibit A to Warrant Agreement.

EXHIBIT F

FORM OF REPRESENTATIVE WARRANT

[attached hereto]

EXHIBIT G

FORM OF WARRANT AGREEMENT

[attached hereto]

Exhibit 4.2

Exhibit 4.3

REPRESENTATIVE'S PURCHASE WARRANT

ARCH THERAPEUTICS, INC.

Warrant Shares: [●] Initial Exercise Date: [●], 2023

This **REPRESENTATIVE'S 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 referred to above as the Initial Exercise Date (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 (as subject to adjustment hereunder, the "Warrant Shares") of Common Stock. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

Section 1. Definitions. Capitalized terms used and not otherwise defined herein shall have the meanings set forth in that certain Underwriting Agreement (the "Underwriting Agreement"), dated [●], 2023, between the Company and Maxim Group LLC, as representative of the several Underwriters named in Schedule I thereto.

Section 2. Exercise.

a) Exercise of Warrant. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company of a duly executed facsimile copy or PDF copy submitted by email (or e-mail attachment) of the Notice of Exercise in the form annexed hereto (the "Notice of Exercise"). Within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the shares specified in the applicable Notice of Exercise by wire transfer or cashier's check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company 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 Company for cancellation within three (3) Trading Days of the date on which the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Business Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

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. 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.

"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 the NYSE, the NYSE American or any tier of The Nasdaq Stock Market (each, a "Trading Market"), the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. ("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 Common Stock is listed or quoted on the OTCQB or OTCQX (each as operated by OTC Markets Group, Inc., or any successor 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 the OTCQB or OTCQX Markets and if prices for the Common Stock are then reported in the OTC Pink Market published by OTC Markets Group Inc. (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 Board of Directors of the Company and reasonably acceptable to the Holder, the fees and expenses of which shall be paid by the Company.

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).

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. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within one Trading Day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% (or, upon election by a Holder prior to the issuance of any Warrants, 9.99%) of the number of shares of 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 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 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 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 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 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.

Section 4. Transfer of Warrant.

a) Transferability. Pursuant to FINRA Rule 5110(e)(1), neither this Warrant nor any Warrant Shares issued upon exercise of this Warrant shall 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 the securities by any person for a period of 180 days immediately following the commencement of sales of the offering pursuant to which this Warrant is being issued, except as permitted under FINRA Rule 5110(e)(2). Subject to the foregoing restriction, this Warrant and all rights hereunder are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers an assignment form to the Company assigning this Warrant in full. This 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 depositary), 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 Company shall register this Warrant, upon records to be maintained by or on behalf of the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company 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. Registration Rights.

a) To the extent the Company does not maintain an effective registration statement for the Warrant Shares and in the further event that the Company files a registration statement with the Securities and Exchange Commission covering the sale of its shares of Common Stock (other than a registration statement on Form S-4 or S-8, or on another form, or in another context, in which such "piggyback" registration would be inappropriate), then, for a period of five (5) years from the commencement of sales of the Offering, the Company shall give written notice of such proposed filing to the Holder as soon as practicable but in no event less than ten (10) days before the anticipated filing date, which notice shall describe the amount and type of securities to be included in such offering, the intended method(s) of distribution, and the name of the proposed managing underwriter or underwriters, if any, of the offering, and offer to the Holder in such notice the opportunity to register the sale of such number of shares of Warrant Shares as such Holder may request in writing within five (5) days following receipt of such notice (a "Piggyback Registration"). The Company shall cause such Warrant Shares to be included in such registration and shall use its commercially reasonable efforts to cause the managing underwriter or underwriters of a proposed underwritten offering to permit the Warrant Shares requested to be included in a Piggyback Registration on the same terms and conditions as any similar securities of the Company and to permit the sale or other disposition of such Warrant Shares in accordance with the intended method(s) of distribution thereof. All Holders proposing to distribute their securities through a Piggyback Registration that involves an underwriter or underwriters shall enter into an underwriting agreement in customary form with the underwriter or underwriters selected for such Piggyback Registration. Furthermore, each Holder must provide such information as reasonably requested by the Company (which information shall be limited to that which is required for disclosure under the Securities Act and the forms, rules and regulations promulgated thereunder) to be included in the registration statement timely or the Company may elect to exclude such Holder from the registration statement.

b) In addition, to the extent the Company does not maintain an effective registration statement for the Warrant Shares, for a period of five (5) years from the commencement of sales of the Offering, the Holder shall be entitled to one (1) demand right for the registration of the Warrant Shares at the Company's expense (other than any underwriting discounts, selling commissions, share transfer taxes applicable to the sale of the Warrant Shares, and fees and disbursements of counsel for the Holder) and one (1) demand right for the registration of the Warrant Shares at the Holder's expense (each, a "Demand Registration"). In the event of a Demand Registration, the Company shall use its commercially reasonable efforts to register the applicable Warrant Shares. All Holders of Warrant Shares proposing to distribute their securities through a Demand Registration that involves an underwriter or underwriters shall enter into an underwriting agreement in customary form with the underwriter or underwriters selected for such Demand Registration. Furthermore, each Holder must provide such information as reasonably requested by the Company (which information shall be limited to that which is required for disclosure under the Securities Act and the forms, rules and regulations promulgated thereunder) to be included in the registration statement timely or the Company may elect to exclude such Holder from the registration statement.

c) Notwithstanding the foregoing, the registration rights described in this Section 5 shall be subject to limitations imposed by the Commission's rules or comments of the Commission staff in connection with its review of the registration statement for any such resale registration. Moreover, notwithstanding the foregoing registration obligations of the Company, if the Company furnishes to the Holders requesting a Demand Registration a certificate signed by the Company's chief executive officer stating that in the good faith judgment of the Company's Board of Directors it would be materially detrimental to the Company and its stockholders for a registration statement to either become effective or remain effective for as long as such registration statement otherwise would be required to remain effective, because such action would (i) materially interfere with a significant acquisition, corporate reorganization, or other similar transaction involving the Company; (ii) require premature disclosure of material information that the Company has a bona fide business purpose for preserving as confidential; or (iii) render the Company unable to comply with requirements under the Securities Act or Exchange Act, then the Company shall have the right to defer taking action with respect to such Demand Registration or withdraw a related registration statement for a period of not more than forty-five (45) calendar days; provided, however, that the Company may not invoke this right more than twice in any twelve (12) month period or during the twelve (12) month period prior to the Termination Date.

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 the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then, such action may be taken or such right may be exercised on the next succeeding Business Day.

d) Authorized Shares.

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; Venue. 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 hereunder shall be made in accordance with Section 7.3 of the Underwriting Agreement.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company, on the one hand, and the Holder or the beneficial owner of this Warrant, on the other hand.

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

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(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

ARCH THERAPEUTICS, INC.
By:_____
Name: Terrence W. Norchi
Title: President and 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:
Phone Number: _____
Email Address: _____
Dated: _____
Holder's Signature:_____
Holder's Address: _____

Exhibit 5.1

Exhibit 5.2

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the use in this Amendment No. 1 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 23, 2023

EXHIBIT 107

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)	___	___	$17,250,000	0.0001102	$1,900.95
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)	___	___	$17,250,000	0.0001102	$1,900.95
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)	___	___	$1,552,500	0.0001102	$171.09
Fees Previously Paid	___	___	___	___	___	___	___	$2,204.00
Carry Forward Securities	___	___	___	___	___	___	___	___
	Total Offering Amounts					$36,052,500		$3,972.99
	Total Fees Previously Paid							$2,204.00
	Total Fee Offsets							$0.00
	Net Fee Due							$1,768.99

(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.