

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

FORM S-1/A
(Amendment No. 5)

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

ARCH THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction of
incorporation or organization)

3841
(Primary Standard Industrial
Classification Code Number)

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

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

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

Ralph V. De Martino
Marc Rivera
ArentFox Schiff LLP
901 K Street NW, Suite 700
Washington, DC 20001
(202) 724-6848

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 462I under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

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

Large accelerated filer
Non-accelerated filer

Accelerated filer
Smaller reporting company
Emerging growth company

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

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

This registration statement contains two prospectuses:

- A prospectus that covers the offer and sale by the registrant of up to \$4,600,000 of Units (consisting of \$4,600,000 of shares of Common Stock and Investor Warrants to purchase up to \$4,600,000 of shares of Common Stock), up to \$4,000,000 of Pre-Funded Units (consisting of Pre-Funded Warrants to purchase up to \$4,000,000 of shares of Common Stock and Investor Warrants to purchase up to \$4,000,000 of shares of Common Stock), up to \$4,000,000 of shares of Common Stock underlying the Pre-Funded Warrants and up to \$4,600,000 of shares of Common Stock underlying the Investor Warrants (the “**Company Prospectus**”); and
- A prospectus that covers the resale of (i) 8,609,230 shares of Common Stock, (ii) up to 85,290,531 shares of Common Stock underlying warrants and (iii) up to 4,544,706 shares of Common Stock issuable upon conversion of convertible promissory notes (the “**Resale Prospectus**”).

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

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

SUBJECT TO COMPLETION, DATED JUNE 20, 2024

PRELIMINARY PROSPECTUS

ARCH THERAPEUTICS, INC.

**969,697 Units (consisting of 969,697 Shares of Common Stock and Investor Warrants to Purchase up to 969,697 Shares of Common Stock)
Up to 969,697 Pre-Funded Units (consisting of Pre-Funded Warrants to Purchase up to 969,697 Shares of Common Stock and Investor Warrants to Purchase up to 969,697 Shares of Common Stock)
Up to 969,697 Shares of Common Stock Underlying the Pre-Funded Warrants and
Up to 969,697 Shares of Common Stock Underlying the Investor Warrants**

We are offering units (“**Units**”), on a firm commitment basis, each Unit consisting of one share of our common stock, par value \$0.001 per share (“**Common Stock**”), and one warrant to purchase one share of our Common Stock (the “**Investor Warrants**”). The Units have no stand-alone rights and will not be certificated or issued as stand-alone securities. The shares of Common Stock can be purchased in this offering only with the accompanying Investor Warrants as part of a Unit (other than pursuant to the underwriters’ option to purchase additional shares of Common Stock and/or Investor Warrants). The shares of Common Stock and Investor Warrants comprising the Units are immediately separable and will be issued separately in this offering. Each Investor Warrant offered hereby will be exercisable on the date of issuance at an assumed exercise price per share of Common Stock of \$4.00 (which equals the minimum bid price per share under the initial listing requirements of the Cboe BZX Exchange, Inc. in Cboe Listing Rule 14.9(b)), and will expire five years from the date of issuance. Pursuant to this prospectus, we are also offering the shares of Common Stock issuable upon exercise of the Investor Warrants.

We are also offering to each purchaser whose purchases of Units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding Common Stock immediately following the consummation of this offering, the opportunity to purchase, if the purchaser so chooses, pre-funded units (“**Pre-Funded Units**”) (each Pre-Funded Unit consisting of one pre-funded warrant (“**Pre-Funded Warrant**”) to purchase one share of Common Stock and one Investor Warrant to purchase one share of Common Stock) in lieu of Units that would otherwise result in the purchaser’s beneficial ownership exceeding 4.99% of our outstanding Common Stock (or at the election of the purchaser, 9.99%). Each Pre-Funded Warrant contained in a Pre-Funded Unit will be exercisable into one share of Common Stock, exercisable until all of the Pre-Funded Warrants are exercised in full. The purchase price of each Pre-Funded Unit will equal the price per Unit being sold to the public in this offering minus \$0.001, and the exercise price of each Pre-Funded Warrant included in the Pre-Funded Unit will be \$0.001 per share of Common Stock. This offering also relates to the shares of Common Stock issuable upon exercise of any Pre-Funded Warrants contained in the Pre-Funded Units sold in this offering. Each Investor Warrant contained in a Pre-Funded Unit will have an assumed exercise price of \$4.00 (which equals the minimum bid price per share under the initial listing requirements of Cboe in Cboe Listing Rule 14.9(b)). The Investor Warrants contained in the Pre-Funded Units will be exercisable immediately and will expire five years from the date of issuance. Pursuant to this prospectus, we are also offering the shares of Common Stock issuable upon exercise of the Pre-Funded Warrants and Investor Warrants contained in the Pre-Funded Units.

Our Common Stock is currently quoted on the QB tier of the OTC Marketplace (“**OTCQB**”) under the symbol “**ARTH**”. The last reported sale price of our Common Stock on June 18, 2024, was \$8.72 (post-Reverse Split, as defined below) per share. The public offering price per Unit and Pre-Funded Unit, and the exercise price of the Investor Warrants, as applicable, will be determined between us and the underwriters based on market conditions at the time of pricing, and may be at a discount to the then current market price. Therefore, the recent market price used throughout this preliminary prospectus may not be indicative of the final offering price. Currently, there is a very limited market for our Common Stock and no established public trading market for the Investor Warrants being offered in this offering. We do not intend to apply for listing of the Pre-Funded Warrants on any securities exchange or other nationally recognized trading system. There is no established public trading market for the Pre-Funded Warrants, and we do not expect a market to develop. We have applied to list our Common Stock and Investor Warrants on Cboe BZX Exchange, Inc. (“**Cboe**”) under the symbols “**ARTH**” and “**ARTHW**,” respectively. There is no assurance that our listing application will be approved by Cboe or The Nasdaq Capital Market, The Nasdaq Global Market, NYSE or NYSE American (each of the NYSE American, The Nasdaq Global Market, The Nasdaq Capital 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 Cboe or an Alternate Exchange, we will not consummate this offering.

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

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

In connection with this offering, we intend to effect a reverse stock split of our Common Stock at a ratio of 1-for-8 (the “Reverse Split**”). All share and per share information in this prospectus, other than the historical financial statements included herein, has been adjusted to reflect the anticipated reverse stock split.**

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

Investing in our securities involves a high degree of risk. Before making any investment in our securities, you should read and carefully consider the risks described in this prospectus under the heading “Risk Factors” beginning on page 22 of this prospectus.

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

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

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

(1) Excludes potential proceeds from the exercise of the Warrants or the Pre-Funded Warrants being offered pursuant to this prospectus.

We have granted the underwriters an option, exercisable within 45 days from the date of this prospectus, to purchase from us, up to an additional 145,454 shares of Common Stock at the public offering price and/or Investor Warrants to purchase up to 145,454 shares of Common Stock (equal to 15% of the shares of Common Stock (and Pre-Funded Warrants, if any) and Investor Warrants sold in this offering), in any combination, at a price per Investor Warrant equal to the public offering price, less, in each case, the underwriting discounts and commissions, to cover over-allotments, if any. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable will be \$, and the total proceeds to us, before expenses, will be \$.

The underwriters expect to deliver the securities to the purchasers on or about , 2024.

Sole Book-Running Manager

Dawson James Securities, Inc.

The date of this prospectus is , 2024

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ABOUT THIS PROSPECTUS

This prospectus relates to the primary offering and sale by Arch Therapeutics, Inc. of 969,697 Units, each consisting of one share of Common Stock and one Investor Warrant to purchase one share of Common Stock.

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

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

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

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

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

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to this registration statement of which this prospectus forms a part, and you may obtain copies of those documents as described below under the heading "**Where You Can Find More Information**" beginning on page [144](#) 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.

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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 [22](#) of this prospectus, and the risks set out below, any of which may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. These risks include, by way of example and not in limitation, risks related to:

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

- General economic and business conditions; and
- Other factors discussed under the section entitled “**Risk Factors.**”

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

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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 22 of this prospectus, “**Management’s Discussion and Analysis of Financial Condition and Results of Operations.**” beginning on page 62, and the financial statements and the accompanying notes beginning on page F-1 of this prospectus.*

Our Company

We are a biotechnology company marketing and developing a number of products based on our innovative AC5® self-assembling technology platform. We believe these products can be important advances in the field of stasis and barrier applications, which includes managing wounds created during surgery, trauma or interventional care, or from disease; stopping bleeding (hemostasis); and controlling leaking (sealant). We have recently devoted a substantial part of our operational effort to the market adoption and commercial sales of AC5 Advanced Wound System, our first product. Our goal is to make care faster and safer for patients by providing 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 product 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 (US) and the European Union (EU), respectively, and which are intended for skin applications, such as management of complicated chronic wounds and acute surgical wounds. Marketing for AC5 Topical Hemostat in the EU has not initiated. Other products are in development for use in minimally invasive or open surgical procedures and include, for example, AC5-G™ for gastrointestinal endoscopic procedures and AC5-V® and AC5 Surgical Hemostat for hemostasis inside the body, all of which are currently investigational devices limited by law to investigational use.

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

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

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

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

Sales and marketing efforts for our AC5 Advanced Wound System, which has received 510(k) marketing clearance from the United States Food and Drug Administration (“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 US 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.

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Operations

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

Our long-term business plan includes the following goals:

- growing revenues and building upon recent commercial momentum by driving product awareness, continued adoption and favorable payment policies for AC5 Advanced Wound System with the now-effective CMS Level II HCPCS code dedicated to AC5;
- conducting biocompatibility, pre-clinical, and clinical studies on our products and product candidates;
- obtaining additional marketing authorization for products in the United States, Europe, and other jurisdictions as we may determine;
- continuing to develop third party relationships to manufacture, distribute, market and otherwise commercialize our products;
- continuing to develop third party 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.

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To support our long-term business goals, we expect to focus on the following activities during the next twelve months:

- further develop our product clinical profile;
- enhance product packaging features;
- identify and address opportunities for supply chain efficiencies;
- assess our technology platform in order to identify and select product candidates for potential advancement into development;
- seek additional funding as required to support the previously described milestones necessary to support our operations;
- 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, maintaining granted patents in desired jurisdictions, and/or adding to our trade secrets in self-assembly, manufacturing, analytical methods and formulation, as appropriate.

Commercialization

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.

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.

For at least the near term future, in order to maximize operational efficiencies and to account for changing landscapes since the COVID-19 pandemic during which both marketing authorizations were received, 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.

We expect the commercialization ramp to be gradual through 2024 and into 2025, while we encourage product use among key opinion leaders and early adopters in developing market channels, and then moderately accelerate.

We recently started to commercialize AC5 Advanced Wound System. We rely on both an internal commercial team and independent sales distributors to drive 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 (VA) hospitals and military 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.

We anticipate that material growth in the physician office setting will require product reimbursement. To that end, we applied to the Centers for Medicare and Medicaid

Services (CMS) for a dedicated Healthcare Common Procedure Coding System (HCPCS) Level II reimbursement code specific to AC5 Advanced Wound System to better enable providers to bill third party payors for AC5 that is used in doctors' offices. The unique HCPCS code, A2020, was granted and made effective on April 1, 2023. A dedicated HCPCS code is an important step toward, although not a guarantee of, coverage and reimbursement, and we intend it to 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.

In support of the government market, we partnered with Lovell Government Services (LGS), a service-disabled veteran-owned small business, to be our government channel distributor. As a direct result of our relationship with LGS, AC5 Advanced Wound System has been added to the four major government contracting vehicles: Federal Supply Schedule (FSS), General Services Administration (GSA) schedule, Defense Logistics Agency's Medical Electronic Catalog Program (ECAT), and Distribution and Pricing Agreement (DAPA). This listing enables purchase by federal government agencies, including the Department of Veterans Affairs (VA), Indian Health Services (IHS), and Department of Defense (DOD) Medical Treatment Facilities, and it allows doctors in government channels to order AC5 Advanced Wound System.

Our internal core team oversees AC5 Advanced Wound System sales, marketing, and inventory distribution from the warehouse to the customer. We envision hiring additional internal sales representatives to support commercialization.

We have partnerships with reputable, value-added independent sales representatives and distributors, and we expect to add more collaborative agreements on a case-by-case basis to expand the overall reach and footprint of the sales organization. Such collaborations may include strategic partners. We anticipate that we will also 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 both 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 do not believe that our current cash on hand as of June 19, 2024 is sufficient to meet our anticipated cash requirements through the end of June 2024, and we must obtain additional financing in order to continue to operate our business. Even if this offering is successful, we could spend our financial resources much faster than we expect, in which case we would need to raise additional capital. 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 22, in which case our current funds may not be sufficient to operate our business for the period we expect.

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

We have an aggregate of \$6,898,221 in principal outstanding as of June 19, 2024 under the 2022 Notes (comprised of an aggregate of \$4,211,720 in principal amount of senior secured 2022 Notes and \$2,686,501 in principal amount of unsecured 2022 Notes) and an aggregate of \$2,400,000 in principal outstanding as of June 19, 2024 under the 2024 Notes (as defined below). The holders of the First Notes (as defined below) have been granted a security interest in substantially all of our assets pursuant to the terms of the security agreement dated July 6, 2022 (the "**Security Agreement**"), pursuant to which we provided a security interest in, and a lien on, substantially all of our assets as collateral for the repayment of the First Notes. The holders of the 2024 Notes have been granted a security interest in substantially all of our assets pursuant to the terms of the security agreement dated May 15, 2024 (the "**2024 Notes Security Agreement**"), pursuant to which we provided a security interest in, and a lien on, substantially all of our assets as collateral for the repayment of the 2024 Notes, *pari passu* with the repayment of the First Notes. If we fail to make payments on the First Notes or 2024 Notes when due or otherwise comply with the covenants contained in the First Notes or the 2024 Notes, the First Note and 2024 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.

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Proposed Listing on Cboe or an Alternate Exchange

Our Common Stock is presently quoted on the OTCQB under the trading symbol "ARTH." In connection with this offering, we have applied to list our Common Stock and Investor Warrants on Cboe 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 Cboe 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 Cboe or an Alternate Exchange approves the listing of our Common Stock by June 30, 2024. The Cboe 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 Cboe listing requirements or the listing requirements of an Alternate Exchange, including but not limited to a reverse split of our outstanding shares of Common Stock.

Implications of Being a Smaller Reporting Company

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

Corporate Information

Arch Therapeutics, Inc. (together with its subsidiary, the "**Company**" or "**Arch**") is a biotechnology company developing and marketing products based on our innovative AC5® self-assembling technology platform. Arch arose from the June 26, 2013 merger (the "**Merger**") of three entities previously known as Arch Biosurgery, Inc., Almah, Inc., and Arch Acquisition Corporation, respectively.

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

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

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

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

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

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Recent Developments

Commercial Update

During its fourth fiscal quarter ended September 30, 2023, the Company experienced a significant increase in AC5 orders, posting record monthly order volumes during both August and September. Taken together, orders from August and September represented more than half of total fiscal year volume, and September orders more than doubled August orders. The Company also observed favorable coverage and reimbursement decisions from multiple payors in different regions of the country with a commensurate increase in paid claims. Early in the fourth fiscal quarter, the Company received its first payment from a provider as a result of a paid claim for reimbursement of AC5 using A2020, and the number of paid claims across different payor networks increased throughout the quarter. Throughout the first fiscal quarter ended December 31, 2023 and second fiscal quarter ending March 31, 2024, the number of providers using AC5 and the number of related coverage and reimbursement decisions continued to expand. While numbers remain expectedly modest, the Company is optimistic that its ongoing efforts will result in contracted pricing opportunities with several regional Medicare Administrator Contractors, which management believes is the next important milestone in the Company's comprehensive strategic commercialization plan.

Charter Amendments

On July 18, 2023, the board of directors of the Company (the "**Board**") adopted resolutions by unanimous written consent, pursuant to which the Board determined that it is advisable and in the best interests of the Company to amend the Articles of Incorporation of the Company (the "**Amendment**") to (i) increase the total number of authorized shares of Common Stock from 12,000,000 to 350,000,000 (the "**Authorized Share Increase**"), (ii) authorize 5,000,000 shares of "blank check" preferred stock of the Company, thereby giving the Board the authority to designate from time to time one or more series of preferred stock (the "**Blank Check Preferred**"), and (iii) provide for a reverse stock split of the outstanding Common Stock, at a ratio within a range of 1-for-1.5 to 1-for-20, with the exact ratio to be determined by the Board subsequent to the applicable approval by the Company's stockholders, within 1 year following the date of such approval, and without correspondingly decreasing the number of authorized shares of Common Stock (the "**Reverse Split**" and, together with the Authorized Share Increase and the Blank Check Preferred, the "**Charter Amendments**"). On August 22, 2023, stockholders representing a majority of the voting power of the then outstanding shares of voting stock of the Company (the "**Majority Stockholders**") executed a written consent approving the Charter Amendments and the Company filed a preliminary Information Statement with the U.S. Securities and Exchange Commission ("SEC") with respect to the transactions contemplated hereby. The Company filed a definitive Information Statement with the SEC and mailed the definitive Information Statement to the Company's stockholders notifying them of the action taken by written consent on September 1, 2023. Accordingly, the Company filed the Amendment with respect to the Authorized Share Increase and the Blank Check Preferred with the Secretary of State of Nevada on September 21, 2023. The Company intends to effect the Reverse Split at a ratio of 1-for-8 prior to the pricing of this offering. All share and per share information in this prospectus, other than the historical financial statements included herein, has been adjusted to give effect to the Reverse Split.

PIPE, Bridge and Note Financings

Uplist PIPE

On November 8, 2023, the Company and certain institutional and accredited individual investors (collectively, the "**PIPE Investors**") entered into a Securities Purchase Agreement, as subsequently amended on June 19, 2024 (as amended, the "**PIPE SPA**"), pursuant to which the Company has agreed to issue and sell to the PIPE Investors, and the PIPE Investors have agreed to purchase from the Company, an aggregate of (i) warrants (the "**PIPE Pre-Funded Warrants**") to purchase an aggregate of 1,430,650 shares of Common Stock (the "**PIPE Pre-Funded Warrant Shares**") and (ii) warrants (the "**PIPE Investor Warrants**") and together with the PIPE Pre-Funded Warrants, the "**PIPE Warrants**") to purchase an aggregate 1,430,650 shares of Common Stock (the "**PIPE Investor Warrant Shares**") and together with the PIPE Pre-Funded Warrant Share, the "**PIPE Warrant Shares**"), at a purchase price of \$4.124 per PIPE Pre-Funded Warrant to purchase one share of Common Stock and accompanying PIPE Investor Warrant to purchase one share of Common Stock, for aggregate gross proceeds of \$5.9 million, before deducting the placement agent's fees and estimated offering expenses, and expected net proceeds of \$5.4 million after deducting the placement agent's fees and estimated offering expenses payable by the Company. The PIPE Pre-Funded Warrants and PIPE Investor Warrants will be issued as part of a private placement offering authorized by the Company's board of directors (the "**Uplist PIPE**"). The Company currently intends to use the net proceeds it receives from the Uplist PIPE for product marketing and for general working capital purposes. The purpose of the Uplist PIPE is mainly to assist the Company in meeting the initial listing requirements of Cboe, including for purposes of the minimum stockholders' equity requirement and the requirement of the Company to achieve its listing in connection with a firm commitment underwritten public offering.

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Between December 13, 2023 and March 28, 2024, certain of the PIPE Investors advanced the Company an aggregate of \$1.25 million as partial prepayment of their respective purchase price under the PIPE SPA, which funds were advanced outside of the escrow provided for in the PIPE SPA, and which funds have been available to the Company in support of its operations (the "**PIPE Advances**"). On May 15, 2024, the 2024 Notes Investors (as defined below) purchased an aggregate of \$2,220,000 in principal amount of 2024 Notes (as defined below) for an aggregate purchase price of \$1,850,000, which amount was paid through the surrender and cancellation of the PIPE Advances by the 2024 Notes Investors and an incremental amount of \$600,000 in cash. Under the PIPE SPA, a PIPE Investor's obligation to purchase PIPE Pre-Funded Warrants and PIPE Investor Warrants is reduced by the purchase price paid by such PIPE Investor for 2024 Notes under the 2024 Notes SPA (as defined below). Accordingly, it is currently anticipated that PIPE Pre-Funded Warrants to purchase an aggregate of 982,056 shares of Common Stock and PIPE Investor Warrants to purchase an aggregate of 982,056 shares of Common Stock will be issued in the Uplist PIPE, for gross proceeds of \$4,050,000, and expected net proceeds of \$3,528,000, while the \$2,220,000 in principal amount of 2024 Notes will automatically convert at the closing of this offering into (i) 2024 Note Conversion Pre-Funded Warrants to purchase an aggregate of 538,182 shares of Common Stock and (ii) 2024 Note Uplist Conversion Warrants to purchase an aggregate of 538,182 shares of Common Stock, reflecting a net addition for the benefit of the PIPE Investors that are 2024 Notes Investors of an aggregate of 89,700 shares underlying the 2024 Note Conversion Pre-Funded Warrants and 2024 Note Uplist Conversion Warrants, respectively, that is the result of the premium of the principal amount of \$2,220,000 of the 2024 Notes over their purchase price of \$1,850,000 (which purchase price, as stated above, has reduced the aggregate purchase price of the securities sold in the PIPE SPA).

The closing of the Uplist PIPE is contingent upon, among other conditions, the registration statement of which this prospectus forms a part being declared effective by the SEC and the approval of the listing of the Common Stock on any securities exchange registered with the SEC as a "national securities exchange" under Section 6 of the Exchange Act (a "**National Exchange**"), and the closing is expected to occur immediately prior to the pricing of this offering.

The Company retained Dawson James Securities, Inc. ("**DJ**"), pursuant to a placement agency agreement, dated November 8, 2023, as placement agent in connection with the Uplist PIPE. The Company will pay DJ a cash fee equal to 8.0% of the aggregate gross proceeds of the Uplist PIPE (expected to be \$472,000), will reimburse DJ for legal and other expenses of up to \$150,000 and will issue to DJ, or its designees, warrants (the "**PIPE Placement Agent Warrants**") to purchase an aggregate of 71,533 shares of Common Stock. The PIPE Placement Agent Warrants will be exercisable at any time and from time to time, in whole or in part, during the five-year period commencing upon issuance, at a price per share equal to \$5.15625 (which is 125% of the price per Unit sold in this offering).

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PIPE Pre-Funded Warrants

The PIPE Pre-Funded Warrants (i) will have a nominal exercise price of \$0.001 per share; (ii) will be exercisable immediately upon issuance; (iii) will be exercisable until all of the PIPE Pre-Funded Warrants are exercised in full; and (iv) will have a provision preventing the exercisability of such PIPE Pre-Funded Warrants if, as a result of the exercise of the PIPE Pre-Funded Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder's, would be deemed to beneficially own more than either 4.99% or 9.99% of the Common Stock (the "**Ownership Limitation**") immediately after giving effect to the exercise of the PIPE Pre-Funded Warrants.

PIPE Investor Warrants

The PIPE Investor Warrants (i) will have an exercise price of \$4.00 per share; (ii) will have a term of exercise equal to 5 years after their issuance date; (iii) will be exercisable immediately upon issuance; and (iv) will have a provision preventing the exercisability of such PIPE Investor Warrants if, as a result of the exercise of the PIPE Investor Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder's, would be deemed to beneficially own more than the Ownership Limitation immediately after giving effect to the exercise of the PIPE Investor Warrants.

Pursuant to the PIPE SPA, the Company has agreed to file no later than sixty (60) days after the closing date of an offering conducted in conjunction with an uplist of the Common Stock to, and in compliance with the rules of, any National Exchange (the "**Uplist Transaction**"), which this offering is intended to be, a registration statement on Form S-4, or other appropriate form, registering the offer by the Company to exchange, on a one-for-one basis, all outstanding PIPE Investor Warrants, 2022 Warrants (as defined below), Uplist Conversion Warrants (as defined below) and Exchange Investor Warrants (as defined below) for newly issued warrants identical to the Investor Warrants being sold in this offering, which warrants are expected to be listed on Cboe under the symbol "ARTHW."

Registration Rights Agreement

The Company also entered into a registration rights agreement with the PIPE Investors dated November 8, 2023 (the "**PIPE Registration Rights Agreement**"), pursuant to which the Company is obligated, subject to certain conditions, to file with the SEC within the earlier of (i) the closing date of the Uplist Transaction and (ii) the 60th calendar day following the date of the PIPE Registration Rights Agreement one or more registration statements to register the PIPE Warrant Shares, the Uplist Conversion Warrant Shares (as defined below) and the 2022 Note Conversion Pre-Funded Warrant Shares (as defined below) for resale under the Securities Act of 1933, as amended (the "Securities Act"). The Company's failure to satisfy certain filing and effectiveness deadlines and certain other requirements set forth in the PIPE Registration Rights Agreement may subject the Company to payment of monetary penalties. The Resale Prospectus currently covers the resale of the PIPE Warrant Shares, the Uplist Conversion Warrant Shares and the 2022 Note Conversion Pre-Funded Warrant Shares.

PIPE Advances

Under the terms of the PIPE Advances, since the Common Stock has not been approved for listing on the Nasdaq Capital Market by March 31, 2024, with respect to a portion of the PIPE Advances, or April 30, 2024, with respect to the remainder of the PIPE Advances, the Company has issued to the advancing parties (A) additional pre-funded warrants (the "**PIPE Advance Penalty Pre-Funded Warrants**") to purchase up to an aggregate of 75,776 shares of Common Stock (which represents a 25% addition) and (B) additional investor warrants (the "**PIPE Advance Penalty Common Warrants**") to purchase up to an aggregate of 75,776 shares of Common Stock. The Resale Prospectus currently covers the resale of the shares of Common Stock underlying the PIPE Advance Penalty Pre-Funded Warrants (the "**PIPE Advance Penalty Pre-Funded Warrant Shares**") and the PIPE Advance Penalty Common Warrants (the "**PIPE Advance Penalty Common Warrant Shares**").

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Backstop Agreement

On June 19, 2024, certain of the PIPE Investors (the "**Backstop Buyers**") agreed that in the event that as of the close of business on the date that is 10 calendar days prior to the date that the Company reasonably expects the closing of the Uplist PIPE to occur (the "**Escrow Date**") there is not an amount of funds in escrow for the PIPE equal to \$5,900,000 less the aggregate purchase price paid for the 2024 Notes (the "**Escrow Minimum Amount**") (such circumstance, an "**Escrow Deficiency**"), then each of the Backstop Buyers will deposit in escrow the purchase price for a pro rata share of an amount, no greater than \$1,500,000, equal to (A) \$320,000 plus (B) (i) \$5,900,000, minus (ii) the amount of funds in escrow on the Escrow Date, minus (iii) the aggregate purchase price paid by PIPE Investors for the 2024 Notes (the "**Backstop Amount**") of additional PIPE Pre-Funded Warrants and PIPE Investor Warrants under the PIPE SPA (such agreement, the "**Backstop Agreement**"), and shall purchase such additional PIPE Pre-Funded Warrants and PIPE Investor Warrants at the Uplist PIPE closing. In consideration for the execution by the Backstop Buyers of the Backstop Agreement, the Company agreed to issue to the Backstop Buyers, as soon as practicable, pre-funded warrants (the "**Execution Backstop Pre-Funded Warrants**"), in form and substance substantially similar to the PIPE Pre-Funded Warrants, to purchase an aggregate of 225,000 shares of Common Stock. The Company also agreed to issue to the Backstop Buyers (i) additional pre-funded warrants (the "**Funding Backstop Pre-Funded Warrants**") and, together with the Execution Backstop Pre-Funded Warrants, the "**Backstop Pre-Funded Warrants**") to purchase an amount of shares of Common Stock equal to 0.5 shares per dollar of funding deposited under the Backstop Agreement, or up to an aggregate of 750,000 shares, and (ii) investor warrants (the "**Backstop Common Warrants**"), in form and substance substantially similar to the PIPE Investor Warrants, to purchase an amount of shares of Common Stock equal to 0.65 shares per dollar of funding deposited under the Backstop Agreement, or up to an aggregate of 975,000 shares. The Resale Prospectus currently covers the resale of the shares of Common Stock underlying the Backstop Pre-Funded Warrants (the "**Backstop Pre-Funded Warrant Shares**") and the Backstop Common Warrants (the "**Backstop Common Warrant Shares**"). This prospectus assumes that no Escrow Deficiency will occur and thus no funding will be deposited under the Backstop Agreement and no Funding Backstop Pre-Funded Warrants or Backstop Common Warrants will be issued.

2024 Notes

On May 15, 2024, the Company entered into a Securities Purchase Agreement (the "**2024 Notes SPA**") with certain institutional and accredited individual investors who are also PIPE Investors (collectively, the "**2024 Notes Investors**") providing for the issuance and sale by the Company to the 2024 Notes Investors certain Secured Promissory Notes (each a "**2024 Note**" and collectively, the "**2024 Notes**") convertible into shares of Common Stock. On June 12, 2024, an additional investor, which is not a PIPE Investor (the "**Additional 2024 Notes Investor**") purchased 2024 Notes in the principal amount of \$180,000, including an original issue discount of \$30,000. The 2024 Notes were issued as part of a convertible notes offering authorized by the Company's board of directors (the "**2024 Notes Financing**").

In connection with the 2024 Notes Financing, the Company issued and sold to the 2024 Notes Investors and Additional 2024 Notes Investor the 2024 Notes in the aggregate principal amount of \$2,400,000, which includes an aggregate \$400,000 original issue discount in respect of the 2024 Notes. The aggregate net proceeds for the sale of the 2024 Notes was approximately \$2,000,000, after deducting issuance discounts. The closing of the sales of the 2024 Notes to the 2024 Notes Investors under the 2024 Notes SPA occurred on May 15, 2024 (the "**2024 Notes Closing Date**"). The Company is using the net proceeds from the 2024 Notes Financing primarily for working capital and general corporate purposes, and has not allocated specific amounts for any specific purposes.

The 2024 Notes become due and payable on June 30, 2024 (the "**2024 Notes Maturity Date**") and may be prepaid provided that an Event of Default (as defined therein) has not occurred. The 2024 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 their issuance date until the 2024 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 2024 Notes. Any amount of principal or interest on the 2024 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 “Default Interest”).

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The 2024 Notes are convertible into an aggregate of 600,000 shares of Common Stock (such shares of Common Stock, the **“2024 Conversion Shares”**) at the option of each holder of the 2024 Notes from their issuance date at the 2024 Conversion Price (as defined below) through the later of (i) the 2024 Notes Maturity Date and (ii) the date of payment of the Default Amount (as defined in the 2024 Note); *provided, however*, the 2024 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 (the **“2024 Notes Ownership Limitation”**) immediately after giving effect to the conversion; and *provided further*, the holder, upon notice to the Company, may increase or decrease the 2024 Notes Ownership Limitation; *provided that* (i) the 2024 Notes 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 2024 Notes Ownership Limitation will not become effective until the 61st day after delivery of such waiver notice.

The initial conversion price of the 2024 Notes (the **“2024 Conversion Price”**) shall be equal to \$4.00 per share and may be reduced or increased proportionately as a result of any stock dividends, recapitalizations, reorganizations, and similar transactions. If the Company fails to deliver the shares of Common Stock issuable upon a conversion by the Deadline (as defined in the 2024 Notes), then the Company is obligated to pay such 2024 Note holder \$5,000 per day in cash for each day beyond the Deadline.

The 2024 Notes contain customary events of default, which include, among other things, (i) the Company’s failure to pay when due any principal or interest payment under the 2024 Notes; (ii) the insolvency of the Company; (iii) delisting of the Common Stock; (iv) the Company’s breach of any material covenant or other material term or condition under the 2024 Notes; and (v) the Company’s breach of any representations or warranties under the 2024 Notes which cannot be cured within five days. Further, Events of Default under the 2024 Notes also include (i) the unavailability of Rule 144 on or after six months from the Issue Date (as defined therein); (ii) the Company’s failure to deliver the shares of Common Stock to the 2024 Note holder upon exercise by such holder of its conversion rights under the 2024 Note; (iii) the Company’s 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) the Company’s failure to complete an uplist to a National Exchange by June 30, 2024.

Upon an Event of Default, the 2024 Notes shall become immediately due and payable and the Company shall pay to each 2024 Note holder an amount equal to 125% (the **“Default Premium”**) multiplied by the sum of the outstanding principal amount of the 2024 Notes plus any accrued and unpaid interest on the unpaid principal amount of the 2024 Notes to the date of payment, plus any Default Interest and any other amounts owed to the holder under the 2024 Notes 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 five percent (5%) to the Default Premium for each subsequent Event of Default. At the election of each 2024 Note holder, the Default Amount may be paid in cash or shares of Common Stock equal to the Default Amount divided by the 2024 Conversion Price at the time of payment.

Upon the closing of this offering, 100% of the then outstanding principal amount of the 2024 Notes shall automatically convert (the **“2024 Notes Automatic Conversion”**) into shares of Common Stock (the **“2024 Notes Automatic Conversion Shares”**), with the conversion price for purposes of such 2024 Notes Automatic Conversion being \$4.125. Upon the 2024 Notes Automatic Conversion and to the extent that the beneficial ownership of a holder of 2024 Notes (a **“2024 Notes Holder”** and, all holders of 2024 Notes together, the **“2024 Notes Holders”**) would increase over the applicable 2024 Notes Ownership Limitation, the 2024 Notes Holder will receive pre-funded warrants (the **“2024 Note Conversion Pre-Funded Warrants”**, and the shares issuable upon exercise thereof, the **“2024 Note Conversion Pre-Funded Warrant Shares”**) in lieu of shares of Common Stock otherwise issuable to the 2024 Notes Holder in connection with the 2024 Notes Automatic Conversion, which 2024 Note Conversion Pre-Funded Warrants shall have an exercise price of \$0.001 per share, may be exercised on a cashless basis, shall be exercisable immediately upon issuance and shall contain a customary beneficial ownership limitation provision.

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In addition, upon the 2024 Notes Automatic Conversion, the 2024 Notes Holder shall receive a warrant (the **“2024 Notes Uplist Conversion Warrant”**, and the shares issuable upon exercise thereof, the **“2024 Notes Uplist Conversion Warrant Shares”**) to purchase a number of shares of Common Stock equal to the number of shares of Common Stock (or shares of Common Stock underlying 2024 Note Conversion Pre-Funded Warrants, if any) issued upon the 2024 Notes Automatic Conversion. The 2024 Notes Uplist Conversion Warrant shall have an exercise price per share of \$4.00 and shall otherwise be identical to the PIPE Investor Warrants. The Company also agreed in the 2024 Notes to file no later than sixty (60) days after the closing of this offering a registration statement on Form S-4, or other appropriate form, registering the offer by the Company to exchange, on a one-for-one basis, all outstanding PIPE Investor Warrants, 2024 Notes Uplist Conversion Warrants and Exchange Investor Warrants for newly issued warrants identical to the Investor Warrants being sold in this offering, which warrants are expected to be listed on Cboe under the symbol “ARTHW.”

Registration Rights Agreement

On the 2024 Notes Closing Date, the Company entered into a Registration Rights Agreement with the 2024 Notes Investors (the **“2024 Notes Registration Rights Agreement”**), pursuant to which the Company is obligated, subject to certain conditions, to file with the Securities and Exchange Commission within 60 days after the 2024 Notes Closing Date one or more registration statements (any such registration statement, a **“2024 Notes Resale Registration Statement”**) to register the 2024 Conversion Shares for resale under the Securities Act. The Company’s failure to satisfy certain filing and effectiveness deadlines with respect to a 2024 Notes Resale Registration Statement and certain other requirements set forth in the 2024 Notes Registration Rights Agreement may subject the Company to payment of monetary penalties.

Security Agreement

In connection with the issuance of the 2024 Notes, the Company entered into a Security Agreement with the Collateral Agent (as defined therein) on behalf of the 2024 Notes Investors on the 2024 Notes Closing Date (the **“2024 Notes Security Agreement”**), pursuant to which the Company and each of its subsidiaries (together with any persons who execute a joinder to the 2024 Notes Security Agreement, the **“2024 Notes Debtors”**) provided as collateral to the 2024 Notes holders a security interest in, and a lien on, substantially all of the 2024 Notes Debtors. Upon an Event of Default under the 2024 Notes, each 2024 Notes holder may exercise its rights to the collateral pursuant to the terms of the 2024 Notes Security Agreement.

Accordingly, it is currently anticipated that at the closing of this offering: (i) (A) 2024 Note Conversion Pre-Funded Warrants with an exercise price of \$0.001 to purchase an aggregate of 538,182 shares of Common Stock and (B) 43,637 2024 Notes Automatic Conversion Shares will be issued upon the 2024 Note Automatic Conversion of the \$2,400,000 of principal amount outstanding under the 2024 Notes; and (ii) the 2024 Note Holders will be issued 2024 Note Uplist Conversion Warrants to purchase an aggregate of 581,819 shares of Common Stock. The expected allocation between shares of Common Stock and 2024 Note Conversion Pre-Funded Warrants in the previous sentence is only an initial estimate based on indications of interest and is subject to change based on the ultimate ownership of the 2024 Note Holders after the Uplist PIPE and this offering. The maximum number of shares of Common Stock and 2024 Note Conversion Pre-Funded Warrants that may be issued, individually and in the aggregate is 581,819.

Bridge Offering

Between July 7, 2023 and September 11, 2023, pursuant to a Securities Purchase Agreement dated July 7, 2023, as subsequently amended (the **“Bridge SPA”**), among the Company and certain institutional and accredited individual investors (collectively, the **“Bridge Investors”**) the Company issued and sold to the Bridge Investors an aggregate of (i) 418,051 shares (the **“Bridge Shares”**) of Common Stock; (ii) warrants (the **“Bridge Pre-Funded Warrants”**) to purchase an aggregate of 756,871 shares of Common

Stock (the “**Bridge Pre-Funded Warrant Shares**”); and (iii) warrants (the “**Common Warrants**” and together with the Bridge Pre-Funded Warrants, the “**Bridge Warrants**”) to purchase an aggregate 2,349,826 shares of Common Stock (the “**Common Warrant Shares**” and together with the Bridge Pre-Funded Warrant Share, the “**Bridge Warrant Shares**”), at a purchase price of \$2.20 per Bridge Share and accompanying Common Warrant to purchase two shares of Common Stock, and \$2.192 per Bridge Pre-Funded Warrant to purchase one share of Common Stock and accompanying Common Warrant to purchase two shares of Common Stock. The Bridge Shares, Bridge Pre-Funded Warrants, and Common Warrants were issued as part of a private placement offering authorized by the Company’s board of directors (the “**Bridge Offering**”).

Pursuant to the Bridge SPA, the Bridge Investors agreed not to sell or otherwise transfer any of the Bridge Shares or Bridge Warrant Shares prior to the one-year anniversary of the Bridge Closing Date. In the event that a Bridge Investor purchases securities in connection with an Uplist Transaction, which this offering is intended to be, and/or in the Uplist PIPE, with an aggregate purchase price equal to at least 4.3 multiplied by the aggregate purchase price paid by the Bridge Investor for the Bridge Shares and Bridge Warrants under the Bridge SPA, the one-year lock-up period will no longer apply to the Bridge Shares and Bridge Warrants. The aggregate gross proceeds for the sale of the Bridge Shares, Bridge Pre-Funded Warrants, and Common Warrants was approximately \$2.6 million, before deducting the placement agent’s fees and other estimated fees and offering expenses payable by the Company. The first closing of the sales of these securities under the Bridge SPA occurred on July 7, 2023 (the “**Bridge Closing Date**”).

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Under the Bridge SPA, the Company also agreed that upon the closing of the next underwritten public offering of Common Stock (a “**Qualifying Offering**”), which the Company agreed is this offering, if the effective offering price to the public per share of Common Stock (the “**Qualifying Offering Price**”) is lower than \$32.00 per share, then the Company shall issue additional Bridge Pre-Funded Warrants (the “**True-Up Pre-Funded Warrants**”), and the shares issuable upon exercise thereof, the “**True-Up Pre-Funded Warrant Shares**”), or shares of Common Stock (the “**True-Up Shares**”) in lieu thereof to the extent necessary to cause the Company to meet the listing requirements of the Company’s proposed trading market in the Uplist Transaction, in an amount reflecting a reduction in the purchase price paid for the Bridge Shares and Bridge Pre-Funded Warrants that equals the proportion by which the Qualifying Offering Price is less than \$32.00. The Company also agreed that the Qualifying Offering Price as a result of this offering is \$4.00. **Accordingly, at the closing of this offering, based on the sale of the Units and Pre-Funded Units at an assumed public offering price of \$4.125 per Unit and \$4.124 per Pre-Funded Unit, which represents the minimum bid price of \$4.00 per share under the initial listing requirements of Cboe in Cboe Listing Rule 14.9(b) plus a value of \$0.125 attributed to the accompanying Investor Warrant, the Company expects to issue (i) True-Up Pre-Funded Warrants with an exercise price of \$0.001 to purchase an aggregate of 6,330,422 shares of Common Stock and (ii) an aggregate of 1,893,919 True-Up Shares to the Bridge Investors.** The expected allocation between True-Up Shares and True-Up Pre-Funded Warrants in the previous sentence is only an initial estimate based on indications of interest and is subject to change based on the ultimate ownership of the Bridge Investors after the Uplist PIPE and this offering. The maximum amount of True-Up Pre-Funded Warrants and True-Up Shares that may be issued, individually and in the aggregate is 8,224,341. The Resale Prospectus currently covers the resale of the True-Up Pre-Funded Warrant Shares and True-Up Shares.

The Company retained DJ as placement agent in connection with the Bridge Offering. The Company paid DJ a cash fee equal to 8.0% of the aggregate gross proceeds of the Bridge Offering and reimbursement of expenses of \$50,000. Additionally, on September 7, 2023 the Company issued to DJ, or its designees, warrants, as subsequently amended (the “**Placement Agent Warrants**”) to purchase an aggregate of 55,242 shares of Common Stock. The Placement Agent Warrants are exercisable at any time and from time to time, in whole or in part, until September 7, 2028, at a price per share equal to \$2.20 (which will increase to \$5.15625 at the closing of the Uplist Transaction, representing 125% of the assumed price per share of Common Stock in the Uplist Transaction, as required by FINRA).

Bridge Pre-Funded Warrants

The Bridge Pre-Funded Warrants (i) have a nominal exercise price of \$0.008 per share; (ii) are exercisable after the earlier of (A) the six-month anniversary after the date of issuance, (B) 120 days after the closing date of an Uplist Transaction, and (C) the date that a registration statement registering the Bridge Pre-Funded Warrant Shares is declared effective; (iii) are exercisable until all of the Bridge Pre-Funded Warrants are exercised in full; and (iv) have a provision preventing the exercisability of such Bridge Pre-Funded Warrants if, as a result of the exercise of the Bridge Pre-Funded Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than the Ownership Limitation immediately after giving effect to the exercise of the Bridge Pre-Funded Warrants.

Common Warrants

The Common Warrants (i) have an exercise price of \$8.00 per share; (ii) have a term of exercise equal to 5 years after their issuance date; (iii) are exercisable after the earlier of (A) the six-month anniversary after the date of issuance and (B) the date that a registration statement registering the Common Warrant Shares is declared effective; (iv) have a provision permitting voluntary adjustments to the exercise price by the Company, subject to the prior written consent of the Common Warrant holder; (v) are automatically exchanged upon the closing of an Uplist Transaction for a new warrant that is identical to the warrants (other than any pre-funded warrants), if any, being issued to investors in such Uplist Transaction, with the number of shares underlying such new warrant being equal to the number of Common Warrant Shares then underlying the Common Warrant multiplied by three and (vi) have a provision preventing the exercisability of such Common Warrants if, as a result of the exercise of the Common Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Company Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than the Ownership Limitation immediately after giving effect to the exercise of the Common Warrants. **Accordingly, at the closing of this offering, the Common Warrants will be cancelled and exchanged for newly issued warrants identical to the Investor Warrants to purchase an aggregate of 7,049,478 shares of Common Stock at an exercise price per share equal to the exercise price per share of the Investor Warrants (the “Exchange Investor Warrants”).**

In addition, as noted above, pursuant to the PIPE SPA, the Company has agreed to file no later than sixty (60) days after the closing date of the Uplist Transaction, a registration statement on Form S-4, or other appropriate form, registering the offer by the Company to exchange, on a one-for-one basis, all outstanding Exchange Investor Warrants for newly issued warrants identical to the Investor Warrants being sold in this offering, which warrants are expected to be listed on Cboe under the symbol “ARTHW.”

Registration Rights Agreement

The Company also entered into a registration rights agreement with the Bridge Investors dated July 7, 2023, as subsequently amended (the “**Registration Rights Agreement**”), pursuant to which the Company is obligated, subject to certain conditions, to file with the SEC within the earlier of (i) 30 days following the closing date of the Uplist Transaction and (ii) January 31, 2024 one or more registration statements (any such registration statement, a “**Resale Registration Statement**”) to register the Bridge Shares, the Bridge Warrant Shares and the shares of Common Stock issuable upon exercise in full of the Exchange Investor Warrants (the “**Exchange Investor Warrant Shares**”) for resale under the Securities Act of 1933, as amended (the “**Securities Act**”). The Company’s failure to satisfy certain filing and effectiveness deadlines with respect to a Resale Registration Statement and certain other requirements set forth in the Registration Rights Agreement may subject the Company to payment of monetary penalties. The Resale Prospectus currently covers the resale of the Bridge Shares and the Bridge Warrant Shares.

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Note Modification Agreements

On April 30, 2024, the Company entered into an amendment (“**Amendment No. 16 to the First Notes**”) with the holders of the Company’s outstanding Senior Secured Convertible Promissory Notes, as separately amended on February 14, 2023, March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023, September 30, 2023, November 8, 2023, November 15, 2023, January 5, 2024 and March 15, 2024 (as amended, the “**First Notes**”), issued in connection with a private placement financing the Company completed on July 6, 2022 (the “**First Closing**”). On April 30, 2024, the Company also entered into an amendment (“**Amendment No. 16 to the Second Notes**”) with the holders of the Company’s outstanding Unsecured Convertible Promissory Notes, as separately amended on

February 14, 2023, March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023, September 30, 2023, November 8, 2023, November 15, 2023, January 5, 2024 and March 15, 2024 (as amended, the “**Second Notes**”), issued in connection with a private placement financing the Company completed on January 18, 2023 (the “**Second Closing**”). On April 30, 2024, the Company also entered into an amendment (“**Amendment No. 11 to the Third Notes**”) with the holders of the Company’s outstanding Unsecured Convertible Promissory Notes, as separately amended on June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023, September 30, 2023, November 8, 2023, November 15, 2023, January 5, 2024 and March 15, 2024 (as amended, the “**Third Notes**”), issued in connection with a private placement financing the Company completed on May 15, 2023 (the “**Third Closing**”). On April 30, 2024, the Company also entered into an amendment (“**Amendment No. 2 to the Fourth Notes**” and, together with Amendment No. 16 to the First Notes, Amendment No. 16 to the Second Notes and Amendment No. 11 to the Third Notes, the “**Amendments to the 2022 Notes**”) with the holders of the Company’s outstanding Unsecured Convertible Promissory Notes, as separately amended on March 15, 2024 (the “**Fourth Notes**” and, together with the First Notes, the Second Notes and the Third Notes, the “**2022 Notes**”), issued in connection with a private placement financing the Company completed on March 12, 2024 (the “**Fourth Closing**”).

Under the Amendments to the 2022 Notes, the following amendments to the 2022 Notes will be simultaneously effective upon the closing of the Uplist Transaction. 95% of the then outstanding principal amount of the 2022 Notes shall automatically convert (the “**Automatic Conversion**”) into shares of Common Stock (the “**Automatic Conversion Shares**”), with the conversion price for purposes of such Automatic Conversion being \$4.00. Upon the Automatic Conversion and to the extent that the beneficial ownership of a holder of 2022 Notes (a “**Holder**” and, all holders of 2022 Notes together, the “**Holders**”) would increase over the applicable Ownership Limitation, the Holder will receive pre-funded warrants (the “**2022 Note Conversion Pre-Funded Warrants**”), and the shares issuable upon exercise thereof, the “**2022 Note Conversion Pre-Funded Warrant Shares**”) in lieu of shares of Common Stock otherwise issuable to the Holder in connection with the Automatic Conversion, which 2022 Note Conversion Pre-Funded Warrants shall have an exercise price of \$0.001 per share, may be exercised on a cashless basis, shall be exercisable immediately upon issuance and shall contain a customary beneficial ownership limitation provision.

In addition, upon the Automatic Conversion, the Holder shall receive a warrant (the “**Uplist Conversion Warrant**”, and the shares issuable upon exercise thereof, the “**Uplist Conversion Warrant Shares**”) to purchase a number of shares of Common Stock equal to 10 times the dollar amount under the 2022 Notes that was converted in the Automatic Conversion. The Uplist Conversion Warrant shall have an exercise price per share of \$4.00 and shall otherwise be identical to the PIPE Investor Warrants. The Company also agreed in the Amendments to the 2022 Notes to file no later than sixty (60) days after the closing of this offering a registration statement on Form S-4, or other appropriate form, registering the offer by the Company to exchange, on a one-for-one basis, all outstanding PIPE Investor Warrants, 2022 Warrants, Uplist Conversion Warrants and Exchange Investor Warrants for newly issued warrants identical to the Investor Warrants being sold in this offering, which warrants are expected to be listed on Cboe under the symbol “ARTHW” (the “**Uplist Conversion Warrants Exchange Offer Obligation**”).

The Amendments to the 2022 Notes also prohibit the Company from engaging in any capital raising transactions, subject to certain exceptions, until the earlier of (A) July 7, 2027, and (B) the first date on which all Holders hold less than 20% of the original amount of the Uplist Conversion Warrants received by each Holder, respectively, in connection with the Automatic Conversion.

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Accordingly, it is currently anticipated that at the closing of this offering: (i) an aggregate of (A) 1,454,034 shares of Common Stock and (B) 2022 Note Conversion Pre-Funded Warrants with an exercise price of \$0.001 to purchase an aggregate of 184,296 shares of Common Stock will be issued upon the Automatic Conversion of an aggregate of \$6,553,310 of principal amount under the 2022 Notes, representing 95% of the \$6,898,221 in principal amount currently outstanding under the 2022 Notes, based on the assumed exercise price of the Investor Warrants being offered as part of the Units and Pre-Funded Units in this offering of \$4.00 per share; and (ii) the Holders will be issued Uplist Conversion Warrants to purchase an aggregate of 65,533,100 shares of Common Stock, representing 10 multiplied by the \$6,553,310 of principal amount converted in the Automatic Conversion. The expected allocation between shares of Common Stock and 2022 Note Conversion Pre-Funded Warrants in the previous sentence is only an initial estimate based on indications of interest and is subject to change based on the ultimate ownership of the Holders after the Uplist PIPE and this offering. The maximum number of shares of Common Stock and 2022 Note Conversion Pre-Funded Warrants that may be issued, individually and in the aggregate is 1,638,330.

Additionally, on July 7, 2023, the Company entered into an amendment (the “**Omnibus Amendment to Notes and Warrants**”) with the Holders of the 2022 Notes, amending the 2022 Notes and related warrants issued at each of the First Closing, Second Closing, and Third Closing (the “**First Warrants**”, “**Second Warrants**” and “**Third Warrants**”, respectively, and collectively with the related warrants issued at the Fourth Closing, the “**2022 Warrants**”). Under the Omnibus Amendment to Notes and Warrants, the 2022 Notes and 2022 Warrants were amended to modify the Most Favored Nation provisions therein to exclude the Bridge Offering.

2022 Notes

The 2022 Notes bear interest on the unpaid principal balance at a rate equal to ten percent (10%) (computed on the basis of the actual number of days elapsed in a 360-day year) per annum accruing from the issuance date until the 2022 Notes become due and payable at maturity or upon their conversion, acceleration or by prepayment, and may become due and payable upon the occurrence of an event of default under the 2022 Notes. The 2022 Notes mature June 30, 2024. Any amount of principal or interest on the 2022 Notes which is not paid when due shall bear interest at the rate of the lesser of (i) eighteen percent (18%) per annum or (ii) the maximum amount allowed by law from the due date thereof until payment in full. As of June 19, 2024, the outstanding unpaid principal balance including all accrued interest under the 2022 Notes totaled \$8,015,282.

The 2022 Notes are convertible into shares of Common Stock at the option of each Holder from the date of issuance at \$73.12 (which will automatically change to \$4.00 as of the closing of the Uplist PIPE through the operation of the Most Favored Nation Provision (as defined below)), subject to adjustment, through the later of (i) June 30, 2024 (the “**Maturity Date**”) or (ii) the date of payment of the Default Amount (as defined in the 2022 Notes).

The 2022 Notes contain events of default, which include, among other things, (i) the Company’s failure to pay when due any principal or interest payment under the 2022 Notes; (ii) our failure to complete an Uplist Transaction by June 30, 2024 and (iii) our default on the Uplist Conversion Warrant Exchange Offer Obligation.

The 2022 Warrants (i) have an exercise price of \$79.52 (which will automatically change to \$4.00 as of the closing of the Uplist PIPE through the operation of the Most Favored Nation Provision) per share; (ii) have a term of exercise equal to 5 years after their issuance date; (iii) became exercisable immediately after their issuance; and (iv) have a provision preventing the exercisability of such 2022 Warrants if, as a result of the exercise of the 2022 Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of our Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than the Ownership Limitation. Pursuant to the “**Most Favored Nation Provision**” contained in the 2022 Notes and the 2022 Warrants, 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.

As discussed above, it is currently anticipated that 95% of the \$6,898,221 unpaid principal balance currently outstanding under the 2022 Notes will convert into (A) 1,454,034 shares of Common Stock and (B) 2022 Note Conversion Pre-Funded Warrants with an exercise price of \$0.001 to purchase an aggregate of 184,296 shares of Common Stock in connection with the Automatic Conversion, such allocation between shares and 2022 Note Conversion Pre-Funded Warrants being subject to change, as described above.

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Under the Third Amended and Restated Registration Rights Agreement, dated as of March 12, 2024, as amended, the Company is required to file a registration statement registering the securities issued in the Second Closing, Third Closing and Fourth Closing, including the applicable 2022 Notes and 2022 Warrants, no later than 45 days following the closing of the Uplist Transaction. The Resale Prospectus currently covers the resale of the shares of Common Stock issuable upon the Automatic Conversion, the

shares of Common Stock issuable upon conversion of the 2022 Notes at their regular conversion price and the shares of Common Stock issuable upon exercise of the 2022 Warrants.

Series 1 and 2 Convertible Notes

On June 4, 2020 and November 6, 2020, the Company issued unsecured 10% Series 1 Convertible Notes (“**Series 1 Notes**”) and Series 2 Convertible Notes, as amended (“**Series 2 Notes**”, and collectively with the Series 1 Notes, the “**Series Convertible Notes**”). The maturity dates of the Series 1 Notes and Series 2 Notes are June 30, 2023 and November 30, 2023, respectively. On July 12, 2023, the Company secured countersigned notices of conversion from all remaining holders of the Series 1 Convertible Notes and provided instructions to its transfer agent to issue a total of 7,489 shares of Common Stock in full satisfaction of all previously outstanding Series 1 Convertible Notes, which had an aggregate of \$718,918 of principal and interest outstanding at the time of conversion.

On November 30, 2023, the Series 2 Notes of \$450,000 principal and outstanding accrued interest of \$137,946 were converted into 6,615 shares of Common Stock.

Bylaw Amendments

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

Equity Incentive Plan

Effective August 13, 2023, the Board adopted and approved the Amended and Restated 2023 Equity Incentive Plan (the “**2023 Plan**”) and reserved 56,896 shares of Common Stock for issuance thereunder to employees, officers, directors and consultants of the Company. The stockholders of the Company approved the plan on August 22, 2023. The Plan has a term of 6 years and is intended to replace the Company’s 2013 Stock Incentive Plan, which expired on June 18, 2023.

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

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

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The Offering

Units being offered	969,697 Units, based on the sale of the Units and Pre-Funded Units at an assumed public offering price of \$4.125 per Unit and \$4.124 per Pre-Funded Unit, which represents the minimum bid price of \$4.00 per share under the initial listing requirements of Cboe in Cboe Listing Rule 14.9(b) plus a value of \$0.125 attributed to the accompanying Investor Warrant. Each Unit will consist of one share of Common Stock and one Investor Warrant to purchase one share of Common Stock. The Units have no stand-alone rights and will not be certificated or issued as stand-alone securities. The shares of Common Stock can be purchased in this offering only with the accompanying Investor Warrants as part of Units (other than pursuant to the underwriters’ option to purchase additional shares of Common Stock and/or Investor Warrants), but the components of the Units will be immediately separable and will be issued separately in this offering.
Pre-Funded Units being offered	We are also offering to each purchaser whose purchases of Units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding Common Stock immediately following the consummation of this offering, the opportunity to purchase, if the purchaser so chooses, Pre-Funded Units (each Pre-Funded Unit consisting of one Pre-Funded Warrant to purchase one share of Common Stock and one Investor Warrant to purchase one share of Common Stock) in lieu of Units that would otherwise result in the purchaser’s beneficial ownership exceeding 4.99% of our outstanding Common Stock (or at the election of the purchaser, 9.99%). Each Pre-Funded Warrant contained in a Pre-Funded Unit will be exercisable into one share of Common Stock, exercisable until all of the Pre-Funded Warrants are exercised in full. The purchase price of each Pre-Funded Unit will equal the price per Unit being sold to the public in this offering minus \$0.001, and the exercise price of each Pre-Funded Warrant included in the Pre-Funded Unit will be \$0.001 per share of Common Stock. This offering also relates to the shares of Common Stock issuable upon exercise of any Pre-Funded Warrants contained in the Pre-Funded Units sold in this offering. For each Pre-Funded Unit we sell, the number of Units we are offering will be decreased on a one-for-one basis. Because we will issue an Investor Warrant as part of each Unit or Pre-Funded Unit, the number of Investor Warrants sold in this offering will not change as a result of a change in the mix of the Units and Pre-Funded Units sold.

After giving effect to the closing of the Uplist PIPE, expected to occur immediately prior to the pricing of this offering, and after giving effect to the issuance of the Automatic Conversion Shares, 2022 Note Conversion Pre-Funded Warrants, 2024 Notes Automatic Conversion Shares, 2024 Note Conversion Pre-Funded Warrants, True-Up Shares and True-Up Pre-Funded Warrants at the closing of this offering, and the assumed exercise in full of the Bridge Pre-Funded Warrants, PIPE Pre-Funded Warrants, True-Up Pre-Funded Warrants, 2022 Note Conversion Pre-Funded Warrants, Execution Backstop Pre-Funded Warrants, PIPE Advance Penalty Pre-Funded Warrants and 2024 Note Conversion Pre-Funded Warrants, if any, (collectively, the “**Pro Forma Pre-Funded Warrants**”), but prior to giving effect to the offering, there would be an aggregate of 13,039,759 shares of Common Stock outstanding, before giving effect to the issuance of the Units and Pre-Funded Units in this offering. The exercise of the Pro Forma Pre-Funded Warrants (which have exercise prices of \$0.001 or \$0.008 and therefore function as common stock equivalents) assumed in the previous sentence is only for illustrative purposes, and there is no assurance as to when, if at all, any of such securities will be exercised.

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Common Stock to be outstanding after the offering(1)

4,916,849 shares (5,062,303 shares if the underwriters exercise their option to purchase additional shares in full, and assuming, in each case, no sale of any Pre-Funded Units and no exercise of the Investor Warrants), which takes into account the issuance of an assumed 1,454,034 shares of Common Stock as a result of the Automatic Conversion (aside from 2022 Note Conversion Pre-Funded Warrants to be exercisable for an expected 184,296 shares of Common Stock) under the 2022 Notes, an assumed 43,637 shares of Common Stock as a result of the 2024 Notes Automatic Conversion (aside from 2024 Note Conversion Pre-Funded Warrants to be exercisable for an expected 538,182 shares of Common Stock) under the 2024 Notes and 1,893,919 True-Up Shares being issued at the closing of this offering (aside from True-Up Pre-Funded Warrants to be exercisable for an expected 6,330,422 shares of Common Stock) and assumes no exercise of the PIPE Pre-Funded Warrants and PIPE Investor Warrants to be issued immediately prior to the pricing of this offering or the 2022 Note Conversion Pre-Funded Warrants, 2024 Note Conversion Pre-Funded Warrants, True-Up Pre-Funded Warrants, Uplist Conversion Warrants, 2024 Note Uplist Conversion Warrants and Exchange Investor Warrants to be issued at the closing of this offering.

Assuming the exercise in full of the Pro Forma Pre-Funded Warrants, there would be 14,009,456 shares (14,154,910 shares if the underwriters exercise their option to purchase additional shares in full) of Common Stock outstanding after this offering.

Over-allotment Option

We have granted the underwriters an option, exercisable for 45 days after the date of this prospectus, to purchase up to an additional 145,454 shares of Common Stock and/or Investor Warrants to purchase up to an additional 145,454 shares of Common Stock (equal to 15% of the shares of Common Stock (and Pre-Funded Warrants, if any) and Investor Warrants sold in this offering), in any combination, at the public offering price per share of Common Stock and per Investor Warrant, respectively, less the underwriting discounts payable by us, solely to cover over-allotments, if any.

Description of Investor Warrants

Each Unit and each Pre-Funded Unit includes an Investor Warrant to purchase one share of Common Stock. The Investor Warrants will have an assumed exercise price per share of Common Stock of \$4.00 (which equals the minimum bid price per share under the initial listing requirements of Cboe in Cboe Listing Rule 14.9(b)), will be immediately separable from the Common Stock or Pre-Funded Warrant, as the case may be, will be exercisable on the date of issuance and will expire five years from the date of issuance. Each Investor Warrant is exercisable for one share of Common Stock, subject to adjustment in the event of stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our Common Stock. A holder may not exercise any portion of an Investor Warrant to the extent that the holder, together with its affiliates and any other person or entity acting as a group, would own more than 4.99% of our outstanding shares of Common Stock after exercise, as such ownership percentage is determined in accordance with the terms of the Investor Warrants, except that upon notice from the holder to us, the holder may waive such limitation up to a percentage not in excess of 9.99% of our outstanding shares of Common Stock.

This prospectus also registers up to 969,697 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.

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Use of proceeds

We estimate that we will receive net proceeds from this offering of approximately \$2.9 million (assuming no sale of any Pre-Funded Warrants) or approximately \$3.5 million if the underwriters exercise their over-allotment option in full, based on the sale of the Units and Pre-Funded Units at an assumed public offering price of \$4.125 per Unit and \$4.124 per Pre-Funded Unit, which represents the minimum bid price of \$4.00 per share under the initial listing requirements of Cboe in Cboe Listing Rule 14.9(b) plus a value of \$0.125 attributed to the accompanying Investor Warrant 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 and for general working capital purposes. See “**Use of Proceeds**” beginning on page 47 of this prospectus for more information.

Market for Common Stock

Our Common Stock is traded on the OTCQB under the symbol “ARTH.” On June 18, 2024, the closing price of our Common Stock was \$8.72 (post-Reverse Split) per share. The public offering price per Unit and Pre-Funded Unit, and the exercise price of the Investor Warrants, as applicable, will be determined between us and the underwriters based on market conditions at the time of pricing, and may be at a discount to the then current market price. Therefore, the recent market price used throughout this preliminary prospectus may not be indicative of the final offering price. We have applied to list our Common Stock on Cboe 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 Cboe or an Alternate Exchange. We cannot guarantee that we will be successful in listing our Common Stock on Cboe or an Alternate Exchange; however, we will not complete this offering unless we are so listed.

Market for Pre-Funded Warrants

There is no established public trading market for the Pre-Funded Warrants, and we do not expect a market to develop. We do not intend to apply for listing of the Pre-Funded Warrants on any securities exchange or other nationally recognized trading system.

Market for Investor Warrants

There is no established public trading market for the Investor Warrants. We have applied to list the Investor Warrants on Cboe under the symbol “ARTHW.” No assurance can be given that such listing will be approved or, if successful, that an active trading market for the Investor Warrants will develop or be sustained.

Risk Factors

See “**Risk Factors**” beginning on page 22 and other information in this prospectus for a discussion of the factors you should consider before you decide to invest in our securities.

Lock-ups

We, our directors and executive officers will enter into customary “lock-up” agreements pursuant to which such persons and entities will agree, for a period of six months after the closing of this offering, not to offer, issue, sell, contract to sell, encumber, grant any option for the sale of, or otherwise dispose of, any shares of Common Stock or any securities convertible into or exchangeable for our Common Stock. See “**Underwriting-Lock-Up Agreements.**”

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- (1) Based on 555,562 shares of Common Stock outstanding on June 19, 2024. Excludes, as of such date, (i) options granted to employees, directors and consultants under our 2013 Stock Incentive Plan (the “**2013 Plan**”) to purchase up to an aggregate of 11,034 shares of Common Stock at exercise prices ranging from \$32.00 to \$1,040.00 per share and with a weighted average exercise price of \$277.94 per share; (ii) 3,717,114 shares of Common Stock issuable upon the exercise of outstanding warrants, having a weighted average exercise price of \$10.05 per share (which includes 2,349,826 Common Warrants that will automatically be cancelled and exchanged for 7,049,478 Exchange Investor Warrants at the closing of this offering); (iii) 1,724,557 shares of Common Stock issuable upon regular (non-Automatic) conversion of the 2022 Notes at the conversion price of \$4.00 per share (taking into account the operation of the Most Favored Nation Provision as a result of the Uplist PIPE); (iv) 982,056 shares of Common Stock to be issuable upon exercise at \$0.001 per share of the PIPE Pre-Funded Warrants expected to be issued immediately prior to the pricing of this offering; (v) 982,056 shares of Common Stock to be issuable upon exercise at \$4.00 per share of the PIPE Investor Warrants expected to be issued immediately prior to the pricing of this offering; (vi) 71,533 shares of Common Stock to be issuable upon exercise at \$5.15625 per share of the PIPE Placement Agent Warrants expected to be issued immediately prior to the pricing of this offering; (vii) 1,893,919 True-Up Shares expected to be issued at the closing of this offering; (viii) 6,330,422 shares of Common Stock to be issuable upon exercise at \$0.001 of the True-Up Pre-Funded Warrants expected to be issued at the closing of this offering; (ix) 65,533,100 shares of Common Stock to be issuable upon exercise at \$4.00 per share of the Uplist Conversion Warrants expected to be issued at the closing of this offering; (x) 7,049,478 shares of Common Stock to be issuable upon exercise at \$4.00 per share of the Exchange Investor Warrants expected to be issued at the closing of this offering; (xi) 538,182 shares of Common Stock to be issuable upon exercise at \$0.001 per share of the 2024 Note Conversion Pre-Funded Warrants expected to be issued at the closing of this offering; (xii) 581,819 shares of Common Stock to be issuable upon exercise at \$4.00 per share of the 2024 Note Uplist Conversion Warrants expected to be issued at the closing of this offering; (xiii) 56,896 shares of Common Stock reserved for future issuance under the 2023 Plan; and (xiv) up to 969,697 shares (1,115,151 shares if the underwriters’ option to purchase additional Investor Warrants is exercised in full) of Common Stock issuable upon exercise at \$4.00 per share of the Investor Warrants to be issued in this offering.

Except as indicated otherwise, the discussion above assumes no sale of any Pre-Funded Units, no issuance of any 2022 Note Conversion Pre-Funded Warrants and no exercise of the underwriters’ option to purchase up to 145,454 additional shares of Common Stock and/or Investor Warrants to purchase up to 145,454 additional shares of Common Stock.

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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 do not believe that our current cash on hand as of June 19, 2024 is sufficient to meet our anticipated cash requirements through the end of June 2024.
- 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.
- Even if this offering is successful, we will need substantial additional funding 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.
- Our obligations under the First Notes and 2024 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 and 2024 Notes could result in our loss of substantially all of our assets.
- The holders of our 2022 Notes and 2024 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 commercialize our products, we will continue to incur losses and will never be profitable.
- 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.

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- 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 flagship 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 Cboe 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 Cboe or an Alternate Exchange is approved, no assurance can be given that an active trading market for our Common Stock or Investor Warrants will develop or be maintained.

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

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Risks Related to our Business, Financial Position and Capital Requirements

There is substantial doubt about our ability to continue as a going concern.

We have only recently commenced commercial sales of our first product, AC5®Advanced Wound System and we have incurred substantial net losses as a result. For the year ended September 30, 2023, the Company recorded a net loss of \$6,982,836 and used cash in operations of \$3,374,216. For the six months ended March 31, 2024, the Company recorded a net loss of \$4,150,791 and used cash in operations of \$1,562,764. These factors raise substantial doubt about the Company's ability to continue as a going concern within one year of the date that the financial statements are issued. In addition, the Company's independent registered public accounting firm, in their report on the Company's September 30, 2023 audited financial statements, raised substantial doubt about the Company's ability to continue as a going concern. The financial statements included herein do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

We do not believe that our current cash on hand as of June 19, 2024 is sufficient to meet our anticipated cash requirements through the end of June 2024.

During the first half of fiscal 2024 and during fiscal 2023 and 2022, 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 US and the EU. Even with the additional funds received from these financings, there exists substantial doubt about our ability to continue as a going concern.

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

As noted above under the risk factor entitled "*There is substantial doubt about our ability to continue as a going concern,*" we have only recently commenced commercial sales of our first product, AC5Advanced 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. 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 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 principal product candidates and additional product candidates, and the underlying technology, including advancing applications and conducting biocompatibility and other preclinical studies and clinical studies;
- raise capital needed to fund our operations;
- enhance investor relations and corporate communications capabilities;
- conduct clinical trials on products and product candidates;
- attempt to obtain regulatory marketing authorizations for product candidates;

- build relationships with additional contract manufacturing partners, and invest in product and process development through such partners;
- maintain, expand and protect our intellectual property portfolio;
- advance additional product candidates and technologies through our research and development pipeline;
- seek to commercialize selected product candidates, which may require regulatory marketing authorization; and
- hire additional regulatory, clinical, quality control, scientific, financial, and management, consultants and advisors.

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To become and remain profitable, we must successfully commercialize 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.

Even if this offering is successful, we will need substantial additional funding 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.

Based on our current operating expenses and working capital requirements, we do not believe that our current cash on hand as of June 19, 2024 is sufficient to meet our anticipated cash requirements through the end of June 2024. We may need to raise additional capital before then.

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.

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

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

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

If we are unable to obtain adequate financing on a timely basis or on acceptable terms in the future, we would likely be required to delay, reduce or eliminate one or more of our

product development activities, which could cause our business to fail.

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

The Bridge SPA contains certain restrictions on the Company's ability to conduct subsequent sales of its equity securities and certain business activities. In particular, until July 7, 2024, the Company will be prohibited from effecting or entering into agreements to effect any issuance by the Company or its subsidiary of Common Stock or Common Stock equivalents (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. The Uplist PIPE has the effect of extending that prohibition to November 8, 2024 with a similar provision.

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

Our obligations under the First Notes and 2024 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 and 2024 Notes could result in our loss of substantially all of our assets.

Our obligations under the First Notes and 2024 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 or 2024 Notes, the First Note or 2024 Notes 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.

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In connection with the First Closing and 2024 Notes closing, the respective note holders were granted a security interest in substantially all of our assets pursuant to the terms of the related security agreements. If we fail to make payments on the First Notes or 2024 Notes when due or otherwise comply with the covenants contained in the First Notes or 2024 Notes, the respective 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 and 2024 Notes (collectively, the "Convertible 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 Convertible 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 Convertible Notes; and (v) our breach of any representations or warranties under the Convertible Notes which cannot be cured within five (5) days. Further, events of default under the Convertible Notes also include (i) the unavailability of Rule 144 at certain times; (ii) our failure to deliver the shares of Common Stock to the respective notes holder upon exercise by such holder of its conversion rights under the Convertible Notes; (iii) our loss of the "bid" price for our Common Stock and/or a market and such loss is not cured during the specified cure periods; and (iv) our failure to complete an Uplist Transaction by June 30, 2024.

The Convertible 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 Convertible Notes, the holders have certain rights upon an event of default. Such rights include that, upon an event of default, the Convertible Notes will become immediately due and payable and we will be obligated to pay to each such note holder an amount equal to (A) 125% (the "Default Premium") multiplied by the sum of (i) the outstanding principal amount of the 2022 Notes plus, (ii) any accrued and unpaid interest on the unpaid principal amount of the 2022 Notes to the date of payment, plus (iii) interest, if any, on the amounts referred to in subsection (i) and/or (ii), at a rate of the lesser of (y) eighteen percent (18%) per annum, or (z) the maximum amount allowed by law from the due date thereof until the same is paid (the "Default Interest Rate") (the then outstanding principal of such Convertible Note to the date of payment, plus the amounts set forth in subsections (i)-(iii) hereof are collectively, the "Default Amount"), and (B) any other amounts owed to the Holder under the respective purchase agreement; *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 \$73.12 (which will automatically change to \$4.00 as of the closing of the Uplist PIPE through the operation of the Most Favored Nation Provision) 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. The Convertible 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 until June 30, 2024 or upon their conversion, acceleration or by prepayment. Any amount of principal or interest on the Convertible 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 Rate.

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.

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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.

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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.

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.

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.

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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.

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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.

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

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

We are subject to extensive and dynamic medical device regulations outside of the U.S., 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 the 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 U.S., the process of obtaining marketing approval or clearance from comparable agencies in foreign countries for new products, or with respect to enhancements or modifications to existing products, could:

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

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

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

Our global regulatory environment is becoming increasingly stringent and unpredictable, which could increase the time, cost and complexity of obtaining marketing

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

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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;

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- 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.

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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, comparable foreign regulatory authorities, or their designees, 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. The global regulatory environment is increasingly stringent and unpredictable, and requirements continue to differ among countries. We expect this global regulatory environment will continue to evolve, potentially impacting the cost, time, or our ability to receive or maintain clearances or approvals.

Regulations also impose extensive compliance and monitoring obligations on our business, and regulatory agencies or their designees review our design and manufacturing processes, labeling, record keeping, and required reports of adverse experiences and other information to identify potential problems with marketed products.

We are also subject to periodic inspections for compliance with applicable quality system regulations (e.g., 21 CFR 820, EU MDR) which govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, and servicing of finished medical devices intended for human use. In addition, the FDA and other regulatory bodies, both in and outside the U.S. (including the Federal Trade Commission, the Office of the Inspector General of the Department of Health and Human Services, the U.S. Department of Justice, and various state Attorneys General), monitor the promotion and advertising of our products. Any adverse regulatory action, depending on its magnitude, may limit our ability to effectively market and sell our products, limit our ability to obtain future premarket approvals or result in a substantial modification to our business practices and operations. 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.

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Discovery after approval of previously unknown problems with any approved product candidate or related manufacturing processes, or failure to comply with regulatory requirements or agreements with regulatory agencies or their designees, 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;
- supply chain disruptions due to dependency on key suppliers;
- reputational damage affecting customer trust and market share;
- litigation costs and financial judgments from adverse effects or non-compliance;

- impacts from changes in regulatory standards or approval processes;
- 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.

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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.

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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.

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

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

Risks Related to our Intellectual Property

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

Our success will depend in large part on our ability to obtain and maintain protection in the U.S. and other countries for the intellectual property rights covering or incorporated into our technology and products. The ability to obtain patents covering technology in the field of medical devices generally is highly uncertain and involves complex legal, technical, scientific and factual questions. We may not be able to obtain and maintain patent protection relating to our technology or products. Many of our owned or licensed patent applications are pending. Even if issued, patents issued or licensed to us may be challenged, narrowed, invalidated, held to be unenforceable or circumvented, or determined not to cover our product candidates or our competitors' products, which could limit our ability to stop competitors from marketing identical or similar products. Because our patent portfolio includes certain patents and applications that are in-licensed on a non-exclusive basis, other parties may be able to develop, manufacture, market and sell products with similar features covered by the same patent rights and technologies, which in turn could significantly undercut the value of any of our product candidates and adversely affect our business. Our licensed MIT European patent No. 1879606 was opposed; however, this patent was maintained in amended form following an administrative hearing. Both parties appealed this decision. MIT granted European patent EP1879606, to which Arch Therapeutics has an exclusive license, was the subject of a hearing at the European Patent Office Board of Appeal (the "**Board of Appeal**") on November 26, 2021 as a result of an appeal by MIT to obtain broader claim scope than was upheld by the European Patent Opposition Division in 2016 and appeals by opponents for the upheld scope to be denied to MIT. At the oral proceedings, in light of concerns expressed by the Board of Appeal, MIT withdrew its appeal and the affected claims, resulting in a formal revocation of the European patent. There is a pending divisional patent application in which the concerns that the Board of Appeal expressed can be addressed. MIT can file further divisional patent applications to seek additional claim scope. There is no guarantee that any divisional patent application will result in a granted patent or that any granted patent will not be opposed and revoked. The Board of Appeal's decision is in relation to the granted European patent EP1879606 and the various national patents that are derived therefrom, and it has no legal significance outside of Europe except in Hong Kong. Further, we cannot be certain in 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 March 31, 2024, we either own or license from others a number of U.S. patents, U.S. patent applications, foreign patents and foreign patent applications.

We have also entered into a license agreement with 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.

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

The 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 between 2024 and 2026 (absent any potential patent term extension), as well as additional patents that have been either allowed, issued or granted in foreign jurisdictions.

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

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

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

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

Risks Related to Ownership of our Common Stock and Investor Warrants

We have pursued an Uplist Transaction by filing an application to list our Common Stock to trade on Cboe. 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 Cboe. In the event we fail to list our Common Stock on Cboe, 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 Cboe. To successfully list our Common Stock, we are required to satisfy certain Cboe 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 Cboe will be denied. No assurances can be given that we will satisfy the listing requirements. If our application is not successful, our Board will weigh the available alternatives to successfully consummate an Uplist Transaction and list our Common Stock on Cboe. 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 Cboe 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 Cboe, our ability to raise additional capital may be adversely affected.

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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 Cboe 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 Cboe 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 Cboe or an Alternate Exchange, we will not complete this offering. Even if our Common Stock is approved for listing on Cboe 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 June 30, 2024 to Cboe 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 Cboe or Alternate Exchange under the symbol "ARTHW," there is no assurance our application will be approved, or even if it is approved, that a public trading market will develop or if one develops that it will

be maintained. Without a public market, the liquidity of the Investor Warrants will remain limited. However, if our Investor Warrants are not approved for listing on Cboe or an Alternate Exchange, we will still complete this offering.

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

On August 22, 2023, the stockholders approved a reverse stock split between 1-for-1.5 to 1-for-20, and the Company intends to effect the Reverse Split at a ratio of 1-for-8 prior to the pricing of this offering, and without correspondingly decreasing the number of authorized shares of Common Stock. Even if our planned Reverse Split increases the market price of our Common Stock sufficiently so that we comply with the minimum market price requirement, no assurance can be given that we will be able to comply with the other standards that we are required to meet in order to be approved for listing on Cboe 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 Cboe or an Alternate Exchange.

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

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

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If this offering is successful, we will be subject to the continued listing requirements of Cboe or an Alternate Exchange. If we are unable to comply with such requirements, our Common Stock and Investor Warrants would be delisted from Cboe 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 Cboe or an Alternate Exchange is approved, if we fail to meet the Cboe or such Alternate Exchange continued listing requirements, including stockholder equity requirements, our Common Stock and Investor Warrants could be subject to delisting by Cboe 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 Cboe 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 Cboe 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.

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

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

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

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

As of September 21, 2023, our articles of incorporation authorize the issuance of up to 350,000,000 shares of Common Stock. The issuance of shares of our Common Stock

upon the exercise of our outstanding warrants or conversion of outstanding convertible notes, summarized below, could result in substantial dilution to our stockholders, which may have a negative effect on the price of our Common Stock.

As of June 19, 2024, there were issued and outstanding (or expected to be issued and outstanding, as specified below): (i) options granted to employees, directors and consultants under the 2013 Plan to purchase up to an aggregate of 11,034 shares of Common Stock at exercise prices ranging from \$32.00 to \$1,040.00 per share and with a weighted average exercise price of \$277.94 per share; (ii) 3,717,114 shares of Common Stock issuable upon the exercise of outstanding warrants, having a weighted average exercise price of \$10.05 per share (which includes 2,349,826 Common Warrants that will automatically be cancelled and exchanged for 7,049,478 Exchange Investor Warrants at the closing of this offering); (iii) 1,724,557 shares of Common Stock issuable upon regular (non-Automatic) conversion of the 2022 Notes at the conversion price of \$4.00 per share (taking into account the operation of the Most Favored Nation Provision as a result of the Uplist PIPE); (iv) 982,056 shares of Common Stock to be issuable upon exercise at \$0.001 per share of the PIPE Pre-Funded Warrants expected to be issued immediately prior to the pricing of this offering; (v) 982,056 shares of Common Stock to be issuable upon exercise at \$4.00 per share of the PIPE Investor Warrants expected to be issued immediately prior to the pricing of this offering; (vi) 71,533 shares of Common Stock to be issuable upon exercise at \$5.15625 per share of the PIPE Placement Agent Warrants expected to be issued immediately prior to the pricing of this offering; (vii) 1,893,919 True-Up Shares expected to be issued at the closing of this offering; (viii) 6,330,422 shares of Common Stock to be issuable upon exercise at \$0.001 of the True-Up Pre-Funded Warrants expected to be issued at the closing of this offering; (ix) 65,533,100 shares of Common Stock to be issuable upon exercise at \$4.00 per share of the Uplist Conversion Warrants expected to be issued at the closing of this offering; (x) 7,049,478 shares of Common Stock to be issuable upon exercise at \$4.00 per share of the Exchange Investor Warrants expected to be issued at the closing of this offering; (xi) 538,182 shares of Common Stock to be issuable upon exercise at \$0.001 per share of the 2024 Note Conversion Pre-Funded Warrants expected to be issued at the closing of this offering; (xii) 581,819 shares of Common Stock to be issuable upon exercise at \$4.00 per share of the 2024 Note Uplist Conversion Warrants expected to be issued at the closing of this offering; (xiii) 56,896 shares of Common Stock reserved for future issuance under the 2023 Plan; and (xiv) up to 969,697 shares (1,115,151 shares if the underwriters' option to purchase additional Investor Warrants is exercised in full) of Common Stock issuable upon exercise at \$4.00 per share of the Investor Warrants to be issued in this offering.

After giving effect to the closing of the Uplist PIPE, expected to occur immediately prior to the pricing of this offering, and after giving effect to the issuance of the Automatic Conversion Shares, 2022 Note Conversion Pre-Funded Warrants, 2024 Notes Automatic Conversion Shares, 2024 Note Conversion Pre-Funded Warrants, True-Up Shares and True-Up Pre-Funded Warrants at the closing of this offering, and the assumed exercise in full of the Bridge Pre-Funded Warrants, PIPE Pre-Funded Warrants, True-Up Pre-Funded Warrants, 2022 Note Conversion Pre-Funded Warrants, Execution Backstop Pre-Funded Warrants, PIPE Advance Penalty Pre-Funded Warrants and 2024 Note Conversion Pre-Funded Warrants, if any, (collectively, the “**Pro Forma Pre-Funded Warrants**”), but prior to giving effect to the offering, there would be an aggregate of 13,039,759 shares of Common Stock outstanding, before giving effect to the issuance of the Units and Pre-Funded Units in this offering. The exercise of the Pro Forma Pre-Funded Warrants (which have exercise prices of \$0.001 or \$0.008 and therefore function as common stock equivalents) assumed in the previous sentence is only for illustrative purposes, and there is no assurance as to when, if at all, any of such securities will be exercised.

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The 2013 Plan expired on June 18, 2023. Finally, on August 13, 2023, the Company adopted and approved the Amended and Restated 2023 Equity Incentive Plan (the “A&R Plan”). As of September 30, 2023, no option awards were granted under the A&R Plan. Any future grants of options, warrants or other securities exercisable or convertible into our Common Stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our Common Stock.

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

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

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

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

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

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

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

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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.

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

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

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

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

Risks Related to This Offering

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

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

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

The public offering price of the Units and Pre-Funded Units being offered in this offering is substantially higher than the net tangible book value per share of our Common Stock prior to the offering. Investors purchasing Units or Pre-Funded Units in this offering may pay an effective price per share of Common Stock that may substantially exceed the pro forma book value of our tangible assets after subtracting our liabilities. Based on an assumed public offering price of \$4.125 per Unit and \$4.124 per Pre-Funded Unit, which represents the minimum bid price of \$4.00 per share under the initial listing requirements of Cboe in Cboe Listing Rule 14.9(b) plus a value of \$0.125 attributed to the

accompanying Investor Warrant, if you purchase shares of our Common Stock in this offering, you will suffer immediate and substantial dilution of \$3.677 per share with respect to the net tangible book value of the Common Stock. See the section entitled “Dilution” below for a more detailed discussion of the dilution you will incur if you purchase securities in this offering. As a result of the dilution to investors purchasing securities in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of a liquidation of our company.

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

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

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

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

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USE OF PROCEEDS

We expect to receive net proceeds of approximately \$2.9 million from this offering or approximately \$3.5 million if the underwriters exercise their option to purchase additional shares of Common Stock and/or Investor Warrants in full, based on an assumed public offering price of \$4.125 per Unit and \$4.124 per Pre-Funded Unit, which represents the minimum bid price of \$4.00 per share under the initial listing requirements of Cboe in Cboe Listing Rule 14.9(b) plus a value of \$0.125 attributed to the accompanying Investor Warrant, after deducting the estimated underwriting discounts and commissions and offering expenses payable by us. We currently intend to use the net proceeds we receive from this offering for product marketing and for general working capital purposes.

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

Each \$0.25 increase (decrease) in the assumed public offering price of \$4.125 per Unit and \$4.124 per Pre-Funded Unit, which represents the minimum bid price of \$4.00 per share under the initial listing requirements of Cboe in Cboe Listing Rule 14.9(b) plus a value of \$0.125 attributed to the accompanying Investor Warrant, 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 \$0.2 million, assuming that the number of Units offered by us, as set forth on the cover page of this prospectus, remains the same. We may also increase or decrease the number of Units we are offering. An increase (decrease) of 1,000,000 in the number of Units we are offering would increase (decrease) the net proceeds to us from this offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, by approximately \$3.8 million, assuming the public offering price stays the same. We do not expect that a change in the offering price or the number of Units by these amounts would have a material effect on our intended uses of the net proceeds from this offering, although it may impact the amount of time prior to which we may need to seek additional capital.

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MARKET PRICE OF AND DIVIDENDS ON COMMON STOCK AND RELATED MATTERS

Market Information

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

We have applied to list our Common Stock and Investor Warrants on Cboe under the symbols “ARTH” and “ARTHW”, respectively. There is no assurance that our listing application will be approved by Cboe, 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 Cboe 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 June 19, 2024, there were approximately 124 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.

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CAPITALIZATION

The following table sets forth our cash and capitalization as of March 31, 2024:

- on an actual basis;
- on a pro forma basis to give effect to (i) the assumed full exercise of all of the Bridge Pre-Funded Warrants, Execution Backstop Pre-Funded Warrants and PIPE Advance Penalty Pre-Funded Warrants, (ii) the expected issuance immediately prior to the pricing of this offering of 982,056 PIPE Pre-Funded Warrants (and related PIPE Investor Warrants) in the Uplist PIPE for net proceeds of approximately \$3,528,000, and assuming the full exercise of all of the PIPE Pre-Funded Warrants, (iii) the expected issuance at the closing of this offering of 1,893,919 True-Up Shares and True-Up Pre-Funded Warrants to purchase an aggregate of 6,330,422 shares of Common Stock, based on the sale of the Units and Pre-Funded Units at an assumed public offering price of \$4.125 per Unit and \$4.124 per Pre-Funded Unit, and assuming the full exercise of all of the True-Up Pre-Funded Warrants, (iv) the issuance of \$2,400,000 in principal amount of the 2024 Notes between May 15, 2024 and June 12, 2024 for net proceeds of \$2,000,000, the expected issuance at the closing of this offering of an aggregate of 581,819 shares of Common Stock (and related 2024 Note Uplist Conversion Warrants) upon the 2024 Notes Automatic Conversion of the full principal amount under the 2024 Notes, assuming no issuance of any 2024 Note Conversion Pre-Funded Warrants, based on the conversion price of \$4.125 per share and (v) the expected issuance at the closing of this offering of an aggregate of 1,638,330 shares of Common Stock (and related Uplist Conversion Warrants) upon the Automatic Conversion of an aggregate of \$6,553,310 of principal amount under the 2022 Notes, assuming no issuance of any 2022 Note Conversion Pre-Funded Warrants, based on the assumed exercise price of the Investor Warrants being offered as part of the Units and Pre-Funded Units in this offering of \$4.00 per share (the events in clauses (i) through (v), the “**Pro Forma Events**”); and
- on a pro forma, as adjusted basis, to give effect to the issuance and sale by us of 969,697 Units in this offering based on an assumed public offering price of \$4.125 per Unit (assuming no sale of any Pre-Funded Units), after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and the receipt by us of the proceeds of such sale.

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

	As of March 31, 2024		Pro Forma As
	Actual	Pro Forma	Adjusted
	(unaudited)	(unaudited)	(unaudited) (1)
Cash	\$ 26,426	\$ 5,563,330	\$ 8,468,330
Total liabilities	12,417,551	3,712,278	3,712,278
Stockholders’ equity (deficit):			
Common stock, \$0.001 par value, 350,000,000 shares authorized as of March 31, 2024, and 555,562 shares, actual, 13,039,759 shares, pro forma and 14,009,456 shares, pro forma as adjusted, issued as of March 31, 2024	556	13,040	14,009
Additional paid-in capital	\$ 55,328,360	\$ 68,735,891	\$ 71,639,921
Accumulated deficit	\$ (66,206,400)	\$ (65,384,238)	\$ (65,384,238)
Total stockholders’ equity (deficit)	\$ (10,877,484)	\$ 3,364,693	\$ 6,269,693
Total capitalization	\$ 1,540,067	\$ 7,076,971	\$ 9,981,971

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(1) A \$0.25 increase or decrease in the assumed public offering price of \$4.125 per Unit and \$4.124 per Pre-Funded Unit, which represents the minimum bid price of \$4.00 per share under the initial listing requirements of Cboe in Cboe Listing Rule 14.9(b) plus a value of \$0.125 attributed to the accompanying Investor Warrant, 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 \$0.2 million, assuming that the number of Units offered by us, as set forth on the cover page of this prospectus, remains the same (assuming no sale of any Pre-Funded Units) and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us and assuming no exercise of the Investor Warrants issued as part of the Units. An increase or decrease of 1,000,000 in the number of Units offered by us, as set forth on the cover page of this prospectus (assuming no sale of any Pre-Funded Units), would increase or decrease the pro forma as adjusted amount of each of cash, additional paid-in capital, total stockholders’ equity (deficit) and total capitalization by approximately \$3.8 million, assuming no change in the assumed public offering price per Unit and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us and assuming no exercise of the Investor Warrants issued as part of the Units.

Except as indicated otherwise, the total number of shares reflected in the discussion and tables above is based on 555,562 shares of our Common Stock outstanding as of March 31, 2024, and excludes, in each case: As of such date, (i) options granted to employees, directors and consultants under the 2013 Plan to purchase up to an aggregate of 11,034 shares of Common Stock at exercise prices ranging from \$32.00 to \$1,040.00 per share and with a weighted average exercise price of \$277.94 per share; (ii) 3,340,562 shares of Common Stock issuable upon the exercise of outstanding warrants, having a weighted average exercise price of \$11.09 per share (which includes 2,349,826 Common Warrants that will automatically be cancelled and exchanged for 7,049,478 Exchange Investor Warrants at the closing of this offering); (iii) 1,724,557 shares of Common Stock issuable upon regular (non-Automatic) conversion of the 2022 Notes at the conversion price of \$4.00 per share (taking into account the operation of the Most Favored Nation Provision as a result of the Uplist PIPE); (iv) 982,056 shares of Common Stock to be issuable upon exercise at \$0.001 per share of the PIPE Pre-Funded Warrants expected to be issued immediately prior to the pricing of this offering; (v) 982,056 shares of Common Stock to be issuable upon exercise at \$4.00 per share of the PIPE Investor Warrants expected to be issued immediately prior to the pricing of this offering; (vi) 71,533 shares of Common Stock to be issuable upon exercise at \$5.15625 per share of the PIPE Placement Agent Warrants expected to be issued immediately prior to the pricing of this offering; (vii) 1,893,919 True-Up Shares expected to be issued at the closing of this offering; (viii) 6,330,422 shares of Common Stock to be issuable upon exercise at \$0.001 of the True-Up Pre-Funded Warrants expected to be issued at the closing of this offering; (ix) 65,533,100 shares of Common Stock to be issuable upon exercise at \$4.00 per share of the Uplist Conversion Warrants expected to be issued at the closing of this offering; (x) 7,049,478 shares of Common Stock to be issuable upon exercise at \$4.00 per share of the Exchange Investor Warrants expected to be issued at the closing of this offering; (xi) 538,182 shares of Common Stock to be issuable upon exercise at \$0.001 per share of the 2024 Note Conversion Pre-Funded Warrants expected to be issued at the closing of this offering; (xii) 581,819 shares of Common Stock to be issuable upon exercise at \$4.00 per share of the 2024 Note Uplist Conversion Warrants expected to be issued at the closing of this offering; (xiii) 56,896 shares of Common Stock reserved for future issuance under the 2023 Plan; and (xiv) up to 969,697 shares (1,115,151 shares if the underwriters’ option to purchase additional Investor Warrants is exercised in full) of Common Stock issuable upon exercise at \$4.00 per share of the Investor Warrants to be issued in this offering.

Except as indicated otherwise, the discussion and table above assume no sale of Pre-Funded Units and no exercise of the underwriters’ option to purchase up to 145,454 additional shares of Common Stock and/or Investor Warrants to purchase up to 145,454 additional shares of Common Stock.

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DILUTION

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

The net tangible book value (deficit) of our Common Stock as of March 31, 2024, was approximately \$(10.9 million), or approximately \$(19.579) per share of Common Stock. Net tangible book value per share represents the amount of our total tangible assets less total liabilities divided by the total number of our shares of Common Stock outstanding as of March 31, 2024.

The following proforma adjustments were made to the shares of Common Stock outstanding as of March 31, 2024 and related net tangible book value to compute our proforma net tangible book value as of March 31, 2024:

- a. Issuance of 7,082,955 shares of Common Stock upon conversion of prefunded warrants, with a par value impact of \$7,083 (see items (i) and (iii) in the paragraph that follows);
- b. Issuance of 1,638,300 shares of Common Stock upon mandatory conversion of the 2022 Notes and cancellation of accrued interest, for an aggregate effect of \$7,580,273 as a result of this offering (see item (v) in the paragraph that follows); and
- c. Issuance of 3,762,912 shares of Common Stock upon mandatory conversion of PIPE instruments, for an aggregate effect of \$6,654,821 as a result of this offering (see items (i), (ii) and (iv) in the paragraph that follows).

Our pro forma net tangible book value as of March 31, 2024 was \$3.4 million, or \$0.258 per share of Common Stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to (i) the assumed full exercise of all of the Bridge Pre-Funded Warrants, Execution Backstop Pre-Funded Warrants and PIPE Advance Penalty Pre-Funded Warrants, (ii) the expected issuance immediately prior to the pricing of this offering of 982,056 PIPE Pre-Funded Warrants (and related PIPE Investor Warrants) in the Uplist PIPE for net proceeds of approximately \$3,528,000, and assuming the full exercise of all of the PIPE Pre-Funded Warrants, (iii) the expected issuance at the closing of this offering of 1,893,919 True-Up Shares and True-Up Pre-Funded Warrants to purchase an aggregate of 6,330,422 shares of Common Stock, based on the sale of the Units and Pre-Funded Units at an assumed public offering price of \$4.125 per Unit and \$4.124 per Pre-Funded Unit, and assuming the full exercise of all of the True-Up Pre-Funded Warrants, (iv) the issuance of \$2,400,000 in principal amount of the 2024 Notes between May 15, 2024 and June 12, 2024 for net proceeds of \$2,000,000, the expected issuance at the closing of this offering of an aggregate of 581,819 shares of Common Stock (and related 2024 Note Uplist Conversion Warrants) upon the 2024 Notes Automatic Conversion of the full principal amount under the 2024 Notes, assuming no issuance of any 2024 Note Conversion Pre-Funded Warrants, based on the conversion price of \$4.125 per share and (v) the expected issuance at the closing of this offering of an aggregate of 1,638,330 shares of Common Stock (and related Uplist Conversion Warrants) upon the Automatic Conversion of an aggregate of \$6,553,310 of principal amount under the 2022 Notes, assuming no issuance of any 2022 Note Conversion Pre-Funded Warrants, based on the assumed exercise price of the Investor Warrants being offered as part of the Units and Pre-Funded Units in this offering of \$4.00 per share. Pro forma net tangible book value per share represents the pro forma net tangible book value divided by the total number of shares outstanding as of March 31, 2024, after giving effect to the pro forma adjustment described above.

After giving further effect to the sale of 969,697 shares of Common Stock included in the Units in this offering at an assumed public offering price of \$4.125 per share of Common Stock included in each Unit (assuming no sale of Pre-Funded Units), and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, and assuming no exercise of the Investor Warrants issued as part of the Units, our pro forma, as adjusted net tangible book value as of March 31, 2024 would have been approximately \$6.3 million, or approximately \$0.448 per share of Common Stock. This amount represents an immediate increase in actual book value of \$20.027 per share to our existing stockholders and immediate dilution of approximately \$3.677 per share to new investors in this offering (attributing no value to the Investor Warrants). We determine dilution by subtracting the as adjusted net tangible book value per share after this offering from the amount of cash that a new investor paid for a share of Common Stock included in each Unit in this offering. The following table illustrates this dilution:

Assumed public offering price per Unit	\$	4.125
Pro forma net tangible book value per share after giving effect to the Pro Forma Events	0.258	
Increase in pro forma net tangible book value per share after giving effect to this offering (including the Pro Forma Events)	0.189	
Pro forma, as adjusted net tangible book value per share as of March 31, 2024 after giving effect to this offering and the Pro Forma Events		(0.448)
Dilution per share to new investors in this offering	\$	3.677
Percentage of Dilution of Investment		89%

If the underwriters exercise their option to purchase additional shares of our Common Stock in full, the pro forma, as adjusted net tangible book value after this offering would be approximately \$0.482 per share, the increase in pro forma net tangible book value per share would be approximately \$0.224 and dilution per share to new investors would be approximately \$3.643 per share.

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Each \$0.25 increase (decrease) in the assumed public offering price of \$4.125 per Unit and \$4.124 per Pre-Funded Unit, which represents the minimum bid price of \$4.00 per share under the initial listing requirements of Cboe in Cboe Listing Rule 14.9(b) plus a value of \$0.125 attributed to the accompanying Investor Warrant, 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 \$0.2 million, assuming that the number of Units offered by us, as set forth on the cover page of this prospectus, remains the same (assuming no sale of any Pre-Funded Warrants) and assuming no exercise of the Investor Warrants issued as part of the Units. We may also increase or decrease the number of Units we are offering. An increase (decrease) of 1,000,000 in the number of Units we are offering would increase (decrease) the net proceeds to us from this offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, by approximately \$3.8 million, assuming the public offering price stays the same (assuming no sale of any Pre-Funded Warrants) and assuming no exercise of the Investor Warrants issued as part of the Units. We do not expect that a change in the offering price or the number of Units by these amounts would have a material effect on our intended uses of the net proceeds from this offering, although it may impact the amount of time prior to which we may need to seek additional capital.

The total number of shares reflected in the discussion and tables above is based on 555,562 shares of our Common Stock outstanding as of March 31, 2024, and excludes, in each case: As of such date, (i) options granted to employees, directors and consultants under the 2013 Plan to purchase up to an aggregate of 11,034 shares of Common Stock at exercise prices ranging from \$32.00 to \$1,040.00 per share and with a weighted average exercise price of \$277.94 per share; (ii) 3,340,562 shares of Common Stock issuable upon the exercise of outstanding warrants, having a weighted average exercise price of \$11.09 per share (which includes 2,349,826 Common Warrants that will automatically be cancelled and exchanged for 7,049,478 Exchange Investor Warrants at the closing of this offering); (iii) 1,724,557 shares of Common Stock issuable upon regular (non-Automatic) conversion of the 2022 Notes at the conversion price of \$4.00 per share (taking into account the operation of the Most Favored Nation Provision as a result of the Uplist PIPE); (iv) 982,056 shares of Common Stock to be issuable upon exercise at \$0.001 per share of the PIPE Pre-Funded Warrants expected to be issued immediately prior to the pricing of this offering; (v) 982,056 shares of Common Stock to be issuable upon exercise at \$4.00 per share of the PIPE Investor Warrants expected to be issued immediately prior to the pricing of this offering; (vi) 71,533 shares of Common Stock to be issuable upon exercise at \$5.15625 per share of the PIPE Placement Agent Warrants expected to be issued immediately prior to the pricing of this offering; (vii) 1,893,919 True-Up Shares expected to be issued at the closing of this offering; (viii) 6,330,422 shares of Common Stock to be issuable upon exercise at \$0.001 of the True-Up Pre-Funded Warrants expected to be issued at the closing of this offering; (ix) 65,533,100 shares of Common Stock to be issuable upon exercise at \$4.00 per share of the Uplist Conversion Warrants expected to be issued at the closing of this offering; (x) 7,049,478 shares of Common Stock to be issuable upon exercise at \$4.00 per share of the Exchange Investor Warrants expected to be issued at the closing of this offering; (xi) 538,182 shares of Common Stock to be issuable upon exercise at \$0.001 per share of the 2024 Note Conversion Pre-Funded Warrants expected to be issued at the closing of this offering; (xii) 581,819 shares of Common Stock to be issuable upon exercise at \$4.00 per share of the 2024 Note Uplist Conversion Warrants expected to be issued at the closing of this offering; (xiii) 56,896 shares of Common Stock reserved for future issuance under the 2023 Plan; and (xiv) up to 969,697 shares (1,115,151 shares if the underwriters' option to purchase additional Investor Warrants is exercised in full) of Common Stock issuable upon exercise at \$4.00 per share of the Investor Warrants to be issued in this offering.

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SELLING STOCKHOLDERS

The Common Stock being offered in the Resale Prospectus by the selling stockholders are the 2022 Inducement Shares, Bridge Shares, True-Up Shares and those issuable to the selling stockholders, upon conversion of the 2022 Notes and 2024 Notes and exercise of the Resale Warrants. For additional information regarding the issuances of such securities, see “**Prospectus Summary**” above. We are registering the shares of Common Stock in order to permit the selling stockholders to offer the shares for resale from time to time. Except for Terrence Norchi, our Chief Executive Officer; Michael Abrams, our Chief Financial Officer; Laurence Hicks, a member of our Board and holder of an ownership interest in Drake Partners LLC and Maxim Group LLC, the selling stockholders have not had any material relationship with us within the past three years.

The table below lists the selling stockholders and other information regarding the beneficial ownership of the shares of Common Stock by each of the selling stockholders. The second column lists the number of shares of Common Stock beneficially owned by each selling stockholder, based on its ownership of the shares of Common Stock, convertible debt and warrants, as of June 19, 2024, assuming exercise of the warrants and conversion of convertible notes held by the selling stockholders on that date, without regard to any limitations on exercises. The third column lists the shares of Common Stock being offered by this prospectus by the selling stockholders. The fourth column assumes the sale of all of the shares offered by the selling stockholders pursuant to this prospectus.

In accordance with the terms of (i) Third Amended and Restated Registration Rights Agreement with certain of the selling stockholders or (ii) the terms of the 2022 Notes, 2022 Warrants and 2022 Placement Agent Warrants held by certain of the selling stockholders, this prospectus generally covers the resale of the sum of (A) the maximum number of shares of Common Stock issuable upon conversion of the 2022 Notes issued to the selling stockholders in the 2022 Private Placement Financing; and (B) the maximum number of shares of Common Stock issuable upon exercise of the 2022 Warrants and 2022 Placement Agent Warrant, determined as if the outstanding 2022 Notes were converted and the 2022 Warrants and 2022 Placement Agent Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the Third Amended and Restated Registration Rights Agreement, 2022 Note, 2022 Warrant or 2022 Placement Agent Warrant, as applicable, without regard to any limitations on the conversion of the 2022 Notes or the exercise of the 2022 Warrants and 2022 Placement Agent Warrants.

This prospectus also covers the maximum number of shares of Common Stock issuable upon exercise of the maximum number of 2022 Note Conversion Pre-Funded Warrants that may be issuable under the 2022 Notes at the closing of the Primary Offering in lieu of Automatic Conversion Shares otherwise issuable, as if such maximum amount of 2022 Note Conversion Pre-Funded Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the 2022 Note Conversion Pre-Funded Warrants, without regard to any limitations on the exercise of 2022 Note Conversion Pre-Funded Warrants.

Additionally, this prospectus covers the maximum number of shares of Common Stock issuable upon exercise of the Uplist Conversion Warrants that are expected to be issued under the 2022 Notes at the closing of the Primary Offering, as if such Uplist Conversion Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the Uplist Conversion Warrants, without regard to any limitations on the exercise of Uplist Conversion Warrants.

In accordance with the terms of (i) 2024 Notes Registration Rights Agreement with certain of the selling stockholders or (ii) the terms of the 2024 Notes held by certain of the selling stockholders, this prospectus generally covers the resale of the maximum number of shares of Common Stock issuable upon conversion of the 2024 Notes issued to the selling stockholders in the 2024 Notes Financing, determined as if the outstanding 2024 Notes were converted in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the 2024 Notes Registration Rights Agreement or 2024 Note, as applicable, without regard to any limitations on the conversion of the 2024 Notes.

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This prospectus also covers the maximum number of shares of Common Stock issuable upon exercise of the maximum number of 2024 Note Conversion Pre-Funded Warrants that may be issuable under the 2024 Notes at the closing of the Primary Offering in lieu of 2024 Notes Automatic Conversion Shares otherwise issuable, as if such maximum amount of 2024 Note Conversion Pre-Funded Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the 2024 Note Conversion Pre-Funded Warrants, without regard to any limitations on the exercise of 2024 Note Conversion Pre-Funded Warrants.

Additionally, this prospectus covers the maximum number of shares of Common Stock issuable upon exercise of the 2024 Notes Uplist Conversion Warrants that are expected to be issued under the 2024 Notes at the closing of the Primary Offering, as if such 2024 Notes Uplist Conversion Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the 2024 Notes Uplist Conversion Warrants, without regard to any limitations on the exercise of 2024 Notes Uplist Conversion Warrants.

In accordance with the terms of (i) Bridge Registration Rights Agreement with certain of the selling stockholders or (ii) the terms of the Bridge Warrants held by certain of the selling stockholders, this prospectus generally covers the resale of the sum of the maximum number of shares of Common Stock issuable upon exercise of the Bridge Warrants determined as if the outstanding Bridge Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the Bridge Registration Rights Agreement and Bridge Warrants, as applicable, without regard to any limitations on the exercise of the Bridge Warrants.

In accordance with the terms of (i) the PIPE Registration Rights Agreement with certain of the selling stockholders or (ii) the PIPE Warrants held by certain of the selling stockholders, this prospectus generally covers the resale of the sum of the maximum number of shares of Common Stock issuable upon exercise of the PIPE Warrants determined as if the outstanding PIPE Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the PIPE Registration Rights Agreement and PIPE Warrants, as applicable, without regard to any limitations on the exercise of the PIPE Warrants.

This prospectus covers the resale of the maximum number of True-Up Shares that may be issuable under the Bridge SPA at the closing of the Primary Offering, based on the sale of the Units and Pre-Funded Units at an assumed public offering price of \$4.125 per Unit and \$4.124 per Pre-Funded Unit, which represents the minimum bid price of \$4.00 per share under the initial listing requirements of Cboe in Cboe Listing Rule 14.9(b) plus a value of \$0.125 attributed to the accompanying Investor Warrant. This prospectus also covers the maximum number of shares of Common Stock issuable upon exercise of the maximum number of True-Up Pre-Funded Warrants that may be issuable under the Bridge SPA at the closing of the Primary Offering in lieu of True-Up Shares otherwise issuable, as if such maximum amount of True-Up Pre-Funded Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the True-Up Pre-Funded Warrants, without regard to any limitations on the exercise of True-Up Pre-Funded Warrants.

This prospectus covers the resale of the sum of the maximum number of shares of Common Stock issuable upon exercise of the Funding Backstop Pre-Funded Warrants and Backstop Common Warrants, based on the assumption that the conditions for the issuance of such warrants under the Backstop Agreement are satisfied, prior to the closing of

the Primary Offering, determined as if such warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in such warrants, as applicable, without regard to any limitations on the exercise of such warrants.

This prospectus covers the resale of the sum of the maximum number of shares of Common Stock issuable upon exercise of the remaining Resale Warrants not otherwise referenced in the foregoing ten paragraphs, determined as if the outstanding Resale Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the Resale Warrants, as applicable, without regard to any limitations on the exercise of the Resale Warrants.

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Under the terms of the 2022 Notes, 2024 Notes and Resale Warrants, a selling stockholder may not convert the notes or exercise the warrants to the extent such exercise would cause such selling stockholder, together with its affiliates and attribution parties, to beneficially own a number of shares of Common Stock which would exceed 4.99% (or 9.99% if elected and as applicable) of our then outstanding Common Stock following such exercise, excluding for purposes of such determination shares of Common Stock issuable upon conversion of the 2022 Notes and 2024 Notes and exercise of the Resale Warrants which have not been exercised. The number of shares in the second column does not reflect this limitation. The selling stockholders may sell all, some or none of their shares in this offering. See “**Plan of Distribution**” on page 61.

Name of Selling Stockholder	Number of shares of Common Stock Owned Prior to Offering	Maximum Number of shares of Common Stock to be Sold Pursuant to this Prospectus	Number of shares of Common Stock Owned After Offering
Tiburon Opportunity Fund LP (1)	794,265	31,394,777	972,379
District 2 Capital Fund LP (2)	327,069	9,664,127	486,721
Bigger Capital Fund, LP (3)	327,198	9,664,123	486,785
Cavalry Fund I LP (4)	423,941	10,428,410	964,176
Sanibel Island Associates LLC (Anestis) (5)	21,767	780,270	16,309
Michael & Ana Parker (6)	280,168	10,262,003	225,560
ProActive Capital Partners, L.P. (7)	64,901	2,378,431	53,195
Michael Abrams (8)	11,408	389,970	8,840
Jason Adelman (9)	21,614	779,941	16,479
Centurion Therapeutics, Inc. (10)	23,802	920,250	1,302
Drake Partners LLC (11)	11,246	389,970	8,678
Terrence Norchi (12)	19,821	259,982	18,111
Michael Tuttle (13)	31,736	1,227,000	1,736
Trina Whitridge GST Trust (14)	76,979	2,825,975	58,343
Mark Woolfson (15)	27,019	974,924	20,601
Steve Woolfson (16)	30,620	1,104,915	23,345
Walleye Opportunities Master Fund Ltd (17)	37,500	3,284,351	957,210
Sixth Borough Capital Fund, LP (18)	37,500	949,133	272,904
Brandt Wilson and Mona Wilson (19)	270,388	4,495,137	957,210
Andrew Stahl (20)	270,388	4,495,137	957,210
John Robert Baleno (21)	9,091	154,545	54,546
Roxanne Rosetto (22)	4,546	77,273	27,273
Robert Forster (23)	22,728	386,363	136,365
Thomas Pilgrim (24)	9,091	154,545	54,546
Rajiv P Dewan (25)	5,000	85,000	30,000
David L McClain (26)	2,500	42,500	15,000
Norman McClain (27)	5,000	85,000	30,000
Ronald Nash (28)	4,546	77,273	27,273
Richard Molinsky (29)	6,819	115,908	40,911
George Benashvili (30)	1,288	21,887	7,725
Dan Armstrong (31)	9,091	154,545	54,546
CNP Consulting (32)	1,750	29,750	10,500
Ivan Chi Vei Tong (33)	2,500	42,500	15,000
Genmark Holdings (34)	9,091	154,545	54,546
Stephen Ross (35)	2,273	38,637	13,638
Efrat Investments (36)	4,546	77,273	27,273
Daniel Shalhoub (37)	2,273	38,637	13,638
Jeffrey and Shiela Negus (38)	2,273	38,637	13,638
Maxim Group LLC (39)	4,760	821	3,939
Total	3,218,494	98,444,466	7,137,449

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- Assuming exercise or conversion of the warrants or convertible notes held by Tiburon Opportunity Fund LP (“**Tiburon**”) or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Tiburon may be deemed to have beneficial ownership of 32,367,156 shares of Common Stock, which includes the following: (i) 1,223 Inducement Pre-Funded Warrant Shares; (ii) 37,510 Legacy Pre-Funded Warrant Shares; (iii) 1,116,834 True-Up Shares; (v) 700,180 Conversion Shares; (vi) 665,171 Automatic Conversion Shares; (vii) 40,261 2022 Warrant Shares; (viii) 665,171 2022 Note Conversion Pre-Funded Warrant Shares; (ix) 319,096 Common Warrant Shares; (x) 125,657 Bridge Pre-Funded Warrant Shares; (xi) 26,606,840 Uplist Conversion Warrant Shares; and (xii) 1,116,834 True-Up Pre-Funded Warrant Shares.
- Assuming exercise or conversion of the warrants or convertible notes held by District 2 Capital Fund LP (“**District 2**”) or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, District 2 may be deemed to have beneficial ownership of 10,150,848 shares of Common Stock, which includes the following: (i) 236 2022 Inducement Shares; (ii) 17,897 Bridge Shares; (iii) 558,393 True-Up Shares; (v) 181,250 Conversion Shares; (vi) 172,188 Automatic Conversion Shares; (vii) 3,144 2022 Warrant Shares; (viii) 172,188 2022 Note Conversion Pre-Funded Warrant Shares; (ix) 159,541 Common Warrant Shares; (x) 61,874 Bridge Pre-Funded Warrant Shares; (xi) 6,887,500 Uplist Conversion Warrant Shares; (xii) 558,393 True-Up Pre-Funded Warrant Shares; (xiii) 178,818 PIPE Investor Warrant Shares; (xiv) 178,818 PIPE Pre-Funded Warrant Shares; (xv) 69,375 2024 Notes Conversion Shares; (xvi) 67,273 2024 Notes Automatic Conversion Shares; (xvii) 67,273 2024 Note Conversion Pre-Funded Warrant Shares; (xviii) 9,472 PIPE Advance Penalty Pre-Funded Warrant Shares; (xiv) 28,125 Execution Backstop Pre-Funded Warrant Shares; (xv) 93,750 Funding Backstop Pre-Funded Warrant Shares; (xvi) 67,273 2024 Notes Uplist Conversion Warrant Shares; (xvii) 9,472 PIPE Advance Penalty Common Warrants; and (xviii) 121,875 Backstop Common Warrants.

3. Assuming exercise or conversion of the warrants or convertible notes held by Bigger Capital Fund, LP ("**Bigger Capital**") or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Bigger Capital may be deemed to have beneficial ownership of 10,150,909 shares of Common Stock, which includes the following: (i) 236 2022 Inducement Shares; (ii) 17,961 Bridge Shares; (iii) 558,391 True-Up Shares; (v) 181,250 Conversion Shares; (vi) 172,188 Automatic Conversion Shares; (vii) 3,144 2022 Warrant Shares; (viii) 172,188 2022 Note Conversion Pre-Funded Warrant Shares; (ix) 159,541 Common Warrant Shares; (x) 61,809 Bridge Pre-Funded Warrant Shares; (xi) 6,887,500 Uplist Conversion Warrant Shares; (xii) 558,391 True-Up Pre-Funded Warrant Shares; (xiii) 178,818 PIPE Investor Warrant Shares; (xiv) 178,818 PIPE Pre-Funded Warrant Shares; (xv) 69,375 2024 Notes Conversion Shares; (xvi) 67,273 2024 Notes Automatic Conversion Shares; (xvii) 67,273 2024 Note Conversion Pre-Funded Warrant Shares; (xviii) 9,472 PIPE Advance Penalty Pre-Funded Warrant Shares; (xiv) 28,125 Execution Backstop Pre-Funded Warrant Shares; (xv) 93,750 Funding Backstop Pre-Funded Warrant Shares; (xvi) 67,273 2024 Notes Uplist Conversion Warrant Shares; (xvii) 9,472 PIPE Advance Penalty Common Warrants; and (xviii) 121,875 Backstop Common Warrants.
4. Assuming exercise or conversion of the warrants or convertible notes held by Cavalry Fund I, LP ("**Cavalry**") or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Cavalry may be deemed to have beneficial ownership of 11,392,587 shares of Common Stock, which includes the following: (i) 189 2022 Inducement Shares; (ii) 36,406 Bridge Shares; (iii) 1,116,771 True-Up Shares; (v) 145,000 Conversion Shares; (vi) 137,750 Automatic Conversion Shares; (vii) 2,516 2022 Warrant Shares; (viii) 137,750 2022 Note Conversion Pre-Funded Warrant Shares; (ix) 319,078 Common Warrant Shares; (x) 123,133 Bridge Pre-Funded Warrant Shares; (xi) 5,510,000 Uplist Conversion Warrant Shares; (xii) 1,116,771 True-Up Pre-Funded Warrant Shares; (xiii) 357,636 PIPE Investor Warrant Shares; (xiv) 357,636 PIPE Pre-Funded Warrant Shares; (xv) 138,750 2024 Notes Conversion Shares; (xvi) 134,545 2024 Notes Automatic Conversion Shares; (xvii) 134,545 2024 Note Conversion Pre-Funded Warrant Shares; (xviii) 18,944 PIPE Advance Penalty Pre-Funded Warrant Shares; (xiv) 56,250 Execution Backstop Pre-Funded Warrant Shares; (xv) 187,500 Funding Backstop Pre-Funded Warrant Shares; (xvi) 134,545 2024 Notes Uplist Conversion Warrant Shares; (xvii) 18,944 PIPE Advance Penalty Common Warrants; and (xviii) 243,750 Backstop Common Warrants.
5. Assuming exercise or conversion of the warrants or convertible notes held by Sanibel Island Associates LLC (Anestis) ("**Sanibel**") or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Sanibel may be deemed to have beneficial ownership of 796,579 shares of Common Stock, which includes the following: (i) 23 2022 Inducement Shares; (ii) 2,573 Bridge Shares; (iii) 18,012 True-Up Shares; (iv) 18,000 Conversion Shares; (v) 17,100 Automatic Conversion Shares; (vi) 302 2022 Warrant Shares; (vii) 17,100 2022 Note Conversion Pre-Funded Warrant Shares; (viii) 5,147 Common Warrant Shares; (ix) 684,000 Uplist Conversion Warrant Shares; and (x) 18,012 True-Up Pre-Funded Warrant Shares.

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6. Assuming the exercise or conversion of the warrants or convertible notes held by Ana Parker or her affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Ms. Parker may be deemed to have beneficial ownership of 10,488,469 shares of Common Stock, which includes the following: (i) 24,035 Bridge Shares; (ii) 240,399 True-Up Shares; (iii) 236,631 Conversion Shares; (iv) 224,799 Automatic Conversion Shares; (v) 224,799 2022 Note Conversion Pre-Funded Warrant Shares; (vi) 68,686 Common Warrant Shares; (vii) 10,308 Bridge Pre-Funded Warrant Shares; (viii) 8,991,946 Uplist Conversion Warrant Shares; and (ix) 240,399 True-Up Pre-Funded Warrant Shares.
7. Assuming exercise of the warrants held by ProActive Capital Partners, L.P. ("**ProActive**") as of June 19, 2024 and disregarding any limitations on exercise applicable to such warrants, ProActive may be deemed to have beneficial ownership of 2,431,626 shares of Common Stock, which includes the following: (i) 8,576 Bridge Shares; (ii) 60,034 True-Up Shares; (iii) 59,158 Conversion Shares; (iv) 51,859 Automatic Conversion Shares; (v) 51,859 2022 Note Conversion Pre-Funded Warrant Shares; (vi) 17,153 Common Warrant Shares; (vii) 2,074,327 Uplist Conversion Warrant Shares; and (viii) 60,034 True-Up Pre-Funded Warrant Shares.
8. Assuming exercise or conversion of the warrants or convertible notes held by Michael Abrams or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Abrams may be deemed to have beneficial ownership of 398,810 shares of Common Stock, which includes the following: (i) 1,287 Bridge Shares; (ii) 9,005 True-Up Shares; (iii) 9,000 Conversion Shares; (iv) 8,550 Automatic Conversion Shares; (v) 8,550 2022 Note Conversion Pre-Funded Warrant Shares; (vi) 2,573 Common Warrant Shares; (vii) 342,000 Uplist Conversion Warrant Shares; and (viii) 9,005 True-Up Pre-Funded Warrant Shares.
9. Assuming exercise or conversion of the warrants or convertible notes held by Jason Adelman or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Adelman may be deemed to have beneficial ownership of 796,420 shares of Common Stock, which includes the following: (i) 2,573 Bridge Shares; (ii) 18,011 True-Up Shares; (iii) 18,000 Conversion Shares; (iv) 17,100 Automatic Conversion Shares; (v) 17,100 2022 Note Conversion Pre-Funded Warrant Shares; (vi) 5,146 Common Warrant Shares; (vii) 684,000 Uplist Conversion Warrant Shares; and (viii) 18,011 True-Up Pre-Funded Warrant Shares.
10. Assuming exercise or conversion of the warrants or convertible notes held by Centurion Therapeutics, Inc. ("**Centurion**") or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Centurion may be deemed to have beneficial ownership of 921,552 shares of Common Stock, which includes the following: (i) 22,500 Conversion Shares; (ii) 21,375 Automatic Conversion Shares; (iii) 21,375 2022 Note Conversion Pre-Funded Warrant Shares; and (iv) 855,000 Uplist Conversion Warrant Shares.
11. Assuming exercise or conversion of the warrants or convertible notes held by Drake Partners LLC ("**Drake Partners**") or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Drake Partners may be deemed to have beneficial ownership of 398,648 shares of Common Stock, which includes the following: (i) 1,287 Bridge Shares; (ii) 9,005 True-Up Shares; (iii) 9,000 Conversion Shares; (iv) 8,550 Automatic Conversion Shares; (v) 8,550 2022 Note Conversion Pre-Funded Warrant Shares; (vi) 2,573 Common Warrant Shares; (vii) 342,000 Uplist Conversion Warrant Shares; and (viii) 9,005 True-Up Pre-Funded Warrant Shares.

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12. Assuming exercise or conversion of the warrants or convertible notes held by Terrence Norchi or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Norchi may be deemed to have beneficial ownership of 278,093 shares of Common Stock, which includes the following: (i) 858 Bridge Shares; (ii) 6,004 True-Up Shares; (iii) 6,000 Conversion Shares; (iv) 5,700 Automatic Conversion Shares; (v) 5,700 2022 Note Conversion Pre-Funded Warrant Shares; (vi) 1,716 Common Warrant Shares; (vii) 228,000 Uplist Conversion Warrant Shares; and (viii) 6,004 True-Up Pre-Funded Warrant Shares.
13. Assuming exercise or conversion of the warrants or convertible notes held by Michael Tuttle or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Tuttle may be deemed to have beneficial ownership of 1,228,736 shares of Common Stock, which includes the following: (i) 30,000 Conversion Shares; (ii) 28,500 Automatic Conversion Shares; (iii) 28,500 2022 Note Conversion Pre-Funded Warrant Shares; and (iv) 1,140,000 Uplist Conversion Warrant Shares.
14. Assuming exercise or conversion of the warrants or convertible notes held by Trina Whitridge GST Trust ("**Whitridge**") or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Whitridge may be deemed to have beneficial ownership of 2,884,318 shares of Common Stock, which includes the following: (i) 46 2022 Inducement Shares; (ii) 9,435 Bridge Shares; (iii) 66,038 True-Up Shares (iv) 65,158 Conversion Shares; (v) 61,900 Automatic Conversion Shares; (vi) 604 2022 Warrant Shares; (vii) 61,900 2022 Note Conversion Pre-Funded Warrant Shares; (viii) 18,868 Common Warrant Shares; (ix) 2,475,987 Uplist Conversion Warrant Shares; and (x) 66,038 True-Up Pre-Funded Warrant Shares.

15. Assuming exercise or conversion of the warrants or convertible notes held by Mark Woolfson or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Woolfson may be deemed to have beneficial ownership of 995,525 shares of Common Stock, which includes the following: (i) 3,217 Bridge Shares; (ii) 22,512 True-Up Shares; (iii) 22,500 Conversion Shares; (iv) 21,375 Automatic Conversion Shares; (v) 21,375 2022 Note Conversion Pre-Funded Warrant Shares; (vi) 6,432 Common Warrant Shares; (vii) 855,000 Uplist Conversion Warrant Shares; and (viii) 22,512 True-Up Pre-Funded Warrant Shares.
16. Assuming exercise or conversion of the warrants or convertible notes held by Steve Woolfson or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Woolfson be deemed to have beneficial ownership of 1,128,260 shares of Common Stock, which consists of the following: (i) 3,645 Bridge Shares; (ii) 25,515 True-Up Shares; (iii) 25,500 Conversion Shares; (iv) 24,225 Automatic Conversion Shares; (v) 24,225 2022 Note Conversion Pre-Funded Warrant Shares; (vi) 7,290 Common Warrant Shares; (vii) 969,000 Uplist Conversion Warrant Shares; and (viii) 25,515 True-Up Pre-Funded Warrant Shares.
17. Assuming exercise or conversion of the warrants held by Walleye Opportunities Master Fund Ltd (“**Walleye**”) or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Walleye may be deemed to have beneficial ownership of 4,241,561 shares of Common Stock, which includes the following: (i) 37,500 Bridge Shares; (ii) 1,116,743 True-Up Shares; (iv) 319,070 Common Warrant Shares; (v) 122,035 Bridge Pre-Funded Warrant Shares; (vi) 1,116,743 True-Up Pre-Funded Warrant Shares; (vii) 286,130 PIPE Investor Warrant Shares; and (viii) 286,130 PIPE Pre-Funded Warrant Shares.
18. Assuming exercise or conversion of the warrants held by Sixth Borough Capital Fund, LP (“**Sixth Borough**”) or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Sixth Borough may be deemed to have beneficial ownership of 1,046,126 shares of Common Stock, which includes the following: (i) 37,500 Bridge Shares; (ii) 318,385 True-Up Shares; (iii) 90,967 Common Warrant Shares; (iv) 7,984 Bridge Pre-Funded Warrant Shares; (v) 318,385 True-Up Pre-Funded Warrant Shares; (vi) 45,000 2024 Notes Conversion Shares; (vii) 43,637 2024 Notes Automatic Conversion Shares; (viii) 43,637 2024 Notes Conversion Pre-Funded Warrants; and (ix) 43,637 2024 Notes Uplist Conversion Warrants.
19. Assuming exercise or conversion of the warrants held by Brandt Wilson and Mona Wilson or their affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Wilson and Mrs. Wilson may be deemed to have beneficial ownership of 5,309,335 shares of Common Stock, which includes the following: (i) 37,500 Bridge Shares; (ii) 1,116,743 True-Up Shares; (iii) 138,750 2024 Notes Conversion Shares; (iv) 134,545 2024 Notes Automatic Conversion Shares; (v) 134,545 2024 Notes Conversion Pre-Funded Warrants; (vi) 18,944 PIPE Advance Penalty Pre-Funded Warrants; (vii) 56,250 Execution Backstop Pre-Funded Warrants; (viii) 187,500 Funding Backstop Pre-Funded Warrants; (ix) 134,545 2024 Notes Uplist Conversion Warrants; (x) 18,944 PIPE Advance Penalty Common Warrants; (xi) 243,750 Backstop Common Warrants; (xii) 319,070 Common Warrant Shares; (xiii) 122,035 Bridge Pre-Funded Warrant Shares; (xiv) 1,116,743 True-Up Pre-Funded Warrant Shares; (xv) 357,636 PIPE Investor Warrant Shares; and (xvi) 357,636 PIPE Pre-Funded Warrant Shares.
20. Assuming exercise or conversion of the warrants held by Andrew Stahl or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Stahl may be deemed to have beneficial ownership of 5,309,335 shares of Common Stock, which includes the following: (i) 37,500 Bridge Shares; (ii) 1,116,743 True-Up Shares; (iii) 138,750 2024 Notes Conversion Shares; (iv) 134,545 2024 Notes Automatic Conversion Shares; (v) 134,545 2024 Notes Conversion Pre-Funded Warrants; (vi) 18,944 PIPE Advance Penalty Pre-Funded Warrants; (vii) 56,250 Execution Backstop Pre-Funded Warrants; (viii) 187,500 Funding Backstop Pre-Funded Warrants; (ix) 134,545 2024 Notes Uplist Conversion Warrants; (x) 18,944 PIPE Advance Penalty Common Warrants; (xi) 243,750 Backstop Common Warrants; (xii) 319,070 Common Warrant Shares; (xiii) 122,035 Bridge Pre-Funded Warrant Shares; (xiv) 1,116,743 True-Up Pre-Funded Warrant Shares; (xv) 357,636 PIPE Investor Warrant Shares; and (xvi) 357,636 PIPE Pre-Funded Warrant Shares.

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21. Assuming exercise or conversion of the warrants held by John Robert Baleno or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Baleno may be deemed to have beneficial ownership of 209,091 shares of Common Stock, which includes the following: (i) 9,091 Bridge Shares; (ii) 63,636 True-Up Shares; (iii) 18,182 Common Warrant Shares; and (iv) 63,636 True-Up Pre-Funded Warrant Shares.
22. Assuming exercise or conversion of the warrants held by Roxanne Rosetto or her affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Ms. Rosetto may be deemed to have beneficial ownership of 104,546 shares of Common Stock, which includes the following: (i) 4,546 Bridge Shares; (ii) 31,818 True-Up Shares; (iii) 9,091 Common Warrant Shares; and (iv) 31,818 True-Up Pre-Funded Warrant Shares.
23. Assuming exercise or conversion of the warrants held by Robert Forster or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Forster may be deemed to have beneficial ownership of 522,728 shares of Common Stock, which includes the following: (i) 22,727 Bridge Shares; (ii) 159,090 True-Up Shares; (iii) 45,455 Common Warrant Shares; and (iv) 159,090 True-Up Pre-Funded Warrant Shares.
24. Assuming exercise or conversion of the warrants held by Thomas Pilgrim or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Pilgrim may be deemed to have beneficial ownership of 209,091 shares of Common Stock, which includes the following: (i) 9,091 Bridge Shares; (ii) 63,636 True-Up Shares; (iii) 18,182 Common Warrant Shares; and (iv) 63,636 True-Up Pre-Funded Warrant Shares.
25. Assuming exercise or conversion of the warrants held by Rajiv P. Dewan or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Dewan may be deemed to have beneficial ownership of 115,000 shares of Common Stock, which includes the following: (i) 5,000 Bridge Shares; (ii) 35,000 True-Up Shares; (iii) 10,000 Common Warrant Shares; and (iv) 35,000 True-Up Pre-Funded Warrant Shares.
26. Assuming exercise or conversion of the warrants held by David L. McClain or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. McClain may be deemed to have beneficial ownership of 57,500 shares of Common Stock, which includes the following: (i) 2,500 Bridge Shares; (ii) 17,500 True-Up Shares; (iii) 5,000 Common Warrant Shares; and (iv) 17,500 True-Up Pre-Funded Warrant Shares.
27. Assuming exercise or conversion of the warrants held by Norman McClain or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. McClain may be deemed to have beneficial ownership of 115,000 shares of Common Stock, which includes the following: (i) 5,000 Bridge Shares; (ii) 35,000 True-Up Shares; (iii) 10,000 Common Warrant Shares; and (iv) 35,000 True-Up Pre-Funded Warrant Shares.
28. Assuming exercise or conversion of the warrants held by Ronald Nash or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Nash may be deemed to have beneficial ownership of 104,546 shares of Common Stock, which consists of the following: (i) 4,546 Bridge Shares; (ii) 31,818 True-Up Shares; (iii) 9,091 Common Warrant Shares; and (iv) 31,818 True-Up Pre-Funded Warrant Shares.
29. Assuming exercise or conversion of the warrants held by Richard Molinsky or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Molinsky may be deemed to have beneficial ownership of 156,819 shares of Common Stock, which includes the following: (i) 6,818 Bridge Shares; (ii) 47,726 True-Up Shares; (iii) 13,636 Common Warrant Shares; and (iv) 47,726 True-Up Pre-Funded Warrant Shares.
30. Assuming exercise or conversion of the warrants held by George Benashivili or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Benashivili may be deemed to have beneficial ownership of 29,612 shares of Common Stock, which includes the following: (i) 1,288 Bridge Shares; (ii) 9,012 True-Up Shares; (iii) 2,575 Common Warrant Shares; and (iv) 9,012 True-Up Pre-Funded Warrant Shares.

31. Assuming exercise or conversion of the warrants held by Dan Armstrong or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Armstrong may be deemed to have beneficial ownership of 209,091 shares of Common Stock, which includes the following: (i) 9,091 Bridge Shares; (ii) 63,636 True-Up Shares; (iii) 18,182 Common Warrant Shares; and (iv) 63,636 True-Up Pre-Funded Warrant Shares.
32. Assuming exercise or conversion of the warrants held by CNP Consulting or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, CNP Consulting may be deemed to have beneficial ownership of 40,250 shares of Common Stock, which includes the following: (i) 1,750 Bridge Shares; (ii) 12,250 True-Up Shares; (iii) 3,500 Common Warrant Shares; and (iv) 12,250 True-Up Pre-Funded Warrant Shares.
33. Assuming exercise or conversion of the warrants held by Ivan Chi Vei Tong or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Tong may be deemed to have beneficial ownership of 57,500 shares of Common Stock, which includes the following: (i) 2,500 Bridge Shares; (ii) 17,500 True-Up Shares; (iii) 5,000 Common Warrant Shares; and (iv) 17,500 True-Up Pre-Funded Warrant Shares.

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34. Assuming exercise or conversion of the warrants held by Genmark Holdings or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Genmark Holdings may be deemed to have beneficial ownership of 209,091 shares of Common Stock, which includes the following: (i) 9,091 Bridge Shares; (ii) 63,636 True-Up Shares; (iii) 18,182 Common Warrant Shares; and (iv) 63,636 True-Up Pre-Funded Warrant Shares.
35. Assuming exercise or conversion of the warrants held by Stephen Ross or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Ross may be deemed to have beneficial ownership of 52,275 shares of Common Stock, which includes the following: (i) 2,273 Bridge Shares; (ii) 15,909 True-Up Shares; (iii) 4,546 Common Warrant Shares; and (iv) 15,909 True-Up Pre-Funded Warrant Shares.
36. Assuming exercise or conversion of the warrants held by Efrat Investments or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Efrat Investments may be deemed to have beneficial ownership of 104,546 shares of Common Stock, which includes the following: (i) 4,546 Bridge Shares; (ii) 31,818 True-Up Shares; (iii) 9,091 Common Warrant Shares; and (iv) 31,818 True-Up Pre-Funded Warrant Shares.
37. Assuming exercise or conversion of the warrants held by Daniel Shalhoub or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Shalhoub may be deemed to have beneficial ownership of 52,275 shares of Common Stock, which includes the following: (i) 2,273 Bridge Shares; (ii) 15,909 True-Up Shares; (iii) 4,546 Common Warrant Shares; and (iv) 15,909 True-Up Pre-Funded Warrant Shares.
38. Assuming exercise or conversion of the warrants held by Jeffrey and Shiela Negus or their affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Negus and Mrs. Negus may be deemed to have beneficial ownership of 52,275 shares of Common Stock, which includes the following: (i) 2,273 Bridge Shares; (ii) 15,909 True-Up Shares; (iii) 4,546 Common Warrant Shares; and (iv) 15,909 True-Up Pre-Funded Warrant Shares.
39. Assuming exercise or conversion of the warrants held by Maxim or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Maxim may be deemed to have beneficial ownership of 821 shares of Common Stock, which consists of the following: (i) 821 2022 Placement Agent Warrant Shares.

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PLAN OF DISTRIBUTION

Each selling stockholder of the securities and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their securities covered hereby on the principal Trading Market or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling stockholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker dealer solicits purchasers;
- block trades in which the broker dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker dealer as principal and resale by the broker dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- in transactions through broker dealers that agree with the selling stockholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell securities under Rule 144 or any other exemption from registration under the Securities Act, if available, rather than under this prospectus.

Broker dealers engaged by the selling stockholders may arrange for other brokers dealers to participate in sales. Broker dealers may receive commissions or discounts from the selling stockholders (or, if any broker dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

In connection with the sale of the securities or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The selling stockholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling stockholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling stockholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the securities. The Company has agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the securities may be resold by the selling stockholders without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, without the requirement for the Company to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect or (ii) all of the securities have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the common stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

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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**”) is a biotechnology company developing and marketing products based on our innovative AC5® self-assembling technology platform. Arch rose from the June 26, 2013 merger (the “**Merger**”) of three entities previously known as Arch Biosurgery, Inc., Almah, Inc., and Arch Acquisition Corporation, respectively.

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

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

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

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

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

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

Our Company

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

Commercial Update

During its fourth fiscal quarter ended September 30, 2023, the Company experienced a significant increase in AC5 orders, posting record monthly order volumes during both August and September. Taken together, orders from August and September represented more than half of total fiscal year volume, and September orders more than doubled August orders. The Company also observed favorable coverage and reimbursement decisions from multiple payors in different regions of the country with a commensurate increase in paid claims. Early in the fourth fiscal quarter, the Company received its first payment from a provider as a result of a paid claim for reimbursement of AC5 using A2020, and the number of paid claims across different payor networks increased throughout the quarter. Throughout the first fiscal quarter ended December 31, 2023 and second fiscal quarter ending March 31, 2024, the number of providers using AC5 and the number of related coverage and reimbursement decisions continued to expand. While numbers remain expectedly modest, the Company is optimistic that its ongoing efforts will result in contracted pricing opportunities with several regional Medicare Administrator Contractors, which management believes is the next important milestone in the Company’s comprehensive strategic commercialization plan.

Core Technology

Our flagship product 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 (US) and the European Union (EU), respectively, and which are intended for skin applications, such as management of complicated chronic wounds and acute surgical wounds. Marketing for AC5 Topical Hemostat in the EU has not initiated. Other products are in development for use in minimally invasive or open surgical procedures and include, for

example, AC5-G™ for gastrointestinal endoscopic procedures and AC5-V® and AC5 Surgical Hemostat for hemostasis inside the body, all of which are currently investigational devices limited by law to investigational use.

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

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

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

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

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

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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.

Operations

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

Our long-term business plan includes the following goals:

- growing revenues and building upon recent commercial momentum by driving product awareness, continued adoption and favorable payment policies for AC5 Advanced Wound System with the now-effective CMS Level II HCPCS code dedicated to AC5;
- conducting biocompatibility, pre-clinical, and clinical studies on our products and product candidates;
- obtaining additional marketing authorization for products in the United States, Europe, and other jurisdictions as we may determine;
- continuing to develop third party relationships to manufacture, distribute, market and otherwise commercialize our products;
- continuing to develop third party 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.

To support our long-term business goals, we expect to focus on the following activities during the next twelve months:

- further develop our product clinical profile;

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- enhance product packaging features;
- identify and address opportunities for supply chain efficiencies;
- assess our technology platform in order to identify and select product candidates for potential advancement into development;
- seek additional funding as required to support the previously described milestones necessary to support our operations;
- 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, maintaining granted patents in desired jurisdictions, and/or adding to our trade secrets in self-assembly, manufacturing, analytical methods and formulation, as appropriate.

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 future capital. We will require significant additional financing to fund our planned operations, including, but not limited to, further research and development relating to AC5; seeking regulatory approval for any product we may choose to develop, launch or license; commercializing any product for which we are able to obtain regulatory approval or certification; seeking to license or acquire new assets or business; supporting our intellectual property rights; pursuing new technologies; and financing the investor relations and incremental administrative costs associated with being a public corporation. We do not presently have, nor do we expect in the near future to have, sufficient revenue to fund our business from operations, and we will need to obtain substantially all of our necessary funding from external sources for the foreseeable future. We may not be able to obtain additional financing on commercially reasonable or acceptable terms when needed, or at all. If we cannot raise the money that we need in order to continue to develop our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations. If any of these were to occur, there is a substantial risk that our business would fail, and our stockholders could lose all of their investments.

The estimated capital requirements could potentially 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*”. 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 June 19, 2024, we do not believe that our current cash on hand is sufficient to meet our anticipated cash requirements through the end of June 2024, and we must obtain additional financing in order to continue to operate our business. Even if this offering is successful, we could spend our financial resources much faster than we expect, in which case we would need to raise additional capital.

Research and Development

Preclinical and clinical testing is required in order to receive regulatory marketing authorizations for our products and to support those products upon and after commercialization, and we anticipate continuing such testing as 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 and related activities, typically with assistance from our team. These third parties can include contract research organizations, academic institutions, consultants, advisors, scientists, clinicians, and 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 complete a biocompatibility assessment using a battery of standard in vitro and in vivo tests. Examples of such tests may include the following, as set forth in ISO 10993 issued by the International Organization for Standardization:

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- in vitro cytotoxicity;
- in vitro blood compatibility;
- irritation/intracutaneous reactivity;
- sensitization (allergic reaction);
- implantation (performed on devices that contact the body’s interior);
- pyrogenicity (causing fever or inflammation); and
- systemic toxicity.

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 plan to 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 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 both 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' AC5 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.

The AC5 technology has also 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.

The AC5 technology 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.

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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/or 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 other collaborators.

In order to enroll patients in a clinical trial, we are required to obtain each patient's informed consent in a form and substance that complies with the FDA and/or other regulatory authority requirements as well as state and federal privacy and human subject protection regulations.

We have completed two randomized controlled clinical studies to date. The first study, which met its primary and secondary endpoints, assessed the safety and performance of AC5 in 46 patients with bleeding skin wounds, including a group of patients taking anti-platelet medications (i.e., a blood thinner) that resulted from excision of skin lesions and followed for 30 days. The second study assessed AC5 on skin, determining that it was neither an irritant nor a sensitizer, and no immunogenic response or other adverse events attributable to this product were reported in any of the approximately 50 enrolled volunteers. The AC5 product candidate in these studies subsequently received marketing authorization and is presently known as AC5 Advanced Wound System in the US and AC5 Topical Hemostat in the EU.

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

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 US.

Commercialization

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.

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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.

For at least the near term future, in order to maximize operational efficiencies and to account for changing landscapes since the COVID-19 pandemic during which both marketing authorizations were received, 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.

We expect the commercialization ramp to be gradual through 2024 and into 2025, while we encourage product use among key opinion leaders and early adopters in developing market channels, and then moderately accelerate.

We recently started to commercialize AC5 Advanced Wound System. We rely on both an internal commercial team and independent sales distributors to drive 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 (VA) hospitals and military 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.

We anticipate that material growth in the physician office setting will require product reimbursement. To that end, we applied to the Centers for Medicare and Medicaid Services (CMS) for a dedicated Healthcare Common Procedure Coding System (HCPCS) Level II reimbursement code specific to AC5 Advanced Wound System to better enable providers to bill third party payors for AC5 that is used in doctors' offices. The unique HCPCS code, A2020, was granted and made effective on April 1, 2023. A dedicated HCPCS code is an important step toward, although not a guarantee of, coverage and reimbursement, and we intend it to 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.

In support of the government market, we partnered with Lovell Government Services (LGS), a service-disabled veteran-owned small business, to be our government channel distributor. As a direct result of our relationship with LGS, AC5 Advanced Wound System has been added to the four major government contracting vehicles: Federal Supply Schedule (FSS), General Services Administration (GSA) schedule, Defense Logistics Agency's Medical Electronic Catalog Program (ECAT), and Distribution and Pricing Agreement (DAPA). This listing enables purchase by federal government agencies, including the Department of Veterans Affairs (VA), Indian Health Services (IHS), and Department of Defense (DOD) Medical Treatment Facilities, and it allows doctors in government channels to order AC5 Advanced Wound System.

Our internal core team oversees AC5 Advanced Wound System sales, marketing, and inventory distribution from the warehouse to the customer. We envision hiring additional internal sales representatives to support commercialization.

We have partnerships with reputable, value-added independent sales representatives and distributors, and we expect to add more collaborative agreements on a case-by-case basis to expand the overall reach and footprint of the sales organization. Such collaborations may include strategic partners. We anticipate that we will also 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 both 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.

The COVID-19 Pandemic Impact on Commercialization

The COVID-19 pandemic environment introduced significant challenges related to product launch, marketing and sales. While the overall environment has improved, negative direct and indirect effects may variously wax and wane. Some effects that we periodically observe include curtailed access to non-US surgeons, facilities, and potential strategic partners, as well as to some US medical facilities.

The pandemic brought additional attention to the tendency for interventions for wounds to be too often considered elective procedures instead of essential or emergent, as National Pressure Ulcer Advisory Panel guidelines and others recommend, resulting in a projected increased risk to limb and life. 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.

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We 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 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.

We believe that these challenges may present an opportunity for new technology, such as ours, to address poorly met needs and limited healthcare overall resources.

Manufacturing

We work with contract manufacturing and related organizations, including those operating under cGMP, as is required by applicable regulatory agencies for production of products 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. 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 research, development, and 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 products.

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.

Industry and Competition

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

Common features of our current and planned products, as described herein, are driven by the mechanism of action, which itself is derived from the underlying physicochemical properties of our AC5 self-assembling peptide technology and Arch's 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 many 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 (www.ncbi.nlm.nih.gov/books/NBK442035), 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 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.

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Chronic wounds affect approximately 2% of the United States Population, accounting for an estimated 6-7 million people (https://www.facs.org/media/buthal55/nonhealing_wounds.pdf; www.doi.org/10.1111/wrr.12994; www.doi.org/10.1186/s13643-016-0400-8; www.doi.org/10.19080/ARR.2020.06.555678).

Diabetic foot ulcers develop in approximately 2 million Americans each year, according to The Health Innovation Program, University of Wisconsin (<https://hip.wisc.edu/DiabeticFootUlcers>), while the annual incidence across developed countries is estimated to be 2-4%, according to Woods et al in 2020 (www.doi.org/10.1371/journal.pone.0232395). Pressure ulcers develop in over 2.5 million Americans each year, according to the United States Agency for Healthcare Research & Quality (www.ahrq.gov/topics/pressure-ulcers.html).

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 (www.doi.org/10.3111/13696998.2014.903258), while Qiu et al in 2021 provided an estimated prevalence of 2-4% (www.doi.org/10.3389/fmed.2021.614059). 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 (www.doi.org/10.1186/s13643-016-0400-8). Woods et al in 2020 stated that only 2/3 of diabetic foot ulcers heal within 12 months (www.doi.org/10.1371/journal.pone.0232395). 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 (www.doi.org/10.1186/s13643-016-0400-8).

The Health Innovation Program, University of Washington, cited that of patients with diabetic foot ulcers in the United States, more than 50% will die within five years and 5% will have an amputation (<https://hip.wisc.edu/DiabeticFootUlcers>). A common phrase in medicine, which we often cite, is, "Save a limb, save a life." Even the amputations that are required to save a patient from a non-healing, progressing chronic wound are associated with additional significant morbidity and mortality. In an examination of mortality rates after amputations from a chronic wound, Meshkin et al performed a systematic literature review and found that of the sixty-one studies yielding approximately 36,000 patients who previously received a nontraumatic major lower extremity amputation, approximately 34% died by year one, 55% died by year two, and 64% died by year five (<http://www.doi.org/10.1053/j.jfas.2020.06.027>). Stern et al in 2017 reported an even higher mortality rate one year after amputation of approximately 48% (www.doi.org/10.1016/j.avsg.2016.12.015).

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 billion) of Medicare beneficiaries were diagnosed with at least one type of wound or wound-related infection (<https://www.doi.org/10.1016/j.jval.2017.07.007>). 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 (<https://www.doi.org/10.12968/jowc.2017.26.sup4.s4>). 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 (www.doi.org/10.1371/journal.pone.0232395). 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 (<https://www.doi.org/10.1007/s12325-017-0478-y>).

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 (<https://www.researchgate.net/publication/340950761>). 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.

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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, will complement other products and procedures by potentially enabling the wound bed to be ready sooner, and will 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 wounds;
- conforms to irregularly shaped wound geometry;
- may be used in either lower acuity (e.g., doctor’s offices) 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 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 (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.

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

- a persistent drive to migrate the site of surgical care from inpatient hospital operating room to progressively lower acuity same-day ambulatory settings due to cost and other potential negative impacts of unnecessary hospitalizations, such as infection risk or occupying scarce resources that may be more usefully deployed elsewhere;
- increased use of anticoagulants and other anti-thrombotic agents (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 in performing more types of procedures in less expensive outpatient settings.

Since the early days of modern MIS in the 1990s, the percent of minimally invasive surgeries 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.

In a trend to make traditional minimally invasive surgery even less invasive, known as NOTES, a procedure is performed through an endoscope that 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 have 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 and 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.

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.
- Reimbursement for some competing products and product categories may be more established, and reimbursement for advanced wound care products, in general, is being re-evaluated by payers, raising potential barriers to use.

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 US and foreign government agencies have broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on our business. Additionally, if we are able to successfully obtain approvals for, and commercialize our product candidates, then the Company and our products may become subject to various federal, state and local laws targeting fraud, abuse, privacy and security in the healthcare industry.

Intellectual Property

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

As of March 31, 2024, we either own or license from others a number of US patents, US patent applications, foreign patents and foreign patent applications.

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

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

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

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

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

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

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Employees

We presently have eight full-time employees, and we 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.

On December 5, 2023, Daniel Yrigoyen resigned, effective as of such date, from his position as an executive officer and as Vice President of Sales of the Company. Effective December 5, 2023 Shawn Carlson was appointed to serve as the Company's Vice President of Sales.

Recent Events

Charter Amendments

On July 18, 2023, the board of directors of the Company (the "**Board**") adopted resolutions by unanimous written consent, pursuant to which the Board determined that it is advisable and in the best interests of the Company to amend the Articles of Incorporation of the Company (the "**Amendment**") to (i) increase the total number of authorized shares of Common Stock from 12,000,000 to 350,000,000 (the "**Authorized Share Increase**"), (ii) authorize 5,000,000 shares of "blank check" preferred stock of the Company, thereby giving the Board the authority to designate from time to time one or more series of preferred stock (the "**Blank Check Preferred**"), and (iii) provide for a reverse stock split of the outstanding Common Stock, at a ratio within a range of 1-for-1.5 to 1-for-20, with the exact ratio to be determined by the Board subsequent to the applicable approval by the Company's stockholders, within 1 year following the date of such approval, and without correspondingly decreasing the number of authorized shares of Common Stock (the "**Reverse Split**") and, together with the Authorized Share Increase and the Blank Check Preferred, the "**Charter Amendments**"). On August 22, 2023, stockholders representing a majority of the voting power of the then outstanding shares of voting stock of the Company (the "**Majority Stockholders**") executed a written consent approving the Charter Amendments and the Company filed a preliminary Information Statement with the SEC with respect to the transactions contemplated hereby. The Company filed a definitive Information Statement with the SEC and mailed the definitive Information Statement to the Company's stockholders notifying them of the action taken by written consent on September 1, 2023. Accordingly, the Company filed the Amendment with respect to the Authorized Share Increase and the Blank Check Preferred with the Secretary of State of Nevada on September 21, 2023. The Company intends to effect the Reverse Split at a ratio of 1-for-8 prior to the pricing of this offering. All share and per share information in this prospectus, other than the historical financial statements included herein, has been adjusted to give effect to the Reverse Split.

Reverse Stock Split

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

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

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PIPE, Bridge and Note Financings

Uplist PIPE

On November 8, 2023, the Company and certain institutional and accredited individual investors (collectively, the **"PIPE Investors"**) entered into a Securities Purchase Agreement, as subsequently amended on June 19, 2024 (as amended, the **"PIPE SPA"**), pursuant to which the Company has agreed to issue and sell to the PIPE Investors, and the PIPE Investors have agreed to purchase from the Company, an aggregate of (i) warrants (the **"PIPE Pre-Funded Warrants"**) to purchase an aggregate of 1,430,650 shares of Common Stock (the **"PIPE Pre-Funded Warrant Shares"**) and (ii) warrants (the **"PIPE Investor Warrants"**) and together with the PIPE Pre-Funded Warrants, the **"PIPE Warrants"**) to purchase an aggregate 1,430,650 shares of Common Stock (the **"PIPE Investor Warrant Shares"**) and together with the PIPE Pre-Funded Warrant Share, the **"PIPE Warrant Shares"**), at a purchase price of \$4.124 per PIPE Pre-Funded Warrant to purchase one share of Common Stock and accompanying PIPE Investor Warrant to purchase one share of Common Stock, for aggregate gross proceeds of \$5.9 million, before deducting the placement agent's fees and estimated offering expenses, and expected net proceeds of \$5.4 million after deducting the placement agent's fees and estimated offering expenses payable by the Company. The PIPE Pre-Funded Warrants and PIPE Investor Warrants will be issued as part of a private placement offering authorized by the Company's board of directors (the **"Uplist PIPE"**). The Company currently intends to use the net proceeds it receives from the Uplist PIPE for product marketing and for general working capital purposes. The purpose of the Uplist PIPE is mainly to assist the Company in meeting the initial listing requirements of Cboe, including for purposes of the minimum stockholders' equity requirement and the requirement of the Company to achieve its listing in connection with a firm commitment underwritten public offering.

Between December 13, 2023 and March 28, 2024, certain of the PIPE Investors advanced the Company an aggregate of \$1.25 million as partial prepayment of their respective purchase price under the PIPE SPA, which funds were advanced outside of the escrow provided for in the PIPE SPA, and which funds have been available to the Company in support of its operations (the **"PIPE Advances"**). On May 15, 2024, the 2024 Notes Investors (as defined below) purchased an aggregate of \$2,220,000 in principal amount of 2024 Notes (as defined below) for an aggregate purchase price of \$1,850,000, which amount was paid through the surrender and cancellation of the PIPE Advances by the 2024 Notes Investors and an incremental amount of \$600,000 in cash. Under the PIPE SPA, a PIPE Investor's obligation to purchase PIPE Pre-Funded Warrants and PIPE Investor Warrants is reduced by the purchase price paid by such PIPE Investor for 2024 Notes under the 2024 Notes SPA (as defined below). Accordingly, it is currently anticipated that PIPE Pre-Funded Warrants to purchase an aggregate of 982,056 shares of Common Stock and PIPE Investor Warrants to purchase an aggregate of 982,056 shares of Common Stock will be issued in the Uplist PIPE, for gross proceeds of \$4,050,000, and expected net proceeds of \$3,528,000, while the \$2,220,000 in principal amount of 2024 Notes will automatically convert at the closing of this offering into (i) 2024 Note Conversion Pre-Funded Warrants to purchase an aggregate of 538,182 shares of Common Stock and (ii) 2024 Note Uplist Conversion Warrants to purchase an aggregate of 538,182 shares of Common Stock, reflecting a net addition for the benefit of the PIPE Investors that are 2024 Notes Investors of an aggregate of 89,700 shares underlying the 2024 Note Conversion Pre-Funded Warrants and 2024 Note Uplist Conversion Warrants, respectively, that is the result of the premium of the principal amount of \$2,220,000 of the 2024 Notes over their purchase price of \$1,850,000 (which purchase price, as stated above, has reduced the aggregate purchase price of the securities sold in the PIPE SPA).

The closing of the Uplist PIPE is contingent upon, among other conditions, the registration statement of which this prospectus forms a part being declared effective by the SEC and the approval of the listing of the Common Stock on any securities exchange registered with the SEC as a "national securities exchange" under Section 6 of the Exchange Act (a **"National Exchange"**), and the closing is expected to occur immediately prior to the pricing of this offering.

The Company retained Dawson James Securities, Inc. (**"DJ"**), pursuant to a placement agency agreement, dated November 8, 2023, as placement agent in connection with the Uplist PIPE. The Company will pay DJ a cash fee equal to 8.0% of the aggregate gross proceeds of the Uplist PIPE (expected to be \$472,000), will reimburse DJ for legal and other expenses of up to \$150,000 and will issue to DJ, or its designees, warrants (the **"PIPE Placement Agent Warrants"**) to purchase an aggregate of 71,533 shares of Common Stock. The PIPE Placement Agent Warrants will be exercisable at any time and from time to time, in whole or in part, during the five-year period commencing upon issuance, at a price per share equal to \$5.15625 (which is 125% of the price per Unit sold in this offering).

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PIPE Pre-Funded Warrants

The PIPE Pre-Funded Warrants (i) will have a nominal exercise price of \$0.001 per share; (ii) will be exercisable immediately upon issuance; (iii) will be exercisable until all of the PIPE Pre-Funded Warrants are exercised in full; and (iv) will have a provision preventing the exercisability of such PIPE Pre-Funded Warrants if, as a result of the exercise of the PIPE Pre-Funded Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder's, would be deemed to beneficially own more than either 4.99% or 9.99% of the Common Stock (the **"Ownership Limitation"**) immediately after giving effect to the exercise of the PIPE Pre-Funded Warrants.

PIPE Investor Warrants

The PIPE Investor Warrants (i) will have an exercise price of \$4.00 per share; (ii) will have a term of exercise equal to 5 years after their issuance date; (iii) will be exercisable immediately upon issuance; and (iv) will have a provision preventing the exercisability of such PIPE Investor Warrants if, as a result of the exercise of the PIPE Investor Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder's, would be deemed to beneficially own more than the Ownership Limitation immediately after giving effect to the exercise of the PIPE Investor Warrants.

Pursuant to the PIPE SPA, the Company has agreed to file no later than sixty (60) days after the closing date of an offering conducted in conjunction with an uplist of the Common Stock to, and in compliance with the rules of, any National Exchange (the **"Uplist Transaction"**), which this offering is intended to be, a registration statement on Form S-4, or other appropriate form, registering the offer by the Company to exchange, on a one-for-one basis, all outstanding PIPE Investor Warrants, 2022 Warrants (as defined below), Uplist Conversion Warrants (as defined below) and Exchange Investor Warrants (as defined below) for newly issued warrants identical to the Investor Warrants being sold in this offering, which warrants are expected to be listed on Cboe under the symbol "ARTHW."

Registration Rights Agreement

The Company also entered into a registration rights agreement with the PIPE Investors dated November 8, 2023 (the **"PIPE Registration Rights Agreement"**), pursuant to which the Company is obligated, subject to certain conditions, to file with the SEC within the earlier of (i) the closing date of the Uplist Transaction and (ii) the 60th calendar day following the date of the PIPE Registration Rights Agreement one or more registration statements to register the PIPE Warrant Shares, the Uplist Conversion Warrant Shares (as defined below) and the 2022 Note Conversion Pre-Funded Warrant Shares (as defined below) for resale under the Securities Act of 1933, as amended (the "Securities Act"). The Company's failure to satisfy certain filing and effectiveness deadlines and certain other requirements set forth in the PIPE Registration Rights Agreement may subject the Company to payment of monetary penalties. The Resale Prospectus currently covers the resale of the PIPE Warrant Shares, the Uplist Conversion Warrant Shares and the 2022 Note Conversion Pre-Funded Warrant Shares.

PIPE Advances

Under the terms of the PIPE Advances, since the Common Stock has not been approved for listing on the Nasdaq Capital Market by March 31, 2024, with respect to a portion of the PIPE Advances, or April 30, 2024, with respect to the remainder of the PIPE Advances, the Company has issued to the advancing parties (A) additional pre-funded warrants (the **"PIPE Advance Penalty Pre-Funded Warrants"**) to purchase up to an aggregate of 75,776 shares of Common Stock (which represents a 25% addition) and (B) additional investor warrants (the **"PIPE Advance Penalty Common Warrants"**) to purchase up to an aggregate of 75,776 shares of Common Stock. The Resale Prospectus currently covers the resale of the shares of Common Stock underlying the PIPE Advance Penalty Pre-Funded Warrants (the **"PIPE Advance Penalty Pre-Funded Warrant Shares"**) and the PIPE Advance Penalty Common Warrants (the **"PIPE Advance Penalty Common Warrant Shares"**).

On June 19, 2024, certain of the PIPE Investors (the “**Backstop Buyers**”) agreed that in the event that as of the close of business on the date that is 10 calendar days prior to the date that the Company reasonably expects the closing of the Uplist PIPE to occur (the “**Escrow Date**”) there is not an amount of funds in escrow for the PIPE equal to \$5,900,000 less the aggregate purchase price paid for the 2024 Notes (the “**Escrow Minimum Amount**”) (such circumstance, an “**Escrow Deficiency**”), then each of the Backstop Buyers will deposit in escrow the purchase price for a pro rata share of an amount, no greater than \$1,500,000, equal to (A) \$320,000 plus (B) (i) \$5,900,000, minus (ii) the amount of funds in escrow on the Escrow Date, minus (iii) the aggregate purchase price paid by PIPE Investors for the 2024 Notes (the “**Backstop Amount**”) of additional PIPE Pre-Funded Warrants and PIPE Investor Warrants under the PIPE SPA (such agreement, the “**Backstop Agreement**”), and shall purchase such additional PIPE Pre-Funded Warrants and PIPE Investor Warrants at the Uplist PIPE closing. In consideration for the execution by the Backstop Buyers of the Backstop Agreement, the Company agreed to issue to the Backstop Buyers, as soon as practicable, pre-funded warrants (the “**Execution Backstop Pre-Funded Warrants**”), in form and substance substantially similar to the PIPE Pre-Funded Warrants, to purchase an aggregate of 225,000 shares of Common Stock. The Company also agreed to issue to the Backstop Buyers (i) additional pre-funded warrants (the “**Funding Backstop Pre-Funded Warrants**” and, together with the Execution Backstop Pre-Funded Warrants, the “**Backstop Pre-Funded Warrants**”) to purchase an amount of shares of Common Stock equal to 0.5 shares per dollar of funding deposited under the Backstop Agreement, or up to an aggregate of 750,000 shares, and (ii) investor warrants (the “**Backstop Common Warrants**”), in form and substance substantially similar to the PIPE Investor Warrants, to purchase an amount of shares of Common Stock equal to 0.65 shares per dollar of funding deposited under the Backstop Agreement, or up to an aggregate of 975,000 shares. The Resale Prospectus currently covers the resale of the shares of Common Stock underlying the Backstop Pre-Funded Warrants (the “**Backstop Pre-Funded Warrant Shares**”) and the Backstop Common Warrants (the “**Backstop Common Warrant Shares**”).

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2024 Notes

On May 15, 2024, the Company entered into a Securities Purchase Agreement (the “**2024 Notes SPA**”) with certain institutional and accredited individual investors who are also PIPE Investors (collectively, the “**2024 Notes Investors**”) providing for the issuance and sale by the Company to the 2024 Notes Investors certain Secured Promissory Notes (each a “**2024 Note**” and collectively, the “**2024 Notes**”) convertible into shares of Common Stock. On June 12, 2024, an additional investor, which is not a PIPE Investor (the “**Additional 2024 Notes Investor**”) purchased 2024 Notes in the principal amount of \$180,000, including an original issue discount of \$30,000. The 2024 Notes were issued as part of a convertible notes offering authorized by the Company’s board of directors (the “**2024 Notes Financing**”).

In connection with the 2024 Notes Financing, the Company issued and sold to the 2024 Notes Investors and Additional 2024 Notes Investor the 2024 Notes in the aggregate principal amount of \$2,400,000, which includes an aggregate \$370,000 original issue discount in respect of the 2024 Notes. The aggregate net proceeds for the sale of the 2024 Notes was approximately \$2,000,000, after deducting issuance discounts. The closing of the sales of the 2024 Notes to the 2024 Notes Investors under the 2024 Notes SPA occurred on May 15, 2024 (the “**2024 Notes Closing Date**”). The Company is using the net proceeds from the 2024 Notes Financing primarily for working capital and general corporate purposes, and has not allocated specific amounts for any specific purposes.

The 2024 Notes become due and payable on June 30, 2024 (the “**2024 Notes Maturity Date**”) and may be prepaid provided that an Event of Default (as defined therein) has not occurred. The 2024 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 their issuance date until the 2024 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 2024 Notes. Any amount of principal or interest on the 2024 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 “**Default Interest**”).

The 2024 Notes are convertible into an aggregate of 600,000 shares of Common Stock (such shares of Common Stock, the “**2024 Conversion Shares**”) at the option of each holder of the 2024 Notes from their issuance date at the 2024 Conversion Price (as defined below) through the later of (i) the 2024 Notes Maturity Date and (ii) the date of payment of the Default Amount (as defined in the 2024 Note); *provided, however*, the 2024 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 (the “**2024 Notes Ownership Limitation**”) immediately after giving effect to the conversion; and *provided further*, the holder, upon notice to the Company, may increase or decrease the 2024 Notes Ownership Limitation; *provided that* (i) the 2024 Notes 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 2024 Notes Ownership Limitation will not become effective until the 61st day after delivery of such waiver notice.

The initial conversion price of the 2024 Notes (the “**2024 Conversion Price**”) shall be equal to \$4.00 per share and may be reduced or increased proportionately as a result of any stock dividends, recapitalizations, reorganizations, and similar transactions. If the Company fails to deliver the shares of Common Stock issuable upon a conversion by the Deadline (as defined in the 2024 Notes), then the Company is obligated to pay such 2024 Note holder \$5,000 per day in cash for each day beyond the Deadline.

The 2024 Notes contain customary events of default, which include, among other things, (i) the Company’s failure to pay when due any principal or interest payment under the 2024 Notes; (ii) the insolvency of the Company; (iii) delisting of the Common Stock; (iv) the Company’s breach of any material covenant or other material term or condition under the 2024 Notes; and (v) the Company’s breach of any representations or warranties under the 2024 Notes which cannot be cured within five days. Further, Events of Default under the 2024 Notes also include (i) the unavailability of Rule 144 on or after six months from the Issue Date (as defined therein); (ii) the Company’s failure to deliver the shares of Common Stock to the 2024 Note holder upon exercise by such holder of its conversion rights under the 2024 Note; (iii) the Company’s 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) the Company’s failure to complete an uplist to a National Exchange by June 30, 2024.

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Upon an Event of Default, the 2024 Notes shall become immediately due and payable and the Company shall pay to each 2024 Note holder an amount equal to 125% (the “**Default Premium**”) multiplied by the sum of the outstanding principal amount of the 2024 Notes plus any accrued and unpaid interest on the unpaid principal amount of the 2024 Notes to the date of payment, plus any Default Interest and any other amounts owed to the holder under the 2024 Notes 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 five percent (5%) to the Default Premium for each subsequent Event of Default. At the election of each 2024 Note holder, the Default Amount may be paid in cash or shares of Common Stock equal to the Default Amount divided by the 2024 Conversion Price at the time of payment.

Upon the closing of this offering, 100% of the then outstanding principal amount of the 2024 Notes shall automatically convert (the “**2024 Notes Automatic Conversion**”) into shares of Common Stock (the “**2024 Notes Automatic Conversion Shares**”), with the conversion price for purposes of such 2024 Notes Automatic Conversion being \$4.125. Upon the 2024 Notes Automatic Conversion and to the extent that the beneficial ownership of a holder of 2024 Notes (a “**2024 Notes Holder**” and, all holders of 2024 Notes together, the “**2024 Notes Holders**”) would increase over the applicable 2024 Notes Ownership Limitation, the 2024 Notes Holder will receive pre-funded warrants (the “**2024 Note Conversion Pre-Funded Warrants**”), and the shares issuable upon exercise thereof, the “**2024 Note Conversion Pre-Funded Warrant Shares**”) in lieu of shares of Common Stock otherwise issuable to the 2024 Notes Holder in connection with the 2024 Notes Automatic Conversion, which 2024 Note Conversion Pre-Funded Warrants shall have an exercise price of \$0.001 per share, may be exercised on a cashless basis, shall be exercisable immediately upon issuance and shall contain a customary beneficial ownership limitation provision.

In addition, upon the 2024 Notes Automatic Conversion, the 2024 Notes Holder shall receive a warrant (the “**2024 Notes Uplist Conversion Warrant**”, and the shares issuable upon exercise thereof, the “**2024 Notes Uplist Conversion Warrant Shares**”) to purchase a number of shares of Common Stock equal to the number of shares of Common

Stock (or shares of Common Stock underlying 2024 Note Conversion Pre-Funded Warrants, if any) issued upon the 2024 Notes Automatic Conversion. The 2024 Notes Uplist Conversion Warrant shall have an exercise price per share of \$4.00 and shall otherwise be identical to the PIPE Investor Warrants. The Company also agreed in the 2024 Notes to file no later than sixty (60) days after the closing of this offering a registration statement on Form S-4, or other appropriate form, registering the offer by the Company to exchange, on a one-for-one basis, all outstanding PIPE Investor Warrants, 2024 Notes Uplist Conversion Warrants and Exchange Investor Warrants for newly issued warrants identical to the Investor Warrants being sold in this offering, which warrants are expected to be listed on Cboe under the symbol “ARTHW.”

Registration Rights Agreement

On the 2024 Notes Closing Date, the Company entered into a Registration Rights Agreement with the 2024 Notes Investors (the “**2024 Notes Registration Rights Agreement**”), pursuant to which the Company is obligated, subject to certain conditions, to file with the Securities and Exchange Commission within 60 days after the 2024 Notes Closing Date one or more registration statements (any such registration statement, a “**2024 Notes Resale Registration Statement**”) to register the 2024 Conversion Shares for resale under the Securities Act. The Company’s failure to satisfy certain filing and effectiveness deadlines with respect to a 2024 Notes Resale Registration Statement and certain other requirements set forth in the 2024 Notes Registration Rights Agreement may subject the Company to payment of monetary penalties.

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Security Agreement

In connection with the issuance of the 2024 Notes, the Company entered into a Security Agreement with the Collateral Agent (as defined therein) on behalf of the 2024 Notes Investors on the 2024 Notes Closing Date (the “**2024 Notes Security Agreement**”), pursuant to which the Company and each of its subsidiaries (together with any persons who execute a joinder to the 2024 Notes Security Agreement, the “**2024 Notes Debtors**”) provided as collateral to the 2024 Notes holders a security interest in, and a lien on, substantially all of the 2024 Notes Debtors. Upon an Event of Default under the 2024 Notes, each 2024 Notes holder may exercise its rights to the collateral pursuant to the terms of the 2024 Notes Security Agreement.

Accordingly, it is currently anticipated that at the closing of this offering: (i) (A) 2024 Note Conversion Pre-Funded Warrants with an exercise price of \$0.001 to purchase an aggregate of 538,182 shares of Common Stock and (B) 43,637 2024 Notes Automatic Conversion Shares will be issued upon the 2024 Note Automatic Conversion of the \$2,400,000 of principal amount outstanding under the 2024 Notes; and (ii) the 2024 Note Holders will be issued 2024 Note Uplist Conversion Warrants to purchase an aggregate of 581,819 shares of Common Stock. The expected allocation between shares of Common Stock and 2024 Note Conversion Pre-Funded Warrants in the previous sentence is only an initial estimate based on indications of interest and is subject to change based on the ultimate ownership of the 2024 Note Holders after the Uplist PIPE and this offering. The maximum number of shares of Common Stock and 2024 Note Conversion Pre-Funded Warrants that may be issued, individually and in the aggregate is 581,819.

Bridge Offering

Between July 7, 2023 and September 11, 2023, pursuant to a Securities Purchase Agreement dated July 7, 2023, as subsequently amended (the “**Bridge SPA**”), among the Company and certain institutional and accredited individual investors (collectively, the “**Bridge Investors**”) the Company issued and sold to the Bridge Investors an aggregate of (i) 418,051 shares (the “**Bridge Shares**”) of Common Stock; (ii) warrants (the “**Bridge Pre-Funded Warrants**”) to purchase an aggregate of 756,871 shares of Common Stock (the “**Bridge Pre-Funded Warrant Shares**”); and (iii) warrants (the “**Common Warrants**” and together with the Bridge Pre-Funded Warrants, the “**Bridge Warrants**”) to purchase an aggregate 2,349,826 shares of Common Stock (the “**Common Warrant Shares**” and together with the Bridge Pre-Funded Warrant Share, the “**Bridge Warrant Shares**”), at a purchase price of \$2.20 per Bridge Share and accompanying Common Warrant to purchase two shares of Common Stock, and \$2.192 per Bridge Pre-Funded Warrant to purchase one share of Common Stock and accompanying Common Warrant to purchase two shares of Common Stock. The Bridge Shares, Bridge Pre-Funded Warrants, and Common Warrants were issued as part of a private placement offering authorized by the Company’s board of directors (the “**Bridge Offering**”).

Pursuant to the Bridge SPA, the Bridge Investors agreed not to sell or otherwise transfer any of the Bridge Shares or Bridge Warrant Shares prior to the one-year anniversary of the Bridge Closing Date. In the event that a Bridge Investor purchases securities in connection with an Uplist Transaction, which this offering is intended to be, and/or in the Uplist PIPE, with an aggregate purchase price equal to at least 4.3 multiplied by the aggregate purchase price paid by the Bridge Investor for the Bridge Shares and Bridge Warrants under the Bridge SPA, the one-year lock-up period will no longer apply to the Bridge Shares and Bridge Warrants. The aggregate gross proceeds for the sale of the Bridge Shares, Bridge Pre-Funded Warrants, and Common Warrants was approximately \$2.6 million, before deducting the placement agent’s fees and other estimated fees and offering expenses payable by the Company. The first closing of the sales of these securities under the Bridge SPA occurred on July 7, 2023 (the “**Bridge Closing Date**”).

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Under the Bridge SPA, the Company also agreed that upon the closing of the next underwritten public offering of Common Stock (a “**Qualifying Offering**”), which the Company agreed is this offering, if the effective offering price to the public per share of Common Stock (the “**Qualifying Offering Price**”) is lower than \$32.00 per share, then the Company shall issue additional Bridge Pre-Funded Warrants (the “**True-Up Pre-Funded Warrants**”, and the shares issuable upon exercise thereof, the “**True-Up Pre-Funded Warrant Shares**”), or shares of Common Stock (the “**True-Up Shares**”) in lieu thereof to the extent necessary to cause the Company to meet the listing requirements of the Company’s proposed trading market in the Uplist Transaction, in an amount reflecting a reduction in the purchase price paid for the Bridge Shares and Bridge Pre-Funded Warrants that equals the proportion by which the Qualifying Offering Price is less than \$32.00. The Company also agreed that the Qualifying Offering Price as a result of this offering is \$4.00. **Accordingly, at the closing of this offering, based on the sale of the Units and Pre-Funded Units at an assumed public offering price of \$4.125 per Unit and \$4.124 per Pre-Funded Unit, which represents the minimum bid price of \$4.00 per share under the initial listing requirements of Cboe in Cboe Listing Rule 14.9(b) plus a value of \$0.125 attributed to the accompanying Investor Warrant, the Company expects to issue (i) True-Up Pre-Funded Warrants with an exercise price of \$0.001 to purchase an aggregate of 6,330,422 shares of Common Stock and (ii) an aggregate of 1,893,919 True-Up Shares to the Bridge Investors.** The expected allocation between True-Up Shares and True-Up Pre-Funded Warrants in the previous sentence is only an initial estimate based on indications of interest and is subject to change based on the ultimate ownership of the Bridge Investors after the Uplist PIPE and this offering. The maximum amount of True-Up Pre-Funded Warrants and True-Up Shares that may be issued, individually and in the aggregate is 8,224,341. The Resale Prospectus currently covers the resale of the True-Up Pre-Funded Warrant Shares and True-Up Shares.

The Company retained DJ as placement agent in connection with the Bridge Offering. The Company paid DJ a cash fee equal to 8.0% of the aggregate gross proceeds of the Bridge Offering and reimbursement of expenses of \$50,000. Additionally, on September 7, 2023 the Company issued to DJ, or its designees, warrants, as subsequently amended (the “**Placement Agent Warrants**”) to purchase an aggregate of 55,242 shares of Common Stock. The Placement Agent Warrants are exercisable at any time and from time to time, in whole or in part, until September 7, 2028, at a price per share equal to \$2.20 (which will increase to \$5.15625 at the closing of the Uplist Transaction, representing 125% of the assumed price per share of Common Stock in the Uplist Transaction, as required by FINRA).

Bridge Pre-Funded Warrants

The Bridge Pre-Funded Warrants (i) have a nominal exercise price of \$0.008 per share; (ii) are exercisable after the earlier of (A) the six-month anniversary after the date of issuance, (B) 120 days after the closing date of an Uplist Transaction, and (C) the date that a registration statement registering the Bridge Pre-Funded Warrant Shares is declared effective; (iii) are exercisable until all of the Bridge Pre-Funded Warrants are exercised in full; and (iv) have a provision preventing the exercisability of such Bridge Pre-Funded Warrants if, as a result of the exercise of the Bridge Pre-Funded Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than the Ownership Limitation immediately after giving effect to the exercise of the Bridge Pre-Funded Warrants.

The Common Warrants (i) have an exercise price of \$8.00 per share; (ii) have a term of exercise equal to 5 years after their issuance date; (iii) are exercisable after the earlier of (A) the six-month anniversary after the date of issuance and (B) the date that a registration statement registering the Common Warrant Shares is declared effective; (iv) have a provision permitting voluntary adjustments to the exercise price by the Company, subject to the prior written consent of the Common Warrant holder; (v) are automatically exchanged upon the closing of an Uplist Transaction for a new warrant that is identical to the warrants (other than any pre-funded warrants), if any, being issued to investors in such Uplist Transaction, with the number of shares underlying such new warrant being equal to the number of Common Warrant Shares then underlying the Common Warrant multiplied by three and (vi) have a provision preventing the exercisability of such Common Warrants if, as a result of the exercise of the Common Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Company Common Stock would be aggregated with the holder's, would be deemed to beneficially own more than the Ownership Limitation immediately after giving effect to the exercise of the Common Warrants. **Accordingly, at the closing of this offering, the Common Warrants will be cancelled and exchanged for newly issued warrants identical to the Investor Warrants to purchase an aggregate of 7,049,478 shares of Common Stock at an exercise price per share equal to the exercise price per share of the Investor Warrants (the "Exchange Investor Warrants").**

In addition, as noted above, pursuant to the PIPE SPA, the Company has agreed to file no later than sixty (60) days after the closing date of the Uplist Transaction, a registration statement on Form S-4, or other appropriate form, registering the offer by the Company to exchange, on a one-for-one basis, all outstanding Exchange Investor Warrants for newly issued warrants identical to the Investor Warrants being sold in this offering, which warrants are expected to be listed on Cboe under the symbol "ARTHW."

Registration Rights Agreement

The Company also entered into a registration rights agreement with the Bridge Investors dated July 7, 2023, as subsequently amended (the "Registration Rights Agreement"), pursuant to which the Company is obligated, subject to certain conditions, to file with the SEC within the earlier of (i) 30 days following the closing date of the Uplist Transaction and (ii) January 31, 2024 one or more registration statements (any such registration statement, a "Resale Registration Statement") to register the Bridge Shares, the Bridge Warrant Shares and the shares of Common Stock issuable upon exercise in full of the Exchange Investor Warrants (the "Exchange Investor Warrant Shares") for resale under the Securities Act of 1933, as amended (the "Securities Act"). The Company's failure to satisfy certain filing and effectiveness deadlines with respect to a Resale Registration Statement and certain other requirements set forth in the Registration Rights Agreement may subject the Company to payment of monetary penalties. The Resale Prospectus currently covers the resale of the Bridge Shares and the Bridge Warrant Shares.

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Note Modification Agreements

On April 30, 2024, the Company entered into an amendment ("Amendment No. 16 to the First Notes") with the holders of the Company's outstanding Senior Secured Convertible Promissory Notes, as separately amended on February 14, 2023, March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023, September 30, 2023, November 8, 2023, November 15, 2023, January 5, 2024 and March 15, 2024 (as amended, the "First Notes"), issued in connection with a private placement financing the Company completed on July 6, 2022 (the "First Closing"). On April 30, 2024, the Company also entered into an amendment ("Amendment No. 16 to the Second Notes") with the holders of the Company's outstanding Unsecured Convertible Promissory Notes, as separately amended on February 14, 2023, March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023, September 30, 2023, November 8, 2023, November 15, 2023, January 5, 2024 and March 15, 2024 (as amended, the "Second Notes"), issued in connection with a private placement financing the Company completed on January 18, 2023 (the "Second Closing"). On April 30, 2024, the Company also entered into an amendment ("Amendment No. 11 to the Third Notes") with the holders of the Company's outstanding Unsecured Convertible Promissory Notes, as separately amended on June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023, September 30, 2023, November 8, 2023, November 15, 2023, January 5, 2024 and March 15, 2024 (as amended, the "Third Notes"), issued in connection with a private placement financing the Company completed on May 15, 2023 (the "Third Closing"). On April 30, 2024, the Company also entered into an amendment ("Amendment No. 2 to the Fourth Notes" and, together with Amendment No. 16 to the First Notes, Amendment No. 16 to the Second Notes and Amendment No. 11 to the Third Notes, the "Amendments to the 2022 Notes") with the holders of the Company's outstanding Unsecured Convertible Promissory Notes, as separately amended on March 15, 2024 (the "Fourth Notes" and, together with the First Notes, the Second Notes and the Third Notes, the "2022 Notes"), issued in connection with a private placement financing the Company completed on March 12, 2024 (the "Fourth Closing").

Under the Amendments to the 2022 Notes, the following amendments to the 2022 Notes will be simultaneously effective upon the closing of the Uplist Transaction. 95% of the then outstanding principal amount of the 2022 Notes shall automatically convert (the "Automatic Conversion") into shares of Common Stock (the "Automatic Conversion Shares"), with the conversion price for purposes of such Automatic Conversion being \$4.00. Upon the Automatic Conversion and to the extent that the beneficial ownership of a holder of 2022 Notes (a "Holder" and, all holders of 2022 Notes together, the "Holders") would increase over the applicable Ownership Limitation, the Holder will receive pre-funded warrants (the "2022 Note Conversion Pre-Funded Warrants"), and the shares issuable upon exercise thereof, the "2022 Note Conversion Pre-Funded Warrant Shares") in lieu of shares of Common Stock otherwise issuable to the Holder in connection with the Automatic Conversion, which 2022 Note Conversion Pre-Funded Warrants shall have an exercise price of \$0.001 per share, may be exercised on a cashless basis, shall be exercisable immediately upon issuance and shall contain a customary beneficial ownership limitation provision.

In addition, upon the Automatic Conversion, the Holder shall receive a warrant (the "Uplist Conversion Warrant", and the shares issuable upon exercise thereof, the "Uplist Conversion Warrant Shares") to purchase a number of shares of Common Stock equal to 10 times the dollar amount under the 2022 Notes that was converted in the Automatic Conversion. The Uplist Conversion Warrant shall have an exercise price per share of \$4.00 and shall otherwise be identical to the PIPE Investor Warrants. The Company also agreed in the Amendments to the 2022 Notes to file no later than sixty (60) days after the closing of this offering a registration statement on Form S-4, or other appropriate form, registering the offer by the Company to exchange, on a one-for-one basis, all outstanding PIPE Investor Warrants, 2022 Warrants, Uplist Conversion Warrants and Exchange Investor Warrants for newly issued warrants identical to the Investor Warrants being sold in this offering, which warrants are expected to be listed on Cboe under the symbol "ARTHW" (the "Uplist Conversion Warrants Exchange Offer Obligation").

The Amendments to the 2022 Notes also prohibit the Company from engaging in any capital raising transactions, subject to certain exceptions, until the earlier of (A) July 7, 2027, and (B) the first date on which all Holders hold less than 20% of the original amount of the Uplist Conversion Warrants received by each Holder, respectively, in connection with the Automatic Conversion.

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Accordingly, it is currently anticipated that at the closing of this offering: (i) an aggregate of (A) 1,454,034 shares of Common Stock and (B) 2022 Note Conversion Pre-Funded Warrants with an exercise price of \$0.001 to purchase an aggregate of 184,296 shares of Common Stock will be issued upon the Automatic Conversion of an aggregate of \$6,553,310 of principal amount under the 2022 Notes, representing 95% of the \$6,898,221 in principal amount currently outstanding under the 2022 Notes, based on the assumed exercise price of the Investor Warrants being offered as part of the Units and Pre-Funded Units in this offering of \$4.00 per share; and (ii) the Holders will be issued Uplist Conversion Warrants to purchase an aggregate of 65,533,100 shares of Common Stock, representing 10 multiplied by the \$6,553,310 of principal amount converted in the Automatic Conversion. The expected allocation between shares of Common Stock and 2022 Note Conversion Pre-Funded Warrants in the previous sentence is only an initial estimate based on indications of interest and is subject to change based on the ultimate ownership of the Holders after the Uplist PIPE and this offering. The maximum number of shares of Common Stock and 2022 Note Conversion Pre-Funded Warrants that may be issued, individually and in the aggregate is 1,638,330.

Additionally, on July 7, 2023, the Company entered into an amendment (the "Omnibus Amendment to Notes and Warrants") with the Holders of the 2022 Notes, amending the 2022 Notes and related warrants issued at each of the First Closing, Second Closing, and Third Closing (the "First Warrants", "Second Warrants" and "Third

Warrants", respectively, and collectively with the related warrants issued at the Fourth Closing, the **"2022 Warrants"**). Under the Omnibus Amendment to Notes and Warrants, the 2022 Notes and 2022 Warrants were amended to modify the Most Favored Nation provisions therein to exclude the Bridge Offering.

2022 Notes

The 2022 Notes bear interest on the unpaid principal balance at a rate equal to ten percent (10%) (computed on the basis of the actual number of days elapsed in a 360-day year) per annum accruing from the issuance date until the 2022 Notes become due and payable at maturity or upon their conversion, acceleration or by prepayment, and may become due and payable upon the occurrence of an event of default under the 2022 Notes. The 2022 Notes mature June 30, 2024. Any amount of principal or interest on the 2022 Notes which is not paid when due shall bear interest at the rate of the lesser of (i) eighteen percent (18%) per annum or (ii) the maximum amount allowed by law from the due date thereof until payment in full. As of June 19, 2024, the outstanding unpaid principal balance including all accrued interest under the 2022 Notes totaled \$8,015,282.

The 2022 Notes are convertible into shares of Common Stock at the option of each Holder from the date of issuance at \$73.12 (which will automatically change to \$4.00 as of the closing of the Uplist PIPE through the operation of the Most Favored Nation Provision (as defined below)), subject to adjustment, through the later of (i) June 30, 2024 (the **"Maturity Date"**) or (ii) the date of payment of the Default Amount (as defined in the 2022 Notes).

The 2022 Notes contain events of default, which include, among other things, (i) the Company's failure to pay when due any principal or interest payment under the 2022 Notes; (ii) our failure to complete an Uplist Transaction by June 30, 2024 and (iii) our default on the Uplist Conversion Warrant Exchange Offer Obligation.

The 2022 Warrants (i) have an exercise price of \$79.52 (which will automatically change to \$4.00 as of the closing of the Uplist PIPE through the operation of the Most Favored Nation Provision) per share; (ii) have a term of exercise equal to 5 years after their issuance date; (iii) became exercisable immediately after their issuance; and (iv) have a provision preventing the exercisability of such 2022 Warrants if, as a result of the exercise of the 2022 Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of our Common Stock would be aggregated with the holder's, would be deemed to beneficially own more than the Ownership Limitation. Pursuant to the **"Most Favored Nation Provision"** contained in the 2022 Notes and the 2022 Warrants, 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.

As discussed above, it is currently anticipated that 95% of the \$6,898,221 unpaid principal balance currently outstanding under the 2022 Notes will convert into (A) 1,454,034 shares of Common Stock and (B) 2022 Note Conversion Pre-Funded Warrants with an exercise price of \$0.001 to purchase an aggregate of 184,296 shares of Common Stock in connection with the Automatic Conversion, such allocation between shares and 2022 Note Conversion Pre-Funded Warrants being subject to change, as described above.

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Under the Third Amended and Restated Registration Rights Agreement, dated as of March 12, 2024, as amended, the Company is required to file a registration statement registering the securities issued in the Second Closing, Third Closing and Fourth Closing, including the applicable 2022 Notes and 2022 Warrants, no later than 45 days following the closing of the Uplist Transaction. The Resale Prospectus currently covers the resale of the shares of Common Stock issuable upon the Automatic Conversion, the shares of Common Stock issuable upon conversion of the 2022 Notes at their regular conversion price and the shares of Common Stock issuable upon exercise of the 2022 Warrants.

Series 1 and 2 Convertible Notes

On June 4, 2020 and November 6, 2020, the Company issued unsecured 10% Series 1 Convertible Notes (**"Series 1 Notes"**) and Series 2 Convertible Notes, as amended (**"Series 2 Notes"**, and collectively with the Series 1 Notes, the **"Series Convertible Notes"**). The maturity dates of the Series 1 Notes and Series 2 Notes are June 30, 2023 and November 30, 2023, respectively. On July 12, 2023, the Company secured countersigned notices of conversion from all remaining holders of the Series 1 Convertible Notes and provided instructions to its transfer agent to issue a total of 7,489 shares of Common Stock in full satisfaction of all previously outstanding Series 1 Convertible Notes, which had an aggregate of \$718,918 of principal and interest outstanding at the time of conversion.

On November 30, 2023, the Series 2 Notes of \$450,000 principal and outstanding accrued interest of \$137,946 were converted into 6,615 shares of Common Stock.

Insurance Financing

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

Warrant Exchange Agreement

On March 10, 2023, the Company entered into exchange agreements (the **"Exchange Agreements"**) with each holder (the **"Warrantholders"**) of the Company's outstanding Series G Warrants to purchase shares of the Company's Common Stock at an exercise price of \$1,120.00 per share and the Company's outstanding Series H Warrants to purchase shares of Common Stock at an exercise price of \$640.00 per share. Pursuant to the Exchange Agreements, the Warrantholders exchanged 4,252 Series G Warrants for 426 shares of Common Stock and 5,385 Series H Warrants for 1,078 shares of Common Stock.

Reimbursements and Support Program

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

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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.

Six Months Ended March 31, 2024 Compared to Six Months Ended March 31, 2023

	March 31, 2024	March 31, 2023	Increase (Decrease) \$
Revenue	\$ 77,733	\$ 22,914	54,819
Operating expenses:			

Cost of revenues	45,161	36,353	8,808
Selling, general and administrative	1,994,534	2,355,701	(361,167)
Research and development	409,449	332,087	77,362
Loss from operations	<u>(2,371,411)</u>	<u>(2,701,227)</u>	<u>329,816</u>
Other Expense	(1,779,380)	(1,306)	(1,778,074)
Net loss	<u>\$ (4,150,791)</u>	<u>\$ (2,702,533)</u>	<u>(1,448,258)</u>

Revenue

Revenue for the six months ended March 31, 2024 was \$77,733 an increase of \$54,819 compared to revenue of \$22,914 for the six months ended March 31, 2023. Revenue for the six months ended March 31, 2024 was the result of several transactions into a single hospital, transactions into VA Hospitals through LGS, and transactions leveraging the dedicated HCPCS code (A2020) that went effective April 1, 2023 through a growing number of providers and offices working with the Company to submit reimbursement claims with numerous payors.

Cost of Revenues

Cost of revenue during the six months ended March 31, 2024 was \$45,161, an increase of \$8,808, compared to cost of revenue of \$36,353 for the six months ended March 31, 2023. The increase in cost of revenues corresponds to the increase in revenues. Cost of revenue includes product costs, third party warehousing, overhead allocation, royalty and shipping costs. An increase in revenue for the six months ended March 31, 2024 led to higher cost of revenues as a result.

Selling, General and Administrative Expense

Selling, general and administrative expense during the six months ended March 31, 2024 was \$1,994,534, a decrease of \$361,167, compared to \$2,355,701 for the six months ended March 31, 2023. The decrease in selling, general and administrative expense for the six months ended March 31, 2024 is primarily attributable to a decrease in professional service costs, most notably legal costs related to financing activities.

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Research and Development Expense

Research and development expense during the six months ended March 31, 2024 was \$409,449, an increase of \$77,362, compared to \$332,087 for the six months ended March 31, 2023. The increase in research and development expense is primarily attributable to an increase in payroll costs.

Other (Expense) Income

Other expense during the six months ended March 31, 2024 was \$1,779,380, an increase of \$1,778,074, compared to other expense of \$1,306 for the six months ended March 31, 2023. The increase in other expense is primarily attributed to an increase in interest expense related to the amortization of debt discount and debt issuance costs for 2022 Notes, Second Notes, Third, and Fourth Notes as well as increase in related interest expense. Additionally, the increase in other expense is primarily attributable to the gain on extinguishment of derivative liabilities that was recognized during the six months ended March 31, 2023 of approximately \$1,200,000 income and did not occur during the six months ended March 31, 2024.

Year Ended September 30, 2023 Compared to Year Ended September 30, 2022

	September 30, 2023	September 30, 2022	Increase (Decrease)
	(\$)	(\$)	(\$)
Revenue	<u>75,724</u>	<u>15,652</u>	<u>60,072</u>
Operating Expenses			
Cost of revenues	78,163	51,489	26,674
Selling, general and administrative	4,371,164	4,519,636	148,472
Research and development	670,880	1,153,333	(482,453)
Loss from Operations	<u>(5,044,483)</u>	<u>(5,708,806)</u>	<u>(664,323)</u>
Other (expense) income	<u>(1,938,353)</u>	<u>432,952</u>	<u>(2,371,305)</u>
Net loss	<u>(6,982,836)</u>	<u>(5,275,854)</u>	<u>(1,706,982)</u>

Revenue

Revenue for the year ended September 30, 2023 was \$75,724, an increase of \$60,072 compared to \$15,652 for the year ended September 30, 2022. Revenue for the year ended September 30, 2023 was the result of multiple transactions into a single hospital as well as transactions into multiple Veterans Administration Hospitals (*the "VA"*) consisting of twenty (20) total units through our distribution partner, Lovell Government Services (*"LGS"*). 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.

Cost of revenues

Cost of revenues during the year ended September 30, 2023 was \$78,163, an increase of \$26,674 compared to \$51,489 for the year ended September 30, 2022. 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, 2023 was \$4,371,164 a decrease of \$148,472 compared to \$4,519,636 for the year ended September 30, 2022. The decrease in selling, general and administrative expense for the year ended September 30, 2023 is primarily attributable to an increase in legal and consulting costs, which were more than offset by a decrease in compensation costs and patent costs.

Research and Development Expense

Research and development expense during the year ended September 30, 2023 was \$670,880 a decrease of \$482,453 compared to \$1,153,333 for the year ended September 30, 2022. The decrease in research and development expense is primarily attributable to a decrease in compensation costs and consulting costs.

Other (Expense) Income

Other expense during the year ended September 30, 2023 was \$1,938,353, an increase of \$2,371,305 compared to total other income of \$432,952 for the year ended September

30, 2022. The increase in other (expense) income is attributable to interest expense partially offset by gain for the extinguishment of derivative liabilities.

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.

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Working Capital

At March 31, 2024, we had total current assets of \$1,533,177 (including cash of \$26,426) and a working capital deficit of \$10,844,374. Our working capital as of March 31, 2024 and September 30, 2023 are summarized as follows:

	<u>March 31, 2024</u>	<u>September 30, 2023</u>
Total Current Assets	\$ 1,533,177	\$ 1,950,090
Total Current Liabilities	12,417,551	9,465,921
Working Capital Deficit	\$ (10,884,374)	\$ (7,515,831)

Total current assets as of March 31, 2024 were \$1,533,177, a decrease of \$416,913, compared to \$1,950,090, as of September 30, 2023. The decrease in current assets is primarily attributable to a decrease in cash and prepaid expenses. Our total current assets as of March 31, 2024 and September 30, 2023 were comprised primarily of cash, inventory and prepaid expenses and other current assets.

Total current liabilities as of March 31, 2024 were \$12,417,551, an increase of \$2,951,630, compared to \$9,465,921 as of September 30, 2023. The increase is primarily due to an increase in shareholder advances and accounts payable, new notes issued during the period, and amortization of the debt discount and debt issuance costs for the notes partially offset by a decrease to the amount owed in connection with the financing of certain insurance premiums and the conversion of the Series 2 and certain Senior Secured convertible note into shares.

Cash Flow for the Six Months Ended March 31, 2024 Compared to the Six Months Ended March 31, 2023

	<u>March 31, 2024</u>	<u>March 31, 2023</u>
Cash Used in Operating Activities	\$ (1,562,764)	\$ (1,249,931)
Cash Provided by Financing Activities	1,366,470	532,486
Net decrease in Cash	\$ (196,294)	\$ (717,445)

Cash Used in Operating Activities

Cash used in operating activities increased by \$312,833 to \$1,562,764 during the six months ended March 31, 2024, compared to \$1,249,931 during the six months ended March 31, 2023. The increase in cash used in operating activities is primarily attributable to an increase in net loss partially offset by an increase in non-cash accretion of debt discounts and issuance costs on convertible notes payable.

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Cash Provided by Financing Activities

Cash provided by financing activities increased by \$833,984 to \$1,366,470 during the six months ended March 31, 2024, compared to \$532,486 cash used in financing activities during the six months ended March 31, 2023. For the six months ended March 31, 2024, the increase in cash provided by financing activities was attributable to an increase in Shareholder and third-party advances related to bridge financing.

Cash Flow for the Year Ended September 30, 2023 Compared to the Year Ended September 30, 2022

	<u>September 30, 2023</u>	<u>September 30, 2022</u>
Cash Used in Operating Activities	\$ (3,374,216)	\$ (4,456,075)
Cash Used in Investing Activities	(4,521)	-
Cash Provided by Financing Activities	2,854,517	2,936,376
Net decrease in cash	\$ (524,220)	\$ (1,519,699)

Cash Used in Operating Activities

Cash used in operating activities decreased \$1,081,859 to \$3,374,216 during the fiscal year ended September 30, 2023 compared to \$4,456,075 for the fiscal year ended September 30, 2022. The decrease in cash used in operating activities is primarily attributable to the accretion of the debt discount, partially offset by a reduction in inventory.

Cash Used in Investing Activities

Cash used in investing activities increased \$4,521 to \$4,521 during the fiscal year ended September 30, 2023, compared to \$0 during the fiscal year ended September 30, 2022. For the fiscal year ended September 30, 2023, cash used in investing activities increased due to the purchase of computer hardware.

Cash Provided by Financing Activities

Cash provided by financing activities decreased \$81,859, to \$2,854,517 for the fiscal year ended September 30, 2023, compared to \$2,936,376 for the fiscal year ended September 30, 2022. For the year ended September 30, 2023, the cash provided by financing activities increased as a result from net proceeds of \$2,209,839 raised from bridge equity financing and proceeds of \$995,000 received from the issuance of unsecured convertible notes partially offset by repayment of financed insurance premium of \$350,332. For the year ended September 30, 2022, the cash provided by financing activities resulted from net proceeds of \$2,936,376 raised from the issuance of senior secured convertible notes, warrants and inducement shares partially offset by repayment of financed insurance premium.

Cash Requirements

We anticipate that our operating expenses, interest expense and other expenses will increase significantly as we continue to implement our business plan and pursue our operational goals. Depending upon additional input from EU and US regulatory authorities, however, we do not expect to generate sufficient revenues from operations before we will need to raise additional capital. Further, our estimates regarding our use of cash could change if we encounter unanticipated difficulties or other issues arise, including

without limitation those set forth under the heading “RISK FACTORS” described in our Annual Report, in which case our current funds may not be sufficient to operate our business for the period we expect.

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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 2022 SPA (see Note 8) and 2023 SPA (see Notes 2 and 12) 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. 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.

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. The continuation of our business as a going concern is dependent upon raising additional capital and eventually attaining and maintaining profitable operations. As of March 31, 2024, there is substantial doubt about the Company’s ability to continue as a going concern. In addition, the Company’s Independent registered public accounting firm, in their report on the Company’s September 30, 2023 audited financial statements, raised substantial doubt about the Company’s ability to continue as a going concern. The financial statements included in this registration statement do not include any adjustments that might be necessary should operations discontinue.

Critical Accounting Policies and Significant Judgments and Estimates

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

Derivative Liabilities

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

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Inventories

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

Complex Financial Instruments

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

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

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

subsequently remeasured.

Recent Accounting Guidance

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

Off-Balance Sheet Arrangements

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

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OUR BUSINESS

Corporate Overview

Arch Therapeutics, Inc. (together with its subsidiary, the “**Company**” or “**Arch**”) is a biotechnology company developing and marketing products based on our innovative AC5® self-assembling technology platform. Arch arose from the June 26, 2013 merger (the “**Merger**”) of three entities previously known as Arch Biosurgery, Inc., Almah, Inc., and Arch Acquisition Corporation, respectively.

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

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

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

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

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

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

Our Company

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

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Core Technology

Our flagship product 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 (US) and the European Union (EU), respectively, and which are intended for skin applications, such as management of complicated chronic wounds and acute surgical wounds. Marketing for AC5 Topical Hemostat in the EU has not initiated. Other products are in development for use in minimally invasive or open surgical procedures and include, for example, AC5-G™ for gastrointestinal endoscopic procedures and AC5-V® and AC5 Surgical Hemostat for hemostasis inside the body, all of which are currently investigational devices limited by law to investigational use.

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

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

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

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

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Sales and marketing efforts for our AC5 Advanced Wound System, which has received 510(k) marketing clearance from the United States Food and Drug Administration (“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 US 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.

Operations

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

Our long-term business plan includes the following goals:

- growing revenues and building upon recent commercial momentum by driving product awareness, continued adoption and favorable payment policies for AC5 Advanced Wound System with the now-effective CMS Level II HCPCS code dedicated to AC5;
- conducting biocompatibility, pre-clinical, and clinical studies on our products and product candidates;

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- 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 third party 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.

To support our long-term business goals, we expect to focus on the following activities during the next twelve months:

- further develop our product clinical profile;
- enhance product packaging features;
- identify and address opportunities for supply chain efficiencies;
- assess our technology platform in order to identify and select product candidates for potential advancement into development;
- seek additional funding as required to support the previously described milestones necessary to support our operations;
- 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, maintaining granted patents in desired jurisdictions, and/or adding to our trade secrets in self-assembly, manufacturing, analytical methods and formulation, as appropriate.

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 future capital. We will require significant additional financing to fund our planned operations, including, but not limited to, further research and development relating to AC5; seeking regulatory approval for any product we may choose to develop, launch or license; commercializing any product for which we are able to obtain regulatory approval or certification; seeking to license or acquire new assets or business; supporting our intellectual property rights; pursuing new technologies; and financing the investor relations and incremental administrative costs associated with being a public corporation. We do not presently have, nor do we expect in the near future to have, sufficient revenue to fund our business from operations, and we will need to obtain substantially all of our necessary funding from external sources for the foreseeable future. We may not be able to obtain additional financing on commercially reasonable or acceptable terms when needed, or at all. If we cannot raise the money that we need in order to continue to develop our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations. If any of these were to occur, there is a substantial risk that our business would fail, and our stockholders could lose all of their investments.

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The estimated capital requirements could potentially 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**”. 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, we do not believe that our current cash on hand as of June 19, 2024 is sufficient to meet our anticipated cash requirements through the end of June 2024, and we must obtain additional financing in order to continue to operate our business. Even if this offering is successful, we could spend our financial resources much faster than we expect, in which case we would need to raise additional capital.

Research and Development

Preclinical and clinical testing is required in order to receive regulatory marketing authorizations for our products and to support those products upon and after commercialization, and we anticipate continuing such testing as 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 and related activities, typically with assistance from our team. These third parties can include contract research organizations, academic institutions, consultants, advisors, scientists, clinicians, and 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 complete a biocompatibility assessment using a battery of standard in vitro and in vivo tests. Examples of such tests may include the following, as set forth in ISO 10993 issued by the International Organization for Standardization:

- in vitro cytotoxicity;
- in vitro blood compatibility;
- irritation/intracutaneous reactivity;

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- sensitization (allergic reaction);
- implantation (performed on devices that contact the body’s interior);
- pyrogenicity (causing fever or inflammation); and
- systemic toxicity.

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 plan to 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 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 both 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’ AC5 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.

The AC5 technology has also 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 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.

The AC5 technology 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.

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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/or 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 other collaborators.

In order to enroll patients in a clinical trial, we are required to obtain each patient’s informed consent in a form and substance that complies with the FDA and/or other regulatory authority requirements as well as state and federal privacy and human subject protection regulations.

We have completed two randomized controlled clinical studies to date. The first study, which met its primary and secondary endpoints, assessed the safety and performance of AC5 in 46 patients with bleeding skin wounds, including a group of patients taking anti-platelet medications (i.e., a blood thinner) that resulted from excision of skin lesions and followed for 30 days. The second study assessed AC5 on skin, determining that it was neither an irritant nor a sensitizer, and no immunogenic response or other adverse events attributable to this product were reported in any of the approximately 50 enrolled volunteers. The AC5 product candidate in these studies subsequently received marketing authorization and is presently known as AC5 Advanced Wound System in the US and AC5 Topical Hemostat in the EU.

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

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 US.

Regulatory

We have engaged and continue to engage third parties in the US 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.

The research, development and clinical programs, as well as manufacturing and marketing operations that may be performed by us or third-parties on our behalf, are subject to extensive regulation in the US and other countries. Notably, for example, AC5 Advanced Wound System is subject to regulation as a medical device under the US Food Drug and Cosmetic Act (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, or others on our behalf, do or will perform, 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 manufacturing;
- 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 US and AC5 Topical Hemostat in EU 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. AC5 self-assembly, which is the desired effect, is consistent with the medical device definition.

Medical devices in the US and EU 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 those that have a new intended use or that use advanced technology not substantially equivalent to that of a legally marketed device.

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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 devices in these jurisdictions, depending upon the intended use. Specifically, AC5 Advanced Wound System is a Class II medical device in the US, and AC5 Topical Hemostat is a Class IIb medical device in EU.

In the US, 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; and
- 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 or European Union Medical Device Regulation 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 (defined below under the section entitled "*European Union Marketing Authorization (CE Mark) Process*");
- 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.

US Class III and certain Class II medical device approvals and EU Class III and certain Class IIa and IIb medical device approvals may require the successful completion of human clinical trials.

US 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 (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 US. The FDA ultimately determines the appropriate regulatory path. For purposes herein, references to regulatory approval and marketing authorization may be used interchangeably.

AC5 Advanced Wound System, which is intended for external use, received marketing authorization through the 510(k) process. To obtain 510(k) 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 US. 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. 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.

We believe that our product candidates for internal use will require a PMA approval prior to commercialization. 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 IRB for the relevant clinical trial sites and comply with applicable FDA regulations, including those relating to good clinical practices (GCP).

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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 appropriate 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 EU member state as being competent to make independent judgments about whether a medical device complies with applicable regulatory requirements in the EU (a “Notified Body” or “Notified Bodies”). 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 *Conformité Européenne* mark (CE 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 or newer European Medical Device Regulations, a CE mark symbol that is placed on a product 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.

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While there are many similarities between the processes required to obtain marketing authorization in the US and EU, 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 510(k) or a 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 EU regulatory bodies implemented a Medical Device Regulation, which revises several aspects of the existing regulatory framework, such as clinical data requirements, and introduces new ones, such as Unique Device Identification. We, and the Notified Bodies who will oversee compliance to the new Medical Device Regulation, face uncertainties in the upcoming years as it is rolled out and enforced, creating risks in several areas, including the CE mark process, data transparency and application review timetables. The Medical Device Regulation became effective on May 26, 2021, although the European Commission has allowed an implementation period to facilitate transition from the Medical Device Directives. This transition period extends until the end of 2027 for high-risk devices and until the end of 2028 for medium and low risk devices.

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 US and EU member states and include:

- product listing and establishment registration;
- compliance by us and/or third-parties upon whom we depend with stringent design, testing, control, documentation and other quality assurance processes and procedures related to product design, manufacturing and commercialization;
- 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, revocation of certificates, criminal prosecution or other sanctions.

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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 (510)k 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 had been reviewed and cleared by the FDA, allowing for the product to be marketed. In line with plans to better harmonize our US and EU 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 US 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 had been reviewed and cleared by the FDA, allowing for the product to be marketed in the US with the aforementioned additions. AC5 Topical Gel was subsequently renamed AC5 Advanced Wound System in the US.

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

During November 2018, we submitted the required documents for AC5 Topical Hemostat to the Notified Body seeking a CE mark.

During April 2020, we received the CE 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 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.

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.

For at least the near term future, in order to maximize operational efficiencies and to account for changing landscapes since the COVID-19 pandemic during which both marketing authorizations were received, 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.

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We expect the commercialization ramp to be gradual through 2024 and into 2025, while we encourage product use among key opinion leaders and early adopters in developing market channels, and then moderately accelerate.

We recently started to commercialize AC5 Advanced Wound System. We rely on both an internal commercial team and independent sales distributors to drive 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 (VA) hospitals and military 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.

We anticipate that material growth in the physician office setting will require product reimbursement. To that end, we applied to the Centers for Medicare and Medicaid Services (CMS) for a dedicated Healthcare Common Procedure Coding System (HCPCS) Level II reimbursement code specific to AC5 Advanced Wound System to better enable providers to bill third party payors for AC5 that is used in doctors' offices. The unique HCPCS code, A2020, was granted and made effective on April 1, 2023. A dedicated HCPCS code is an important step toward, although not a guarantee of, coverage and reimbursement, and we intend it to 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.

In support of the government market, we partnered with Lovell Government Services (LGS), a service-disabled veteran-owned small business, to be our government channel distributor. As a direct result of our relationship with LGS, AC5 Advanced Wound System has been added to the four major government contracting vehicles: Federal Supply Schedule (FSS), General Services Administration (GSA) schedule, Defense Logistics Agency's Medical Electronic Catalog Program (ECAT), and Distribution and Pricing Agreement (DAPA). This listing enables purchase by federal government agencies, including the Department of Veterans Affairs (VA), Indian Health Services (IHS), and Department of Defense (DOD) Medical Treatment Facilities, and it allows doctors in government channels to order AC5 Advanced Wound System.

Our internal core team oversees AC5 Advanced Wound System sales, marketing, and inventory distribution from the warehouse to the customer. We envision hiring additional internal sales representatives to support commercialization.

We have partnerships with reputable, value-added independent sales representatives and distributors, and we expect to add more collaborative agreements on a case-by-case basis to expand the overall reach and footprint of the sales organization. Such collaborations may include strategic partners. We anticipate that we will also 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 both 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.

The COVID-19 Pandemic Impact on Commercialization

The COVID-19 pandemic environment introduced significant challenges related to product launch, marketing and sales. While the overall environment has improved, negative direct and indirect effects may variously wax and wane. Some effects that we periodically observe include curtailed access to non-US surgeons, facilities, and potential strategic partners, as well as to some US medical facilities.

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The pandemic brought additional attention to the tendency for interventions for wounds to be too often considered elective procedures instead of essential or emergent, as National Pressure Ulcer Advisory Panel guidelines and others recommend, resulting in a projected increased risk to limb and life. 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 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 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.

We believe that these challenges may present an opportunity for new technology, such as ours, to address poorly met needs and limited healthcare overall resources.

Manufacturing

We work with contract manufacturing and related organizations, including those operating under cGMP, as is required by applicable regulatory agencies for production of products 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. 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 research, development, and 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 products.

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.

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The manufacturing methods that we use to produce our current products 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. Our current products are synthesized from naturally occurring [ingredients amino acids] that, while not sourced from humans or other animals, 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. 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 AC5 self-assembling peptide technology and Arch’s 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 many 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 (www.ncbi.nlm.nih.gov/books/NBK442035), 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 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 (https://www.facs.org/media/buthal55/nonhealing_wounds.pdf; www.doi.org/10.1111/wrr.12994; www.doi.org/10.1186/s13643-016-0400-8; www.doi.org/10.19080/ARR.2020.06.555678).

Diabetic foot ulcers develop in approximately 2 million Americans each year, according to The Health Innovation Program, University of Wisconsin (<https://hip.wisc.edu/DiabeticFootUlcers>), while the annual incidence across developed countries is estimated to be 2-4%, according to Woods et al in 2020 (www.doi.org/10.1371/journal.pone.0232395). Pressure ulcers develop in over 2.5 million Americans each year, according to the United States Agency for Healthcare Research & Quality (www.ahrq.gov/topics/pressure-ulcers.html).

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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 (www.doi.org/10.3111/13696998.2014.903258), while Qiu et al in 2021 provided an estimated prevalence of 2-4% (www.doi.org/10.3389/fmed.2021.614059). 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 (www.doi.org/10.1186/s13643-016-0400-8). Woods et al in 2020 stated that only 2/3 of diabetic foot ulcers heal within 12 months (www.doi.org/10.1371/journal.pone.0232395). 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 (www.doi.org/10.1186/s13643-016-0400-8).

The Health Innovation Program, University of Washington, cited that of patients with diabetic foot ulcers in the United States, more than 50% will die within five years and 5% will have an amputation (<https://hip.wisc.edu/DiabeticFootUlcers>). A common phrase in medicine, which we often cite, is, “Save a limb, save a life.” Even the amputations that are required to save a patient from a non-healing, progressing chronic wound are associated with additional significant morbidity and mortality. In an examination of mortality rates after amputations from a chronic wound, Meshkin et al performed a systematic literature review and found that of the sixty-one studies yielding approximately 36,000 patients who previously received a nontraumatic major lower extremity amputation, approximately 34% died by year one, 55% died by year two, and 64% died by year five (<http://www.doi.org/10.1053/j.jfas.2020.06.027>). Stern et al in 2017 reported an even higher mortality rate one year after amputation of approximately 48% (www.doi.org/10.1016/j.avsg.2016.12.015).

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 (<https://www.doi.org/10.1016/j.jval.2017.07.007>). 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 (<https://www.doi.org/10.12968/jowc.2017.26.sup4.s4>). 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 (www.doi.org/10.1371/journal.pone.0232395). 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 (<https://www.doi.org/10.1007/s12325-017-0478-y>).

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 (<https://www.researchgate.net/publication/340950761>). 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.

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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, less 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, will complement other products and procedures by potentially enabling the wound bed to be ready sooner, and will 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 wounds;
- conforms to irregularly shaped wound geometry;
- may be used in either lower acuity (e.g., doctor’s offices) 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 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 (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;

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- able to protect the wounds in tissues and organs where used;

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

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

- a persistent drive to migrate the site of surgical care from inpatient hospital operating room to progressively lower acuity same-day ambulatory settings due to cost and other potential negative impacts of unnecessary hospitalizations, such as infection risk or occupying scarce resources that may be more usefully deployed elsewhere;
- increased use of anticoagulants and other anti-thrombotic agents (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 in performing more types of procedures in less expensive outpatient settings.

Since the early days of modern MIS in the 1990s, the percent of minimally invasive surgeries 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.

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In a trend to make traditional minimally invasive surgery even less invasive, known as NOTES, a procedure is performed through an endoscope that 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 have 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 and 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.

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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.

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.
- Reimbursement for some competing products and product categories may be more established, and reimbursement for advanced wound care products, in general, is being re-evaluated by payers, raising potential barriers to use.

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 US and foreign government agencies have broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on our business. Additionally, if we are able to successfully obtain approvals for, and commercialize our product candidates, then the Company and our products may become subject to various federal, state and local laws targeting fraud, abuse, privacy and security in the healthcare industry.

Intellectual Property

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

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As of March 31, 2024, we either own or license from others a number of US patents, US patent applications, foreign patents and foreign patent applications.

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

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

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

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

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

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

Employees

We presently have eight full-time employees, and we 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.

On December 5, 2023, Daniel Yrigoyen resigned, effective as of such date, from his position as an executive officer and as Vice President of Sales of the Company. Effective December 5, 2023 Shawn Carlson was appointed to serve as the Company's Vice President of Sales.

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Properties

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

Legal Proceedings

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

Dr. Avtar Dhillon served as our Chairman of the Board from April 2013 through July 2018, and as an advisor to us from July 2018 until his termination on August 6, 2021. Dr. Avtar Dhillon was not a director, officer, or control person at the time of his termination. 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 was scheduled for May 23, 2024. At the same time, the SEC charged Dr. Avtar Dhillon with violations of the antifraud and certain other provisions of federal securities laws in connection with the sales of securities of certain public companies, including his sale of shares of the Company. On October 20, 2022, the United States District Court for the Central District of California entered a final judgment as to Dr. Avtar Dhillon, in favor of the SEC, pursuant to which he is (1) prohibited from acting as an officer or director of any issuer that has a class of securities registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or that is required to file reports pursuant to Section 15(d) of the Exchange Act and (2) permanently restrained and enjoined from violating, directly or indirectly, (i) Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, (ii) Section 17(a) of the Securities Act, and (iii) Section 17(b) of the Securities Act. The Company has fully cooperated with the DOJ and the SEC and has not been implicated in or charged with any wrongdoing.

DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

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

Name	Position	Age	Director/Officer Since
Dr. Terrence W. Norchi	President, Chief Executive Officer and Chairman of the Board of Directors	58	April 2013
Michael S. Abrams	Chief Financial Officer	52	May 2021
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.

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 Cboe Listing Rule 14.10(c)(1)(B). 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 Cboe Listing Rules applicable to all such board committees. Dr. Terrence W. Norchi would not qualify as “independent” under Cboe 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, Cboe Listing Rule 14.10(c)(1)(B) 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 Cboe Listing Rule 14.10(c)(1)(B) 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.

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Committees of the Board of Directors

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

Audit Committee

On August 15, 2022, our Board of Directors established a separate standing audit committee within the meaning of Section 3(a)(58)(A) of the Exchange Act. The Audit Committee consists of Mr. Punit Dhillon, serving as the Chairman of the Audit Committee, Mr. Laurence Hicks, and Dr. Guy Fish. Our Board has determined that the three directors currently serving on our Audit Committee are independent within the meaning of the Cboe Listing 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 SEC rules.

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

Compensation Committee

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

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

Nominating and Corporate Governance Committee

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

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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.

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EXECUTIVE COMPENSATION

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

Summary Compensation Table

Name	Fiscal Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards (\$)(1)	All other Compensation (\$)	Total (\$)
Dr. Terrence W. Norchi, <i>President and Chief Executive Officer</i>	2023	450,500	-	-	40,500	-	491,000
	2022	450,500	-	-	-	-	450,500
Michael S. Abrams <i>Chief Financial Officer</i>	2023	325,000	-	-	29,160	-	354,160
	2022	325,000	-	-	-	-	325,000
Daniel Yrigoyen(2) <i>VP of Sales</i>	2023	325,000	-	-	16,200	-	341,200
	2022	316,667	-	-	9,075	-	325,742

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

(2) On December 5, 2023, Daniel Yrigoyen resigned, effective as of such date, from his position as an executive officer and as Vice President of Sales.

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.

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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.

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Daniel M. Yrigoyen

On July 12, 2021, we entered into an executive employment agreement with Mr. Yrigoyen, our former 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.

On December 5, 2023, Daniel Yrigoyen resigned, effective as of such date, from his position as an executive officer and as Vice President of Sales of the Company.

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

Name	Option Awards				Stock Awards	
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)
Dr. Terrence W. Norchi	312	(1)	560.00	03/23/2024		
	250	(2)	304.00	01/21/2025		
	221	(3)	448.00	08/17/2025		
	781	(4)	624.00	05/02/2026		
	406	(5)	1,040.00	02/02/2027		
	225	(6)	680.00	07/18/2028		
	625	(7)	366.72	12/19/2029		
	625	(8)	164.48	09/26/2031		
	417	208(9)	164.48	09/26/2031		
	217	564(10)	64.16	11/9/2032		
Michael S. Abrams	260	52(11)	212.64	05/02/2031		
	145	72(12)	164.48	09/26/2031		
	156	406(13)	64.16	11/9/2032		
Daniel M. Yrigoyen	67	26(14)	144.00	06/29/2031		
	83	41(15)	164.48	09/26/2031	93(16)	19,500
	41	52(17)	96.8	05/23/2032		
	86	225(18)	64.16	11/9/2032		

- (1) Represents an option to purchase 312 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.

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- (2) Represents an option to purchase 250 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 221 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 781 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 406 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 225 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 625 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 625 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 625 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 781 shares of Common Stock with a grant date of November 10, 2022. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.
- (11) Represents an option to purchase 312 shares of Common Stock with a grant date of May 3, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with 30% of the shares vested immediately on the date of grant and the remaining shares to vest in 24 equal installments commencing on the first anniversary on the date of grant.
- (12) Represents an option to purchase 218 shares of Common Stock with a grant date of September 27, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.

- (13) Represents an option to purchase 562 shares of Common Stock with a grant date of November 10, 2022. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.
- (14) Represents an option to purchase 93 shares of Common Stock with a grant date of July 30, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant and the remaining shares to vest in 24 equal installments commencing on the first anniversary on the date of grant.
- (15) Represents an option to purchase 125 shares of Common Stock with a grant date of September 27, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.
- (16) Represents an option to purchase 93 shares of Common Stock with a grant date of July 30, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant and the remaining shares to vest in 24 equal installments commencing on the first anniversary on the date of grant.
- (17) Represents an option to purchase 93 shares of Common Stock with a grant date of May 24, 2022. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.
- (18) Represents an option to purchase 312 shares of Common Stock with a grant date of November 10, 2022. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant

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Compensation of Directors

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

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

Director Compensation Table

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

- (1) Mr. Dhillon was appointed as a member of the Board on July 19, 2018. The aggregate number of shares of Common Stock underlying option awards outstanding as of September 30, 2023 held by Mr. Dhillon was 781.
- (2) Mr. Hicks was appointed as a member of the Board on September 27, 2021. The aggregate number of shares of Common Stock underlying option awards outstanding as of September 30, 2023 held by Mr. Hicks was 312.
- (3) Dr. Fish was appointed as a member of the Board on December 31, 2021. The aggregate number of shares of Common Stock underlying option awards outstanding as of September 30, 2023 held by Dr. Fish was 312.

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CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Related Party Transactions

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

On June 22, 2020, the Company entered into a Series J Warrant Issuance Agreement (the "**Keyes Sulat Agreement**") with the Keyes Sulat Revocable Trust (the "**Trust**"), also a holder of outstanding Series D Warrants, resulting in approximately \$82,000 of proceeds as a result of the full exercise of the Trust's Series D Warrants. Under the terms of the Keyes Sulat Agreement, in exchange for fully exercising the Trust's remaining Series D Warrants for 284 shares of Common Stock on June 22, 2020, the Trust was issued Series J Warrants to purchase 213 shares of Common Stock at an exercise price of \$400.00 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 October 25, 2023, no Series J Warrants remain outstanding.

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

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

Review, Approval or Ratification of Transactions with Related Persons

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

consistent with the best interests of the Company and its stockholders. The procedures described above have been approved by resolutions adopted by our Board.

Subject to some exceptions, Cboe Listing Rule 14.10(c)(1)(B) 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 Cboe Listing Rule 14.10(c)(1)(B) 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.

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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 555,562 shares of our Common Stock outstanding on June 19, 2024. Shares of our Common Stock subject to options, warrants, or other rights currently exercisable or exercisable within 60 days of June 19, 2024 are deemed to be beneficially owned and outstanding for computing the share ownership and percentage of the person holding such options, warrants or other rights, but are not deemed outstanding for computing the percentage of any other person.

The number of shares beneficially owned after the offering assumes (i) the sale of 969,697 shares of Common Stock and 969,697 Investor Warrants included in the Units in this offering at an assumed public offering price of \$4.125 per Unit (assuming no sale of Pre-Funded Units); (ii) the expected issuance immediately prior to the pricing of this offering of 982,056 PIPE Pre-Funded Warrants and 982,056 PIPE Investor Warrants in the Uplist PIPE, (iii) the expected issuance at the closing of this offering of 538,182 2024 Note Conversion Pre-Funded Warrants, 43,637 2024 Notes Automatic Conversion Shares and 581,819 2024 Notes Uplist Conversion Warrants upon the 2024 Notes Automatic Conversion of an aggregate of \$2,400,000 of principal amount under the 2024 Notes, (iv) the expected issuance at the closing of this offering of 1,893,919 True-Up Shares and True-Up Pre-Funded Warrants to purchase an aggregate of 6,330,422 shares of Common Stock, based on the sale of the Units and Pre-Funded Units at an assumed public offering price of \$4.125 per Unit and \$4.124 per Pre-Funded Unit; (v) the expected issuance at the closing of this offering of an aggregate of 1,638,330 shares of Common Stock and 65,533,100 Uplist Conversion Warrants upon the Automatic Conversion of an aggregate of \$6,553,310 of principal amount under the 2022 Notes, assuming no issuance of any 2022 Note Conversion Pre-Funded Warrants, based on the assumed exercise price of the Investor Warrants being offered as part of the Units and Pre-Funded Units in this offering of \$4.00 per share; (vi) no exercise of the Investor Warrants, PIPE Investor Warrants, PIPE Pre-Funded Warrants, True-Up Pre-Funded Warrants, Bridge Pre-Funded Warrants, Uplist Conversion Warrants, Exchange Investor Warrants, or 2024 Notes Uplist Conversion Warrants; (vii) the exchange of the 2,349,826 Common Warrants for 7,049,478 Exchange Investor Warrants, at the closing of this offering; and (viii) no issuance of any Funding Backstop Pre-Funded Warrants or Backstop Common Warrants. The expected allocation between True-Up Shares and True-Up Pre-Funded Warrants in the previous sentence is only an initial estimate based on indications of interest and is subject to change based on the ultimate ownership of the Bridge Investors after the Uplist PIPE and this offering. The maximum amount of True-Up Pre-Funded Warrants and True-Up Shares that may be issued, individually and in the aggregate is 8,224,341. The percentage of shares beneficially owned after the offering is based on an assumed 4,916,849 shares of Common Stock to be outstanding, based on the assumptions set forth in this paragraph.

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

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned (1)	Number of Shares Beneficially Owned after the Offering**	Percentage of Shares Beneficially Owned after the Offering
<i>5%+ Stockholders:</i>				
Tiburon Opportunity Fund LP (2)	29,150	4.99%	487,325	9.99%
Bigger Capital Fund, LP & District 2 Capital Fund LP (3)	37,500	6.75%	459,453	9.43%
Walleye Opportunities Master Fund Ltd (4)	37,500	6.75%	508,587	9.99%
Cavalry Fund I LP (5)	37,500	6.75%	252,827	5.19%
Brandt & Mona Wilson (6)	37,500	6.75%	508,587	9.99%
Ana and Michael Parker (7)	37,500	6.75%	487,325	9.99%
Andrew Stahl (8)	37,500	6.75%	508,587	9.99%
Sixth Borough Capital Fund, LP (9)	37,500	6.75%	493,289	9.99%
<i>Named Executive Officers and Directors:</i>				
Terrence Norchi (10)	19,826	3.50%	258,678	5.06%
Punit Dhillon (11)	773	*	773	*%
Laurence Hicks (12)	11,129	1.97	369,403	7.07%

Michael Abrams (13)	11,327	2.00	369,601	7.08%
Daniel Yrigoyen (14)	94	*	94	*%
Guy Fish (15)	291	*	291	*%
Named Officers and Directors as a Group	43,744	7.45%	999,144	17.19%

* Less than 1%.

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

Shares of our Common Stock subject to options, warrants, or other rights currently exercisable or convertible or exercisable or convertible within 60 days of June 19, 2024, 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.

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- (2) Represents shares of Common Stock underlying warrants that have beneficial ownership blockers. Excludes (a) 700,180 Conversion Shares; (b) 55,352 2022 Warrants; (c) 125,657 Bridge Pre-Funded Warrants with unsatisfied exercise restrictions; and (d) 319,096 Common Warrants with unsatisfied exercise restrictions held in the aggregate by Tiburon Opportunity Fund LP, all of which are subject to conversion or exercise restrictions that prohibit conversion or exercise until such time as the holder would not beneficially own, after such conversion or exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of June 19, 2024, Tiburon Opportunity Fund LP has not waived such limitation.
- (3) Represents 37,500 shares of Common Stock owned by, and split evenly between, Bigger Capital Fund, LP and District 2 Capital Fund LP with a common control person. Excludes (a) 362,500 Conversion Shares; (b) 138,750 2024 Notes Conversion Shares; (c) 18,944 PIPE Advance Penalty Pre-Funded Warrants; (d) 56,250 Execution Backstop Pre-Funded Warrants; (e) 18,944 PIPE Advance Penalty Common Warrants; (f) 21,379 2022 Warrants; (g) 123,683 Bridge Pre -Funded Warrants with unsatisfied exercise restrictions; and (h) 319,082 Common Warrants with unsatisfied exercise restrictions held in the aggregate by Bigger Capital Fund, LP and District 2 Capital Fund LP, all of which are subject to conversion or exercise restrictions that prohibit conversion or exercise until such time as the holder would not beneficially own, after such conversion or exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of June 19, 2024, neither Bigger Capital Fund, LP, nor District 2 Capital Fund LP has waived such limitation.
- (4) Represents 37,500 shares of Common Stock owned by Walleye Opportunities Master Fund Ltd. Excludes (a) 122,035 Bridge PreFunded Warrants with unsatisfied exercise restrictions; and (b) 319,070 Common Warrants with unsatisfied exercise restrictions, all of which are subject to exercise restrictions that prohibit exercise until such time as the holder would not beneficially own, after such exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of June 19, 2024, Walleye Opportunities Master Fund Ltd has not waived such limitation.

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- (5) Represents 37,500 shares of Common Stock owned by Cavalry Fund I LP. Excludes (a) 145,000 Conversion Shares; (b) 138,750 2024 Notes Conversion Shares; (c) 18,944 PIPE Advance Penalty Pre-Funded Warrants; (d) 56,250 Execution Backstop Pre-Funded Warrants; (e) 18,944 PIPE Advance Penalty Common Warrants; (f) 8,552 2022 Warrants; (g) 123,133 Bridge Pre-Funded Warrants with unsatisfied exercise restrictions; and (h) 319,078 Common Warrants with unsatisfied exercise restrictions, all of which are subject to conversion or exercise restrictions that prohibit conversion or exercise until such time as the holder would not beneficially own, after such conversion or exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of June 19, 2024, Cavalry Fund I LP has not waived such limitation.
- (6) Represents 37,500 shares of Common Stock owned individually by Brandt and Mona Wilson. Excludes (a) 138,750 2024 Notes Conversion Shares; (b) 18,944 PIPE Advance Penalty Pre-Funded Warrants; (c) 56,250 Execution Backstop Pre-Funded Warrants; (d) 18,944 PIPE Advance Penalty Common Warrants; (e) 122,035 Bridge Pre-Funded Warrants with unsatisfied exercise restrictions; and (f) 319,070 Common Warrants with unsatisfied exercise restrictions, all of which are subject to exercise restrictions that prohibit exercise until such time as the holder would not beneficially own, after such exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of June 19, 2024, neither Brandt Wilson nor Mona Wilson had waived such limitation.
- (7) Represents (i) 29,431 shares of Common Stock owned individually by Ana Parker, Michael A. Parker's spouse; (ii) 4,757 shares of Common Stock owned individually by Mr. Parker; (iii) 3,125 shares of Common Stock owned through Tungsten, of which Mr. Parker is the sole manager and (iv) 188 shares of restricted stock granted to Mr. Parker on September 27, 2021. Excludes (a) 10,308 Bridge Pre-Funded Warrants with unsatisfied exercise restrictions; (b) 68,686 Common Warrants with unsatisfied exercise restrictions; (c) 12,945 First Conversion Shares; (d) 6,036 First Warrant Shares; (e) any of the 2,143 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 2,930 shares that may be acquired upon the exercise of Series K Warrants (which expire on August 11, 2026), since such warrants cannot be exercised until such time as the holder would not beneficially own, after such exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case such waiver will become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of June 19, 2024, neither Ms. Parker nor Mr. Parker have waived such limitation. The number of shares beneficially owned after the offering assumes, for illustrative purposes only, the above referenced stockholder's participation in the Uplist Transaction in an amount equal to 4.3 times their participation in the Bridge Offering; however, no assurance can be given that the stockholder will participate in such amount or at all, and no commitment has been made on their part.

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- (8) Represents 37,500 shares of Common Stock owned individually by Andrew Stahl. Excludes (a) 138,750 2024 Notes Conversion Shares; (b) 18,944 PIPE Advance Penalty Pre-Funded Warrants; (c) 56,250 Execution Backstop Pre-Funded Warrants; (d) 18,944 PIPE Advance Penalty Common Warrants; (e) 122,035 Bridge Pre-Funded Warrants with unsatisfied exercise restrictions; and (f) 319,070 Common Warrants with unsatisfied exercise restrictions, all of which are subject to exercise restrictions that prohibit exercise until such time as the holder would not beneficially own, after such exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of June 19, 2024, Mr. Stahl had not waived such limitation.
- (9) Represents 37,500 shares of Common Stock owned by Sixth Borough Capital Fund, LP. Excludes (a) 7,984 Bridge Pre-Funded Warrants with unsatisfied exercise restrictions; and (b) 90,967 Common Warrants with unsatisfied exercise restrictions, all of which are subject to exercise restrictions that prohibit exercise until such time as the holder would not beneficially own, after such exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of June 19, 2024, Sixth Borough Capital Fund, LP has not waived such limitation. The number of shares beneficially owned after the offering assumes, for illustrative purposes only, the above referenced stockholder's participation in the Uplist Transaction in an amount equal to 4.3 times their participation in the Bridge Offering; however, no assurance can be given that the stockholder will participate in such amount or at all, and no commitment has been made on their part.
- (10) Represents (a) 6,250 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) 887 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) 706 shares of restricted stock granted to Dr. Norchi on May 3, 2016; (d) 406 shares of restricted stock granted to Dr. Norchi on February 3, 2017; (e) 225 shares of restricted stock granted to Dr. Norchi on July 19, 2018; (f) 328 First Conversion Shares; (g) 302 First Warrants; and (h) 45 First Inducement Shares; (i) 4,146 shares subject to options exercisable within 60 days after June 19, 2024; and (j) 858 shares of common stock purchased. Excludes 1,716 Common Warrants with unsatisfied exercise restrictions. Dr. Norchi disclaims beneficial ownership of the securities held by Twelve Pins Partners, LLC except to the extent of his pecuniary interest therein. The number of shares beneficially owned after the offering assumes, for illustrative purposes only, the above referenced stockholder's participation in the Uplist Transaction in an amount equal to 4.3 times their participation in the Bridge Offering; however, no assurance can be given that the stockholder will participate in such amount or at all, and no commitment has been made on their part.

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- (11) Represents 773 shares of Common Stock subject to options exercisable within 60 days after June 19, 2024.
- (12) Represents 304 shares of Common Stock subject to options exercisable within 60 days after June 19, 2024. Includes (i) 17 shares of Common Stock, (ii) 492 First Conversion Shares, (iii) 453 First Warrant Shares, (iv) 68 First Inducement Shares; and (v) 1,287 shares of common stock held by Drake Partners Equity LLC, in which Mr. Hicks has an ownership interest. Excludes 2,573 Common Warrants with unsatisfied exercise restrictions held by Drake Partners Equity LLC, in which Mr. Hicks has an ownership interest. The number of shares beneficially owned after the offering assumes, for illustrative purposes only, the above referenced stockholder's participation in the Uplist Transaction in an amount equal to 4.3 times their participation in the Bridge Offering; however, no assurance can be given that the stockholder will participate in such amount or at all, and no commitment has been made on their part.
- (13) Represents (i) 492 First Conversion Shares; (ii) 453 First Warrant Shares; (iii) 68 First Inducement Shares; (iv) 1,287 shares of common stock purchased, and (v) 519 shares of Common Stock subject to options exercisable within 60 days after June 19, 2024. Excludes 2,573 Common Warrants with unsatisfied exercise restrictions. The number of shares beneficially owned after the offering assumes, for illustrative purposes only, the above referenced stockholder's participation in the Uplist Transaction in an amount equal to 4.3 times their participation in the Bridge Offering; however, no assurance can be given that the stockholder will participate in such amount or at all, and no commitment has been made on their part.
- (14) Represents 94 shares of restricted stock granted to Mr. Yrigoyen on July 30, 2021.
- (15) Represents 291 shares of Common Stock subject to options exercisable within 60 days after June 19, 2024.

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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 Cboe. 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 4,916,849 shares of Common Stock issued and outstanding, assuming (i) the sale of 969,697 shares of Common Stock included in the Units in this offering at an assumed public offering price of \$4.125 per Unit (assuming no sale of Pre-Funded Units); (ii) the expected issuance immediately prior to the pricing of this offering of 982,056 PIPE Pre-Funded Warrants in the Uplist PIPE, (iii) the expected issuance at the closing of this offering of 1,893,919 True-Up Shares and True-Up Pre-Funded Warrants to purchase an aggregate of 6,330,422 shares of Common Stock, based on the sale of the Units and Pre-Funded Units at an assumed public offering price of \$4.125 per Unit and \$4.124 per Pre-Funded Unit; (iv) the expected issuance at the closing of this offering of an aggregate of 1,454,034 shares of Common Stock upon the Automatic Conversion of an aggregate of \$6,553,310 of principal amount under the 2022 Notes, aside from 2022 Note Conversion Pre-Funded Warrants to be exercisable for an expected 184,296 shares of Common Stock, based on the assumed exercise price of the Investor Warrants being offered as part of the Units and Pre-Funded Units in this offering of \$4.00 per share; (v) no exercise of the Investor Warrants, PIPE Investor Warrants, PIPE Pre-Funded Warrants, True-Up Pre-Funded Warrants, Bridge Pre-Funded Warrants, Uplist Conversion Warrants, Exchange Investor Warrants, 2024 Note Conversion Pre-Funded Warrants, 2022 Note Conversion Pre-Funded Warrants, Execution Backstop Pre-Funded Warrants and PIPE Advance Penalty Pre-Funded Warrants; and (vi) the expected issuance at the closing of this offering of 2024 Note Conversion Pre-Funded Warrants to purchase an aggregate of 538,182 shares of Common Stock and 43,637 2024 Notes Automatic Conversion shares (and related 2024 Note Uplist Conversion Warrants) upon the 2024 Notes Automatic Conversion of the full principal amount under the 2024 Notes. The expected allocation between True-Up Shares and True-Up Pre-Funded Warrants in the previous sentence is only an initial estimate based on indications of interest and is subject to change based on the ultimate ownership of the Bridge Investors after the Uplist PIPE and this offering. The maximum amount of True-Up Pre-Funded Warrants and True-Up Shares that may be issued, individually and in the aggregate is 8,224,341. Assuming the exercise in full of the Bridge Pre-Funded Warrants, PIPE Pre-Funded Warrants, True-Up Pre-Funded Warrants and 2022 Note Conversion Pre-Funded Warrants, Execution Backstop Pre-Funded Warrants, PIPE Advance Penalty Pre-Funded Warrants and 2024 Note Conversion Pre-Funded Warrants, if any, (which have exercise prices of \$0.001 or \$0.008 and therefore function as common stock equivalents) there would be 14,009,456 shares (14,154,910 shares if the underwriters exercise their option to purchase additional shares in full) of Common Stock outstanding after this offering. All of the shares of Common Stock sold in this offering, including the shares of Common Stock issuable upon exercise of the Investor Warrants included in the Units and Pre-Funded Units sold in this offering, will be freely transferable without restriction or further registration under the Securities Act by persons other than by our affiliates. In addition, for each Bridge Investor that purchases Units or Pre-Funded Units in this offering (or securities in the Uplist PIPE) with an aggregate purchase price equal to at least 4.3 multiplied by the aggregate purchase price paid by the Bridge Investor for the Bridge Shares and Bridge Warrants under the Bridge SPA, their Bridge Shares and the shares underlying their Bridge Warrants will not be subject to the Bridge Lock-Up (defined below), and their Bridge Shares (but not their Common Warrants, which are being cancelled and exchange for Exchange Investor Warrants, the shares underlying which are not included in the Resale Prospectus) would be freely transferable without restriction or further registration due to their inclusion in the Resale Prospectus. Further, all of the other securities registered under the Resale Prospectus will be freely transferable without restriction upon the effectiveness of the registration statement of which this prospectus forms a part. Those securities are comprised of (i) 2,691,266 shares of Common Stock and (ii) 87,188,215 shares of common stock underlying warrants (such amounts assuming all of the Common Warrants are exchanged into the Exchange Investor Warrants at the closing of this offering and no

issuance of 2022 Note Conversion Pre-Funded Warrants, 2024 Note Conversion Pre-Funded Warrants or True-Up Shares).

In addition, pursuant to the PIPE SPA, the Company has agreed to file no later than sixty (60) days after the closing date of the Uplist Transaction, a registration statement on Form S-4, or other appropriate form, registering the offer by the Company to exchange, on a one-for-one basis, all outstanding PIPE Investor Warrants, 2022 Warrants, Uplist Conversion Warrants and Exchange Investor Warrants for newly issued warrants identical to the Investor Warrants being sold in this offering, which warrants are expected to be listed on Cboe under the symbol "ARTHW."

Lock-Up Agreements

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

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Bridge Lock-Up

Pursuant to the Bridge SPA, the Bridge Investors agreed (the "**Bridge Lock-Up**") not to sell or otherwise transfer any of the Bridge Shares or Bridge Warrant Shares prior to the one-year anniversary of the Bridge Closing Date. In the event that a Bridge Investor purchases securities in connection with an offering conducted in conjunction with an uplist of the Common Stock to any of, and in compliance with the rules of, the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (the "**Uplist Transaction**"), which this offering is intended to be, and/or in the Uplist PIPE, with an aggregate purchase price equal to at least 4.3 multiplied by the aggregate purchase price paid by the Bridge Investor for the Bridge Shares and Bridge Warrants under the Bridge SPA, the one-year lock-up period will no longer apply to the Bridge Shares and Bridge Warrants. The PIPE Investors have agreed to purchase approximately \$5.9 million in the Uplist PIPE, and other Bridge Investors may purchase securities in this offering at a level that will result in the early termination of the lock-up period specified in the Lock-Up Agreements. Investors in this offering should not assume that any of the Bridge Investors will be subject to a lock-up after the completion of this offering.

Rule 144

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

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

- 1% of the number of shares of our Common Stock then outstanding, which will equal an assumed approximately 48,605 shares immediately after this offering; or
- if and when our Common Stock is listed on Cboe 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.

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DESCRIPTION OF SECURITIES

Authorized Capital Stock

Pursuant to our amended and restated articles of incorporation, as amended, as of September 21, 2023, our authorized capital stock consists of 350,000,000 shares of Common Stock. The following description summarizes the material terms of our capital stock. Because it is only a summary, it may not contain all the information that is important to you. In connection with this offering, we intend to effect a reverse stock split of our Common Stock at a ratio of 1-for-8 prior to the pricing of this offering.

Preferred Stock

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

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

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

- the designation, stated value and liquidation preference of the series;
- the number of shares authorized within the series;
- the offering price;
- the dividend rate or rates (or method of calculation), the date or dates from which dividends shall accrue, and whether such dividends shall be cumulative or noncumulative and, if cumulative, the dates from which dividends shall commence to cumulate;
- any redemption or sinking fund provisions;
- the amount that shares of the series shall be entitled to receive in the event of our liquidation, dissolution or winding-up;

- the terms and conditions, if any, on which shares of the series shall be convertible or exchangeable for shares of our stock of any other class or classes, or other series of the same class;
- the voting rights, if any, of shares of the series; the status as to reissuance or sale of shares of the series redeemed, purchased or otherwise reacquired, or surrendered to us on conversion or exchange;
- the conditions and restrictions, if any, on the payment of dividends or on the making of other distributions on, or the purchase, redemption or other acquisition by us or any subsidiary, of the common stock or of any other class of our shares ranking junior to the shares of the series as to dividends or upon liquidation;
- the conditions and restrictions, if any, on the creation of indebtedness by us or by any subsidiary, or on the issuance of any additional stock ranking on a parity with or prior to the shares of the series as to dividends or upon liquidation; and
- any additional dividend, liquidation, redemption, sinking or retirement fund and other rights, preferences, privileges, limitations and restrictions of the series.

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

Common Stock Issued and Outstanding; Common Stock Registered Hereby

As of June 19, 2024, there were issued and outstanding 555,562 shares of Common Stock. Of our authorized and unissued shares of Common Stock, we are registering under the registration statement of which this prospectus forms a part 969,697 shares of Common Stock to be issued as part of the Units (or upon exercise of the Pre-Funded Warrants to be issued as part of the Pre-Funded Units, in lieu thereof).

The holders of our Common Stock, par value \$0.001 per share, are entitled to one vote per share on all matters submitted to a vote of our stockholders, including the election of directors. Our articles of incorporation do not provide for cumulative voting in the election of directors, and our amended and restated bylaws provide that directors are elected by a plurality vote of the votes cast and entitled to vote on the election of directors at any meeting for the election of directors at which a quorum is present. Matters other than the election of directors to be voted on by stockholders are generally approved if, at a duly convened stockholder meeting, the number of votes cast in favor of the action exceeds the number of votes cast in opposition to the action, unless a different vote for the action is required by applicable law, our articles of incorporation or our amended and restated bylaws. Applicable Nevada law requires any amendment to our articles of incorporation to be approved by stockholders holding shares entitling them to exercise at least a majority of the voting power of the Company. The holders of our Common Stock will be entitled to cash dividends as may be declared, if any, by our Board from funds available. Upon liquidation, dissolution or winding up of our Company, the holders of our Common Stock will be entitled to receive pro rata all assets available for distribution to the holders. All rights of our holders of Common Stock described in this paragraph could be subject to any preferential voting, liquidation or other rights of any series of preferred stock that we may authorize and issue in the future. Our amended and restated articles of incorporation do not currently authorize us to issue any class of preferred stock. Our Common Stock is presently traded on the QB tier of the OTC Marketplace under the trading symbol "ARTH". We have applied to list our Common Stock on Cboe 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 Cboe or an Alternate Exchange, we will not complete this offering.

Units to be Issued in this Offering

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

Pre-Funded Units to be Issued in this Offering

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

Pre-Funded Warrants to be Issued in this Offering

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

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

Duration and Exercise Price

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

Exercisability

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

percentage ownership is determined in accordance with the terms of the Pre-Funded Warrants. Purchasers of Pre-Funded Units in this offering may also elect prior to the issuance of the Pre-Funded Warrants to have the initial exercise limitation set at 9.99% of our outstanding Common Stock.

Cashless Exercise

In lieu of making the cash payment otherwise contemplated to be made to us upon exercise in payment of the aggregate exercise price, the holder may elect instead to exercise its Pre-Funded Warrants on a cashless basis and receive upon such exercise (either in whole or in part) the net number of shares of Common Stock determined according to a formula set forth in the Pre-Funded Warrant.

Fundamental Transactions

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

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Transferability

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

Fractional Shares

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

Trading Market

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

Right as a Shareholder

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

Investor Warrants to be Issued in this Offering

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

The Investor Warrants issued in this offering entitle the registered holders to purchase Common Stock at an assumed exercise price equal to \$4.00 per share (which equals the minimum bid price per share under the initial listing requirements of Cboe in Cboe Listing Rule 14.9(b)), 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.

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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 \$ _____, 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 Cboe under the symbol " ARTHW ." No assurance can be given that our listing application will be approved. Subject to applicable laws, the Investor Warrants may be transferred at the option of the holders upon surrender of the Investor Warrants to us, together with the appropriate instruments of transfer.

Fundamental Transactions. If a fundamental transaction occurs, then the successor entity will succeed to, and be substituted for us, and may exercise every right and power that we may exercise and will assume all of our obligations under the Investor Warrants with the same effect as if such successor entity had been named in the Investor Warrant itself. If holders of our Common Stock are given a choice as to the securities, cash or property to be received in a fundamental transaction, then the holder shall be given the same choice as to the consideration it receives upon any exercise of the Investor Warrant following such fundamental transaction. In the event of a Fundamental Transaction (as defined in each Investor Warrant) approved by our Board of Directors, the holders of the Investor Warrants have the right to require us or a successor entity to redeem the Investor Warrants for cash in the amount of the Black Scholes Value (as defined in each Investor Warrant) of the unexercised portion of the Investor Warrants as of the date of the consummation of the Fundamental Transaction. In the event of a Fundamental Transaction which is not approved by our Board of Directors, the holders of the Investor Warrants have the right to require us or a successor entity to redeem the Investor Warrants for the consideration paid in the Fundamental Transaction in the amount of the Black Scholes Value of the unexercised portion of the Investor Warrants as of the date of the consummation of the 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.

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.

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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.

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UNDERWRITING

We are offering the units described in this prospectus through the underwriters named below. We have entered into an underwriting agreement dated , 2024 with Dawson James Securities, Inc. as the representative of the several underwriters named below (“**Dawson**” or the “**Representative**”), in connection with this offering. Dawson is acting as the sole book-running manager in this offering. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and the underwriters have agreed to purchase, at the public offering price, less the underwriting discounts and commissions, as set forth on the cover page of this prospectus, the number of Units and Pre-Funded Units set forth opposite their respective names below.

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

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

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

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

Option to Purchase Additional Shares and/or Investor Warrants

We have granted the underwriters an option, exercisable for 45 days after the date of this prospectus, to purchase up to an additional shares of Common Stock and/or Investor

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

Discounts and Commissions

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

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

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

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

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

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Indemnification

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

Lock-Up Agreements

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

Exclusivity Tail

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

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

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Right of First Refusal

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

Other Relationships

Dawson has served as our placement agent for the Bridge Offering and the Uplist PIPE. In connection with the Bridge Offering, the Company paid Dawson a cash fee equal to 8.0% of the aggregate gross proceeds of the Bridge Offering, which was \$193,977, and reimbursement of expenses of \$50,000. Additionally, on September 7, 2023 the Company issued to Dawson, or its designees, the Placement Agent Warrants to purchase an aggregate of 55,242 shares of Common Stock. The Placement Agent Warrants are exercisable at any time and from time to time, in whole or in part, until September 7, 2028, at a price per share equal to \$2.20 (which will increase to \$5.15625 at the closing of the Uplist Transaction, representing 125% of the assumed price per share of Common Stock in the Uplist Transaction, as required by FINRA). The Company will pay Dawson a cash fee equal to 8.0% of the aggregate gross proceeds of the Uplist PIPE (expected to be \$472,000), will reimburse DJ for legal and other expenses of up to \$150,000 and will issue to Dawson, or its designees, the PIPE Placement Agent Warrants to purchase an aggregate of 71,533 shares of Common Stock. The PIPE Placement Agent Warrants will be exercisable at any time and from time to time, in whole or in part, during the five-year period commencing upon issuance, at a price per share equal to \$5.15625 (which is 125% of the price per Unit sold in this offering).

The above warrants and the underlying shares may be deemed to be compensation by FINRA, and therefore will be subject to FINRA Rule 5110(e)(1). In accordance with FINRA Rule 5110(e)(1), neither the warrants nor any of our shares of common stock issued upon exercise of the 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 by any person, for a period of 180 days immediately following the commencement date of sales in this offering, subject to certain exceptions. In addition, the foregoing warrants may not be exercised more than five years from the date of commencement of sales in this offering.

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.

Cboe Listing

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

Price Stabilization, Short Positions

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

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

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

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

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

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

These stabilizing transactions, short sales, purchases to cover positions created by short sales, the imposition of penalty bids and syndicate covering transactions may have the effect of raising or maintaining the market price of our Common Stock or preventing or retarding a decline in the market price of our Common Stock. As a result of these activities, the price of our Common Stock may be higher than the price that otherwise might exist in the open market. The underwriters may carry out these transactions on Cboe, 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 Cboe 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.

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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.

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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.

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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.

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LEGAL MATTERS

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

EXPERTS

Weinberg & Company, P.A., an independent registered public accounting firm, has audited our consolidated financial statements as of and for the year ended September 30, 2023, 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.

Baker Tilly US, LLP, an independent registered public accounting firm, has audited our consolidated financial statements as of and for the year ended September 30, 2022, 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.

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Arch Therapeutics, Inc.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Arch Therapeutics, Inc. and Subsidiary (the Company) as of September 30, 2023, the related consolidated statements of operations, changes in stockholders' deficit, and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of September 30, 2023, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, during the year ended September 30, 2023, the Company incurred a net loss and utilized cash flows in operations, and has had recurring losses since inception. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regards to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. 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 audit 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 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 audit, 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 audit included performing procedures to assess the risks of material misstatement of the 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 financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides 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 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 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.

Convertible note transactions

As described in Note 7 to the financial statements, during the year ended September 30, 2023, the Company issued unsecured convertible promissory notes totaling \$1.3 million. In connection with the issuance of the convertible notes, the Company granted noteholders shares of the Company's common stock, and warrants to acquire shares of the Company's common stock. The Company allocated the proceeds received to the convertible notes, shares of common stock, and warrants based upon their relative fair value. The Company used a Black Scholes model to determine the fair value of the warrants issued.

We identified the accounting for the issuance of the convertible notes, shares of common stock, and warrants as a critical audit matter because of the significance of the account balances, and due to the complexity involved in assessing the classification and presentation of the convertible notes and warrants. The auditing for these transactions required a high degree of audit judgement including evaluating the reasonableness of the significant judgements made by management in determining the appropriate accounting.

The primary audit procedures we performed to address this critical audit matter included the following, among others:

- We read the convertible note and warrant agreements, and relevant documentation.
- We obtained the Company's analysis of the accounting of the convertible note and warrants issued in accordance with relevant accounting standards.
- We evaluated the reasonableness of the Company's methodology for allocation of proceeds including the Company's consideration of relevant accounting standards.
- We developed independent estimates for the relative fair value of the warrants and shares of common stock issued based on the assumptions and data used by management.

We have served as the Company's auditor since 2024.

/s/ Weinberg & Company, P.A.
Los Angeles, California

[Table of Contents](#)**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Shareholders of Arch Therapeutics Inc. and Subsidiary

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Arch Therapeutics, Inc. and Subsidiary (the "Company") as of September 30, 2022, the related consolidated statements of operations, changes in stockholders' deficit, and cash flows for the year 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 the results of its operations and its cash flows for the year ended September 30, 2022, in conformity with accounting principles generally accepted in the United States of America.

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 audit. 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 audit 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 audit, 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ Baker Tilly US, LLP

We served as the Company's auditor from 2013 to 2024.

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

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Arch Therapeutics, Inc. and Subsidiary
Consolidated Balance Sheets
As of September 30, 2023 and 2022

	September 30, 2023	September 30, 2022
ASSETS		
Current assets:		
Cash	\$ 222,720	\$ 746,940
Inventory	1,364,504	1,414,848
Prepaid expenses and other current assets	362,866	436,407
Total current assets	<u>1,950,090</u>	<u>2,598,195</u>
Long-term assets:		
Property and equipment, net	4,599	2,044
Other assets	3,500	3,500
Total long-term assets	<u>8,099</u>	<u>5,544</u>
Total assets	<u>\$ 1,958,189</u>	<u>\$ 2,603,739</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 2,304,207	\$ 1,328,000
Accrued expenses and other liabilities	467,496	318,505
Insurance premium financing	243,285	247,933
Convertible notes payable, senior secured, current portion, net of discount	3,519,103	—
Convertible notes payable, unsecured, current portion, net of discount	1,658,702	—
Convertible notes payable, Series 2, unsecured, current portion	450,000	550,000
Accrued interest, current portion	823,128	127,781
Derivative liability, current portion	—	748,275
Total current liabilities	<u>9,465,921</u>	<u>3,320,494</u>
Long-term liabilities:		
Convertible notes payable, senior secured, net of discount	—	1,662,492
Convertible notes payable, unsecured, long-term	—	699,781
Convertible notes payable, Series 2, unsecured, long-term	—	450,000
Accrued interest, long-term	—	204,575
Derivative liability, long-term	—	459,200

Total long-term liabilities	—	3,476,048
Total liabilities	9,465,921	6,796,542
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized, none issued and outstanding as of September 30, 2023 and 2022	—	—
Common stock, \$0.001 par value, 350,000,000 and 4,000,000 shares authorized as of September 30, 2023 and 2022, 4,689,446 and 1,252,734 shares issued and outstanding as of September 30, 2023 and 2022	4,689	1,252
Additional paid-in capital	54,543,188	50,878,718
Accumulated deficit	(62,055,609)	(55,072,773)
Total stockholders' deficit	(7,507,732)	(4,192,803)
Total liabilities and stockholders' deficit	\$ 1,958,189	\$ 2,603,739

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

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**Arch Therapeutics, Inc. and Subsidiary
Consolidated Statements of Operations
For the Years Ended September 30, 2023 and 2022**

	Fiscal Year Ended September 30, 2023	Fiscal Year Ended September 30, 2022
Revenue	\$ 75,724	\$ 15,652
Operating expenses:		
Cost of revenues	78,163	51,489
Selling, general and administrative expenses	4,371,164	4,519,636
Research and development expenses	670,880	1,153,333
Total costs and expenses	5,120,207	5,724,458
Loss from operations	(5,044,483)	(5,708,806)
Other income (expense):		
Interest expense	(3,096,550)	(567,048)
Change in fair value of derivative liability	1,158,197	1,000,000
Total other expense, net	(1,938,353)	432,952
Net loss	\$ (6,982,836)	\$ (5,275,854)
Loss per share - basic and diluted		
Net loss per common share - basic and diluted	\$ (2.27)	\$ (4.40)
Weighted common shares - basic and diluted	3,074,115	1,199,575

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

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**Arch Therapeutics, Inc. and Subsidiary
Consolidated Statements of Changes in Stockholders' Deficit
For the Years Ended September 30, 2023 and 2022**

<i>Fiscal Year Ended September 30, 2023</i>	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at September 30, 2022	—	\$ —	1,252,734	\$ 1,252	\$ 50,878,718	\$ (55,072,773)	\$ (4,192,803)
Net loss	—	—	—	—	—	(6,982,836)	(6,982,836)
Issuance of common stock and warrants for cash, net	—	—	3,344,321	3,345	2,206,495	—	2,209,840
Issuance of common stock upon conversion of convertible notes	—	—	59,912	60	718,858	—	718,918
Issuance of common stock and warrants with convertible notes	—	—	20,210	20	440,297	—	440,317
Exchange of warrants into common stock	—	—	12,019	12	49,265	—	49,277
Stock-based compensation expense	—	—	250	—	249,555	—	249,555
Balance at September 30, 2023	—	\$ —	4,689,446	\$ 4,689	\$ 54,543,188	\$ (62,055,609)	\$ (7,507,732)

<i>Fiscal Year Ended</i> <u>September 30, 2022</u>	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at September 30, 2021	—	\$ —	1,186,901	\$ 1,186	\$ 48,770,059	\$ (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	—	\$ —	1,252,734	\$ 1,252	\$ 50,878,718	\$ (55,072,773)	\$ (4,192,803)

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

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Arch Therapeutics, Inc. and Subsidiary
Consolidated Statements of Cash Flows
For the Years Ended September 30, 2023 and 2022

	Fiscal Year Ended September 30, 2023	Fiscal Year Ended September 30, 2022
Cash flows from operating activities:		
Net loss	\$ (6,982,836)	\$ (5,275,854)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	1,966	3,196
Stock-based compensation	249,555	499,583
Change in fair value of derivative liability	(1,158,197)	(1,000,000)
Inventory obsolescence charge	—	248,073
Amortization of debt discount	2,310,860	302,049
Changes in operating assets and liabilities:		
(Increase) decrease in:		
Inventory	50,344	(569,156)
Prepaid expenses and other current assets	421,091	225,124
Increase (decrease) in:		
Accounts payable	976,207	846,869
Accrued interest	659,690	265,000
Accrued expenses and other liabilities	97,104	(959)
Net cash used in operating activities	<u>(3,374,216)</u>	<u>(4,456,075)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(4,521)	—
Net cash used in investing activities	<u>(4,521)</u>	<u>—</u>
Cash flows from financing activities:		
Repayment of insurance premium financing	(350,322)	(106,257)
Proceeds received from senior secured convertible notes, net of financing costs	—	3,042,633
Proceeds from unsecured convertible notes	995,000	—
Proceeds from issued common stock and warrants, net of financing costs	2,209,839	—
Net cash provided by financing activities	<u>2,854,517</u>	<u>2,936,376</u>
Net (decrease) increase in cash	(524,220)	(1,519,699)
Cash, beginning of year	746,940	2,266,639
Cash, end of year	<u>\$ 222,720</u>	<u>\$ 746,940</u>
Non-cash financing activities:		
Financing of insurance premium	\$ 347,550	\$ 354,190
Issuance of restricted stock	\$ —	\$ 8,959
Fair value of 2022 Warrants issued	\$ —	\$ 1,470,133
Fair value of 2022 Inducement Shares issued	\$ —	\$ 314,523
Relative fair value of common stock and warrants issued with notes payable	\$ 1,159,247	\$ —
Fair value of commons stock issued for warrants	\$ 49,277	\$ —
Exchange of Series 2 Convertible Notes into Senior Secured Notes (See Note 6)	\$ —	\$ 699,781
Issuance of restricted stock in consideration for services performed	\$ —	\$ 30,840
Fair Value of 2022 Placement Agent Warrants (see Note 6)	\$ —	\$ 219,894
Unpaid issuance costs in accounts payable	\$ 110,576	\$ 73,048

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

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Arch Therapeutics, Inc. and Subsidiary
Notes to the Consolidated Financial Statements
For the Years Ended September 30, 2023 and 2022

1. DESCRIPTION OF BUSINESS

Arch Therapeutics, Inc. (together with its subsidiary, the “Company” or “Arch”) is a biotechnology company developing and marketing a products based on our innovative AC5® self-assembling technology platform. Arch is the result of the merger (the “Merger”) of three entities on June 26, 2013, previously known as Arch Biosurgery, Inc., Almah, Inc., and Arch Acquisition Corporation, respectively.

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

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

Arch Acquisition Corporation, or Merger Sub, was a wholly owned subsidiary of Almah, Inc., formed for the purpose of the Merger transaction, pursuant to which Merger Sub merged with and into ABS, and ABS thereafter became the wholly owned subsidiary of the Company. The ticker symbol under which its Common Stock trades changed from “AACH” to “ARTH”, accordingly.

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

We believe these that our products can be important advances in the field of stasis and barrier applications, which includes managing wounds created during surgery, trauma or interventional care, or from disease; stopping bleeding (hemostasis); and controlling leaking (sealant). We have recently devoted a substantial part of our operational effort to the market adoption and commercial sales of AC5 Advanced Wound System, our first product. Our goal is to make care faster and safer for patients by providing 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.

[Table of Contents](#)Going Concern

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The Company has not yet generated sufficient revenues to fund operations and relies on issuance of debt and equity instruments to generate working capital. As reflected in the accompanying financial statements, for the year ended September 30, 2023, the Company recorded a net loss of \$6,982,836 and used cash in operations of \$3,374,216. These factors raise substantial doubt about the Company’s ability to continue as a going concern within one year of the date that the financial statements are issued. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

In evaluating the going concern position of the Company, management has considered potential funding providers and believes that financing to fund future operations could be provided by equity and/or debt financing. Even if the Company is able to obtain additional financing, it may contain undue restrictions on our operations, in the case of debt financing, or cause substantial dilution for our stockholders, in the case of equity financing.

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 1200, effective January 17, 2023 (the “Reverse Share Split”). All information included in these consolidated financial statements has been adjusted, on a retrospective basis, to reflect the Reverse Share Split, unless otherwise stated. All outstanding securities entitling their holders to purchase shares of Common Stock or acquire shares of Common Stock, including stock options, restricted stock units, and warrants, were adjusted as a result of the Reverse Stock Split, as required by the terms of those securities.

In accordance with the “Segment Reporting” Topic of the Accounting Standards Codification, the Company’s chief operating decision maker (the Company’s President and Chief Executive Officer) determined that the Company has only one reporting unit.

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. Significant estimates include the assumptions used in the accrual for potential liabilities, the net realizable value of inventory, the valuation of debt and equity instruments, the fair value of derivative liabilities, valuation of equity instruments issued for services, and deferred tax valuation allowances. Actual results could differ from those estimates.

[Table of Contents](#)Revenue recognition

In accordance with Financial Accounting Standard Board’s (“FASB”) Accounting Standards Codification (“ASC”) Topic 606, *Revenue from Contracts with Customers*, 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 upon shipment from the Company’s third-party warehouse which is when control of the product is transferred to the customers. In circumstances where the transaction price is not able to be determined at the time of shipment, the Company does not recognize revenue or any receivable amount until such time that the final transaction price is established and shipped

to customer.

Cost of Revenues

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

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, 2023 and 2022.

Inventories

Inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out (“FIFO”) basis. 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 Company records adjustments to its inventory for estimated obsolescence or diminution in net realizable value equal to the difference between the cost of the inventory and the estimated net realizable value. When evidence exists that the net realizable value of inventory is lower than its cost, the difference is recognized as a loss in the period in which it occurs. Once inventory has been written down, it creates a new cost basis for inventory that may not subsequently be written up. For the year ended September 30, 2023 there was no write-downs of inventories. For the year ended September 30, 2022, the Company recorded write-down of inventories of \$248,073.

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. For the years ended September 30, 2023 and 2022 there has not been any impairment of long-lived assets.

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Leases

The Company determines whether a contract is, or contains, a lease at inception. Operating lease right-of-use (“ROU”) assets and liabilities are recognized at lease commencement based on the present value of unpaid 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.

The Company leases its office facility on a month to month basis with a monthly lease of approximately \$,500. The terms of the lease provide break options allowing both landlord and tenant to terminate on provision of not less than one month’s prior written notice.

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.

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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.

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.

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.

Loss per Common Share

Basic earnings (loss) per share is computed by dividing the net income (loss) applicable to common stockholders by the weighted average number of shares of common stock outstanding during the year, excluding shares of unvested restricted common stock. Shares of restricted stock are included in the basic weighted average number of common shares outstanding from the time they vest. Diluted earnings (loss) per share is computed by dividing the net income applicable to common stockholders by the weighted average number of common shares outstanding plus the number of additional common shares that would have been outstanding if all dilutive potential common shares had been issued, using the treasury stock method. Shares of restricted stock are included in the diluted weighted average number of common shares outstanding from the date they are granted. Potential common shares are excluded from the computation when their effect is antidilutive.

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For the years ended September 30, 2023 and 2022, the calculations of basic and diluted loss per share are the same because potential dilutive securities would have had an anti-dilutive effect. The potentially dilutive securities consisted of the following:

	<u>September 30,</u> <u>2023</u>	<u>September 30,</u> <u>2022</u>
Stock Options	102,125	98,626
Stock Warrants	26,284,002	806,452
Convertible notes payable	738,763	652,202
Unvested restricted common stock	-	250
Total	<u>27,124,890</u>	<u>1,557,530</u>

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, 2023 and 2022, the carrying amounts of cash, accounts payables and accrued expense and other liabilities approximate fair value because of their short-term nature. The carrying amounts for the Company’s convertible notes (see Notes 6, 7, and 8) approximate fair value because borrowing rates and terms are similar to comparable market participants.

Financial Statement Reclassification

Certain balances in the prior year consolidated financial statements have been reclassified for comparison purposes to conform to the presentation in the current period consolidated financial statements. During the year ended September 30, 2023, the Company reclassified the carrying amount of Exchange Notes of \$699,781 (see Notes 7 and 8) that were previously included in the Convertible Notes Payable, Senior Secured to Convertible notes payable, unsecured.

Recent Accounting Pronouncements

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt — Modifications and Extinguishments (Subtopic 470-50), Compensation — Stock Compensation (Topic 718), and Derivatives and Hedging — Contracts in Entity’s Own Equity (Subtopic 815-40): Issuer’s Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options (“ASU 2021-04”). ASU 2021-04 provides guidance as to how an issuer should account for a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option (i.e., a warrant) that remains classified after modification or exchange as an exchange of the original instrument for a new instrument. An issuer should measure the effect of a modification or exchange as the difference between the fair value of the modified or exchanged warrant and the fair value of that warrant immediately before modification or exchange and then apply a recognition model that comprises four categories of transactions and the corresponding accounting treatment for each category (equity issuance, debt origination, debt modification, and modifications unrelated to equity issuance

and debt origination or modification). ASU 2021-04 is effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply the guidance provided in ASU 2021-04 prospectively to modifications or exchanges occurring on or after the effective date. The Company adopted ASU 2021-04 effective October 1, 2022. The adoption of ASU 2021-04 did not have any impact on the Company's consolidated financial statement presentation or disclosures.

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Other recent accounting pronouncements and guidance issued by the FASB, its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the Securities and Exchange Commission did not or are not believed by management to have a material impact on the Company's present or future financial statements.

3. INVENTORIES

Inventories consist of the following:

	September 30, 2023	September 30, 2022
Finished Goods	\$ 40,969	\$ 9,063
Goods-in-process	1,323,535	1,405,785
Total	<u>\$ 1,364,504</u>	<u>\$ 1,414,848</u>

4. INSURANCE PREMIUM FINANCING

During July 2023 and 2022, the Company entered into a financing agreement with First Insurance Funding to fund a portion of its insurance policies. As part of the agreement, First Insurance Funding agreed to finance the insurance policies of the Company of approximately \$395,000 and \$354,000, respectively and with an average interest rate per annum of 8.7% and 2.99%, respectively. The Company is required to make monthly payments of approximately \$35,000 through April 2024.

The outstanding balance as of September 30, 2023 and 2022 was \$243,285 and \$247,933, respectively.

5. DERIVATIVE LIABILITIES

In June 2018 and May 2019, the Company issued its Series F Warrants, Series G Warrants, and Series H Warrants. Pursuant to the terms of the respective warrant agreements, the Company was required to purchase its Series F Warrants, Series G Warrants and Series H Warrants for an amount of cash equal to \$ 36.00, \$22.00 and \$10.66, respectively, (the "Minimum Value"). As a result, the Company accounted for the Series F Warrants, Series G Warrants and the Series H Warrants in accordance with ASC 815-10 and were recorded as liabilities at the greater of the Minimum Value or fair value. These warrants were marked to fair value each reporting period using the Black Scholes Model and the corresponding change in the fair value of the warrants were reported in the Consolidated Statement of Operations.

As of September 30, 2021, the estimated fair value of the derivative liabilities was \$2,207,475. During the year ended September 30, 2022, certain Series F and Series H warrants expired unexercised. As a result, the Company recognized a gain of \$1,000,000 to account the expiration of the corresponding derivative liability. As of September 30, 2022, the estimated fair value of the derivative liabilities was \$1,207,475.

On March 10, 2023, the Company entered into exchange agreements with the holders of the Series G Warrants and the Series H Warrants. Pursuant to the exchange agreements, the warrant holders exchanged 34,013 Series G Warrants for 3,402 shares of Common Stock and 43,077 Series H Warrants for 8,617 shares of Common Stock. As a result, the Company recorded \$49,277 to account the fair value of the common stock issued and recorded a change in fair value of \$1,158,197 to account for extinguishment of the corresponding derivative liability. As of September 30, 2023, there are no instruments accounted as derivative liability.

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Fair Value Measurements Using Significant Unobservable Inputs - Year Ended September 30, 2023

(Level 3)

	Series G	Series H	Total
Beginning balance at September 30, 2022	\$ 748,275	\$ 459,200	\$ 1,207,475
Exchange of warrants into common stock	(13,947)	(35,330)	(49,277)
Extinguishment of derivative liabilities	(734,328)	(423,870)	(1,158,197)
Ending balance at September 30, 2023	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

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
Expiration of derivative liability	(1,000,000)	—	—
Ending balance at September 30, 2022	<u>\$ —</u>	<u>\$ 748,275</u>	<u>\$ 459,200</u>

As of March 10, 2023 and September 30, 2022, the derivative liabilities were valued at the greater of their minimum value or by using the Black Scholes option pricing model with the following assumptions:

	Series G		Series H	
	March 10, 2023	Series G	September 30, 2022	Series H
Date of valuation				
Closing price per share of Common Stock	\$ 4.10	\$ 4.10	\$ 3.84	\$ 3.84
Exercise price per share	\$ 140.00	\$ 80.00	\$ 140.00	\$ 80.00
Expected volatility	179.41%	141.03%	132.97%	122.50%
Risk-free interest rate	4.91%	4.75%	4.05%	4.14%
Dividend yield	—	—	—	—
Remaining expected term of underlying securities (years)	0.24	1.31	0.69	1.57

6. CONVERTIBLE NOTES PAYABLE, SENIOR SECURED

	September 30, 2023	September 30, 2022
Senior Secured Convertible Promissory Notes (the “2022 Notes”, includes \$6,000 of related party notes)	\$ 4,230,000	\$ 4,230,000
Unamortized debt discount	(710,897)	(2,567,508)
Net Balance	3,519,103	1,662,492
Current Balance	(3,519,103)	-
Non-Current Balance	-	1,662,492

In July 2022, the Company entered into a Securities Purchase Agreement (the “SPA”) with certain institutional and accredited individual investors and issued Senior Secured Convertible Promissory Notes (the “2022 Notes”) in the aggregate of \$4,230,000 in exchange for cash proceeds of \$3,525,000, net of original issue discount (OID) of \$705,000.

The 2022 Notes are secured by tangible and intangible assets of the Company, bears interest at a rate of 10% per annum payable at maturity or upon conversion, originally matured January 6, 2024 (which was subsequently extended to March 15, 2024), and are convertible into shares of the Company’s common stock at a conversion price of \$9.14 per share. The 2022 Notes contain customary events of default. Further, events of default under the 2022 Notes also include (i) the unavailability of Rule 144 on or after January 6, 2023; (ii) our failure to deliver the shares of common stock to the 2022 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 March 15, 2024 (the “Uplist Transaction”). During the year ended September 2023, for no additional consideration, the 2022 Notes were amended several times in order to allow the Company to issue additional notes payable, extend the completion date for the Uplist Transaction, and amend certain provisions with regards to mandatory conversion of the notes upon the Uplist Transaction.

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In connection with the issuance of the 2022 Notes, the Company granted the 2022 Notes noteholders 425,562 warrants to purchase shares of common stock. The warrants are fully vested, exercisable at \$9.94 per share and expire in 5 years. The Company estimated the relative fair value of the warrants to be \$1,470,000 using the Black Scholes option pricing model. The Company also issued note holders 63,842 shares of the Company’s common stock with a relative fair value of \$15,000. The Company also issued 31,510 warrants to purchase shares of common stock to the placement agent that assisted in the 2022 Notes offering. The placement agent warrants are fully vested, exercisable at \$10.06 per share and will expire in 5 years. The Company estimated the relative fair value of the placement agent warrants to be \$219,894 using the Black Scholes option pricing model. The Company incurred direct legal and professional fees of \$555,414 as part of this offering.

The Company recorded 2022 Notes with total principal of \$4,230,000. In addition, total debt discount of \$2,870,000 was recorded to account for the 2022 Notes OID of \$705,000, the relative fair value of the warrants of \$1,470,000, the relative fair value of common stock issued of \$15,000, and direct legal and professional fees incurred in the 2022 Notes offering of \$555,414. The debt discount is being amortized over the term of the notes using the effective interest rate method. During the year ended September 30, 2022, the Company amortized debt discount of \$302,000.

As of September 30, 2022, outstanding balance of the 2022 Notes payable was \$4,230,000 and unamortized debt discount was \$2,567,508, or a net balance of \$1,662,492. During the year ended September 2023, the Company amortized debt discount of \$1,857,000. As of September 30, 2023, outstanding balance of the 2022 Notes payable amounted to \$4,230,000 and unamortized debt discount was \$710,897, or a net balance of \$3,519,103. As of September 30, 2023 and 2022, notes payable in the aggregate of \$96,000, respectively, are issued to two officers and a member of the Board of Directors of the Company.

7. CONVERTIBLE NOTES PAYABLE, UNSECURED

	September 30, 2023	September 30, 2022
Exchanged notes (July 2022)	\$ 699,781	\$ 699,781
Second closing notes (January 2023)	636,000	-
Third closing notes (March, April, May, 2023)	702,720	-
Total	2,038,501	\$ 699,781
Unamortized debt discount	(379,799)	-
Net Balance	1,658,702	699,781
Current Balance	(1,658,702)	-
Non-Current Balance	-	699,781

Exchanged Notes (July 2022)

In relation to the issuance of the 2022 Notes (see Note 6), certain noteholders of the Company’s Series 2 note payable (see Note 8) agreed to exchange their Series 2 notes payable consisting of \$600,000 principal and accrued interest of \$99,781 for \$699,781 of Unsecured Convertible Promissory Notes (the “Exchanged Notes”) on substantially the same terms as the 2022 Notes, except that the Exchanged Notes are subordinate to the 2022 Notes and are unsecured. The notes bear interest at a rate of 10% per annum payable at maturity or upon conversion, originally matured January 6, 2024 (which was subsequently extended to March 15, 2024), and are convertible into shares of the Company’s common stock at a conversion price of \$9.14 per share. At September 30, 2022, there was no discount recorded for the Exchanged Notes.

Second Closing Notes (January 2023)

In January 2023, pursuant to the SPA (see Note 6), as amended, investors agreed to purchase Unsecured Convertible Promissory Notes (the “Second Closing Notes”) in the aggregate of \$636,000 in exchange for cash proceeds of \$530,000, net of original issue discount (OID) of \$106,000. The notes are unsecured, bear interest at a rate of 10% per annum, originally matured January 6, 2024 (which was subsequently extended to March 15, 2024), and are convertible into shares of the Company’s common stock with a conversion price of \$9.14 per share.

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In connection with the issuance of the Second Closing Notes, the Company granted the Second Closing Notes noteholders (i) 127,968 warrants to purchase shares of common stock. The warrants are fully vested, exercisable at \$9.94 per share and expire in 5 years. The Company determined the relative fair value of the warrants to be \$256,000 using the Black Scholes option pricing model; and (ii) 9,598 shares of common stock with a relative fair value of \$6,000. The Company also issued 6,565 warrants to purchase shares of the Company’s common stock to the placement agent who assisted in the Second Closing offering. The placement agent warrants are fully vested, exercisable at \$10.06 per share and will expire in 5 years. The Company determined the relative fair value of the placement agent warrants to be \$3,000 using the Black Scholes option pricing model. Furthermore, the Company also incurred direct legal and professional fees of \$31,000 as part of this offering.

Third Closing Notes (March, April and May 2023)

In March, April and May 2023, pursuant to the SPA, as amended, investors agreed to purchase Unsecured Convertible Promissory Notes (the “Third Closing Notes”) in the aggregate of \$703,000 in exchange for cash proceeds of \$488,000, net of original issue discount (OID) of \$215,000. The notes are unsecured, bear interest at a rate of 10% per

annum, originally matured January 6, 2024 (which was subsequently extended to March 15, 2024), and are convertible into shares of the Company's common stock with a conversion price of \$9.14 per share.

In connection with the issuance of the Third Closing Notes, the Company granted the Third Closing Notes noteholders (i) 141,396 warrants to purchase shares of common stock. The warrants are fully vested, exercisable at \$9.94 per share and expire in 5 years. The Company determined the relative fair value of the warrants to be \$164,000 using the Black Scholes option pricing model; and (ii) 10,608 shares of common stock with a relative fair value of \$18,000. The Company also incurred direct legal and professional fees of \$5,000 as part of this offering.

The Second Closing Notes and Third Closing Notes contain events of default similar to the 2022 Notes (See Note 6). Subsequent to issuance, for no additional consideration, the Second Closing Notes and Third Closing Notes were amended several times in order to allow the Company to issue additional notes payable, extend the completion date of the Uplist Transaction, and amend certain provisions with regards mandatory conversion of the notes upon the Uplist Transaction.

Debt discount on unsecured convertible promissory notes

As a result of the issuance of the Second Closing and the Third Closing Notes, the Company recorded debt discount in the aggregate of \$34,000 to account for the Second Closing and the Third Closing Notes OID of \$321,000, the relative fair value of the warrants issued of \$433,000, the relative fair value of common stock issued of \$44,000, and direct legal and professional fees incurred of \$36,000. The debt discount is being amortized over the term of the notes using the effective interest rate method.

During the year ended September 30, 2023, the Company amortized debt discount of \$454,000. As of September 30, 2023, outstanding balance of the Exchange notes, Second Closing Notes, and Third Closing Notes was \$2,039,000 and unamortized debt discount of \$380,000, or a net balance of \$1,659,000.

The warrants issued with the 2022 Notes, the Second Closing Notes, and the Third Closing Notes were valued using the Black Scholes option pricing model with the following assumptions:

	First closing		Second Closing		Third Closing
	Note holders	Placement Agent	Note holders	Placement Agent	Note holders
Date of valuation	July 6, 2022		January 18, 2023		May 15, 2023
Closing price per share of Common Stock	\$ 9.98	\$ 9.98	\$ 5.76	\$ 5.76	\$ 2.77
Exercise price per share	\$ 9.94	\$ 10.06	\$ 9.94	\$ 10.06	\$ 9.94
Expected volatility	88.44%	88.44%	111.31%	111.31%	114.33%
Risk-free interest rate	2.96%	2.96%	3.43%	3.43%	3.46%
Dividend yield	—	—	—	—	—
Remaining expected term of underlying securities (years)	5.0	5.0	5.0	5.0	5.0

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8. CONVERTIBLE NOTES PAYABLE, SERIES 1 AND 2

	2023	2022
Series 1 Convertible Notes (converted in July 2023)	\$ -	\$ 550,000
Series 2 Convertible Notes (converted in November 2023)	450,000	450,000
Total	450,000	1,000,000
Current Balance	(450,000)	(550,000)
Non-Current Balance	\$ -	\$ 450,000

Series 1 Convertible Notes

On June 4, 2020, the Company issued unsecured 10% Series 1 Convertible Notes in the aggregate principal amount of \$550,000. The maturity dates of the Series 1 Notes was June 30, 2023, and all were converted in July 2023.

The Series 1 Convertible Notes provide, among other things:

- (i) interest at a rate of 10% per annum;
- (ii) term of approximately three years;
- (iii) allow for the Company's ability to prepay the Series Convertible Notes, in whole or in part, at any time;
- (iv) allow the automatic conversion of the Series 1 Convertible Notes upon a change of control into shares of the Company's common stock, at a conversion price of \$54.00 per share;
- (v) allow the holders to convert the principal of the Series 1 Convertible Notes, along with accrued interest, in whole or in part, into shares of common stock at the conversion price of \$54.00 per share;
- (vi) allow for the Company's ability to convert all note obligations outstanding upon a qualified equity financing into shares of common stock at the corresponding price per share of the qualified equity financing;
- (vii) the Company's ability to convert the principal of the Series 1 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;
- (viii) 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, subject to a conversion multiplier of 4.5, as amended.

As of September 30, 2022, outstanding balance of the Series 1 Convertible Notes amounted to \$550,000.

During the year ended September 30, 2023, pursuant to the terms of the convertible notes agreement, the Company issued 59,912 shares of common stock to convert the outstanding notes payable of \$550,000 and accrued interest of \$168,918 for a total of \$718,918. There are no Series 1 convertible notes payable outstanding as of September 30, 2023.

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Series 2 Convertible Notes

On November 6, 2020, the Company issued its unsecured Series 2 10% Convertible Notes Payable in exchange for cash proceeds of \$1,050,000. The Series 2 Convertible Notes have similar terms and provisions with the Series 1 Convertible Notes (see above), except the maturity dates of the Series 2 Notes was November 30, 2023, and the notes were all converted in November 2023.

As of September 30, 2021, outstanding balance of the Series 2 Convertible Notes amounted to \$1,050,000. During the year ended September 30, 2022, as a part of a separate 2022 Convertible Note Offering (see Note 6), certain holders of the Series 2 Notes agreed to exchange their Series 2 Notes with an aggregate principal amount of \$600,000 and accrued interest of approximately \$100,000 for promissory notes of the Company on substantially similar terms to those of the 2022 Notes (the "Exchange Notes", see Note 7).

As of September 30, 2023 and 2022, outstanding balance of the Series 2 Convertible Notes amounted to \$450,000 and \$1,000,000, respectively.

9. INCOME TAXES

The principal components of the Company's net deferred tax assets consisted of the following at September 30:

	2023	2022
Net operating loss & charitable contribution carryforwards	\$ 12,905,738	\$ 11,485,524
Capitalized expenditures	1,396,415	1,535,736
Research and experimentation credit carryforwards	1,014,466	946,246
Stock based compensation	1,491,338	1,427,946
Property and Equipment	1,531	2,616
Accrued expenses	746,143	162,191
Inventory allowance	51,463	70,805
Gross deferred tax assets	17,607,094	15,631,061
Deferred tax asset valuation allowance	(17,607,094)	(15,631,061)
Net deferred tax assets	\$ -	\$ -

The provision (benefit) for income taxes differs from the tax computed with the statutory federal income tax rate as follows:

	2023	2022
Expected income tax (benefit) at federal statutory rate	21.00%	21.00%
Increase due to:		
State income taxes – net of federal benefit	0.24%	3.65%
Permanent Differences:		
Stock based compensation	-%	(18.10)%
R&D, taken as a credit	(0.16)%	(0.23)%
Adjustment to fair value of derivative	3.48%	3.98%
Other	-%	(1.14)%
Change in Valuation Allowance	(24.56)%	(9.16)%
Total Income Tax Provision (Benefit)	-%	-%

As of September 30, 2023 and 2022, the Company had federal net operating loss carryforwards totaling approximately \$48,200,000 and \$42,700,000, 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, 2023 and 2022, the Company has federal net operating loss carryforwards with an indefinite life of \$26,444,000 and \$20,945,000. As of September 30, 2023 and 2022, the Company had federal research and experimentation credit carryforwards of \$679,000 and \$626,000, respectively, which may be available to offset future income tax liabilities and which would begin to expire in 2028.

As of September 30, 2023 and 2022, the Company had state net operating loss carryforwards of approximately \$44,570,000 and \$40,367,000, respectively, which may be available to offset future taxable income and which would begin to expire in 2030. As of September 30, 2023 and 2022, the Company had state research and experimentation credit carryforwards of \$425,000 and \$406,000, respectively, which may be able to offset future income tax liabilities and which begin to expire in 2023.

As the Company has not yet achieved profitable operations, management believes the tax benefits as of September 30, 2023 and 2022 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 2023 by approximately \$1,976,000 and increased in 2022 by approximately \$483,000. The Company's effective income tax rate differed from the federal statutory rate due to state taxes and the Company's full valuation allowance, 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, 2023, the Company is open to examination in the U.S. federal and certain state jurisdictions for tax years ended September 30, 2023, 2022, 2021 and 2020. In addition, any loss years remain open to the extent that losses are available for carryover to future years. Therefore, the tax years ended 2010 through 2021 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, 2023 and continues to evaluate the impact of the CARES act on the business.

10. STOCKHOLDERS DEFICIT**Common Stock**

During the year ended September 30, 2023, the Company issued 3,436,712 shares of Common Stock, par value \$0.001, as follows: (i) 250 shares issued in connection with the vesting of a restricted stock grant; (ii) 3,344,321 shares issued in connection with certain financing activities involving the sale of Common Stock and warrants to certain accredited investors in exchange for the net cash proceeds of \$2,209,839 (the "Bridge Offering"); (iii) 20,210 inducement shares issued in connection with the closing of the Second Notes and Third Notes; (iv) 12,019 shares issued in connection with the exchange of Series G and Series H warrants for Common Stock; and (v) 9,912 shares issued in connection with the conversion of the Company's outstanding Series 1 Notes into Common stock.

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[Common Stock Options](#)

Common Stock Options activity under the 2013 Plan for the year ended September 30, 2023 and 2022 follows:

	Option Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at September 30, 2021	124,495	\$ 58.00	1.86	\$ 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
Awarded	24,500	\$ 8.00		
Forfeited/Cancelled	(21,001)	\$ 68.00		
Outstanding at September 30, 2023	102,125	\$ 38.00	3.9	\$ —
Vested at September 30, 2023	82,940	\$ 44.00	4.89	\$ —
Vested and expected to vest at September 30, 2023	102,125	\$ 38.00	3.9	\$ —

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. The stock options issued to employees and directors vest over a period of 36 months, and options issued to consultants vest over a period of 12 months. The weighted average exercise price for all options was \$10.02. Options issued to employees and consultants expire in 5 years. Options issued to management and directors expire after 10 years. Total fair value of the stock options issued was \$47,609 using the Black-Scholes Option Pricing Model. The following assumptions were used to calculate the fair value - expected volatility, 86.8% - 98.5%, risk-free interest rate, 1.5% - 3.5%, expected dividend yield, 0%, expected term, 3.6 - 5.8 years.

During the year ended September 30, 2023, the Company granted 20,875 options to employees and directors and 3,625 options to consultants to purchase shares of common stock under the 2013 Plan. The stock options issued to employees vest over a period of 36 months, and options issued to consultants and directors vest over a period of 12 months. The exercise price for all options granted was \$8.02. Options issued to employees and consultants expire in 5 years. Options issued to management and directors expire after 10 years. Total fair value of the stock options issued \$156,275 using the Black-Scholes Option Pricing Model. The following assumptions were used to calculate the fair value - expected volatility, 102.8% - 103.4%, risk-free interest rate, 3.8% - 4.0%, expected dividend yield, 0%, expected term, 4.1 - 5.8 years.

Pursuant to the vesting terms of the stock options, Share-based compensation expense recorded in the Company's Consolidated Statements of Operations for the year ended September 30, 2023 and 2022 resulting from stock options awarded to the Company's employees, directors and consultants was approximately \$246,000 and \$459,000, respectively. Of this amount during the years ended September 30, 2023 and 2022, \$57,000 and \$148,000, respectively, were recorded as research and development expenses, and \$189,000 and \$311,000, respectively were recorded as general and administrative expenses in the Company's Consolidated Statements of Operations.

As of September 30, 2023, there is approximately \$162,000 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 1.80 years. As of September 30, 2023, 0 shares are available for future grants under the 2013 Plan as the plan is now expired.

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[Common Stock Warrants](#)

Common Stock Warrants activity for the year ended September 30, 2023 and 2022 follows:

	Warrants Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at September 30, 2021	349,380	\$ 53.28	1.8	\$ -
Awarded	457,072	\$ 9.95	3.8	-
Forfeited/Cancelled	-	\$ -	-	-
Outstanding at September 30, 2022	806,452	\$ 28.72	2.9	\$ -
Awarded	25,572,245	\$ 0.85	4.8	13,958,846
Exchanged	(77,090)	\$ 106.47	-	-
Forfeited/Cancelled	(17,605)	\$ 50.20	-	-
Outstanding at September 30, 2023	26,284,002	\$ 0.85	4.8	\$ 13,958,846
Vested at September 30, 2023	26,284,002	\$ -	-	\$ -
Vested and expected to vest at September 30, 2023	26,284,002	\$ -	-	\$ -

[Restricted Stock](#)

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 vested in three separate tranches on January 12, 2022, July 12, 2022 and January 12, 2023.

Restricted stock activity in shares under the 2013 Plan for the years ended September 30, 2023 and 2022 follows:

	2023	2022
Non Vested at September 30, 2022 and 2021	250	2,250
Awarded	—	—
Vested	(250)	(2,000)
Forfeited	—	—
Non Vested at September 30, 2023 and 2022	—	250

The weighted average restricted stock award date fair value information for the years ended September 30, 2023 and 2022 follows:

	2023	2022
Non Vested at September 30, 2022 and 2021	\$ 18.00	\$ 19.76
Awarded	—	—
Vested	(18.00)	(19.90)
Forfeited	—	—
Non Vested at September 30, 2023 and 2022	\$ —	\$ 18.00

For the years ended September 30, 2023 and 2022 compensation expense recorded for the restricted stock awards was approximately \$,000 and \$40,000, respectively. As of September 30, 2023, there is no unrecognized compensation expense related to unvested stock-based compensation arrangements granted under the 2013 Plan.

11. 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, 2023 and 2022, no amounts have been accrued related to such indemnification provisions.

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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, 2023 and 2022. For the years ended September 30, 2023 and 2022, 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, 2023.

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 US 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.

12. SUBSEQUENT EVENTS

In October and November 2023, the Company received shareholder advances in the aggregate of \$450,000 to support the operations of the Company.

On November 8, 2023, the Company entered into a Securities Purchase Agreement (the "PIPE SPA") with certain institutional and accredited individual investors (collectively, the "Investors") providing for the issuance and sale by the Company to the Investors of (i) pre-funded warrants (the "PIPE Pre-Funded Warrants") and (ii) warrants (the "PIPE Common Warrants" and together with the PIPE Pre-Funded Warrants, the "PIPE Warrants"). The PIPE Warrants will be issued as part of a private placement offering authorized by the Company's Board of Directors (the "PIPE Offering"). The estimated aggregate gross proceeds for the sale of the PIPE Warrants will be approximately \$7.1 million, before deducting the placement agent's fees and other estimated fees and offering expenses payable by the Company. The closing of the PIPE Offering is contingent upon, among other conditions, a registration statement that registers the PIPE Warrant shares for resale being declared effective by the SEC, and the approval of the listing of the Common Stock on Nasdaq. The closing is expected to occur immediately prior to the pricing of the Uplist Transaction.

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In November 2023, certain provisions of the Company's Convertible Notes Payable, Senior Secured (See Note 6) and Exchange Notes (see Note 7) were amended to extend the date of the completion of an Uplist Transaction to March 15, 2024. In addition, upon effectivity of the Uplist Transaction, 50% of the then outstanding principal amount of the Convertible Notes Payable, Senior Secured and Exchange Notes shall automatically convert (the "Automatic Conversion") into shares of Common Stock, with the conversion price for purposes of such Automatic Conversion of \$4.00. Upon the Automatic Conversion and to the extent that the beneficial ownership of a holder of Convertible Notes Payable, Senior Secured and Convertible Notes Payable, Unsecured would increase over the applicable Ownership Limitation, the Holder will receive pre-funded warrants in lieu of shares of Common Stock otherwise issuable to the Holder in connection with the Automatic Conversion, which may be exercised on a cashless basis, shall be exercisable immediately upon issuance and shall contain a customary beneficial ownership limitation provision. In addition, upon the Automatic Conversion, the Holder shall receive a warrant (the "Uplist Conversion Warrant") to purchase a number of shares of Common Stock equal to 6.3812 times the dollar amount under the Convertible Notes Payable, Senior Secured and Convertible Notes Payable, Unsecured that was converted in the Automatic Conversion. The Uplist Conversion Warrant shall have an exercise price per share of \$4.00 and shall otherwise be identical to the PIPE Common Warrant.

In November 2023, the Company amended the Second A&R Registration Rights Agreement to that certain Second Amended and Restated Registration Rights Agreement, dated as of May 15, 2023 to (I) extend the filing deadline by which the Company is obligated to file with the SEC a registration statement under the Securities Act of 1933, as

amended, registering certain securities issued in the 2022 Convertible Note Offering to the earlier of (i) the date that is 30 days following the Uplist Transaction and (ii) January 31, 2024 (such date was subsequently extended to March 15, 2024), and (II) to provide for the inclusion of the Registerable Securities (as defined therein) in the Uplist S-1 (as defined therein).

In November 2023, the Company also entered into an amendment to the Bridge SPA, with certain institutional and accredited individual investors that participated in the Bridge Offering. Under amendment, upon the closing of the next underwritten public offering of Common Stock (the "Qualifying Offering"), which the Company agreed is the Uplist Transaction, if the effective offering price to the public per share of Common Stock (the "Qualifying Offering Price") is lower than \$4.00 per share, then the Company shall issue additional Bridge Pre-Funded Warrants, or shares of Common Stock in lieu thereof to the extent necessary to cause the Company to meet the listing requirements of the Company's proposed trading market in the Uplist Transaction, in an amount reflecting a reduction in the purchase price paid for the Bridge Shares and Bridge Pre-Funded Warrants that equals the proportion by which the Qualifying Offering Price is less than \$4.00.

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Arch Therapeutics, Inc. and Subsidiary

Condensed Consolidated Balance Sheets

As of March 31, 2024 (Unaudited) and September 30, 2023

	March 31, 2024	September 30, 2023
	(unaudited)	
ASSETS		
Current assets:		
Cash	\$ 26,426	\$ 222,720
Inventory	1,329,593	1,364,504
Prepaid expenses and other current assets	177,158	362,866
Total current assets	<u>1,533,177</u>	<u>1,950,090</u>
Long-term assets:		
Property and equipment, net	3,390	4,599
Other assets	3,500	3,500
Total long-term assets	<u>6,890</u>	<u>8,099</u>
Total assets	<u>\$ 1,540,067</u>	<u>\$ 1,958,189</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 2,969,520	\$ 2,304,207
Accrued interest	1,026,963	823,128
Shareholders advances related to bridge financing	1,125,000	-
Accrued expenses and other liabilities	363,092	467,496
Insurance premium financing	34,755	243,285
Convertible notes payable, senior secured, current portion, net of discount	4,211,720	3,519,103
Convertible notes payable, unsecured, current portion, net of discount	2,686,501	1,658,702
Convertible notes payable, Series 2, unsecured, current portion	-	450,000
Total current liabilities	<u>12,417,551</u>	<u>9,465,921</u>
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized, none issued and outstanding as of March 31, 2024 and September 30, 2023	-	-
Common stock, \$0.001 par value, 350,000,000 authorized as of March 31, 2024 and September 30, 2023; 4,444,364 and 4,689,446 shares issued and outstanding as of March 31, 2024 and September 30, 2023	4,444	4,689
Additional paid-in capital	55,324,472	54,543,188
Accumulated deficit	(66,206,400)	(62,055,609)
Total stockholders' deficit	<u>(10,877,484)</u>	<u>(7,507,732)</u>
Total liabilities and stockholders' deficit	<u>\$ 1,540,067</u>	<u>\$ 1,958,189</u>

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

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Arch Therapeutics, Inc. and Subsidiary

Condensed Consolidated Statements of Operations (Unaudited)

For the Three and Six Months Ended March 31, 2024 and 2023

	For the three months ended		For the six months ended	
	March 31, 2024	March 31, 2023	March 31, 2024	March 31, 2023
Revenue	\$ 31,866	\$ 16,654	\$ 77,733	\$ 22,914
Operating expenses:				
Cost of revenues	21,555	18,718	45,161	36,353
Selling, general and administrative expenses	683,184	1,252,786	1,994,534	2,355,701
Research and development expenses	203,869	170,634	409,449	332,087
	908,608	1,442,138	2,449,144	2,724,141
Total operating expenses	<u>(876,742)</u>	<u>(1,425,484)</u>	<u>(2,371,411)</u>	<u>(2,701,227)</u>
Loss from operations	<u>(844,876)</u>	<u>(1,408,830)</u>	<u>(2,293,678)</u>	<u>(2,678,313)</u>
Other (expense) income:				
Interest expense	(592,397)	(635,190)	(1,779,380)	(1,159,503)
Gain on extinguishment of derivative liabilities	-	1,158,197	-	1,158,197
Total other (expense) income, net	<u>(592,397)</u>	<u>523,007</u>	<u>(1,779,380)</u>	<u>(1,306)</u>
Net loss	<u>\$ (1,469,139)</u>	<u>\$ (902,477)</u>	<u>\$ (4,150,791)</u>	<u>\$ (2,702,533)</u>

Net loss per common share - basic and diluted	\$ (0.33)	\$ (0.71)	\$ (0.90)	\$ (2.15)
Weighted common shares - basic and diluted	4,497,111	1,263,585	4,602,623	1,258,099

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

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Arch Therapeutics, Inc. and Subsidiary

Condensed Consolidated Statements of Changes in Stockholders' Deficit (Unaudited)
For the Three and Six Months Ended March 31, 2024 and 2023

	Preferred Stock Shares	Amount	Common Stock Shares	Amount	Additional Paid- in Capital	Accumulated Deficit	Total Stockholders' Deficit
Balance at September 30, 2023	-	\$ -	4,689,446	\$ 4,689	\$ 54,543,188	\$ (62,055,609)	\$ (7,507,732)
Net loss	-	-	-	-	-	(2,681,652)	(2,681,652)
Issuance of common stock upon conversion of convertible notes	-	-	52,918	53	587,906	-	587,959
Stock-based compensation expense	-	-	-	-	25,909	-	25,909
Balance at December 31, 2023	-	-	4,742,364	4,742	55,157,003	(64,737,261)	(9,575,516)
Net loss	-	-	-	-	-	(1,469,139)	(1,469,139)
Issuance of common stock upon conversion of convertible notes	-	-	2,000	2	18,278	-	18,280
Issuance of warrants, net of financing costs	-	-	-	-	148,891	-	148,891
Exchange of common stock into warrants	-	-	(300,000)	(300)	300	-	-
Balance at March 31, 2024	-	\$ -	4,444,364	\$ 4,444	\$ 55,324,472	\$ (66,206,400)	\$ (10,877,484)
Balance at September 30, 2022	-	\$ -	1,252,734	\$ 1,252	\$ 50,878,718	\$ (55,072,773)	\$ (4,192,803)
Net loss	-	-	-	-	-	(1,800,056)	(1,800,056)
Stock-based compensation expense	-	-	-	-	104,026	-	104,026
Balance at December 31, 2022	-	-	1,252,734	1,252	50,982,744	(56,872,829)	(5,888,833)
Net loss	-	-	-	-	-	(902,477)	(902,477)
Vesting of restricted stock	-	-	250	-	-	-	-
Issuance of common stock and warrants, net of financing costs	-	-	9,598	10	287,410	-	287,420
Exchange of warrants into common stock	-	-	12,019	13	49,265	-	49,278
Stock-based compensation expense	-	-	-	-	68,524	-	68,524
Balance at March 31, 2023	-	\$ -	1,274,601	\$ 1,275	\$ 51,387,943	\$ (57,775,306)	\$ (6,386,088)

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

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Arch Therapeutics, Inc. and Subsidiary

Condensed Consolidated Statements of Cash Flows (Unaudited)
For the Six Months Ended March 31, 2024 and 2023

	For the Six Months Ended	
	March 31, 2024	March 31, 2023
Cash flows from operating activities:		
Net loss	\$ (4,150,791)	\$ (2,702,533)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	1,209	1,043
Stock-based compensation	25,909	172,550
Gain on extinguishment of derivative liabilities	-	(1,158,197)
Accretion of discount and debt issuance costs on convertible notes payable	1,437,588	846,147
Changes in operating asset and liabilities:		
Inventory	34,911	12,464
Prepaid expenses and other current assets	185,707	280,058
Accounts payable	665,314	1,097,894
Accrued interest	341,793	313,356
Accrued expenses and other liabilities	(104,404)	(112,713)
Net cash used in operating activities	(1,562,764)	(1,249,931)
Cash flows from financing activities:		
Repayment of insurance premium financing	(208,530)	(212,514)
Shareholder advances related to bridge financing	1,125,000	230,000
Proceeds from unsecured convertible notes	450,000	515,000
Net cash provided by financing activities	1,366,470	532,486
Net decrease in cash	(196,294)	(717,445)
Cash, beginning of period	222,720	746,940
Cash, end of period	\$ 26,426	\$ 29,495

Non-cash financing activities:

Exchange of Senior Secured and Series 2 Convertible notes and accrued interest into common stock	\$ 606,239	\$ -
Relative fair value of warrants issued – fourth close	\$ 148,891	\$ -
Conversion of convertible notes and accrued interest to common stock, net	\$ 606,239	\$ -
Exchange of Series G and Series H warrants for common stock	\$ -	\$ 49,278
Issuance of restricted stock	\$ -	\$ 3,019
Fair value of warrants issued - second close	\$ -	\$ 256,439
Fair value of inducement shares issued - second close	\$ -	\$ 25,840
Fair value of placement agent warrants - second close	\$ -	\$ 28,093

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

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ARCH THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
THREE AND SIX-MONTHS ENDED MARCH 31, 2024 AND 2023
(Unaudited)

I. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Arch Therapeutics, Inc. (together with its subsidiary, the “Company” or “Arch”) is a biotechnology company developing and marketing products based on our innovative AC5® self-assembling technology platform. The Company’s products are in the field of stasis and barrier applications, which includes managing wounds created during surgery, trauma or interventional care, or from disease; stopping bleeding (hemostasis); and controlling leaking (sealant).

Basis of presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) and the applicable rules and regulations of the Securities and Exchange Commission (the “SEC”) regarding interim financial reporting. Certain information and note disclosures normally included in the financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. These condensed financial statements should be read in conjunction with the financial statements contained in the Company’s Annual Report on Form 10-K for the year ended September 30, 2023, filed with the SEC. The accompanying condensed financial statements are unaudited, but in the opinion of management contain all adjustments, including normal recurring adjustments, necessary to present fairly the Company’s financial position as of March 31, 2024, and the results of its operations and its cash flows for the three and six months ended March 31, 2024 and 2023. The balance sheet as of September 30, 2023 is derived from the Company’s audited financial statements. The results of operations for the three and six months ended March 31, 2024 are not necessarily indicative of the results of operations to be expected for the full fiscal year ending September 30, 2024.

In accordance with the “Segment Reporting” Topic of the Accounting Standards Codification, the Company’s chief operating decision maker (the Company’s President and Chief Executive Officer) determined that the Company has only one reporting unit.

The condensed 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.

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Going Concern

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The Company has not yet generated sufficient revenues to fund operations and relies on issuance of debt and equity instruments to generate working capital. As reflected in the accompanying financial statements, for the six months ended March 31, 2024, the Company recorded a net loss of \$4,150,791 and used cash in operations of \$1,562,764. These factors raise substantial doubt about the Company’s ability to continue as a going concern within one year of the date that the financial statements are issued. In addition, the Company’s independent registered public accounting firm, in its report on the Company’s September 30, 2023, financial statements, raised substantial doubt about the Company’s ability to continue as a going concern. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

The Company expects to incur substantial expenses for the foreseeable future relating to research, development and commercialization of its current and its potential future products. The Company has not yet generated sufficient revenues to fund operations and relies on issuance of debt and equity instruments to generate working capital. In evaluating the going concern position of the Company, management has considered potential funding providers and believes that financing to fund future operations could be provided by equity and/or debt financing. Even if the Company is able to obtain additional financing, it may contain undue restrictions on our operations, in the case of debt financing, or cause substantial dilution for our stockholders, in the case of equity financing.

Reverse stock split

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 1200, effective January 17, 2023. Accordingly, all share and per share amounts presented herein with respect to common stock have been retroactively adjusted to reflect the above-described reverse stock split for all periods presented.

Use of Estimates

Management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenue and expense during the reporting periods. Significant estimates include the assumptions used in the accrual for potential liabilities, the net realizable value of inventory, the valuation of debt and equity instruments, the fair value of derivative liabilities, valuation of equity instruments issued for services, and deferred tax valuation allowances. Actual results could differ from those estimates.

Revenue

The Company recognizes revenue in accordance with Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers* (“ASC 606”), through a five-step process: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) a performance obligation is satisfied.

The Company’s source of revenue is product sales. Contracts with customers contain a single performance obligation and the Company recognizes revenue from product sales

when the Company has satisfied our performance obligation by transferring control of the product to the customers. Control of the product transfers to the customer upon shipment from the Company's third-party warehouse. In circumstances where the transaction price is not able to be determined at the time of shipment, the Company does not recognize revenue or any receivable amount until such time that the final transaction price is established.

Cost of Revenue

Cost of revenue includes product costs, warehousing, overhead allocation and royalty expense.

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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 condensed consolidated financial statements based on their fair values. In accordance with ASC 718, the Company has elected to use the Black-Scholes Option Pricing Model (the "*Black-Scholes Model*") to determine the fair value of options granted and recognizes the compensation cost of share-based awards on a straight-line basis over the vesting period of the award.

The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by the fair value of the Common Stock and a number of other assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. The expected life for awards uses the simplified method for all "plain vanilla" options, as defined in ASC 718-10-S99, and the contractual term for all other employee and non-employee awards. The risk-free interest rate assumption is based on observed interest rates appropriate for the terms of the Company's awards. The dividend yield assumption is based on history and the expectation of paying no dividends. Stock-based compensation expense, when recognized in the condensed 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 condensed 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 March 31, 2024 and September 30, 2023, the carrying amounts of cash, accounts payables and accrued expense and other liabilities approximate fair value because of their short-term nature. The carrying amounts for the Series Convertible Notes, 2022 Notes, Second Notes, Third Notes and the Fourth Notes approximate fair value because borrowing rates and terms are similar to comparable market participants.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in Accounting Standards Codification ("ASC") 480, *Distinguishing Liabilities from Equity* ("ASC 480"), and ASC 815, *Derivatives and Hedging* ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted when the warrants are issued and at the end each subsequent quarterly period while the warrants are outstanding. For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be liability classified and recorded at their initial fair value on the date of issuance and remeasured at fair value at each balance sheet date thereafter. Changes in the estimated fair value of the warrants are recognized as a non-cash gain or loss on the statements of operations. The Company has determined that the warrants issued in June 2018 and May 2019 equity financing (see Note 3) meet the requirements for liability classification. During the three months ended March 31, 2023, \$1,158,197 was recorded to gain on extinguishment of derivative liability for the exchange of the Series G warrants and Series H warrants to 12,019 shares of common stock with a fair value of \$49,278.

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Loss per Common Share

Basic earnings (loss) per share is computed by dividing the net income (loss) applicable to common stockholders by the weighted average number of shares of common stock outstanding during the year, excluding shares of unvested restricted common stock. Shares of restricted stock are included in the basic weighted average number of common shares outstanding from the time they vest. Diluted earnings (loss) per share is computed by dividing the net income applicable to common stockholders by the weighted average number of common shares outstanding plus the number of additional common shares that would have been outstanding if all dilutive potential common shares had been issued, using the treasury stock method. Shares of restricted stock are included in the diluted weighted average number of common shares outstanding from the date they are granted. Potential common shares are excluded from the computation when their effect is antidilutive.

For the periods ended March 31, 2024 and 2023, the calculations of basic and diluted loss per share are the same because potential dilutive securities would have had an anti-dilutive effect. The potentially dilutive securities consisted of the following:

	<u>March 31,</u> <u>2024</u>	<u>March 31,</u> <u>2023</u>
Stock options	88,275	104,325
Stock warrants	26,724,240	847,021
Convertible notes payable	754,744	721,790
Total	<u>27,567,259</u>	<u>1,673,136</u>

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.

Risks and uncertainties – 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 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. The extent to which recent events, including recent wars in Ukraine and Israel/Gaza, will impact the global economy and the Company is uncertain and cannot be reasonably measured.

2. INVENTORIES

Inventories consist of the following:

	March 31, 2024	September 30, 2023
Finished Goods	\$ 65,980	\$ 40,969
Goods-in-Process	1,263,613	1,323,535
Total	\$ 1,329,593	\$ 1,364,504

Inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out ("FIFO") basis. 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 Company records adjustments to its inventory for estimated obsolescence or diminution in net realizable value equal to the difference between the cost of the inventory and the estimated net realizable value. Once inventory has been written down, it creates a new cost basis for inventory that may not be subsequently written up. For the periods ended March 31, 2024 and 2023, the Company did not record any write-down of inventories.

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3. WARRANT DERIVATIVE LIABILITY

As of March 31, 2024 and September 30, 2023, there are no financial instruments accounted as a derivative liability.

The Company previously issued warrants (Series G and Series H warrants) that were accounted for in accordance with ASC 815-10 as the Company is required to purchase the Series G, and Series H warrants for an amount of cash per share equal to \$22.00 and \$10.66, respectively, (the "Minimum Value"). Accordingly, the warrants were recorded as liabilities at the greater of the Minimum Value or fair value at each reporting period.

During the three months ended March 31, 2023, the Company issued 12,019 shares of common stock with a fair value of \$49,278 in exchange for the cancellation of the Series G and Series H warrants. As a result, during the three month ended March 31, 2023, the Company recorded a gain of \$1,158,197 to account for the extinguishment of derivative liability.

4. CONVERTIBLE NOTES PAYABLE, SENIOR SECURED

	March 31, 2024	September 30, 2023
Senior Secured Convertible Promissory Notes (the "2022 Notes")	\$ 4,211,720	\$ 4,230,000
Unamortized debt discount	-	(710,897)
Net Balance	\$ 4,211,720	\$ 3,519,103

In July 2022, the Company entered into a Securities Purchase Agreement (the "SPA") with certain institutional and accredited individual investors and issued Senior Secured Convertible Promissory Notes (the "2022 Notes") in the aggregate of \$4,230,000 in exchange for cash proceeds of \$3,525,000, net of original issue discount (OID) of \$705,000.

The 2022 Notes are secured by tangible and intangible assets of the Company, bears interest at a rate of 10% per annum payable at maturity or upon conversion, matures on June 30, 2024, as amended, and are convertible into shares of the Company's common stock at a conversion price of \$9.14 per share.

The 2022 Notes contain customary events of default. Further, events of default under the 2022 Notes also include (i) the unavailability of Rule 144 on or after January 6, 2023; (ii) our failure to deliver the shares of common stock to the 2022 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 April 30, 2024 (the "Uplist Transaction"). During the year ended September 2023, for no additional consideration, the 2022 Notes were amended several times in order to allow the Company to issue additional notes payable, extend the completion date for the Uplist Transaction, and amend certain provisions with regards to mandatory conversion of the notes upon the Uplist Transaction.

In connection with the issuance of the 2022 Notes, the Company granted the 2022 Notes noteholders 425,555 warrants to purchase shares of common stock. The warrants are fully vested, exercisable at \$9.94 per share and expire in 5 years. The Company estimated the relative fair value of the warrants to be \$1,470,000 using the Black Scholes option pricing model. The Company also issued note holders 63,834 shares of the Company's common stock with a relative fair value of \$315,000. The Company also issued 31,510 warrants to purchase shares of common stock to the placement agent that assisted in the 2022 Notes offering. The placement agent warrants are fully vested, exercisable at \$10.06 per share and will expire in 5 years. The Company estimated the relative fair value of the placement agent warrants to be \$108,000 using the Black Scholes option pricing model. The Company incurred direct legal and professional fees of \$271,000 as part of this offering.

The Company recorded 2022 Notes with total principal of \$4,230,000. In addition, total debt discount of \$2,870,000 was recorded to account for the 2022 Notes OID of \$705,000, the relative fair value of the warrants of \$1,578,000, the relative fair value of common stock issued of \$315,000, and direct legal and professional fees incurred in the 2022 Notes offering of \$271,000. The debt discount was amortized over the term of the notes using the effective interest rate method.

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As of September 30, 2023, outstanding balance of the 2022 Notes payable was \$4,230,000 and unamortized debt discount was \$710,897, or a net balance of \$3,519,103.

On December 26, 2023, the Company issued a total of 2,000 shares of Common Stock in partial satisfaction of the outstanding Senior Secured Convertible Promissory Notes with the principal balance of \$18,280.

On February 14, 2024, the Company entered into an amendment to the 2022 Notes, under which 95% of the principal amount of the Notes shall automatically convert, upon the closing of an Uplist Transaction, as defined, with a conversion price of \$0.50 per share, into pre-funded warrants with an exercise price of \$0.000125 per share, exercisable immediately. In addition, the note holder shall receive a warrant to purchase 80 times the dollar amount of the notes that are converted, with an exercise price per share of \$0.50. There is no impact to the amendment until the Uplist transaction is completed.

During the three and six months ended March 31, 2024, the Company amortized debt discount of \$46,965 and \$710,897, respectively. As of March 31, 2024, the outstanding balance of the 2022 Notes payable amounted to \$4,211,720 and no unamortized debt discount was remaining. On April 30, 2024, the convertible notes payable was amended in order to extend the maturity date to June 30, 2024. There were no compensation provided to the note holder nor any changes in the other terms of the notes payable.

5. CONVERTIBLE NOTES PAYABLE, UNSECURED

	March 31, 2024	September 30, 2023
Exchanged notes (July 2022)	\$ 699,781	\$ 699,781
Second closing notes (January 2023)	636,000	636,000
Third closing notes (March, April, May, 2023)	702,720	702,720
Fourth closing notes (March, 2024)	648,000	-
Total	2,686,501	2,038,501
Unamortized debt discount	-	(379,799)
Net balance	<u>\$ 2,686,501</u>	<u>\$ 1,658,702</u>

Exchanged Notes (July 2022)

In relation to the issuance of the 2022 Notes (see Note 4), certain noteholders of the Company's Series 2 note payable agreed to exchange their Series 2 notes payable consisting of \$600,000 principal and accrued interest of \$99,781 for \$699,781 of Unsecured Convertible Promissory Notes (the "Exchanged Notes") on substantially the same terms as the 2022 Notes, except that the Exchanged Notes are subordinate to the 2022 Notes and are unsecured. The notes bear interest at a rate of 10% per annum payable at maturity or upon conversion, mature June 30, 2024, as amended, and are convertible into shares of the Company's common stock at a conversion price of \$9.14 per share. At March 31, 2024 and September 30, 2023, there was no unamortized discount for the Exchanged Notes.

Second Closing Notes (January 2023)

In January 2023, the Company issued Unsecured Convertible Promissory Notes (the "Second Closing Notes") in the aggregate of \$36,000 in exchange for cash proceeds of \$530,000, net of original issue discount (OID) of \$106,000. The notes are unsecured, bear interest at a rate of 10% per annum, matures on June 30, 2024, as amended, and are convertible into shares of the Company's common stock with a conversion price of \$9.14 per share.

In connection with the issuance of the Second Closing Notes, the Company granted the Second Closing Notes noteholders 127,968 warrants to purchase shares of common stock and 9,598 shares of common stock. The warrants are fully vested, exercisable at \$9.94 per share and expire in 5 years. The Company determined the relative fair value of the warrants to be \$256,000 and the relative fair value of the 9,598 shares of common stock to be \$26,000. The Company also issued 6,565 placement agent warrants to purchase shares of the Company's common stock. The placement agent warrants are fully vested, exercisable at \$10.06 per share and will expire in 5 years. The Company determined the relative fair value of the placement agent warrants to be \$13,000. Furthermore, the Company also incurred direct legal and professional fees of \$31,000 as part of this offering.

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On February 14, 2024, the Company entered into an amendment to the Second Closing Notes, under which 95% of the principal amount of the Notes shall automatically convert, upon the closing of an Uplist Transaction, as defined, with a conversion price of \$0.50 per share, into pre-funded warrants with an exercise price of \$0.000125 per share, exercisable immediately. In addition, the note holder shall receive a warrant to purchase 80 times the dollar amount of the notes that are converted, with an exercise price per share of \$0.50.

Third Closing Notes (March, April and May 2023)

In March, April and May 2023, the Company issued Unsecured Convertible Promissory Notes (the "Third Closing Notes") in the aggregate of \$703,000 in exchange for cash proceeds of \$488,000, net of original issue discount (OID) of \$215,000, and. The notes are unsecured, bear interest at a rate of 10% per annum, matures on June 30, 2024, as amended, and are convertible into shares of the Company's common stock with a conversion price of \$9.14 per share.

In connection with the issuance of the Third Closing Notes, the Company granted the Third Closing Notes noteholders 141,396 warrants to purchase shares of common stock and 10,608 shares of common stock. The warrants are fully vested, exercisable at \$9.94 per share and expire in 5 years. The Company determined the relative fair value of the warrants to be \$164,000, and the relative fair value of the 10,608 shares of common stock to be \$18,000. The Company also incurred direct legal and professional fees of \$5,000 as part of this offering.

The Second Closing Notes and Third Closing Notes contain events of default similar to the 2022 Notes. Subsequent to issuance, for no additional consideration, the Second Closing Notes and Third Closing Notes were amended several times in order to allow the Company to issue additional notes payable, extend the completion date of the Uplist Transaction, and amend certain provisions with regards mandatory conversion of the notes upon the Uplist Transaction.

On February 14, 2024, the Company entered into an amendment to the Third Closing Notes, under which 95% of the principal amount of the Notes shall automatically convert, upon the closing of an Uplist Transaction, as defined, with a conversion price of \$0.50 per share, into pre-funded warrants with an exercise price of \$0.000125 per share, exercisable immediately. In addition, the note holder shall receive a warrant to purchase 80 times the dollar amount of the notes that are converted, with an exercise price per share of \$0.50.

Fourth Closing Notes (March 2024)

On March 12, 2024, investors agreed to purchase Unsecured Convertible Promissory Notes (the "Fourth Closing Notes") in the aggregate principal amount of \$48,000 in exchange for cash proceeds of \$450,000, net of an OID of \$198,000. The notes are unsecured, bears interest at a rate of 10% per annum, and matures June 30, 2024, as amended, and are convertible into shares of the Company's common stock with a conversion price of \$9.14 per share.

In connection with the issuance of the Fourth Closing Notes, the Company granted the Fourth Closing Notes noteholders 130,383 warrants to purchase shares of common stock and 9,782 pre-funded warrants. The warrants are fully vested, exercisable at \$9.94 per share, and expire in 5 years, and prefunded warrants have similar terms, however, are exercisable at \$0.001 per share. The Company determined the relative fair value of the warrants and pre-funded warrants to be approximately \$148,891.

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On February 14, 2024, the Company entered into an amendment to the Fourth Closing Notes, under which 95% of the principal amount of the Notes shall automatically convert, upon the closing of an Uplist Transaction, as defined, with a conversion price of \$0.50 per share, into pre-funded warrants with an exercise price of \$0.000125 per share, exercisable immediately. In addition, the note holder shall receive a warrant to purchase 80 times the dollar amount of the notes that are converted, with an exercise price per share of \$0.50.

6. CONVERTIBLE NOTES PAYABLE, SERIES 2

	March 31, 2024	September 30, 2023
Series 2 Convertible Notes (converted in November 2023)	\$ -	\$ 450,000

On November 6, 2020, the Company issued its unsecured Series 2 10% Convertible Notes Payable in exchange for cash proceeds of \$450,000. The notes matured on November 30, 2023, and the notes were all converted in November 2023. As of September 30, 2023, outstanding balance of the Series 2 Convertible Notes amounted to \$450,000.

On November 30, 2023, the Series 2 Convertible Notes of \$450,000 and outstanding accrued interest of \$137,946, were converted into 52,918 shares of the Company's common stock.

7. STOCKHOLDERS DEFICIT

Common Stock

In January 2024 certain shareholders of the Company exchanged a total of 300,000 shares of Company's Common Stock for 300,073 of pre-funded warrants to purchase shares of Common Stock. At the date of the exchange, the fair value of the common stock received approximates the fair value of the warrants issued. The pre-funded warrants are fully vested, exercisable at \$0.001 per share, and expire in 5 years.

2013 Stock Incentive Plan

On September 1, 2023, a majority of shareholders approved the 2023 Stock Plan with 455,169 common shares reserved to be issued under the plan. As of March 31, 2024, there were no issuances under the new plan.

On June 18, 2013, the Company established the 2013 Stock Incentive Plan (the "2013 Plan"). Under the 2013 Plan, the Company can issue or grant a total of 185,571 shares, as amended. On June 18, 2023, the 2013 Stock Incentive Plan expired, and no shares are available for grants under the 2013 Plan.

Common Stock Options

Stock compensation activity under the 2013 Plan for the six months ended March 31, 2024 follows:

	Option Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at September 30, 2023	102,125	\$ 38.00	5.58	\$ -
Awarded	-	-	-	-
Forfeited/Cancelled	(1,825)	(67.00)	-	-
Outstanding at December 31, 2023	100,300	38.00	4.00	11,000
Awarded	-	-	-	-
Forfeited/Cancelled	(12,025)	(58.00)	-	-
Outstanding at March 31, 2024	88,275	\$ 35.00	5.00	-
Vested at March 31, 2024	74,769	\$ 39.00	3.50	-
Vested and expected to vest at March 31, 2024	88,275	\$ 35.00	5.00	-

During the six months ended March 31, 2024 and 2023, the Company recorded stock compensation expense of \$5,909 and \$172,550 to account the fair value of the stock options that vested.

As of March 31, 2024, there is approximately \$45,000 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 1.34 years.

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Restricted Stock

For the three months ended March 31, 2024 and 2023, compensation expense recorded for the restricted stock awards was approximately \$0 and \$1,000, respectively. For the six months ended March 31, 2024 and 2023, compensation expense recorded for the restricted stock awards was approximately \$0 and \$3,000, respectively.

As of March 31, 2023, there was no unrecognized compensation expense related to unvested stock-based compensation arrangements granted under the 2013 Plan.

8. SHAREHOLDER ADVANCES RELATED TO BRIDGE FINANCING

During the period ended March 31, 2024, the Company received \$1,125,000 in shareholder advances provided as a partial prepayment of securities to be issued pursuant to a Securities Purchase Agreement dated November 8, 2023 (the "PIPE SPA"). If the transaction underlying the PIPE SPA, with respect to \$1,000,000 of these advances, was not consummated by March 31, 2024, as amended, the Company would be obligated to repay all of the advances within three business days thereafter, provided, however, that in lieu of repayment each investor may in its sole discretion elect to receive, by notice to the Company, prefunded warrants and common warrants in lieu of repayment as if the PIPE SPA transaction had closed. If the transaction underlying the PIPE SPA, with respect to \$125,000 of these advances, was not consummated by April 30, 2024, as amended, the Company would be obligated to repay all of the advances within three business days thereafter, provided, however, that in lieu of repayment each investor may in its sole discretion elect to receive, by notice to the Company, prefunded warrants and common warrants in lieu of repayment as if the PIPE SPA transaction had closed.

With respect to \$1,000,000 of the above referenced shareholder advances, if the Company's Common Stock had not been approved to be listed on a qualifying national exchange by April 2, 2024, as amended, then the amount of prefunded warrants and common warrants that would otherwise be issuable in connection with the PIPE SPA specific to those advances shall be increased by twenty-five percent. With respect to \$125,000 of the above referenced shareholder advances, if the Company's Common Stock had not been approved to be listed on a qualifying national exchange by May 2, 2024, as amended, then the amount of prefunded warrants and common warrants that would otherwise be issuable in connection with the PIPE SPA specific to those advances shall be increased by twenty-five percent.

As of May 9, 2024, the Company had not been approved to be listed on a qualifying national exchange, had not repaid any advances, and had not received notice from any investors to receive pre-funded warrants and common warrants in lieu of prepayment.

9. SUBSEQUENT EVENTS

From April 1, 2024 through April 3, 2024, the Company raised an additional \$125,000 from three investors in the form of shareholder advances provided as a partial prepayment of each investor's purchase price set forth on their respective signature pages to the PIPE SPA. If the transaction underlying the PIPE SPA, with respect to these advances, was not consummated by April 30, 2024, as amended, the Company would be obligated to repay all of the advances within three business days thereafter, provided, however, that in lieu of repayment each investor may in its sole discretion elect to receive, by notice to the Company, prefunded warrants and common warrants in lieu of repayment as if the PIPE SPA transaction had closed.

With respect to the \$125,000 of the above referenced shareholder advances received in April 2024, if the Company's Common Stock had not been approved to be listed on a qualifying national exchange by May 2, 2024, as amended, then the amount of prefunded warrants and common warrants that would otherwise be issuable in connection with the PIPE SPA specific to these advances shall be increased by twenty-five percent.

As of May 9, 2024, the Company had not been approved to be listed on a qualifying national exchange, had not repaid any advances, and had not received notice from any investors to receive pre-funded warrants and common warrants in lieu of repayment.

From April 12, 2024 through May 1, 2024, the Company raised an additional \$600,000 in shareholder advances from five investors. Such amounts are expected to be exchanged into a new senior secured note with 20% OID. Upon closing, all prior shareholder advances are expected to be applied toward or exchanged into the new senior note with a maturity date of June 30, 2024.

In May 2024, the Company issued its convertible notes payable totaling \$2,220,000, in exchange for cash of \$1,850,000, net of original issue discount of \$370,000. The convertible notes payable are secured by the Company's tangible and intangible assets, bears interest at a rate of 10% per annum, convertible to common stock at a conversion price of \$0.50 per share and will mature on June 30, 2024. In addition, upon the closing of a transaction that results in the uplist of the Company's common stock to a National Exchange, 100% of the then outstanding principal amount shall automatically convert into shares of common stock at a conversion price of \$0.515625 per share, subject beneficial ownership limitation.

On June 12, 2024, the Company completed a second closing of its convertible notes payable totaling \$180,000, in exchange for cash of \$150,000, net of original issue discount of \$30,000. All other terms were identical to the convertible notes payable issued by the Company in May 2024.

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969,697 Units (consisting of 969,697 Shares of Common Stock and Investor Warrants to Purchase up to 969,697 Shares of Common Stock)
Up to 969,697 Pre-Funded Units (consisting of Pre-Funded Warrants to Purchase up to 969,697 Shares of Common Stock and Investor Warrants to Purchase up to 969,697 Shares of Common Stock)
Up to 969,697 Shares of Common Stock Underlying the Pre-Funded Warrants and Up to 969,697 Shares of Common Stock Underlying the Investor Warrants

ARCH THERAPEUTICS, INC.

PRELIMINARY PROSPECTUS

Sole Book-Running Manager

Dawson James Securities, Inc.

, 2023

Until , 2023 (25 days after the date of this prospectus), all dealers that buy, sell or trade our securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

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

SUBJECT TO COMPLETION, DATED JUNE 20, 2024

PRELIMINARY PROSPECTUS

ARCH THERAPEUTICS, INC.

8,609,230 Shares of Common Stock

Up to 1,724,557 Shares of Common Stock underlying the 2022 Notes upon Regular Conversion
Up to 1,638,330 Shares of Common Stock underlying the 2022 Notes upon Automatic Conversion
Up to 50,792 Shares of Common Stock underlying the 2022 Warrants and 2022 Placement Agent Warrants

Up to 38,733 Shares of Common Stock underlying the Inducement Pre-Funded Warrants and Legacy Pre-Funded Warrants

Up to 600,000 Shares of Common Stock underlying the 2024 Notes upon 2024 Notes Regular Conversion
Up to 581,819 Shares of Common Stock underlying the 2024 Notes upon 2024 Notes Automatic Conversion

Up to 11,331,038 Shares of Common Stock underlying the Common Warrants, Bridge Pre-Funded Warrants and True-Up Pre-Funded Warrants

Up to 67,171,430 Shares of Common Stock underlying the Uplist Conversion Warrants and 2022 Note Conversion Pre-Funded Warrants

Up to 1,163,638 Shares of Common Stock underlying the 2024 Notes Uplist Conversion Warrants and 2024 Note Conversion Pre-Funded Warrants

3,433,348 Shares of Common Stock underlying the PIPE Pre-Funded Warrants and PIPE Investor Warrants

Up to 151,552 Shares of Common Stock underlying the PIPE Advance Penalty Pre-Funded Warrants and PIPE Advance Penalty Common Warrants

Up to 1,950,000 Shares of Common Stock underlying the Execution Backstop Pre-Funded Warrants, Funding Backstop Pre-Funded Warrants and Backstop Common Warrants

This prospectus relates to the offer and sale of up to 98,444,466 shares of our common stock, par value \$0.001 per share ("Common Stock"), by the selling stockholders identified in this prospectus. The shares of Common Stock being offered include:

- 730 shares of Common Stock (the “**2022 Inducement Shares**”) issued to selling stockholders in the second and third closings that we completed on January 18, 2023, and May 15, 2023, respectively in the private placement (the “**2022 Private Placement Financing**”) under the 2022 Notes SPA (as defined in this prospectus), 384,159 shares of Common Stock (the “**Bridge Shares**”) issued in our private placement that we completed on July 7, 2023 (the “**2023 Bridge Financing**”) and up to 8,224,341 shares of Common Stock (the “**True-Up Shares**”) that we may be required to issue in lieu of True-Up Pre-Funded Warrants (as defined below) pursuant to the securities purchase agreement dated July 7, 2023, as amended, related to the 2023 Bridge Financing (the “**Bridge SPA**”);
- Up to 1,223 shares of Common Stock (the “**Inducement Pre-Funded Warrant Shares**”) issuable to selling stockholders upon exercise, at an exercise price of \$0.008 per share, of our warrants (the “**Inducement Pre-Funded Warrants**”) issued in lieu of shares otherwise issuable under the 2022 Notes SPA (as defined in this prospectus) in the fourth closing of our 2022 Private Placement Financing;
- Up to 37,510 shares of Common Stock (the “**Legacy Pre-Funded Warrant Shares**”) issuable to selling stockholders upon exercise, at an exercise price of \$0.008 per share, of our warrants (the “**Legacy Pre-Funded Warrants**”) acquired in a private secondary transaction from a former stockholder of the Company;
- Up to 1,724,557 shares of Common Stock (the “**Conversion Shares**”) issuable to selling stockholders upon conversion (a “**Regular Conversion**”) of our convertible notes issued in the 2022 Private Placement Financing at a conversion price of \$4.00 (which takes into account the change to \$4.00 as of the closing of the Uplist PIPE through the operation of the Most Favored Nation Provision (as defined in this prospectus), from the original conversion price of \$73.12) per share, under Article I thereof;
- Up to 1,638,330 shares of Common Stock (the “**Automatic Conversion Shares**”) issuable to selling stockholders upon conversion of 95% of our convertible notes issued in the 2022 Private Placement Financing upon the Automatic Conversion (as defined in this prospectus);
- Up to 49,971 shares of Common Stock (the “**2022 Warrant Shares**”) issuable to selling stockholders upon exercise, at an exercise price of \$4.00 (which takes into account the change to \$4.00 as of the closing of the Uplist PIPE through the operation of the Most Favored Nation Provision, from the original conversion price of \$79.52) per share, of our warrants (the “**2022 Warrants**”) issued in the second, third and fourth closing of our 2022 Private Placement Financing;
- Up to 1,638,330 shares of Common Stock (“**2022 Note Conversion Pre-Funded Warrant Shares**”) issuable to the selling stockholders upon exercise, at an exercise price of \$0.001 per share, of our pre-funded warrants (the “**2022 Note Conversion Pre-Funded Warrants**”) issuable upon the Automatic Conversion in lieu of Automatic Conversion Shares to the extent needed to prevent any holder from beneficially owning more than 4.99% (or upon election 9.99%) of our outstanding Common Stock;
- Up to 65,533,100 shares of Common Stock (“**Uplist Conversion Warrant Shares**”) issuable to the selling stockholders upon exercise, at an exercise price of \$4.00 per share, of our warrants (“**Uplist Conversion Warrants**”) issuable upon the Automatic Conversion.
- Up to 600,000 shares of Common Stock (the “**2024 Conversion Shares**”) issuable to selling stockholders upon conversion (a “**2024 Notes Regular Conversion**”) of our convertible notes (the “**2024 Notes**”) issued pursuant to the securities purchase agreement, dated as of May 15, 2024, among the Company and the purchasers signatory thereto (the “**2024 Notes SPA**”; such issuance and sale, the “**2024 Notes Financing**”) at their conversion price of \$4.00 per share, under Article I thereof;
- Up to 581,819 shares of Common Stock (the “**2024 Notes Automatic Conversion Shares**”) issuable to selling stockholders upon conversion of 100% of the 2024 Notes upon the 2024 Notes Automatic Conversion (as defined in this prospectus);
- Up to 581,819 shares of Common Stock (“**2024 Note Conversion Pre-Funded Warrant Shares**”) issuable to the selling stockholders upon exercise, at an exercise price of \$0.001 per share, of our pre-funded warrants (the “**2024 Note Conversion Pre-Funded Warrants**”) issuable upon the 2024 Notes Automatic Conversion in lieu of 2024 Notes Automatic Conversion Shares to the extent needed to prevent any holder from beneficially owning more than 4.99% (or upon election 9.99%) of our outstanding Common Stock;
- Up to 581,819 shares of Common Stock (“**2024 Notes Uplist Conversion Warrant Shares**”) issuable to the selling stockholders upon exercise, at an exercise price of \$4.00 per share, of our warrants (“**2024 Notes Uplist Conversion Warrants**”) issuable upon the 2024 Notes Automatic Conversion.
- Up to 821 shares of Common Stock (the “**2022 Placement Agent Warrant Shares**”) issuable to the selling stockholders upon exercise, at an exercise price of \$4.00 (which takes into account the change to \$4.00 as of the closing of the Uplist PIPE through the operation of the Most Favored Nation Provision, from the original conversion price of \$80.48) per share, of placement agent warrants issued in the 2022 Private Placement Financing (the “**2022 Placement Agent Warrants**”);
- Up to 2,349,826 shares of Common Stock (the “**Common Warrant Shares**”) issuable to selling stockholders upon exercise, at an exercise price of \$8.00 per share, of our warrants (the “**Common Warrants**”) issued in the 2023 Bridge Financing;

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- Up to 756,871 shares of Common Stock (“**Bridge Pre-Funded Warrant Shares**” and together with the Common Warrant Shares, the “**Bridge Warrant Shares**”) issuable to the selling stockholders upon exercise, at an exercise price of \$0.008 per share, of pre-funded warrants issued in the 2023 Bridge Financing (the “**Bridge Pre-Funded Warrants**”) and together with the Common Warrants, the “**Bridge Warrants**”);
 - Up to 8,224,341 shares of Common Stock (the “**True-Up Pre-Funded Warrant Shares**”) issuable to selling stockholders upon exercise, at an exercise price of \$0.001 per share, of our pre-funded warrants (the “**True-Up Pre-Funded Warrants**”) that we may be required to issue to the Bridge Investors (as defined in this prospectus) as a result of the Primary Offering being at a price per share below \$32.00, pursuant to the Bridge SPA;
 - Up to 1,716,674 shares of Common Stock (the “**PIPE Investor Warrant Shares**”) issuable to selling stockholders upon exercise, at an exercise price of \$4.00 per share, of our warrants (the “**PIPE Investor Warrants**”) to be issued in the private placement (the “**Uplist PIPE**”) pursuant to the securities purchase agreement dated November 8, 2023 (the “**PIPE SPA**”);
 - Up to 1,716,674 shares of Common Stock (“**PIPE Pre-Funded Warrant Shares**” and together with the PIPE Investor Warrant Shares, the “**PIPE Warrant Shares**”) issuable to the selling stockholders upon exercise, at an exercise price of \$0.001 per share, of pre-funded warrants to be issued in the Uplist PIPE (the “**PIPE Pre-Funded Warrants**”) and together with the PIPE Investor Warrants, the “**PIPE Warrants**”);
 - Up to 75,776 shares of Common Stock (the “**PIPE Advance Penalty Pre-Funded Warrant Shares**”) issuable to selling stockholders upon exercise, at an exercise price of \$0.001 per share, of our pre-funded warrants (the “**PIPE Advance Penalty Pre-Funded Warrants**”) issued pursuant to the PIPE Advances (as defined in this prospectus);
 - Up to 75,776 shares of Common Stock (the “**PIPE Advance Penalty Common Warrant Shares**”) issuable to selling stockholders upon exercise, at an exercise price of \$4.00 per share, of our warrants (the “**PIPE Advance Penalty Common Warrants**”) issued pursuant to the PIPE Advances;
 - Up to 225,000 shares of Common Stock (the “**Execution Backstop Pre-Funded Warrant Shares**”) issuable to selling stockholders upon exercise, at an exercise price of \$0.001 per share, of our pre-funded warrants (the “**Execution Backstop Pre-Funded Warrants**”) issued pursuant to the Backstop Agreement (as defined in this prospectus);
 - Up to 750,000 shares of Common Stock (the “**Funding Backstop Pre-Funded Warrant Shares**”) issuable to selling stockholders upon exercise, at an exercise price of \$0.001 per share, of our pre-funded warrants (the “**Execution Backstop Pre-Funded Warrants**”) issuable pursuant to the Backstop Agreement; and

- Up to 975,000 shares of Common Stock (the “**Backstop Common Warrant Shares**”) issuable to selling stockholders upon exercise, at an exercise price of \$4.00 per share, of our warrants (the “**Backstop Common Warrants**”) issuable pursuant to the Backstop Agreement.

The selling stockholders may sell the shares of Common Stock to be registered hereby from time to time on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale, in the over-the-counter market, in one or more transactions otherwise than on these exchanges or systems or in the over-the-counter market, such as privately negotiated transactions, or using a combination of these methods, and at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. See the disclosure under the heading “**Plan of Distribution**” beginning on page 51 of this prospectus for more information.

We will not receive any proceeds from the resale of Common Stock by the selling stockholders.

We originally offered and sold the securities issued or issuable in connection with the 2022 Private Placement Financing, Uplist PIPE, Bridge Offering and the 2024 Notes Financing under an exemption from the registration requirements of the Securities Act of 1933, as amended (the “**Securities Act**”), pursuant to Section 4(a)(2) thereof and Rule 506 of Regulation D promulgated thereunder.

Our Common Stock is traded on the QB tier of the OTC Marketplace (“**OTCQB**”) under the symbol “**ARTH**”. On June 18, 2024, the closing price of our Common Stock was \$8.72 (post-Reverse Split, as defined below) per share. In connection with the offering pursuant to the Company Prospectus, which precedes this prospectus in the registration statement of which this prospectus forms a part (the “**Primary Offering**”), described below, we have applied to list our Common Stock and Investor Warrants (as defined in the Company Prospectus) on the Cboe BZX Exchange, Inc. (“**Cboe**”) under the symbols “**ARTH**” and “**ARTHW**,” respectively.

In the Primary Offering, we are offering 969,697 units (“**Units**”), on a firm commitment basis, at an assumed public offering price of \$4.125 per Unit (which represents the minimum bid price of \$4.00 per share under the initial listing requirements of Cboe in Cboe Listing Rule 14.9(b) plus a value of \$0.125 attributed to the accompanying Investor Warrant), each Unit consisting of one share of 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 the Primary 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 the Primary Offering. Each Investor Warrant offered by the Company Prospectus will be exercisable on the date of issuance at an assumed exercise price per share of Common Stock of \$4.00 (which equals the minimum bid price per share under the initial listing requirements of Cboe in Cboe Listing Rule 14.9(b)), and will expire five years from the date of issuance. Pursuant to the Company Prospectus, we are also offering the shares of Common Stock issuable upon exercise of the Investor Warrants.

We are also offering in the Primary Offering to each purchaser whose purchases of Units would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding Common Stock immediately following the consummation of the Primary Offering, the opportunity to purchase, if the purchaser so chooses, pre-funded units (“**Pre-Funded Units**”) (each Pre-Funded Unit consisting of one pre-funded warrant (“**Pre-Funded Warrant**”) to purchase one share of Common Stock and one Investor Warrant to purchase one share of Common Stock) in lieu of Units that would otherwise result in the purchaser’s beneficial ownership exceeding 4.99% of our outstanding Common Stock (or at the election of the purchaser, 9.99%). Each Pre-Funded Warrant contained in a Pre-Funded Unit will be exercisable into one share of Common Stock, exercisable until all of the Pre-Funded Warrants are exercised in full. The purchase price of each Pre-Funded Unit will equal the price per Unit being sold to the public in the Primary Offering minus \$0.001, and the exercise price of each Pre-Funded Warrant included in the Pre-Funded Unit will be \$0.001 per share of Common Stock. The Primary Offering also relates to the shares of Common Stock issuable upon exercise of any Pre-Funded Warrants contained in the Pre-Funded Units sold in the Primary Offering. Each Investor Warrant contained in a Pre-Funded Unit will have an assumed exercise price of \$4.00 (which equals the minimum bid price per share under the initial listing requirements of Cboe in Cboe Listing Rule 14.9(b)). The Investor Warrants contained in the Pre-Funded Units will be exercisable immediately and will expire five years from the date of issuance. Pursuant to the Company Prospectus, we are also offering the shares of Common Stock issuable upon exercise of the Pre-Funded Warrants and Investor Warrants contained in the Pre-Funded Units.

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

The final public offering price per Unit and Pre-Funded Unit, and the exercise price of the Investor Warrants, as applicable, will be determined through negotiation between the underwriters and us at the time of pricing, considering our historical performance and capital structure, prevailing market conditions, and overall assessment of our business, and may be at a discount to the current market price.

In the Primary Offering, we have granted the underwriters an option, exercisable within 45 days from the date of the Company Prospectus, to purchase from us, up to an additional 145,454 shares of Common Stock at the public offering price and/or Investor Warrants to purchase up to 145,454 shares of Common Stock (equal to 15% of the shares of Common Stock (and Pre-Funded Warrants, if any) and Investor Warrants sold in the Primary 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.

We estimate that we will receive net proceeds from the Primary Offering of approximately \$2.9 million or approximately \$3.5 million if the underwriters exercise their over-allotment option in full, after deducting the underwriting discounts and commissions and estimating offering expenses payable by us.

In connection with the Primary Offering, we intend to effect a reverse stock split of our Common Stock at a ratio of 1-for-8 (the “Reverse Split”). All share and per share information in this prospectus, other than the historical financial statements included herein, has been adjusted to reflect the anticipated reverse stock split.

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

Investing in our Common Stock involves a high degree of risk. Before making any investment in our Common Stock, you should read and carefully consider the risks described in this prospectus under the heading “**Risk Factors**” beginning on page 18 of this prospectus.

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

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

This prospectus is dated , 2023

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ABOUT THIS PROSPECTUS

This prospectus relates to the offering by the selling stockholders identified in this prospectus of shares of our Common Stock referenced on the cover page of this prospectus.

You should rely only on the information that we have provided or incorporated by reference in this prospectus, any applicable prospectus supplement and any related free writing prospectus that we may authorize to be provided to you. We have not authorized anyone to provide you with different information. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus, any applicable prospectus supplement or any related free writing prospectus that we may authorize to be provided to you. You must not rely on any unauthorized information or representation. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information in this prospectus, any applicable prospectus supplement or any related free writing prospectus is accurate only as of the date on the front of the document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus, any applicable prospectus supplement or any related free writing prospectus, or any sale of a security registered under the Registration Statement of which this prospectus forms a part.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to this registration statement of which this prospectus forms a part, and you may obtain copies of those documents as described below under the heading “**WHERE YOU CAN FIND MORE INFORMATION**” beginning on page [124](#) 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.

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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 [18](#) of this prospectus, and the risks set out below, any of which may cause our or our industry’s actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. These risks include, by way of example and not in limitation, risks related to:

- Our ability to continue as a going concern;
- Our ability to obtain financing necessary to operate our business;
- Our limited operating history;
- Our ability to comply with the terms and covenants of our existing agreements and outstanding convertible notes, including the First Notes (as defined below) which are secured by security interests in substantially all of our assets;
- The dilutive effect of our outstanding warrants and convertible notes;
- The results of our research and development activities, including uncertainties relating to the preclinical and clinical testing of our product candidates;
- The commercialization of our primary product candidate;

- Our ability to develop, obtain required approvals for and commercialize our product candidates;
- Our ability to recruit and retain qualified key executives, and medical and science personnel;
- Our ability to develop and maintain an effective sales force to market our approved product candidates;
- Our ability to manage any future growth we may experience;
- Our ability to obtain and maintain protection of our intellectual property;
- Our dependence on third party manufacturers, suppliers, research organizations, academic institutions, testing laboratories and other potential collaborators;
- The size and growth of the potential markets for any of our approved product candidates, and the rate and degree of market acceptance of any of our approved product candidates;
- Our ability to successfully complete potential acquisitions and collaborative arrangements;
- Competition in our industry;
- The impact of the COVID-19 pandemic, and related responses of businesses and governments to the pandemic, on our operations and personnel, on commercial activity in the markets in which we operate and on our results of operations;
- General economic and business conditions; and
- Other factors discussed under the section entitled “**Risk Factors.**”

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

PROSPECTUS SUMMARY

Our Company

We are a biotechnology company marketing and developing a number of products based on our innovative AC5 self-assembling technology platform. We believe these products can be important advances in the field of stasis and barrier applications, which includes managing wounds created during surgery, trauma or interventional care, or from disease; stopping bleeding (hemostasis); and controlling leaking (sealant). We have recently devoted a substantial part of our operational effort to the market adoption and commercial sales of AC5 Advanced Wound System, our first product. Our goal is to make care faster and safer for patients by providing 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 product 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 (US) and the European Union (EU), respectively, and which are intended for skin applications, such as management of complicated chronic wounds and acute surgical wounds. Marketing for AC5 Topical Hemostat in the EU has not initiated. Other products are in development for use in minimally invasive or open surgical procedures and include, for example, AC5-G™ for gastrointestinal endoscopic procedures and AC5-V™ and AC5 Surgical Hemostat for hemostasis inside the body, all of which are currently investigational devices limited by law to investigational use.

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

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

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

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

dressing and to control mild to moderate bleeding, each during the management of injured skin and the micro-environment of an acute surgical wound. AC5 Topical Hemostat has not yet been marketed in Europe but has received marketing authorization.

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Sales and marketing efforts for our AC5 Advanced Wound System, which has received 510(k) marketing clearance from the United States Food and Drug Administration (“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 US 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.

Operations

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

Our long-term business plan includes the following goals:

- growing revenues and building upon recent commercial momentum by driving product awareness, continued adoption and favorable payment policies for AC5 Advanced Wound System with the now-effective CMS Level II HCPCS code dedicated to AC5;
- conducting biocompatibility, pre-clinical, and clinical studies on our products and product candidates;

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- 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 third party 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.

To support our long-term business goals, we expect to focus on the following activities during the next twelve months:

- further develop our product clinical profile;
- enhance product packaging features;
- identify and address opportunities for supply chain efficiencies;
- assess our technology platform in order to identify and select product candidates for potential advancement into development;
- seek additional funding as required to support the previously described milestones necessary to support our operations;
- 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, maintaining granted patents in desired jurisdictions, and/or adding to our trade secrets in self-assembly, manufacturing, analytical methods and formulation, as appropriate.

Commercialization

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.

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.

For at least the near term future, in order to maximize operational efficiencies and to account for changing landscapes since the COVID-19 pandemic during which both marketing authorizations were received, 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.

We expect the commercialization ramp to be gradual through 2024 and into 2025, while we encourage product use among key opinion leaders and early adopters in developing

market channels, and then moderately accelerate.

We recently started to commercialize AC5 Advanced Wound System. We rely on both an internal commercial team and independent sales distributors to drive 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 (VA) hospitals and military 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.

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We anticipate that material growth in the physician office setting will require product reimbursement. To that end, we applied to the Centers for Medicare and Medicaid Services (CMS) for a dedicated Healthcare Common Procedure Coding System (HCPCS) Level II reimbursement code specific to AC5 Advanced Wound System to better enable providers to bill third party payors for AC5 that is used in doctors' offices. The unique HCPCS code, A2020, was granted and made effective on April 1, 2023. A dedicated HCPCS code is an important step toward, although not a guarantee of, coverage and reimbursement, and we intend it to 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.

In support of the government market, we partnered with Lovell Government Services (LGS), a service-disabled veteran-owned small business, to be our government channel distributor. As a direct result of our relationship with LGS, AC5 Advanced Wound System has been added to the four major government contracting vehicles: Federal Supply Schedule (FSS), General Services Administration (GSA) schedule, Defense Logistics Agency's Medical Electronic Catalog Program (ECAT), and Distribution and Pricing Agreement (DAPA). This listing enables purchase by federal government agencies, including the Department of Veterans Affairs (VA), Indian Health Services (IHS), and Department of Defense (DOD) Medical Treatment Facilities, and it allows doctors in government channels to order AC5 Advanced Wound System.

Our internal core team oversees AC5 Advanced Wound System sales, marketing, and inventory distribution from the warehouse to the customer. We envision hiring additional internal sales representatives to support commercialization.

We have partnerships with reputable, value-added independent sales representatives and distributors, and we expect to add more collaborative agreements on a case-by-case basis to expand the overall reach and footprint of the sales organization. Such collaborations may include strategic partners. We anticipate that we will also 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 both 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 do not believe that our current cash on hand as of June 19, 2024 is sufficient to meet our anticipated cash requirements through the end of June 2024, and we must obtain additional financing in order to continue to operate our business. Even if the Primary Offering (as defined below) is successful, we could spend our financial resources much faster than we expect, in which case we would 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 18, in which case our current funds may not be sufficient to operate our business for the period we expect.

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

We have an aggregate of \$6,898,221 in principal outstanding as of June 19, 2024 under the 2022 Notes and an aggregate of \$2,400,000 in principal outstanding as of June 19, 2024 under the 2024 Notes (as defined below). The holders of the First Notes (as defined below) have been granted a security interest in substantially all of our assets pursuant to the terms of the security agreement dated July 6, 2022 (the "**Security Agreement**"), pursuant to which we provided a security interest in, and a lien on, substantially all of our assets as collateral for the repayment of the First Notes. The holders of the 2024 Notes have been granted a security interest in substantially all of our assets pursuant to the terms of the security agreement dated May 15, 2024 (the "**2024 Notes Security Agreement**"), pursuant to which we provided a security interest in, and a lien on, substantially all of our assets as collateral for the repayment of the 2024 Notes, *pari passu* with the repayment of the First Notes. If we fail to make payments on the First Notes or 2024 Notes when due or otherwise comply with the covenants contained in the First Notes or the 2024 Notes, the First Note and 2024 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.

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Proposed Listing on Cboe or an Alternate Exchange

Our Common Stock is presently quoted on the OTCQB under the trading symbol "ARTH." In connection with the offering pursuant to the Company Prospectus (the "**Primary Offering**"), we have applied to list our Common Stock and Investor Warrants on Cboe under the symbols "ARTH" and "ARTHW," respectively. Although we have applied to list the Investor Warrants, there is no established public trading market for the Investor Warrants and without an active trading market, the liquidity of the Investor Warrants will be limited. No assurance can be given that our listing application for our Common Stock and Investor Warrants will be approved by Cboe or an Alternate Exchange. If our listing application is approved, our Common Stock will cease to be traded on the OTCQB. The Primary Offering will occur only if Cboe or an Alternate Exchange approves the listing of our Common Stock by June 30, 2024. The Cboe 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 Cboe listing requirements or the listing requirements of an Alternate Exchange, including but not limited to a reverse split of our outstanding shares of Common Stock.

Implications of Being a Smaller Reporting Company

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

Corporate Information

Arch Therapeutics, Inc. (together with its subsidiary, the "**Company**" or "**Arch**") is a biotechnology company developing and marketing a products based on our innovative

AC5® self-assembling technology platform. Arch arose from the June 26, 2013 merger (the “**Merger**”) of three entities previously known as Arch Biosurgery, Inc., Almah, Inc., and Arch Acquisition Corporation, respectively.

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

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

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

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

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

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The Transactions

The shares of our Common Stock being offered for resale by selling stockholders named herein pursuant to this prospectus were issued or are issuable in connection with (i) the 2022 Private Placement Financing, (ii) the Bridge Offering, (iii) the Uplist PIPE, (iv) the 2024 Notes Financing and (v) legacy security issuances.

Uplist PIPE

On November 8, 2023, the Company and certain institutional and accredited individual investors (collectively, the “**PIPE Investors**”) entered into a Securities Purchase Agreement, as subsequently amended on June 19, 2024 (as amended, the “**PIPE SPA**”), pursuant to which the Company has agreed to issue and sell to the PIPE Investors, and the PIPE Investors have agreed to purchase from the Company, an aggregate of (i) warrants (the “**PIPE Pre-Funded Warrants**”) to purchase an aggregate of 1,430,650 shares of Common Stock (the “**PIPE Pre-Funded Warrant Shares**”) and (ii) warrants (the “**PIPE Investor Warrants**”) and together with the PIPE Pre-Funded Warrants, the “**PIPE Warrants**”) to purchase an aggregate 1,430,650 shares of Common Stock (the “**PIPE Investor Warrant Shares**” and together with the PIPE Pre-Funded Warrant Share, the “**PIPE Warrant Shares**”), at a purchase price of \$4.124 per PIPE Pre-Funded Warrant to purchase one share of Common Stock and accompanying PIPE Investor Warrant to purchase one share of Common Stock, for aggregate gross proceeds of \$5.9 million, before deducting the placement agent’s fees and estimated offering expenses, and expected net proceeds of \$5.4 million after deducting the placement agent’s fees and estimated offering expenses payable by the Company. The PIPE Pre-Funded Warrants and PIPE Investor Warrants will be issued as part of a private placement offering authorized by the Company’s board of directors (the “**Uplist PIPE**”). The Company currently intends to use the net proceeds it receives from the Uplist PIPE for product marketing and for general working capital purposes. The purpose of the Uplist PIPE is mainly to assist the Company in meeting the initial listing requirements of Cboe, including for purposes of the minimum stockholders’ equity requirement and the requirement of the Company to achieve its listing in connection with a firm commitment underwritten public offering.

Between December 13, 2023 and March 28, 2024, certain of the PIPE Investors advanced the Company an aggregate of \$1.25 million as partial prepayment of their respective purchase price under the PIPE SPA, which funds were advanced outside of the escrow provided for in the PIPE SPA, and which funds have been available to the Company in support of its operations (the “**PIPE Advances**”). On May 15, 2024, the 2024 Notes Investors (as defined below) purchased an aggregate of \$2,220,000 in principal amount of 2024 Notes (as defined below) for an aggregate purchase price of \$1,850,000, which amount was paid through the surrender and cancellation of the PIPE Advances by the 2024 Notes Investors and an incremental amount of \$600,000 in cash. Under the PIPE SPA, a PIPE Investor’s obligation to purchase PIPE Pre-Funded Warrants and PIPE Investor Warrants is reduced by the purchase price paid by such PIPE Investor for 2024 Notes under the 2024 Notes SPA (as defined below). Accordingly, it is currently anticipated that PIPE Pre-Funded Warrants to purchase an aggregate of 982,056 shares of Common Stock and PIPE Investor Warrants to purchase an aggregate of 982,056 shares of Common Stock will be issued in the Uplist PIPE, for gross proceeds of \$4,050,000, and expected net proceeds of \$3,528,000, while the \$2,220,000 in principal amount of 2024 Notes will automatically convert at the closing of the Primary Offering into (i) 2024 Note Conversion Pre-Funded Warrants to purchase an aggregate of 538,182 shares of Common Stock and (ii) 2024 Note Uplist Conversion Warrants to purchase an aggregate of 538,182 shares of Common Stock, reflecting a net addition for the benefit of the PIPE Investors that are 2024 Notes Investors of an aggregate of 89,700 shares underlying the 2024 Note Conversion Pre-Funded Warrants and 2024 Note Uplist Conversion Warrants, respectively, that is the result of the premium of the principal amount of \$2,220,000 of the 2024 Notes over their purchase price of \$1,850,000 (which purchase price, as stated above, has reduced the aggregate purchase price of the securities sold in the PIPE SPA).

The closing of the Uplist PIPE is contingent upon, among other conditions, the registration statement of which this prospectus forms a part being declared effective by the SEC and the approval of the listing of the Common Stock on any securities exchange registered with the SEC as a “national securities exchange” under Section 6 of the Exchange Act (a “**National Exchange**”), and the closing is expected to occur immediately prior to the pricing of the Primary Offering.

The Company retained Dawson James Securities, Inc. (“**DJ**”), pursuant to a placement agency agreement, dated November 8, 2023, as placement agent in connection with the Uplist PIPE. The Company will pay DJ a cash fee equal to 8.0% of the aggregate gross proceeds of the Uplist PIPE (expected to be \$472,000), will reimburse DJ for legal and other expenses of up to \$150,000 and will issue to DJ, or its designees, warrants (the “**PIPE Placement Agent Warrants**”) to purchase an aggregate of 71,533 shares of Common Stock. The PIPE Placement Agent Warrants will be exercisable at any time and from time to time, in whole or in part, during the five-year period commencing upon issuance, at a price per share equal to \$5.15625 (which is 125% of the price per Unit sold in the Primary Offering).

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PIPE Pre-Funded Warrants

The PIPE Pre-Funded Warrants (i) will have a nominal exercise price of \$0.001 per share; (ii) will be exercisable immediately upon issuance; (iii) will be exercisable until all of the PIPE Pre-Funded Warrants are exercised in full; and (iv) will have a provision preventing the exercisability of such PIPE Pre-Funded Warrants if, as a result of the exercise of the PIPE Pre-Funded Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than either 4.99% or 9.99% of the Common Stock (the “**Ownership Limitation**”) immediately after giving effect to the exercise of the PIPE Pre-Funded Warrants.

PIPE Investor Warrants

The PIPE Investor Warrants (i) will have an exercise price of \$4.00 per share; (ii) will have a term of exercise equal to 5 years after their issuance date; (iii) will be exercisable immediately upon issuance; and (iv) will have a provision preventing the exercisability of such PIPE Investor Warrants if, as a result of the exercise of the PIPE Investor Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than the Ownership Limitation immediately after giving effect to the exercise of the PIPE Investor Warrants.

Pursuant to the PIPE SPA, the Company has agreed to file no later than sixty (60) days after the closing date of an offering conducted in conjunction with an uplist of the Common Stock to, and in compliance with the rules of, any National Exchange (the “**Uplist Transaction**”), which the Primary Offering is intended to be, a registration statement on Form S-4, or other appropriate form, registering the offer by the Company to exchange, on a one-for-one basis, all outstanding PIPE Investor Warrants, 2022 Warrants (as defined below), Uplist Conversion Warrants (as defined below) and Exchange Investor Warrants (as defined below) for newly issued warrants identical to the Investor Warrants being sold in the Primary Offering, which warrants are expected to be listed on Cboe under the symbol “ARTHW.”

Registration Rights Agreement

The Company also entered into a registration rights agreement with the PIPE Investors dated November 8, 2023 (the “**PIPE Registration Rights Agreement**”), pursuant to which the Company is obligated, subject to certain conditions, to file with the SEC within the earlier of (i) the closing date of the Uplist Transaction and (ii) the 60th calendar day following the date of the PIPE Registration Rights Agreement one or more registration statements to register the PIPE Warrant Shares, the Uplist Conversion Warrant Shares (as defined below) and the 2022 Note Conversion Pre-Funded Warrant Shares (as defined below) for resale under the Securities Act of 1933, as amended (the “Securities Act”). The Company’s failure to satisfy certain filing and effectiveness deadlines and certain other requirements set forth in the PIPE Registration Rights Agreement may subject the Company to payment of monetary penalties.

PIPE Advances

Under the terms of the PIPE Advances, since the Common Stock has not been approved for listing on the Nasdaq Capital Market by March 31, 2024, with respect to a portion of the PIPE Advances, or April 30, 2024, with respect to the remainder of the PIPE Advances, the Company has issued to the advancing parties (A) additional pre-funded warrants (the “**PIPE Advance Penalty Pre-Funded Warrants**”) to purchase up to an aggregate of 75,776 shares of Common Stock (which represents a 25% addition) and (B) additional investor warrants (the “**PIPE Advance Penalty Common Warrants**”) to purchase up to an aggregate of 75,776 shares of Common Stock. The Resale Prospectus currently covers the resale of the shares of Common Stock underlying the PIPE Advance Penalty Pre-Funded Warrants (the “**PIPE Advance Penalty Pre-Funded Warrant Shares**”) and the PIPE Advance Penalty Common Warrants (the “**PIPE Advance Penalty Common Warrant Shares**”).

Backstop Agreement

On June 19, 2024, certain of the PIPE Investors (the “**Backstop Buyers**”) agreed that in the event that as of the close of business on the date that is 10 calendar days prior to the date that the Company reasonably expects the closing of the Uplist PIPE to occur (the “**Escrow Date**”) there is not an amount of funds in escrow for the PIPE equal to \$5,900,000 less the aggregate purchase price paid for the 2024 Notes (the “**Escrow Minimum Amount**”) (such circumstance, an “**Escrow Deficiency**”), then each of the Backstop Buyers will deposit in escrow the purchase price for a pro rata share of an amount, no greater than \$1,500,000, equal to (A) \$320,000 plus (B) (i) \$5,900,000, minus (ii) the amount of funds in escrow on the Escrow Date, minus (iii) the aggregate purchase price paid by PIPE Investors for the 2024 Notes (the “**Backstop Amount**”) of additional PIPE Pre-Funded Warrants and PIPE Investor Warrants under the PIPE SPA (such agreement, the “**Backstop Agreement**”), and shall purchase such additional PIPE Pre-Funded Warrants and PIPE Investor Warrants at the Uplist PIPE closing. In consideration for the execution by the Backstop Buyers of the Backstop Agreement, the Company agreed to issue to the Backstop Buyers, as soon as practicable, pre-funded warrants (the “**Execution Backstop Pre-Funded Warrants**”), in form and substance substantially similar to the PIPE Pre-Funded Warrants, to purchase an aggregate of 225,000 shares of Common Stock. The Company also agreed to issue to the Backstop Buyers (i) additional pre-funded warrants (the “**Funding Backstop Pre-Funded Warrants**”) and, together with the Execution Backstop Pre-Funded Warrants, the “**Backstop Pre-Funded Warrants**”) to purchase an amount of shares of Common Stock equal to 0.5 shares per dollar of funding deposited under the Backstop Agreement, or up to an aggregate of 750,000 shares, and (ii) investor warrants (the “**Backstop Common Warrants**”), in form and substance substantially similar to the PIPE Investor Warrants, to purchase an amount of shares of Common Stock equal to 0.65 shares per dollar of funding deposited under the Backstop Agreement, or up to an aggregate of 975,000 shares. The Resale Prospectus currently covers the resale of the shares of Common Stock underlying the Backstop Pre-Funded Warrants (the “**Backstop Pre-Funded Warrant Shares**”) and the Backstop Common Warrants (the “**Backstop Common Warrant Shares**”).

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2024 Notes

On May 15, 2024, the Company entered into a Securities Purchase Agreement (the “**2024 Notes SPA**”) with certain institutional and accredited individual investors who are also PIPE Investors (collectively, the “**2024 Notes Investors**”) providing for the issuance and sale by the Company to the 2024 Notes Investors certain Secured Promissory Notes (each a “**2024 Note**” and collectively, the “**2024 Notes**”) convertible into shares of Common Stock. On June 12, 2024, an additional investor, which is not a PIPE Investor (the “**Additional 2024 Notes Investor**”) purchased 2024 Notes in the principal amount of \$180,000, including an original issue discount of \$30,000. The 2024 Notes were issued as part of a convertible notes offering authorized by the Company’s board of directors (the “**2024 Notes Financing**”).

In connection with the 2024 Notes Financing, the Company issued and sold to the 2024 Notes Investors and Additional 2024 Notes Investors the 2024 Notes in the aggregate principal amount of \$2,400,000, which includes an aggregate \$370,000 original issue discount in respect of the 2024 Notes. The aggregate net proceeds for the sale of the 2024 Notes was approximately \$2,000,000, after deducting issuance discounts. The closing of the sales of the 2024 Notes to the 2024 Notes Investors under the 2024 Notes SPA occurred on May 15, 2024 (the “**2024 Notes Closing Date**”). The Company is using the net proceeds from the 2024 Notes Financing primarily for working capital and general corporate purposes, and has not allocated specific amounts for any specific purposes.

The 2024 Notes become due and payable on June 30, 2024 (the “**2024 Notes Maturity Date**”) and may be prepaid provided that an Event of Default (as defined therein) has not occurred. The 2024 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 their issuance date until the 2024 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 2024 Notes. Any amount of principal or interest on the 2024 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 “**Default Interest**”).

The 2024 Notes are convertible into an aggregate of 600,000 shares of Common Stock (such shares of Common Stock, the “**2024 Conversion Shares**”) at the option of each holder of the 2024 Notes from their issuance date at the 2024 Conversion Price (as defined below) through the later of (i) the 2024 Notes Maturity Date and (ii) the date of payment of the Default Amount (as defined in the 2024 Note); *provided, however*, the 2024 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 (the “**2024 Notes Ownership Limitation**”) immediately after giving effect to the conversion; and *provided further*, the holder, upon notice to the Company, may increase or decrease the 2024 Notes Ownership Limitation; *provided that* (i) the 2024 Notes 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 2024 Notes Ownership Limitation will not become effective until the 61st day after delivery of such waiver notice.

The initial conversion price of the 2024 Notes (the “**2024 Conversion Price**”) shall be equal to \$4.00 per share and may be reduced or increased proportionately as a result of any stock dividends, recapitalizations, reorganizations, and similar transactions. If the Company fails to deliver the shares of Common Stock issuable upon a conversion by the Deadline (as defined in the 2024 Notes), then the Company is obligated to pay such 2024 Note holder \$5,000 per day in cash for each day beyond the Deadline.

The 2024 Notes contain customary events of default, which include, among other things, (i) the Company’s failure to pay when due any principal or interest payment under the 2024 Notes; (ii) the insolvency of the Company; (iii) delisting of the Common Stock; (iv) the Company’s breach of any material covenant or other material term or condition under the 2024 Notes; and (v) the Company’s breach of any representations or warranties under the 2024 Notes which cannot be cured within five days. Further, Events of Default under the 2024 Notes also include (i) the unavailability of Rule 144 on or after six months from the Issue Date (as defined therein); (ii) the Company’s failure to deliver the shares of Common Stock to the 2024 Note holder upon exercise by such holder of its conversion rights under the 2024 Note; (iii) the Company’s 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) the Company's failure to complete an uplist to a National Exchange by June 30, 2024.

Upon an Event of Default, the 2024 Notes shall become immediately due and payable and the Company shall pay to each 2024 Note holder an amount equal to 125% (the "Default Premium") multiplied by the sum of the outstanding principal amount of the 2024 Notes plus any accrued and unpaid interest on the unpaid principal amount of the 2024 Notes to the date of payment, plus any Default Interest and any other amounts owed to the holder under the 2024 Notes 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 five percent (5%) to the Default Premium for each subsequent Event of Default. At the election of each 2024 Note holder, the Default Amount may be paid in cash or shares of Common Stock equal to the Default Amount divided by the 2024 Conversion Price at the time of payment.

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Upon the closing of an Uplist Transaction, which the Primary Offering is intended to be, 100% of the then outstanding principal amount of the 2024 Notes shall automatically convert (the "2024 Notes Automatic Conversion") into shares of Common Stock (the "2024 Notes Automatic Conversion Shares"), with the conversion price for purposes of such 2024 Notes Automatic Conversion being \$4.125. Upon the 2024 Notes Automatic Conversion and to the extent that the beneficial ownership of a holder of 2024 Notes (a "2024 Notes Holder" and, all holders of 2024 Notes together, the "2024 Notes Holders") would increase over the applicable 2024 Notes Ownership Limitation, the 2024 Notes Holder will receive pre-funded warrants (the "2024 Note Conversion Pre-Funded Warrants", and the shares issuable upon exercise thereof, the "2024 Note Conversion Pre-Funded Warrant Shares") in lieu of shares of Common Stock otherwise issuable to the 2024 Notes Holder in connection with the 2024 Notes Automatic Conversion, which 2024 Note Conversion Pre-Funded Warrants shall have an exercise price of \$0.001 per share, may be exercised on a cashless basis, shall be exercisable immediately upon issuance and shall contain a customary beneficial ownership limitation provision.

In addition, upon the 2024 Notes Automatic Conversion, the 2024 Notes Holder shall receive a warrant (the "2024 Notes Uplist Conversion Warrant", and the shares issuable upon exercise thereof, the "2024 Notes Uplist Conversion Warrant Shares") to purchase a number of shares of Common Stock equal to the number of shares of Common Stock (or shares of Common Stock underlying 2024 Note Conversion Pre-Funded Warrants, if any) issued upon the 2024 Notes Automatic Conversion. The 2024 Notes Uplist Conversion Warrant shall have an exercise price per share of \$4.00 and shall otherwise be identical to the PIPE Investor Warrants. The Company also agreed in the 2024 Notes to file no later than sixty (60) days after the closing of the Primary Offering a registration statement on Form S-4, or other appropriate form, registering the offer by the Company to exchange, on a one-for-one basis, all outstanding PIPE Investor Warrants, 2024 Notes Uplist Conversion Warrants and Exchange Investor Warrants for newly issued warrants identical to the Investor Warrants being sold in the Primary Offering, which warrants are expected to be listed on Cboe under the symbol "ARTHW."

Registration Rights Agreement

On the 2024 Notes Closing Date, the Company entered into a Registration Rights Agreement with the 2024 Notes Investors (the "2024 Notes Registration Rights Agreement"), pursuant to which the Company is obligated, subject to certain conditions, to file with the Securities and Exchange Commission within 60 days after the 2024 Notes Closing Date one or more registration statements (any such registration statement, a "2024 Notes Resale Registration Statement") to register the 2024 Conversion Shares for resale under the Securities Act. The Company's failure to satisfy certain filing and effectiveness deadlines with respect to a 2024 Notes Resale Registration Statement and certain other requirements set forth in the 2024 Notes Registration Rights Agreement may subject the Company to payment of monetary penalties.

Security Agreement

In connection with the issuance of the 2024 Notes, the Company entered into a Security Agreement with the Collateral Agent (as defined therein) on behalf of the 2024 Notes Investors on the 2024 Notes Closing Date (the "2024 Notes Security Agreement"), pursuant to which the Company and each of its subsidiaries (together with any persons who execute a joinder to the 2024 Notes Security Agreement, the "2024 Notes Debtors") provided as collateral to the 2024 Notes holders a security interest in, and a lien on, substantially all of the 2024 Notes Debtors. Upon an Event of Default under the 2024 Notes, each 2024 Notes holder may exercise its rights to the collateral pursuant to the terms of the 2024 Notes Security Agreement.

Accordingly, it is currently anticipated that at the closing of the Primary Offering: (i) (A) 2024 Note Conversion Pre-Funded Warrants with an exercise price of \$0.001 to purchase an aggregate of 538,182 shares of Common Stock and (B) 43,637 2024 Notes Automatic Conversion Shares will be issued upon the 2024 Note Automatic Conversion of the \$2,400,000 of principal amount outstanding under the 2024 Notes; and (ii) the 2024 Note Holders will be issued 2024 Note Uplist Conversion Warrants to purchase an aggregate of 581,819 shares of Common Stock. The expected allocation between shares of Common Stock and 2024 Note Conversion Pre-Funded Warrants in the previous sentence is only an initial estimate based on indications of interest and is subject to change based on the ultimate ownership of the 2024 Note Holders after the Uplist PIPE and the Primary Offering. The maximum number of shares of Common Stock and 2024 Note Conversion Pre-Funded Warrants that may be issued, individually and in the aggregate is 581,819.

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We are registering for resale by the selling shareholders named herein (i) up to 3,433,348 PIPE Warrant Shares, (ii) up to 75,776 PIPE Advance Penalty Pre-Funded Warrant Shares, (iii) up to 75,776 PIPE Advance Penalty Common Warrant Shares, (iv) up to 975,000 Backstop Pre-Funded Warrant Shares, (v) up to 975,000 Backstop Common Warrant Shares, (vi) up to 600,000 2024 Conversion Shares, (vii) up to 581,819 2024 Notes Automatic Conversion Shares, (viii) up to 581,819 2024 Note Conversion Pre-Funded Warrant Shares and (ix) up to 581,819 2024 Notes Uplist Conversion Warrant Shares.

Bridge Offering

Between July 7, 2023 and September 11, 2023, pursuant to a Securities Purchase Agreement dated July 7, 2023, as subsequently amended (the "Bridge SPA"), among the Company and certain institutional and accredited individual investors (collectively, the "Bridge Investors") the Company issued and sold to the Bridge Investors an aggregate of (i) 418,051 shares (the "Bridge Shares") of Common Stock; (ii) warrants (the "Bridge Pre-Funded Warrants") to purchase an aggregate of 756,871 shares of Common Stock (the "Bridge Pre-Funded Warrant Shares"); and (iii) warrants (the "Common Warrants" and together with the Bridge Pre-Funded Warrants, the "Bridge Warrants") to purchase an aggregate 2,349,826 shares of Common Stock (the "Common Warrant Shares" and together with the Bridge Pre-Funded Warrant Share, the "Bridge Warrant Shares"), at a purchase price of \$2.20 per Bridge Share and accompanying Common Warrant to purchase two shares of Common Stock, and \$2.192 per Bridge Pre-Funded Warrant to purchase one share of Common Stock and accompanying Common Warrant to purchase two shares of Common Stock. The Bridge Shares, Bridge Pre-Funded Warrants, and Common Warrants were issued as part of a private placement offering authorized by the Company's board of directors (the "Bridge Offering").

Pursuant to the Bridge SPA, the Bridge Investors agreed not to sell or otherwise transfer any of the Bridge Shares or Bridge Warrant Shares prior to the one-year anniversary of the Bridge Closing Date. In the event that a Bridge Investor purchases securities in connection with an Uplist Transaction, which the Primary Offering is intended to be, and/or in the Uplist PIPE, with an aggregate purchase price equal to at least 4.3 multiplied by the aggregate purchase price paid by the Bridge Investor for the Bridge Shares and Bridge Warrants under the Bridge SPA, the one-year lock-up period will no longer apply to the Bridge Shares and Bridge Warrants. The aggregate gross proceeds for the sale of the Bridge Shares, Bridge Pre-Funded Warrants, and Common Warrants was approximately \$2.6 million, before deducting the placement agent's fees and other estimated fees and offering expenses payable by the Company. The first closing of the sales of these securities under the Bridge SPA occurred on July 7, 2023 (the "Bridge Closing Date").

Under the Bridge SPA, the Company also agreed that upon the closing of the next underwritten public offering of Common Stock (a "Qualifying Offering"), which the Company agreed is the Primary Offering, if the effective offering price to the public per share of Common Stock (the "Qualifying Offering Price") is lower than \$32.00 per share, then the Company shall issue additional Bridge Pre-Funded Warrants (the "True-Up Pre-Funded Warrants", and the shares issuable upon exercise thereof, the "True-Up Pre-Funded Warrant Shares"), or shares of Common Stock (the "True-Up Shares") in lieu thereof to the extent necessary to cause the Company to meet the listing

requirements of the Company's proposed trading market in the Uplist Transaction, in an amount reflecting a reduction in the purchase price paid for the Bridge Shares and Bridge Pre-Funded Warrants that equals the proportion by which the Qualifying Offering Price is less than \$32.00. The Company also agreed that the Qualifying Offering Price as a result of the Primary Offering is \$4.00. **Accordingly, at the closing of the Primary Offering, based on the sale of the Units and Pre-Funded Units at an assumed public offering price of \$4.125 per Unit and \$4.124 per Pre-Funded Unit, which represents the minimum bid price of \$4.00 per share under the initial listing requirements of Cboe in Cboe Listing Rule 14.9(b) plus a value of \$0.125 attributed to the accompanying Investor Warrant, the Company expects to issue (i) True-Up Pre-Funded Warrants with an exercise price of \$0.001 to purchase an aggregate of 6,330,422 shares of Common Stock and (ii) an aggregate of 1,893,919 True-Up Shares to the Bridge Investors.** The expected allocation between True-Up Shares and True-Up Pre-Funded Warrants in the previous sentence is only an initial estimate based on indications of interest and is subject to change based on the ultimate ownership of the Bridge Investors after the Uplist PIPE and the Primary Offering. The maximum amount of True-Up Pre-Funded Warrants and True-Up Shares that may be issued, individually and in the aggregate is 8,224,341.

The Company retained DJ as placement agent in connection with the Bridge Offering. Pursuant to an engagement agreement, the Company paid DJ a cash fee equal to 8.0% of the aggregate gross proceeds of the Bridge Offering and reimbursement of expenses of \$50,000. Additionally, on September 7, 2023 the Company issued to DJ, or its designees, warrants, as subsequently amended (the "**Bridge Placement Agent Warrants**") to purchase an aggregate of 55,242 shares of Common Stock (the "**Bridge Placement Agent Warrant Shares**"). The Bridge Placement Agent Warrants are exercisable at any time and from time to time, in whole or in part, until September 7, 2028, at a price per share equal to \$2.20 (which will increase to \$5.15625 at the closing of the Uplist Transaction, representing 125% of the assumed price per share of Common Stock in the Uplist Transaction, as required by FINRA).

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Bridge Pre-Funded Warrants

The Bridge Pre-Funded Warrants (i) have a nominal exercise price of \$0.008 per share; (ii) are exercisable after the earlier of (A) the six-month anniversary after the date of issuance, (B) 120 days after the closing date of an Uplist Transaction, and (C) the date that a registration statement registering the Bridge Pre-Funded Warrant Shares is declared effective; (iii) are exercisable until all of the Bridge Pre-Funded Warrants are exercised in full; and (iv) have a provision preventing the exercisability of such Bridge Pre-Funded Warrants if, as a result of the exercise of the Bridge Pre-Funded Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder's, would be deemed to beneficially own more than the Ownership Limitation immediately after giving effect to the exercise of the Bridge Pre-Funded Warrants.

Common Warrants

The Common Warrants (i) have an exercise price of \$8.00 per share; (ii) have a term of exercise equal to 5 years after their issuance date; (iii) are exercisable after the earlier of (A) the six-month anniversary after the date of issuance and (B) the date that a registration statement registering the Common Warrant Shares is declared effective; (iv) have a provision permitting voluntary adjustments to the exercise price by the Company, subject to the prior written consent of the Common Warrant holder; (v) are automatically exchanged upon the closing of an Uplist Transaction for a new warrant that is identical to the warrants (other than any pre-funded warrants), if any, being issued to investors in such Uplist Transaction, with the number of shares underlying such new warrant being equal to the number of Common Warrant Shares then underlying the Common Warrant multiplied by three and (vi) have a provision preventing the exercisability of such Common Warrants if, as a result of the exercise of the Common Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Company Common Stock would be aggregated with the holder's, would be deemed to beneficially own more than the Ownership Limitation immediately after giving effect to the exercise of the Common Warrants. **Accordingly, at the closing of the Primary Offering, the Common Warrants will be cancelled and exchanged for newly issued warrants (the "Exchange Investor Warrants") identical to the Investor Warrants to purchase an aggregate of 7,049,478 shares of Common Stock (the "Exchange Investor Warrant Shares") at an exercise price per share equal to the exercise price per share of the Investor Warrants.**

In addition, as noted above, pursuant to the PIPE SPA, the Company has agreed to file no later than sixty (60) days after the closing date of the Uplist Transaction, a registration statement on Form S-4, or other appropriate form, registering the offer by the Company to exchange, on a one-for-one basis, all outstanding Exchange Investor Warrants for newly issued warrants identical to the Investor Warrants being sold in the Primary Offering, which warrants are expected to be listed on Cboe under the symbol "ARTHW."

Registration Rights Agreement

The Company also entered into a registration rights agreement with the Bridge Investors dated July 7, 2023, as subsequently amended (the "**Registration Rights Agreement**"), pursuant to which the Company is obligated, subject to certain conditions, to file with the SEC within the earlier of (i) 30 days following the closing date of the Uplist Transaction and (ii) January 31, 2024 one or more registration statements (any such registration statement, a "**Resale Registration Statement**") to register the Bridge Shares, the Bridge Warrant Shares and the Exchange Investor Warrant Shares for resale under the Securities Act of 1933, as amended (the "**Securities Act**"). The Company's failure to satisfy certain filing and effectiveness deadlines with respect to a Resale Registration Statement and certain other requirements set forth in the Registration Rights Agreement may subject the Company to payment of monetary penalties.

We are registering for resale by the selling shareholders named herein (i) 384,159 Bridge Shares (which is less than the 418,051 total Bridge Shares originally issued because a former stockholder exchanged 33,892 Bridge Shares for a near equivalent amount of Legacy Pre-Funded Warrants, as discuss below), (ii) up to 8,224,341 True-Up Shares, (iii) up to 8,224,341 True-Up Pre-Funded Warrant Shares and (iii) up to 3,106,697 Bridge Warrant Shares.

2022 Private Placement Financing

On July 7, 2022, the Company announced that it had entered into a Securities Purchase Agreement, as subsequently amended (the "**2022 SPA**") with certain institutional and accredited individual investors (collectively, the "**2022 Investors**") providing for the issuance and sale by the Company to the 2022 Investors of (i) Senior Secured Convertible Promissory Notes (the "**First Notes**"); (ii) warrants (the "**First Warrants**") to purchase 53,195 shares of Common Stock (the "**First Warrant Shares**"); and (iii) 7,980 shares of Common Stock (the "**First Inducement Shares**"), equal to 15% of the principal amount of the Senior Secured Convertible Promissory Notes divided by the closing price of the Common Stock immediately prior to the First Closing Date (as defined below). The securities were issued as part of a convertible note offering authorized by the Company's board of directors (the "**2022 Private Placement Financing**"). The first closing of the sales of these securities under the 2022 SPA (the "**First Closing**") occurred on July 6, 2022 (the "**First Closing Date**"). The Company retained Maxim Group LLC ("**Maxim**") as placement agent in connection with the First Closing. Pursuant to an engagement agreement the Company entered into with Maxim (the "**2022 Engagement Letter**"), that we entered into with Maxim, we agreed, among other things, to (i) pay Maxim 10% of the gross proceeds in the First Closing from certain institutional investors, or \$240,000, and (ii) issue Maxim, or its designees, warrants ("**First Placement Agent Warrants**") to purchase up to 10% of the aggregate number of shares sold to the institutional investors in the First Closing, or warrants to purchase up to 3,939 shares of Common Stock.

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On January 18, 2023, the Company entered into Amendment No. 1 to the 2022 SPA (the "**Amendment**"), with certain Investors in connection with the second closing of the 2022 Private Placement Financing (the "**Second Closing**") for the issuance and sale by the Company to such Investors of an aggregate of (i) Unsecured Convertible Promissory Notes (each a "**Second Note**" and collectively, the "**Second Notes**") in the aggregate principal amount of \$636,000, which includes an aggregate \$106,000 original issue discount in respect of the Second Notes; (ii) warrants (the "**Second Warrants**") to purchase an aggregate of 15,996 shares of Common Stock at an exercise price of \$79.52 (which will automatically change to \$4.00 as of the closing of the Uplist PIPE through the operation of the Most Favored Nation Provision) per share (the "**Second Warrant Shares**"); and (iii) 1,200 shares of Common Stock (the "**Second Inducement Shares**"). The aggregate gross proceeds for the sale of the Second Notes, Second Warrants, and Second Inducement Shares was approximately \$530,000, before deducting the placement agent's fees and other estimated fees and offering expenses payable by the Company

of approximately \$15,000. The Second Closing of the sales of these securities under the 2022 SPA, as amended, occurred on January 18, 2023 (the “**Second Closing Date**”). The Company retained Maxim as placement agent in connection with the private placement of \$500,000 of the Second Notes to the institutional investors. Pursuant to the 2022 Engagement Letter, the Company agreed, among other things, to (i) pay Maxim 10% of the gross proceeds in the Second Closing of the 2022 Private Placement Financing from the institutional investors, or \$50,000, and (ii) issue to Maxim, or its designees, warrants (the “**2022 Placement Agent Warrants**”) to purchase up to 10% of the aggregate number of shares sold to the institutional investors in the Second Closing of the Convertible Notes Offering, or warrants to purchase up to 821 shares of Common Stock at a price per share equal to \$80.48 (which will automatically change to \$4.00 as of the closing of the Uplist PIPE through the operation of the Most Favored Nation Provision) (the “**2022 Placement Agent Warrant Shares**”).

On May 15, 2023, the Company entered into Amendment No. 2 to the 2022 SPA related to the 2022 Private Placement Financing (the “**Second Amendment**”) with an Investor in connection with the third closing of the 2022 Private Placement Financing (the “**Third Closing**”) for the issuance and sale by the Company to an Investor of an aggregate of (i) Unsecured Convertible Promissory Notes (each a “**Third Note**” and collectively, the “**Third Notes**”) in the aggregate principal amount of \$703,000, which includes an aggregate \$215,000 original issue discount in respect of the Third Notes; (ii) warrants (the “**Third Warrants**”) to purchase an aggregate of 17,675 shares of Common Stock at an exercise price of \$79.52 (which will automatically change to \$4.00 as of the closing of the Uplist PIPE through the operation of the Most Favored Nation Provision) per share (the “**Third Warrant Shares**”); and (iii) 1,326 shares of Common Stock (the “**Third Inducement Shares**” and together with the Second Inducement Shares, the “**2022 Inducement Shares**”). The aggregate gross proceeds for the sale of the Third Notes, Third Warrants, and Third Inducement Shares was approximately \$488,000, before deducting any estimated fees and offering expenses payable by the Company. The Company did not engage a placement agent in connection with the issuance of the Third Notes, Third Warrants, and Third Inducement Shares. The Third Closing of the sales of these securities under the 2022 SPA, as amended, occurred on May 15, 2023 (the “**Third Closing Date**”).

On March 12, 2024, the Company entered into Amendment No. 3 to the 2022 SPA (the “**Third Amendment**”), with certain Investors in connection with the fourth closing of the 2022 Private Placement Financing (the “**Fourth Closing**”) for the issuance and sale by the Company to such Investors of an aggregate of (i) Unsecured Convertible Promissory Notes (each a “**Fourth Note**” and collectively, the “**Fourth Notes**”) in the aggregate principal amount of \$648,000, which includes an aggregate \$108,000 original issue discount in respect of the Fourth Notes; (ii) Warrants (the “**Fourth Warrants**”) to purchase an aggregate of 16,298 shares (the “**Fourth Warrant Shares**” and, together with the Second Warrant Shares and Third Warrant Shares, the “**2022 Warrant Shares**”) at an exercise price of \$79.52 (which will automatically change to \$4.00 as of the closing of the Uplist PIPE through the operation of the Most Favored Nation Provision) per share of Common Stock; and (iii) Pre-Funded Warrants (the “**Inducement Pre-Funded Warrants**”) to purchase an aggregate of 1,223 shares of Common Stock (the “**Inducement Pre-Funded Warrant Shares**”) at an exercise price of \$0.008 per share, in lieu of shares of Common Stock otherwise issuable under the 2022 SPA. The aggregate net proceeds for the sale of the Fourth Notes, Fourth Warrants and Inducement Pre-Funded Warrants was approximately \$450,000, after deducting issuance discounts. The fourth closing of the sales of these securities under the 2022 SPA occurred on March 12, 2024 (the “**Fourth Closing Date**”).

2022 Notes

The First Notes, Second Notes, Third Notes and Fourth Notes (collectively, the “**2022 Notes**”) bear interest on the unpaid principal balance at a rate equal to ten percent (10%) (computed on the basis of the actual number of days elapsed in a 360-day year) per annum accruing from the issuance date until the 2022 Notes become due and payable at maturity or upon their conversion, acceleration or by prepayment, and may become due and payable upon the occurrence of an event of default under the 2022 Notes. The 2022 Notes mature on June 30, 2024. Any amount of principal or interest on the 2022 Notes that is not paid when due shall bear interest at the rate of the lesser of (i) eighteen percent (18%) per annum or (ii) the maximum amount allowed by law from the due date thereof until payment in full.

The 2022 Notes are convertible into shares of Common Stock at the option of each Holder from the date of issuance at \$73.12 (which will automatically change to \$4.00 as of the closing of the Uplist PIPE through the operation of the Most Favored Nation Provision) (the “**Conversion Price**”), subject to adjustment, through the later of (i) June 30, 2024 (the “**Maturity Date**”) or (ii) the date of payment of the Default Amount (as defined in the 2022 Notes).

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The 2022 Notes contain events of default, which include, among other things, (i) the Company’s failure to pay when due any principal or interest payment under the 2022 Notes; (ii) our failure to complete an Uplist Transaction by June 30, 2024 and (iii) our default on the Uplist Conversion Warrant Exchange Offer Obligation (as defined below).

The First Warrants, Second Warrants, Third Warrants and Fourth Warrants (collectively, the “**2022 Warrants**”) (i) have an exercise price of \$79.52 (which will automatically change to \$4.00 as of the closing of the Uplist PIPE through the operation of the Most Favored Nation Provision) per share; (ii) have a term of exercise equal to 5 years after their issuance date; (iii) became exercisable immediately after their issuance; and (iv) have a provision preventing the exercisability of such 2022 Warrants if, as a result of the exercise of the 2022 Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of our Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than the Ownership Limitation. Pursuant to the “**Most Favored Nation Provision**” contained in the 2022 Notes and the 2022 Warrants, as long as the 2022 Notes and 2022 Warrants remain outstanding, upon the issuance of any security in connection with any potential future financing activity on terms more favorable than the existing terms, the Company has an obligation to notify the holders of the 2022 Notes and 2022 Warrants of such more favorable terms, and to use best efforts to effect such terms in the 2022 Notes and 2022 Warrants.

Note Modification Agreements

On April 30, 2024, the Company entered into (i) an amendment (“**Amendment No. 16 to the First Notes**”) with the holders of the First Notes, (ii) an amendment (“**Amendment No. 16 to the Second Notes**”) with the holders of the Second Notes, (iii) an amendment (“**Amendment No. 11 to the Third Notes**”) with the holders of the Third Notes and (iv) an amendment (“**Amendment No. 2 to the Fourth Notes**”) and, together with Amendment No. 16 to the First Notes, Amendment No. 16 to the Second Notes and Amendment No. 11 to the Third Notes, the “**Amendments to the 2022 Notes**”).

Under the Amendments to the 2022 Notes, the following amendments to the 2022 Notes will be simultaneously effective upon the closing of the Uplist Transaction. 95% of the then outstanding principal amount of the 2022 Notes shall automatically convert (the “**Automatic Conversion**”) into shares of Common Stock (the “**Automatic Conversion Shares**”), with the conversion price for purposes of such Automatic Conversion being \$4.00. Upon the Automatic Conversion and to the extent that the beneficial ownership of a holder of 2022 Notes (a “**Holder**” and, all holders of 2022 Notes together, the “**Holders**”) would increase over the applicable Ownership Limitation, the Holder will receive pre-funded warrants (the “**2022 Note Conversion Pre-Funded Warrants**”), and the shares issuable upon exercise thereof, the “**2022 Note Conversion Pre-Funded Warrant Shares**”) in lieu of shares of Common Stock otherwise issuable to the Holder in connection with the Automatic Conversion, which 2022 Note Conversion Pre-Funded Warrants shall have an exercise price of \$0.001 per share, may be exercised on a cashless basis, shall be exercisable immediately upon issuance and shall contain a customary beneficial ownership limitation provision.

In addition, upon the Automatic Conversion, the Holder shall receive a warrant (the “**Uplist Conversion Warrant**”, and the shares issuable upon exercise thereof, the “**Uplist Conversion Warrant Shares**”) to purchase a number of shares of Common Stock equal to 10 times the dollar amount under the 2022 Notes that was converted in the Automatic Conversion. The Uplist Conversion Warrant shall have an exercise price per share of \$4.00 and shall otherwise be identical to the PIPE Investor Warrants. The Company also agreed in the Amendments to the 2022 Notes to file no later than sixty (60) days after the closing of the Uplist Transaction a registration statement on Form S-4, or other appropriate form, registering the offer by the Company to exchange, on a one-for-one basis, all outstanding PIPE Investor Warrants, 2022 Warrants, Uplist Conversion Warrants and Exchange Investor Warrants for newly issued warrants identical to the Investor Warrants being sold in the Uplist Transaction, which warrants are expected to be listed on Cboe under the symbol “ARTHW” (the “**Uplist Conversion Warrants Exchange Offer Obligation**”).

The Amendments to the 2022 Notes also prohibit the Company from engaging in any capital raising transactions, subject to certain exceptions, until the earlier of (A) July 7, 2027, and (B) the first date on which all Holders hold less than 20% of the original amount of the Uplist Conversion Warrants received by each Holder, respectively, in connection with the Automatic Conversion.

Accordingly, it is currently anticipated that at the closing of the Primary Offering: (i) an aggregate of (A) 1,454,034 shares of Common Stock and (B) 2022 Note Conversion Pre-Funded Warrants with an exercise price of \$0.001 to purchase an aggregate of 184,296 shares of Common Stock will be issued upon the Automatic Conversion of an aggregate of \$6,553,310 of principal amount under the 2022 Notes, representing 95% of the \$6,898,221 in principal amount currently outstanding as of May 15, 2024 under the 2022 Notes, based on the assumed exercise price of the Investor Warrants being offered as part of the Units and Pre-Funded Units in the Primary Offering of \$4.00 per share; and (ii) the Holders will be issued Uplist Conversion Warrants to purchase an aggregate of 65,533,100 shares of Common Stock, representing 10 multiplied by the \$6,553,310 of principal amount converted in the Automatic Conversion. The expected allocation between shares of Common Stock and 2022 Note Conversion Pre-Funded Warrants in the previous sentence is only an initial estimate based on indications of interest and is subject to change based on the ultimate ownership of the Holders after the Uplist PIPE and the Primary Offering. The maximum number of shares of Common Stock and 2022 Note Conversion Pre-Funded Warrants that may be issued, individually and in the aggregate is 1,638,330.

Additionally, on July 7, 2023, the Company entered into an amendment (the “Omnibus Amendment to Notes and Warrants”) with the Holders of the 2022 Notes, amending the 2022 Notes and 2022 Warrants. Under the Omnibus Amendment to Notes and Warrants, the 2022 Notes and 2022 Warrants were amended to modify the Most Favored Nation provisions therein to exclude the Bridge Offering.

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Under the registration rights agreement, dated as of March 12, 2024, as amended, (as amended, the “Third Amended and Restated Registration Rights Agreement”) the Company is required to file a registration statement registering the securities issued in the Second Closing, Third Closing and Fourth Closing, including the applicable 2022 Notes and 2022 Warrants, no later than 45 days following the closing of the Uplist Transaction. Due to the operation of the Most Favored Nation Provision, the number of Conversion Shares underlying the First Notes will increase due to the Uplist PIPE, and thus we are also registering for resale the Conversion Shares underlying the First Notes.

We are registering for resale by the selling shareholders named herein (i) up to 1,724,557 Conversion Shares, (ii) up to 1,638,330 Automatic Conversion Shares; (iii) up to 1,638,330 2022 Note Conversion Pre-Funded Warrant Shares; (iv) 730 2022 Inducement Shares; (v) up to 1,223 Inducement Pre-Funded Warrant Shares; (vi) up to 49,971 2022 Warrant Shares; (vii) up to 65,533,100 Uplist Conversion Warrant Shares; and (viii) up to 821 2022 Placement Agent Warrant Shares.

Legacy Pre-Funded Warrants

During March 2024, one of the selling shareholders acquired pre-funded warrants (the “Legacy Pre-Funded Warrants”) to purchase an aggregate of 37,510 shares (the “Legacy Pre-Funded Warrant Shares”) of Common Stock, with an exercise price of \$0.008 per share, from a former stockholder of the Company. Some of the Legacy Pre-Funded Warrants were issued to such former stockholder in exchange for the surrender by the former stockholder to the Company of Bridge Shares, First Inducement Shares and 2022 Inducement Shares, previously held by such former stockholder. We are registering for resale by the selling shareholder named herein up to 37,510 Legacy Pre-Funded Warrant Shares.

Recent Developments

Bylaw Amendments

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

Equity Incentive Plan

Effective August 13, 2023, the Board adopted and approved the Amended and Restated 2023 Equity Incentive Plan (the “2023 Plan”) and reserved 56,896 shares of Common Stock for issuance thereunder to employees, officers, directors and consultants of the Company. The stockholders of the Company approved the plan on August 22, 2023. The Plan has a term of 6 years and is intended to replace the Company’s 2013 Stock Incentive Plan, which expired on June 18, 2023.

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

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

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The Offering

Common Stock being offered

Up to 98,444,466 shares of Common Stock, including (i) up to 3,433,348 PIPE Warrant Shares; (ii) up to 75,776 PIPE Advance Penalty Pre-Funded Warrant Shares; (iii) up to 75,776 PIPE Advance Penalty Common Warrant Shares; (iv) up to 975,000 Backstop Pre-Funded Warrant Shares; (v) up to 975,000 Backstop Common Warrant Shares; (vi) up to 600,000 2024 Conversion Shares; (vii) up to 581,819 2024 Notes Automatic Conversion Shares; (viii) up to 581,819 2024 Note Conversion Pre-Funded Warrant Shares; (ix) up to 581,819 2024 Notes Uplist Conversion Warrant Shares; (x) 384,159 Bridge Shares; (xi) up to 8,224,341 True-Up Shares; (xii) up to 8,224,341 True-Up Pre-Funded Warrant Shares; (xiii) up to 3,106,697 Bridge Warrant Shares; (xiv) up to 1,724,557 Conversion Shares; (xv) up to 1,638,330 Automatic Conversion Shares; (xvi) up to 1,638,330 2022 Note Conversion Pre-Funded Warrant Shares; (xvii) 730 2022 Inducement Shares; (xviii) up to 1,223 Inducement Pre-Funded Warrant Shares; (xix) up to 49,971 2022 Warrant Shares; (xx) up to 65,533,100 Uplist Conversion Warrant Shares; (xxi) up to 821 2022 Placement Agent Warrant Shares; and (xxii) up to 37,510 Legacy Pre-Funded Warrant Shares.

Common Stock outstanding prior to the offering 555,562 (as of June 19, 2024)

Common Stock to be outstanding after the offering(1): 83,582,494

Use of proceeds We will not receive any of the proceeds from the sale or other disposition of shares of our Common Stock by the selling stockholders. We may receive proceeds upon exercise for cash of the Inducement Pre-Funded Warrants, Legacy Pre-Funded Warrants, 2024 Note Conversion Pre-Funded Warrants, PIPE Advance Penalty Pre-Funded Warrants, Backstop Pre-Funded Warrants, 2024 Notes Uplist Conversion Warrants, PIPE Advance Penalty Common Warrants, Backstop Common Warrants, 2022 Warrants issued in the Second, Third and Fourth Closings, 2022 Note Conversion Pre-Funded Warrants, 2022 Placement Agent Warrants, Bridge Warrants, True-Up Pre-Funded Warrants, PIPE Warrants and Uplist Conversion Warrants (collectively, the “Resale Warrants”) in which case such proceeds will be used for general working capital purposes. However, each of the aforementioned warrants contains a cashless exercise provision.

Market for common stock: Our Common Stock is traded on the QB tier of the OTC Marketplace (“OTCQB”) under the symbol “ARTH”. On June 18, 2024, the closing price of our Common Stock was \$8.72 (post-split) per share.

Risk Factors See “Risk Factors” beginning on page 18 and other information in this prospectus for a discussion of the factors you should consider before you decide to invest in our Common Stock.

(1) Assumes (a) the full exercise of the Inducement Pre-Funded Warrants, Legacy Pre-Funded Warrants, PIPE Advance Penalty Pre-Funded Warrants, Backstop Pre-Funded Warrants, 2024 Notes Uplist Conversion Warrants, PIPE Advance Penalty Common Warrants, Backstop Common Warrants, 2022 Warrants issued in the second, third and fourth closings of the 2022 Private Placement Financing, 2022 Placement Agent Warrants, Bridge Pre-Funded Warrants, PIPE Warrants and Uplist Conversion Warrants; (b) the Automatic Conversion of 95% of the face amount of the 2022 Notes into the maximum amount of Automatic Conversion Shares, and no issuance of any 2022 Note Conversion Pre-Funded Warrants; (c) the 2024 Notes Automatic Conversion of 100% of the face amount of the 2024 Notes into the maximum amount of 2024 Automatic Conversion Shares, and no issuance of any 2024 Note Conversion Pre-Funded Warrants; (d) the issuance of the Exchange Investor Warrants and cancellation of the Common Warrants at the closing of the Uplist Transaction; (e) the conversion of the remaining 5% of the outstanding amount of the 2022 Notes into 86,228 Conversion Shares at the conversion price of \$4.00 (taking into account the operation of the Most Favored Nation Provision as a result of the Uplist PIPE) per share and (f) the expected issuance at the closing of the Primary Offering of 8,224,341 True-Up Shares and no True-Up Pre-Funded Warrants. Common Stock outstanding as of June 19, 2024 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 11,034 shares of Common Stock at exercise prices ranging from \$32.00 to \$1,040.00 per share and with a weighted average exercise price of \$277.94 per share; (ii) 3,717,114 shares of Common Stock issuable upon the exercise of outstanding warrants, having a weighted average exercise price of \$10.05 per share (which includes 2,349,826 Common Warrants that will automatically be cancelled and exchanged for 7,049,478 Exchange Investor Warrants at the closing of the Primary Offering); (iii) 1,724,557 shares of Common Stock issuable upon regular (non-Automatic) conversion of the 2022 Notes at the conversion price of \$4.00 per share (taking into account the operation of the Most Favored Nation Provision as a result of the Uplist PIPE); (iv) 982,056 shares of Common Stock to be issuable upon exercise at \$0.001 per share of the PIPE Pre-Funded Warrants expected to be issued immediately prior to the pricing of the Primary Offering; (v) 982,056 shares of Common Stock to be issuable upon exercise at \$4.00 per share of the PIPE Investor Warrants expected to be issued immediately prior to the pricing of the Primary Offering; (vi) 71,533 shares of Common Stock to be issuable upon exercise at \$5.15625 per share of the PIPE Placement Agent Warrants expected to be issued immediately prior to the pricing of the Primary Offering; (vii) 1,893,919 True-Up Shares expected to be issued at the closing of the Primary Offering; (viii) 6,330,422 shares of Common Stock to be issuable upon exercise at \$0.001 of the True-Up Pre-Funded Warrants expected to be issued at the closing of the Primary Offering; (ix) 65,533,100 shares of Common Stock to be issuable upon exercise at \$4.00 per share of the Uplist Conversion Warrants expected to be issued at the closing of the Primary Offering; (x) 7,049,478 shares of Common Stock to be issuable upon exercise at \$4.00 per share of the Exchange Investor Warrants expected to be issued at the closing of the Primary Offering; (xi) 538,182 shares of Common Stock to be issuable upon exercise at \$0.001 per share of the 2024 Note Conversion Pre-Funded Warrants expected to be issued at the closing of the Primary Offering; (xii) 581,819 shares of Common Stock to be issuable upon exercise at \$4.00 per share of the 2024 Note Uplist Conversion Warrants expected to be issued at the closing of the Primary Offering; (xiii) 56,896 shares of Common Stock reserved for future issuance under the 2023 Plan; and (xiv) up to 969,697 shares (1,115,151 shares if the underwriters’ option to purchase additional Investor Warrants is exercised in full) of Common Stock issuable upon exercise at \$4.00 per share of the Investor Warrants to be issued in the Primary Offering.

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 do not believe that our current cash on hand as of June 19, 2024 is sufficient to meet our anticipated cash requirements through the end of June 2024.
- 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.
- Even if the Primary Offering is successful, we will need substantial additional funding 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.
- Our obligations under the First Notes and 2024 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 and 2024 Notes could result in our loss of substantially all of our assets.
- The holders of our 2022 Notes and 2024 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 commercialize our products, we will continue to incur losses and will never be profitable.
- 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.

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- 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 flagship 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 Cboe there is no assurance that our application will be approved.
- Even if the Primary Offering is successful and our application to list our Common Stock and Investor Warrants on Cboe or an Alternate Exchange is approved, no assurance can be given that an active trading market for our Common Stock or Investor Warrants will develop or be maintained.

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

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Risks Related to our Business, Financial Position and Capital Requirements

There is substantial doubt about our ability to continue as a going concern.

We have only recently commenced commercial sales of our first product, AC5®Advanced Wound System and we have incurred substantial net losses as a result. For the year ended September 30, 2023, the Company recorded a net loss of \$6,982,836 and used cash in operations of \$3,374,216. For the six months ended March 31, 2024, the Company recorded a net loss of \$4,150,791 and used cash in operations of \$1,562,764. These factors raise substantial doubt about the Company's ability to continue as a going concern within one year of the date that the financial statements are issued. In addition, the Company's independent registered public accounting firm, in their report on the Company's September 30, 2023 audited financial statements, raised substantial doubt about the Company's ability to continue as a going concern. The financial statements included herein do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

We do not believe that our current cash on hand as of June 19, 2024 is sufficient to meet our anticipated cash requirements through the end of June 2024.

During the first half of fiscal 2024 and during fiscal 2023 and 2022, 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 US and the EU. Even with the additional funds received from these financings, there exists substantial doubt about our ability to continue as a going concern.

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

As noted above under the risk factor entitled "*There is substantial doubt about our ability to continue as a going concern,*" we have only recently commenced commercial sales of our first product, AC5Advanced 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. 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 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 principal product candidates and additional product candidates, and the underlying technology, including advancing applications and conducting biocompatibility and other preclinical studies and clinical studies;
- raise capital needed to fund our operations;
- enhance investor relations and corporate communications capabilities;
- conduct clinical trials on products and product candidates;
- attempt to obtain regulatory marketing authorizations for product candidates;
- build relationships with additional contract manufacturing partners, and invest in product and process development through such partners;
- maintain, expand and protect our intellectual property portfolio;
- advance additional product candidates and technologies through our research and development pipeline;
- seek to commercialize selected product candidates, which may require regulatory marketing authorization; and
- hire additional regulatory, clinical, quality control, scientific, financial, and management, consultants and advisors.

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To become and remain profitable, we must successfully commercialize 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.

Even if the Primary Offering is successful, we will need substantial additional funding 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.

Based on our current operating expenses and working capital requirements, we do not believe that our current cash on hand as of June 19, 2024 is sufficient to meet our anticipated cash requirements through the end of June 2024. We may need to raise additional capital before then.

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.

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

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

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

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

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

The Bridge SPA contains certain restrictions on the Company's ability to conduct subsequent sales of its equity securities and certain business activities. In particular, until July 7, 2024, the Company will be prohibited from effecting or entering into agreements to effect any issuance by the Company or its subsidiary of Common Stock or Common Stock equivalents (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. The Uplist PIPE has the effect of extending that prohibition to November 8, 2024 with a similar provision.

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

Our obligations under the First Notes and 2024 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 and 2024 Notes could result in our loss of substantially all of our assets.

Our obligations under the First Notes and 2024 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 or 2024 Notes, the First Note or 2024 Notes 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.

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In connection with the First Closing and 2024 Notes closing, the respective note holders were granted a security interest in substantially all of our assets pursuant to the terms of the related security agreements. If we fail to make payments on the First Notes or 2024 Notes when due or otherwise comply with the covenants contained in the First Notes or 2024 Notes, the respective 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 and 2024 Notes (collectively, the "Convertible 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 Convertible 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 Convertible Notes; and (v) our breach of any representations or warranties under the Convertible Notes which cannot be cured within five (5) days. Further, events of default under the Convertible Notes also include (i) the unavailability of Rule 144 at certain times; (ii) our failure to deliver the shares of Common Stock to the respective notes holder upon exercise by such holder of its conversion rights under the Convertible Notes; (iii) our loss of the "bid" price for our Common Stock and/or a market and such loss is not cured during the specified cure periods; and (iv) our failure to complete an Uplist Transaction by June 30, 2024.

The Convertible 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 Convertible Notes, the holders have certain rights upon an event of default. Such rights include that, upon an event of default, the Convertible Notes will become immediately due and payable and we will be obligated to pay to each such note holder an amount equal to (A) 125% (the "Default Premium") multiplied by the sum of (i) the outstanding principal amount of the 2022 Notes plus, (ii) any accrued and unpaid interest on the unpaid principal amount of the 2022 Notes to the date of payment, plus (iii) interest, if any, on the amounts referred to in subsection (i) and/or (ii), at a rate of the lesser of (y) eighteen percent (18%) per annum, or (z) the maximum amount allowed by law from the due date thereof until the same is paid (the "Default Interest Rate") (the then outstanding principal of such Convertible Note to the date of payment, plus the amounts set forth in subsections (i)-(iii) hereof are collectively, the "Default Amount"), and (B) any other amounts owed to the Holder under the respective purchase agreement; *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 \$73.12 (which will automatically change to \$4.00 as of the closing of the Uplist PIPE through the operation of the Most Favored Nation Provision) 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. The Convertible 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 until June 30, 2024 or upon their conversion, acceleration or by prepayment. Any amount of principal or interest on the Convertible 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 Rate.

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.

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

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

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

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

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

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

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

We 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.

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.

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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We are subject to extensive and dynamic medical device regulations outside of the U.S., 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 the 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 U.S., 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.

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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;

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- 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, comparable foreign regulatory authorities, or their designees, 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. The global regulatory environment is increasingly stringent and unpredictable, and requirements continue to differ among countries. We expect this global regulatory environment will continue to evolve, potentially impacting the cost, time, or our ability to receive or maintain clearances or approvals.

Regulations also impose extensive compliance and monitoring obligations on our business, and regulatory agencies or their designees review our design and manufacturing processes, labeling, record keeping, and required reports of adverse experiences and other information to identify potential problems with marketed products.

We are also subject to periodic inspections for compliance with applicable quality system regulations (e.g., 21 CFR 820, EU MDR) which govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, and servicing of finished medical devices intended for human use. In addition, the FDA and other regulatory bodies, both in and outside the U.S. (including the Federal Trade Commission, the Office of the Inspector General of the Department of Health and Human Services, the U.S. Department of Justice, and various state Attorneys General), monitor the promotion and advertising of our products. Any adverse regulatory action, depending on its magnitude, may limit our ability to effectively market and sell our products, limit our ability to obtain future premarket approvals or result in a substantial modification to our business practices and operations. 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 or agreements with regulatory agencies or their designees, 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;
- supply chain disruptions due to dependency on key suppliers;

- reputational damage affecting customer trust and market share;
- litigation costs and financial judgments from adverse effects or non-compliance;
- impacts from changes in regulatory standards or approval processes;
- 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.

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

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

Risks Related to our Intellectual Property

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

Our success will depend in large part on our ability to obtain and maintain protection in the U.S. and other countries for the intellectual property rights covering or incorporated into our technology and products. The ability to obtain patents covering technology in the field of medical devices generally is highly uncertain and involves complex legal, technical, scientific and factual questions. We may not be able to obtain and maintain patent protection relating to our technology or products. Many of our owned or licensed patent applications are pending. Even if issued, patents issued or licensed to us may be challenged, narrowed, invalidated, held to be unenforceable or circumvented, or determined not to cover our product candidates or our competitors' products, which could limit our ability to stop competitors from marketing identical or similar products. Because our patent portfolio includes certain patents and applications that are in-licensed on a non-exclusive basis, other parties may be able to develop, manufacture, market and sell products with similar features covered by the same patent rights and technologies, which in turn could significantly undercut the value of any of our product candidates and adversely affect our business. Our licensed MIT European patent No. 1879606 was opposed; however, this patent was maintained in amended form following an administrative hearing. Both parties appealed this decision. MIT granted European patent EP1879606, to which Arch Therapeutics has an exclusive license, was the subject of a hearing at the European Patent Office Board of Appeal (the "**Board of Appeal**") on November 26, 2021 as a result of an appeal by MIT to obtain broader claim scope than was upheld by the European Patent Opposition Division in 2016 and appeals by opponents for the upheld scope to be denied to MIT. At the oral proceedings, in light of concerns expressed by the Board of Appeal, MIT withdrew its appeal and the affected claims, resulting in a formal revocation of the European patent. There is a pending divisional patent application in which the concerns that the Board of Appeal expressed can be addressed. MIT can file further divisional patent applications to seek additional claim scope. There is no guarantee that any divisional patent application will result in a granted patent or that any granted patent will not be opposed and revoked. The Board of Appeal's decision is in relation to the granted European patent EP1879606 and the various national patents that are derived therefrom, and it has no legal significance outside of Europe except in Hong Kong. Further, we cannot be certain in 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 March 31, 2024, we either own or license from others a number of U.S. patents, U.S. patent applications, foreign patents and foreign patent applications.

We have also entered into a license agreement with Massachusetts Institute of Technology and Versitech Limited (MIT) pursuant to which we have been granted exclusive

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

The 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 between 2024 and 2026 (absent any potential patent term extension), as well as additional patents that have been either allowed, issued or granted in foreign jurisdictions.

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

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

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

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

Risks Related to Ownership of our Common Stock

We have pursued an Uplist Transaction by filing an application to list our Common Stock to trade on Cboe. 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 Cboe. In the event we fail to list our Common Stock on Cboe, 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 Cboe. To successfully list our Common Stock, we are required to satisfy certain Cboelisting 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 Cboe will be denied. No assurances can be given that we will satisfy the listing requirements. If our application is not successful, our Board will weigh the available alternatives to successfully consummate an Uplist Transaction and list our Common Stock on Cboe. 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 Cboe 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 Cboe, our ability to raise additional capital may be adversely affected.

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There is not now, and there may not ever be, an active market for our Common Stock, which trades in the over-the-counter market in low volumes and at volatile prices. Even if the Primary Offering is successful and our application to list our Common Stock on Cboe 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 Cboe 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 Cboe or an Alternate Exchange, we will not complete the Primary Offering. Even if our Common Stock is approved for listing on Cboe 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 June 30, 2024 to Cboe 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.

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

On August 22, 2023, the stockholders approved a reverse stock split between 1-for-1.5 to 1-for-20, and the Company intends to effect the Reverse Split at a ratio of 1-for-8 prior to the pricing of the Primary Offering, and without correspondingly decreasing the number of authorized shares of Common Stock. Even if our planned Reverse Split increases the market price of our Common Stock sufficiently so that we comply with the minimum market price requirement, no assurance can be given that we will be able to comply with the other standards that we are required to meet in order to be approved for listing on Cboe or an Alternate Exchange or maintain a listing of our Common Stock on such exchange. Our failure to meet these requirements prior to listing will result in the Primary Offering not occurring and our failure to meet these requirements following listing may result in our Common Stock being delisted from Cboe or an Alternate Exchange.

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

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

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

Even if the Primary Offering is successful and our application to list our Common Stock on Cboe or an Alternate Exchange is approved, if we fail to meet the Cboe or such Alternate Exchange continued listing requirements, including stockholder equity requirements, our Common Stock could be subject to delisting by Cboe or such Alternate Exchange, which could reduce the liquidity of our Common Stock materially and result in a corresponding material reduction in the price of our Common Stock. 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 when you wish to do so. Further, if we were to be delisted from Cboe or an Alternate Exchange, our Common Stock 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 Cboe 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.

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.

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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, "Even if the Primary Offering is successful, we will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts and could cause our business to fail." Sales of substantial amounts of our Common Stock in the public market or the perception that such sales could occur, could adversely affect the trading price of our Common Stock, and may make it more difficult for you to sell your Common Stock at a time and price that you deem appropriate. We are unable to predict the effect that such sales may have on the prevailing price of our Common Stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

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

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

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

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

As of June 19, 2024, there were issued and outstanding (or expected to be issued and outstanding, as specified below): (i) options granted to employees, directors and consultants under the 2013 Plan to purchase up to an aggregate of 11,034 shares of Common Stock at exercise prices ranging from \$32.00 to \$1,040.00 per share and with a weighted average exercise price of \$277.94 per share; (ii) 3,717,114 shares of Common Stock issuable upon the exercise of outstanding warrants, having a weighted average exercise price of \$10.05 per share (which includes 2,349,826 Common Warrants that will automatically be cancelled and exchanged for 7,049,478 Exchange Investor Warrants

at the closing of the Primary Offering); (iii) 1,724,557 shares of Common Stock issuable upon regular (non-Automatic) conversion of the 2022 Notes at the conversion price of \$4.00 per share (taking into account the operation of the Most Favored Nation Provision as a result of the Uplist PIPE); (iv) 982,056 shares of Common Stock to be issuable upon exercise at \$0.001 per share of the PIPE Pre-Funded Warrants expected to be issued immediately prior to the pricing of the Primary Offering; (v) 982,056 shares of Common Stock to be issuable upon exercise at \$4.00 per share of the PIPE Investor Warrants expected to be issued immediately prior to the pricing of the Primary Offering; (vi) 71,533 shares of Common Stock to be issuable upon exercise at \$5.15625 per share of the PIPE Placement Agent Warrants expected to be issued immediately prior to the pricing of the Primary Offering; (vii) 1,893,919 True-Up Shares expected to be issued at the closing of the Primary Offering; (viii) 6,330,422 shares of Common Stock to be issuable upon exercise at \$0.001 of the True-Up Pre-Funded Warrants expected to be issued at the closing of the Primary Offering; (ix) 65,533,100 shares of Common Stock to be issuable upon exercise at \$4.00 per share of the Uplist Conversion Warrants expected to be issued at the closing of the Primary Offering; (x) 7,049,478 shares of Common Stock to be issuable upon exercise at \$4.00 per share of the Exchange Investor Warrants expected to be issued at the closing of the Primary Offering; (xi) 538,182 shares of Common Stock to be issuable upon exercise at \$0.001 per share of the 2024 Note Conversion Pre-Funded Warrants expected to be issued at the closing of the Primary Offering; (xii) 581,819 shares of Common Stock to be issuable upon exercise at \$4.00 per share of the 2024 Note Uplist Conversion Warrants expected to be issued at the closing of the Primary Offering; (xiii) 56,896 shares of Common Stock reserved for future issuance under the 2023 Plan; and (xiv) up to 969,697 shares (1,115,151 shares if the underwriters' option to purchase additional Investor Warrants is exercised in full) of Common Stock issuable upon exercise at \$4.00 per share of the Investor Warrants to be issued in the Primary Offering.

After giving effect to the closing of the Uplist PIPE, expected to occur immediately prior to the pricing of the Primary Offering, and after giving effect to the issuance of the Automatic Conversion Shares, 2022 Note Conversion Pre-Funded Warrants, 2024 Notes Automatic Conversion Shares, 2024 Note Conversion Pre-Funded Warrants, True-Up Shares and True-Up Pre-Funded Warrants at the closing of the Primary Offering, and the assumed exercise in full of the Bridge Pre-Funded Warrants, PIPE Pre-Funded Warrants, True-Up Pre-Funded Warrants, 2022 Note Conversion Pre-Funded Warrants, Execution Backstop Pre-Funded Warrants, PIPE Advance Penalty Pre-Funded Warrants and 2024 Note Conversion Pre-Funded Warrants, if any, (collectively, the "**Pro Forma Pre-Funded Warrants**"), but prior to giving effect to the Primary Offering, there would be an aggregate of 13,039,759 shares of Common Stock outstanding, before giving effect to the issuance of the Units and Pre-Funded Units in the Primary Offering. The exercise of the Pro Forma Pre-Funded Warrants (which have exercise prices of \$0.001 or \$0.008 and therefore function as common stock equivalents) assumed in the previous sentence is only for illustrative purposes, and there is no assurance as to when, if at all, any of such securities will be exercised.

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The 2013 Plan expired on June 18, 2023. Finally, on August 13, 2023, the Company adopted and approved the Amended and Restated 2023 Equity Incentive Plan (the "**A&R Plan**"). As of September 30, 2023, no option awards were granted under the A&R Plan. Any future grants of options, warrants or other securities exercisable or convertible into our Common Stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our Common Stock.

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

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

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

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

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

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

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

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

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

Those indemnification obligations could result in our Company incurring substantial expenditures to cover the cost of settlement or damage awards against our directors or

officers, which we may be unable to recoup. These provisions and resultant costs may also discourage us from bringing a lawsuit against any of our current or former directors or officers for breaches of their fiduciary duties and may similarly discourage the filing of derivative litigation by our stockholders against our directors and officers even if such actions, if successful, might otherwise benefit us or our stockholders.

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

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

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

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

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

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

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

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

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

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

SELLING STOCKHOLDERS

The Common Stock being offered by the selling stockholders are the 2022 Inducement Shares, Bridge Shares, True-Up Shares and those issuable to the selling stockholders, upon conversion of the 2022 Notes and 2024 Notes and exercise of the Resale Warrants. For additional information regarding the issuances of such securities, see "**The Transactions**" above. We are registering the shares of Common Stock in order to permit the selling stockholders to offer the shares for resale from time to time. Except for Terrence Norchi, our Chief Executive Officer; Michael Abrams, our Chief Financial Officer; Laurence Hicks, a member of our Board and holder of an ownership interest in Drake Partners LLC and Maxim Group LLC, the selling stockholders have not had any material relationship with us within the past three years.

The table below lists the selling stockholders and other information regarding the beneficial ownership of the shares of Common Stock by each of the selling stockholders. The second column lists the number of shares of Common Stock beneficially owned by each selling stockholder, based on its ownership of the shares of Common Stock, convertible debt and warrants, as of June 19, 2024, assuming exercise of the warrants and conversion of convertible notes held by the selling stockholders on that date, without regard to any limitations on exercises. The third column lists the shares of Common Stock being offered by this prospectus by the selling stockholders. The fourth column assumes the sale of all of the shares offered by the selling stockholders pursuant to this prospectus.

In accordance with the terms of (i) Third Amended and Restated Registration Rights Agreement with certain of the selling stockholders or (ii) the terms of the 2022 Notes, 2022 Warrants and 2022 Placement Agent Warrants held by certain of the selling stockholders, this prospectus generally covers the resale of the sum of (A) the maximum number of shares of Common Stock issuable upon conversion of the 2022 Notes issued to the selling stockholders in the 2022 Private Placement Financing; and (B) the maximum number of shares of Common Stock issuable upon exercise of the 2022 Warrants and 2022 Placement Agent Warrant, determined as if the outstanding 2022 Notes were converted and the 2022 Warrants and 2022 Placement Agent Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the Third Amended and Restated Registration Rights Agreement, 2022 Note, 2022 Warrant or 2022 Placement Agent Warrant, as applicable, without regard to any limitations on the conversion of the

This prospectus also covers the maximum number of shares of Common Stock issuable upon exercise of the maximum number of 2022 Note Conversion Pre-Funded Warrants that may be issuable under the 2022 Notes at the closing of the Primary Offering in lieu of Automatic Conversion Shares otherwise issuable, as if such maximum amount of 2022 Note Conversion Pre-Funded Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the 2022 Note Conversion Pre-Funded Warrants, without regard to any limitations on the exercise of 2022 Note Conversion Pre-Funded Warrants.

Additionally, this prospectus covers the maximum number of shares of Common Stock issuable upon exercise of the Uplist Conversion Warrants that are expected to be issued under the 2022 Notes at the closing of the Primary Offering, as if such Uplist Conversion Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the Uplist Conversion Warrants, without regard to any limitations on the exercise of Uplist Conversion Warrants.

In accordance with the terms of (i) 2024 Notes Registration Rights Agreement with certain of the selling stockholders or (ii) the terms of the 2024 Notes held by certain of the selling stockholders, this prospectus generally covers the resale of the maximum number of shares of Common Stock issuable upon conversion of the 2024 Notes issued to the selling stockholders in the 2024 Notes Financing, determined as if the outstanding 2024 Notes were converted in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the 2024 Notes Registration Rights Agreement or 2024 Note, as applicable, without regard to any limitations on the conversion of the 2024 Notes.

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This prospectus also covers the maximum number of shares of Common Stock issuable upon exercise of the maximum number of 2024 Note Conversion Pre-Funded Warrants that may be issuable under the 2024 Notes at the closing of the Primary Offering in lieu of 2024 Notes Automatic Conversion Shares otherwise issuable, as if such maximum amount of 2024 Note Conversion Pre-Funded Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the 2024 Note Conversion Pre-Funded Warrants, without regard to any limitations on the exercise of 2024 Note Conversion Pre-Funded Warrants.

Additionally, this prospectus covers the maximum number of shares of Common Stock issuable upon exercise of the 2024 Notes Uplist Conversion Warrants that are expected to be issued under the 2024 Notes at the closing of the Primary Offering, as if such 2024 Notes Uplist Conversion Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the 2024 Notes Uplist Conversion Warrants, without regard to any limitations on the exercise of 2024 Notes Uplist Conversion Warrants.

In accordance with the terms of (i) Bridge Registration Rights Agreement with certain of the selling stockholders or (ii) the terms of the Bridge Warrants held by certain of the selling stockholders, this prospectus generally covers the resale of the sum of the maximum number of shares of Common Stock issuable upon exercise of the Bridge Warrants determined as if the outstanding Bridge Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the Bridge Registration Rights Agreement and Bridge Warrants, as applicable, without regard to any limitations on the exercise of the Bridge Warrants.

In accordance with the terms of (i) the PIPE Registration Rights Agreement with certain of the selling stockholders or (ii) the PIPE Warrants held by certain of the selling stockholders, this prospectus generally covers the resale of the sum of the maximum number of shares of Common Stock issuable upon exercise of the PIPE Warrants determined as if the outstanding PIPE Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the PIPE Registration Rights Agreement and PIPE Warrants, as applicable, without regard to any limitations on the exercise of the PIPE Warrants.

This prospectus covers the resale of the maximum number of True-Up Shares that may be issuable under the Bridge SPA at the closing of the Primary Offering, based on the sale of the Units and Pre-Funded Units at an assumed public offering price of \$4.125 per Unit and \$4.124 per Pre-Funded Unit, which represents the minimum bid price of \$4.00 per share under the initial listing requirements of Cboe in Cboe Listing Rule 14.9(b) plus a value of \$0.125 attributed to the accompanying Investor Warrant. This prospectus also covers the maximum number of shares of Common Stock issuable upon exercise of the maximum number of True-Up Pre-Funded Warrants that may be issuable under the Bridge SPA at the closing of the Primary Offering in lieu of True-Up Shares otherwise issuable, as if such maximum amount of True-Up Pre-Funded Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the True-Up Pre-Funded Warrants, without regard to any limitations on the exercise of True-Up Pre-Funded Warrants.

This prospectus covers the resale of the sum of the maximum number of shares of Common Stock issuable upon exercise of the Funding Backstop Pre-Funded Warrants and Backstop Common Warrants, based on the assumption that the conditions for the issuance of such warrants under the Backstop Agreement are satisfied, prior to the closing of the Primary Offering, determined as if such warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in such warrants, as applicable, without regard to any limitations on the exercise of such warrants.

This prospectus covers the resale of the sum of the maximum number of shares of Common Stock issuable upon exercise of the remaining Resale Warrants not otherwise referenced in the foregoing ten paragraphs, determined as if the outstanding Resale Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the Resale Warrants, as applicable, without regard to any limitations on the exercise of the Resale Warrants.

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Under the terms of the 2022 Notes, 2024 Notes and Resale Warrants, a selling stockholder may not convert the notes or exercise the warrants to the extent such exercise would cause such selling stockholder, together with its affiliates and attribution parties, to beneficially own a number of shares of Common Stock which would exceed 4.99% (or 9.99% if elected and as applicable) of our then outstanding Common Stock following such exercise, excluding for purposes of such determination shares of Common Stock issuable upon conversion of the 2022 Notes and 2024 Notes and exercise of the Resale Warrants which have not been exercised. The number of shares in the second column does not reflect this limitation. The selling stockholders may sell all, some or none of their shares in this offering. See “**Plan of Distribution**” on page [51](#).

Name of Selling Stockholder	Number of shares of Common Stock Owned Prior to Offering	Maximum Number of shares of Common Stock to be Sold Pursuant to this Prospectus	Number of shares of Common Stock Owned After Offering
Tiburon Opportunity Fund LP (1)	794,265	31,394,777	972,379
District 2 Capital Fund LP (2)	327,069	9,664,127	486,721

Bigger Capital Fund, LP (3)	327,198	9,664,123	486,785
Cavalry Fund I LP (4)	423,941	10,428,410	964,176
Sanibel Island Associates LLC (Anestis) (5)	21,767	780,270	16,309
Michael & Ana Parker (6)	280,168	10,262,003	225,560
ProActive Capital Partners, L.P. (7)	64,901	2,378,431	53,195
Michael Abrams (8)	11,327	389,970	8,759
Jason Adelman (9)	21,614	779,941	16,479
Centurion Therapeutics, Inc. (10)	23,802	920,250	1,302
Drake Partners LLC (11)	11,129	389,970	8,561
Terrence Norchi (12)	19,826	259,982	18,116
Michael Tuttle (13)	31,736	1,227,000	1,736
Trina Whitridge GST Trust (14)	76,979	2,825,975	58,343
Mark Woolfson (15)	27,019	974,924	20,601
Steve Woolfson (16)	30,620	1,104,915	23,345
Walleye Opportunities Master Fund Ltd (17)	37,500	3,284,351	957,210
Sixth Borough Capital Fund, LP (18)	37,500	949,133	272,904
Brandt Wilson and Mona Wilson (19)	270,388	4,495,137	957,210
Andrew Stahl (20)	270,388	4,495,137	957,210
John Robert Baleno (21)	9,091	154,545	54,546
Roxanne Rosetto (22)	4,546	77,273	27,273
Robert Forster (23)	22,728	386,363	136,365
Thomas Pilgrim (24)	9,091	154,545	54,546
Rajiv P Dewan (25)	5,000	85,000	30,000
David L McClain (26)	2,500	42,500	15,000
Norman McClain (27)	5,000	85,000	30,000
Ronald Nash (28)	4,546	77,273	27,273
Richard Molinsky (29)	6,819	115,908	40,911
George Benashvili (30)	1,288	21,887	7,725
Dan Armstrong (31)	9,091	154,545	54,546
CNP Consulting (32)	1,750	29,750	10,500
Ivan Chi Vei Tong (33)	2,500	42,500	15,000
Genmark Holdings (34)	9,091	154,545	54,546
Stephen Ross (35)	2,273	38,637	13,638
Efrat Investments (36)	4,546	77,273	27,273
Daniel Shalhoub (37)	2,273	38,637	13,638
Jeffrey and Shiela Negus (38)	2,273	38,637	13,638
Maxim Group LLC (39)	4,760	821	3,939
Total	3,218,301	98,444,466	7,137,256

- Assuming exercise or conversion of the warrants or convertible notes held by Tiburon Opportunity Fund LP (“**Tiburon**”) or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Tiburon may be deemed to have beneficial ownership of 32,367,156 shares of Common Stock, which includes the following: (i) 1,223 Inducement Pre-Funded Warrant Shares; (ii) 37,510 Legacy Pre-Funded Warrant Shares; (iii) 1,116,834 True-Up Shares; (v) 700,180 Conversion Shares; (vi) 665,171 Automatic Conversion Shares; (vii) 40,261 2022 Warrant Shares; (viii) 665,171 2022 Note Conversion Pre-Funded Warrant Shares; (ix) 319,096 Common Warrant Shares; (x) 125,657 Bridge Pre-Funded Warrant Shares; (xi) 26,606,840 Uplist Conversion Warrant Shares; and (xii) 1,116,834 True-Up Pre-Funded Warrant Shares.

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- Assuming exercise or conversion of the warrants or convertible notes held by District 2 Capital Fund LP (“**District 2**”) or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, District 2 may be deemed to have beneficial ownership of 10,150,848 shares of Common Stock, which includes the following: (i) 236 2022 Inducement Shares; (ii) 17,897 Bridge Shares; (iii) 558,393 True-Up Shares; (v) 181,250 Conversion Shares; (vi) 172,188 Automatic Conversion Shares; (vii) 3,144 2022 Warrant Shares; (viii) 172,188 2022 Note Conversion Pre-Funded Warrant Shares; (ix) 159,541 Common Warrant Shares; (x) 61,874 Bridge Pre-Funded Warrant Shares; (xi) 6,887,500 Uplist Conversion Warrant Shares; (xii) 558,393 True-Up Pre-Funded Warrant Shares; (xiii) 178,818 PIPE Investor Warrant Shares; (xiv) 178,818 PIPE Pre-Funded Warrant Shares; (xv) 69,375 2024 Notes Conversion Shares; (xvi) 67,273 2024 Notes Automatic Conversion Shares; (xvii) 67,273 2024 Note Conversion Pre-Funded Warrant Shares; (xviii) 9,472 PIPE Advance Penalty Pre-Funded Warrant Shares; (xiv) 28,125 Execution Backstop Pre-Funded Warrant Shares; (xv) 93,750 Funding Backstop Pre-Funded Warrant Shares; (xvi) 67,273 2024 Notes Uplist Conversion Warrant Shares; (xvii) 9,472 PIPE Advance Penalty Common Warrants; and (xviii) 121,875 Backstop Common Warrants.
- Assuming exercise or conversion of the warrants or convertible notes held by Bigger Capital Fund, LP (“**Bigger Capital**”) or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Bigger Capital may be deemed to have beneficial ownership of 10,150,909 shares of Common Stock, which includes the following: (i) 236 2022 Inducement Shares; (ii) 17,961 Bridge Shares; (iii) 558,391 True-Up Shares; (v) 181,250 Conversion Shares; (vi) 172,188 Automatic Conversion Shares; (vii) 3,144 2022 Warrant Shares; (viii) 172,188 2022 Note Conversion Pre-Funded Warrant Shares; (ix) 159,541 Common Warrant Shares; (x) 61,809 Bridge Pre-Funded Warrant Shares; (xi) 6,887,500 Uplist Conversion Warrant Shares; (xii) 558,391 True-Up Pre-Funded Warrant Shares; (xiii) 178,818 PIPE Investor Warrant Shares; (xiv) 178,818 PIPE Pre-Funded Warrant Shares; (xv) 69,375 2024 Notes Conversion Shares; (xvi) 67,273 2024 Notes Automatic Conversion Shares; (xvii) 67,273 2024 Note Conversion Pre-Funded Warrant Shares; (xviii) 9,472 PIPE Advance Penalty Pre-Funded Warrant Shares; (xiv) 28,125 Execution Backstop Pre-Funded Warrant Shares; (xv) 93,750 Funding Backstop Pre-Funded Warrant Shares; (xvi) 67,273 2024 Notes Uplist Conversion Warrant Shares; (xvii) 9,472 PIPE Advance Penalty Common Warrants; and (xviii) 121,875 Backstop Common Warrants.
- Assuming exercise or conversion of the warrants or convertible notes held by Cavalry Fund I, LP (“**Cavalry**”) or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Cavalry may be deemed to have beneficial ownership of 11,392,587 shares of Common Stock, which includes the following: (i) 189 2022 Inducement Shares; (ii) 36,406 Bridge Shares; (iii) 1,116,771 True-Up Shares; (v) 145,000 Conversion Shares; (vi) 137,750 Automatic Conversion Shares; (vii) 2,516 2022 Warrant Shares; (viii) 137,750 2022 Note Conversion Pre-Funded Warrant Shares; (ix) 319,078 Common Warrant Shares; (x) 123,133 Bridge Pre-Funded Warrant Shares; (xi) 5,510,000 Uplist Conversion Warrant Shares; (xii) 1,116,771 True-Up Pre-Funded Warrant Shares; (xiii) 357,636 PIPE Investor Warrant Shares; (xiv) 357,636 PIPE Pre-Funded Warrant Shares; (xv) 138,750 2024 Notes Conversion Shares; (xvi) 134,545 2024 Notes Automatic Conversion Shares; (xvii) 134,545 2024 Note Conversion Pre-Funded Warrant Shares; (xviii) 18,944 PIPE Advance Penalty Pre-Funded Warrant Shares; (xiv) 56,250 Execution Backstop Pre-Funded Warrant Shares; (xv) 187,500 Funding Backstop Pre-Funded Warrant Shares; (xvi) 134,545 2024 Notes Uplist Conversion Warrant Shares; (xvii) 18,944 PIPE Advance Penalty Common Warrants; and (xviii) 243,750 Backstop Common Warrants.
- Assuming exercise or conversion of the warrants or convertible notes held by Sanibel Island Associates LLC (Anestis) (“**Sanibel**”) or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Sanibel may be deemed to have beneficial ownership of 796,579 shares of Common Stock, which includes the following: (i) 23 2022 Inducement Shares; (ii) 2,573 Bridge Shares; (iii) 18,012 True-Up Shares; (iv) 18,000 Conversion Shares; (v) 17,100 Automatic Conversion Shares; (vi) 302 2022 Warrant Shares; (vii) 17,100 2022 Note Conversion Pre-Funded Warrant Shares; (viii) 5,147 Common Warrant Shares; (ix) 684,000 Uplist Conversion Warrant Shares; and (x) 18,012 True-Up Pre-Funded Warrant Shares.

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6. Assuming the exercise or conversion of the warrants or convertible notes held by Ana Parker or her affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Ms. Parker may be deemed to have beneficial ownership of 10,488,469 shares of Common Stock, which includes the following: (i) 24,035 Bridge Shares; (ii) 240,399 True-Up Shares; (iii) 236,631 Conversion Shares; (iv) 224,799 Automatic Conversion Shares; (v) 224,799 2022 Note Conversion Pre-Funded Warrant Shares; (vi) 68,686 Common Warrant Shares; (vii) 10,308 Bridge Pre-Funded Warrant Shares; (viii) 8,991,946 Uplist Conversion Warrant Shares; and (ix) 240,399 True-Up Pre-Funded Warrant Shares.
7. Assuming exercise of the warrants held by ProActive Capital Partners, L.P. (“**ProActive**”) as of June 19, 2024 and disregarding any limitations on exercise applicable to such warrants, ProActive may be deemed to have beneficial ownership of 2,431,626 shares of Common Stock, which includes the following: (i) 8,576 Bridge Shares; (ii) 60,034 True-Up Shares; (iii) 59,158 Conversion Shares; (iv) 51,859 Automatic Conversion Shares; (v) 51,859 2022 Note Conversion Pre-Funded Warrant Shares; (vi) 17,153 Common Warrant Shares; (vii) 2,074,327 Uplist Conversion Warrant Shares; and (viii) 60,034 True-Up Pre-Funded Warrant Shares.
8. Assuming exercise or conversion of the warrants or convertible notes held by Michael Abrams or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Abrams may be deemed to have beneficial ownership of 398,810 shares of Common Stock, which includes the following: (i) 1,287 Bridge Shares; (ii) 9,005 True-Up Shares; (iii) 9,000 Conversion Shares; (iv) 8,550 Automatic Conversion Shares; (v) 8,550 2022 Note Conversion Pre-Funded Warrant Shares; (vi) 2,573 Common Warrant Shares; (vii) 342,000 Uplist Conversion Warrant Shares; and (viii) 9,005 True-Up Pre-Funded Warrant Shares.
9. Assuming exercise or conversion of the warrants or convertible notes held by Jason Adelman or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Adelman may be deemed to have beneficial ownership of 796,420 shares of Common Stock, which includes the following: (i) 2,573 Bridge Shares; (ii) 18,011 True-Up Shares; (iii) 18,000 Conversion Shares; (iv) 17,100 Automatic Conversion Shares; (v) 17,100 2022 Note Conversion Pre-Funded Warrant Shares; (vi) 5,146 Common Warrant Shares; (vii) 684,000 Uplist Conversion Warrant Shares; and (viii) 18,011 True-Up Pre-Funded Warrant Shares.
10. Assuming exercise or conversion of the warrants or convertible notes held by Centurion Therapeutics, Inc. (“**Centurion**”) or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Centurion may be deemed to have beneficial ownership of 921,552 shares of Common Stock, which includes the following: (i) 22,500 Conversion Shares; (ii) 21,375 Automatic Conversion Shares; (iii) 21,375 2022 Note Conversion Pre-Funded Warrant Shares; and (iv) 855,000 Uplist Conversion Warrant Shares.
11. Assuming exercise or conversion of the warrants or convertible notes held by Drake Partners LLC (“**Drake Partners**”) or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Drake Partners may be deemed to have beneficial ownership of 398,648 shares of Common Stock, which includes the following: (i) 1,287 Bridge Shares; (ii) 9,005 True-Up Shares; (iii) 9,000 Conversion Shares; (iv) 8,550 Automatic Conversion Shares; (v) 8,550 2022 Note Conversion Pre-Funded Warrant Shares; (vi) 2,573 Common Warrant Shares; (vii) 342,000 Uplist Conversion Warrant Shares; and (viii) 9,005 True-Up Pre-Funded Warrant Shares.

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12. Assuming exercise or conversion of the warrants or convertible notes held by Terrence Norchi or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Norchi may be deemed to have beneficial ownership of 278,093 shares of Common Stock, which includes the following: (i) 858 Bridge Shares; (ii) 6,004 True-Up Shares; (iii) 6,000 Conversion Shares; (iv) 5,700 Automatic Conversion Shares; (v) 5,700 2022 Note Conversion Pre-Funded Warrant Shares; (vi) 1,716 Common Warrant Shares; (vii) 228,000 Uplist Conversion Warrant Shares; and (viii) 6,004 True-Up Pre-Funded Warrant Shares.
13. Assuming exercise or conversion of the warrants or convertible notes held by Michael Tuttle or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Tuttle may be deemed to have beneficial ownership of 1,228,736 shares of Common Stock, which includes the following: (i) 30,000 Conversion Shares; (ii) 28,500 Automatic Conversion Shares; (iii) 28,500 2022 Note Conversion Pre-Funded Warrant Shares; and (iv) 1,140,000 Uplist Conversion Warrant Shares.
14. Assuming exercise or conversion of the warrants or convertible notes held by Trina Whitridge GST Trust (“**Whitridge**”) or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Whitridge may be deemed to have beneficial ownership of 2,884,318 shares of Common Stock, which includes the following: (i) 46 2022 Inducement Shares; (ii) 9,435 Bridge Shares; (iii) 66,038 True-Up Shares (iv) 65,158 Conversion Shares; (v) 61,900 Automatic Conversion Shares; (vi) 604 2022 Warrant Shares; (vii) 61,900 2022 Note Conversion Pre-Funded Warrant Shares; (viii) 18,868 Common Warrant Shares; (ix) 2,475,987 Uplist Conversion Warrant Shares; and (x) 66,038 True-Up Pre-Funded Warrant Shares.
15. Assuming exercise or conversion of the warrants or convertible notes held by Mark Woolfson or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Woolfson may be deemed to have beneficial ownership of 995,525 shares of Common Stock, which includes the following: (i) 3,217 Bridge Shares; (ii) 22,512 True-Up Shares; (iii) 22,500 Conversion Shares; (iv) 21,375 Automatic Conversion Shares; (v) 21,375 2022 Note Conversion Pre-Funded Warrant Shares; (vi) 6,432 Common Warrant Shares; (vii) 855,000 Uplist Conversion Warrant Shares; and (viii) 22,512 True-Up Pre-Funded Warrant Shares.
16. Assuming exercise or conversion of the warrants or convertible notes held by Steve Woolfson or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Woolfson may be deemed to have beneficial ownership of 1,128,260 shares of Common Stock, which consists of the following: (i) 3,645 Bridge Shares; (ii) 25,515 True-Up Shares; (iii) 25,500 Conversion Shares; (iv) 24,225 Automatic Conversion Shares; (v) 24,225 2022 Note Conversion Pre-Funded Warrant Shares; (vi) 7,290 Common Warrant Shares; (vii) 969,000 Uplist Conversion Warrant Shares; and (viii) 25,515 True-Up Pre-Funded Warrant Shares.
17. Assuming exercise or conversion of the warrants held by Walleye Opportunities Master Fund Ltd (“**Walleye**”) or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Walleye may be deemed to have beneficial ownership of 4,241,561 shares of Common Stock, which includes the following: (i) 37,500 Bridge Shares; (ii) 1,116,743 True-Up Shares; (iii) 319,070 Common Warrant Shares; (iv) 122,035 Bridge Pre-Funded Warrant Shares; (v) 1,116,743 True-Up Pre-Funded Warrant Shares; (vi) 286,130 PIPE Investor Warrant Shares; and (vii) 286,130 PIPE Pre-Funded Warrant Shares.
18. Assuming exercise or conversion of the warrants held by Sixth Borough Capital Fund, LP (“**Sixth Borough**”) or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Sixth Borough may be deemed to have beneficial ownership of 1,046,126 shares of Common Stock, which includes the following: (i) 37,500 Bridge Shares; (ii) 318,385 True-Up Shares; (iii) 90,967 Common Warrant Shares; (iv) 7,984 Bridge Pre-Funded Warrant Shares; (v) 318,385 True-Up Pre-Funded Warrant Shares; (vi) 45,000 2024 Notes Conversion Shares; (vii) 43,637 2024 Notes Automatic Conversion Shares; (viii) 43,637 2024 Notes Conversion Pre-Funded Warrants; and (ix) 43,637 2024 Notes Uplist Conversion Warrants.

19. Assuming exercise or conversion of the warrants held by Brandt Wilson and Mona Wilson or their affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Wilson and Mrs. Wilson may be deemed to have beneficial ownership of 5,309,335 shares of Common Stock, which includes the following: (i) 37,500 Bridge Shares; (ii) 1,116,743 True-Up Shares; (iii) 138,750 2024 Notes Conversion Shares; (iv) 134,545 2024 Notes Automatic Conversion Shares; (v) 134,545 2024 Notes Conversion Pre-Funded Warrants; (vi) 18,944 PIPE Advance Penalty Pre-Funded Warrants; (vii) 56,250 Execution Backstop Pre-Funded Warrants; (viii) 187,500 Funding Backstop Pre-Funded Warrants; (ix) 134,545 2024 Notes Uplift Conversion Warrants; (x) 18,944 PIPE Advance Penalty Common Warrants; (xi) 243,750 Backstop Common Warrants; (xii) 319,070 Common Warrant Shares; (xiii) 122,035 Bridge Pre-Funded Warrant Shares; (xiv) 1,116,743 True-Up Pre-Funded Warrant Shares; (xv) 357,636 PIPE Investor Warrant Shares; and (xvi) 357,636 PIPE Pre-Funded Warrant Shares.
20. Assuming exercise or conversion of the warrants held by Andrew Stahl or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Stahl may be deemed to have beneficial ownership of 5,309,335 shares of Common Stock, which includes the following: (i) 37,500 Bridge Shares; (ii) 1,116,743 True-Up Shares; (iii) 138,750 2024 Notes Conversion Shares; (iv) 134,545 2024 Notes Automatic Conversion Shares; (v) 134,545 2024 Notes Conversion Pre-Funded Warrants; (vi) 18,944 PIPE Advance Penalty Pre-Funded Warrants; (vii) 56,250 Execution Backstop Pre-Funded Warrants; (viii) 187,500 Funding Backstop Pre-Funded Warrants; (ix) 134,545 2024 Notes Uplift Conversion Warrants; (x) 18,944 PIPE Advance Penalty Common Warrants; (xi) 243,750 Backstop Common Warrants; (xii) 319,070 Common Warrant Shares; (xiii) 122,035 Bridge Pre-Funded Warrant Shares; (xiv) 1,116,743 True-Up Pre-Funded Warrant Shares; (xv) 357,636 PIPE Investor Warrant Shares; and (xvi) 357,636 PIPE Pre-Funded Warrant Shares.

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21. Assuming exercise or conversion of the warrants held by John Robert Baleno or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Baleno may be deemed to have beneficial ownership of 209,091 shares of Common Stock, which includes the following: (i) 9,091 Bridge Shares; (ii) 63,636 True-Up Shares; (iii) 18,182 Common Warrant Shares; and (iv) 63,636 True-Up Pre-Funded Warrant Shares.
22. Assuming exercise or conversion of the warrants held by Roxanne Rosetto or her affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Ms. Rosetto may be deemed to have beneficial ownership of 104,546 shares of Common Stock, which includes the following: (i) 4,546 Bridge Shares; (ii) 31,818 True-Up Shares; (iii) 9,091 Common Warrant Shares; and (iv) 31,818 True-Up Pre-Funded Warrant Shares.
23. Assuming exercise or conversion of the warrants held by Robert Forster or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Forster may be deemed to have beneficial ownership of 522,728 shares of Common Stock, which includes the following: (i) 22,727 Bridge Shares; (ii) 159,090 True-Up Shares; (iii) 45,455 Common Warrant Shares; and (iv) 159,090 True-Up Pre-Funded Warrant Shares.
24. Assuming exercise or conversion of the warrants held by Thomas Pilgrim or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Pilgrim may be deemed to have beneficial ownership of 209,091 shares of Common Stock, which includes the following: (i) 9,091 Bridge Shares; (ii) 63,636 True-Up Shares; (iii) 18,182 Common Warrant Shares; and (iv) 63,636 True-Up Pre-Funded Warrant Shares.
25. Assuming exercise or conversion of the warrants held by Rajiv P. Dewan or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Dewan may be deemed to have beneficial ownership of 115,000 shares of Common Stock, which includes the following: (i) 5,000 Bridge Shares; (ii) 35,000 True-Up Shares; (iii) 10,000 Common Warrant Shares; and (iv) 35,000 True-Up Pre-Funded Warrant Shares.
26. Assuming exercise or conversion of the warrants held by David L. McClain or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. McClain may be deemed to have beneficial ownership of 57,500 shares of Common Stock, which includes the following: (i) 2,500 Bridge Shares; (ii) 17,500 True-Up Shares; (iii) 5,000 Common Warrant Shares; and (iv) 17,500 True-Up Pre-Funded Warrant Shares.
27. Assuming exercise or conversion of the warrants held by Norman McClain or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. McClain may be deemed to have beneficial ownership of 115,000 shares of Common Stock, which includes the following: (i) 5,000 Bridge Shares; (ii) 35,000 True-Up Shares; (iii) 10,000 Common Warrant Shares; and (iv) 35,000 True-Up Pre-Funded Warrant Shares.
28. Assuming exercise or conversion of the warrants held by Ronald Nash or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Nash may be deemed to have beneficial ownership of 104,546 shares of Common Stock, which consists of the following: (i) 4,546 Bridge Shares; (ii) 31,818 True-Up Shares; (iii) 9,091 Common Warrant Shares; and (iv) 31,818 True-Up Pre-Funded Warrant Shares.
29. Assuming exercise or conversion of the warrants held by Richard Molinsky or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Molinsky may be deemed to have beneficial ownership of 156,819 shares of Common Stock, which includes the following: (i) 6,818 Bridge Shares; (ii) 47,726 True-Up Shares; (iii) 13,636 Common Warrant Shares; and (iv) 47,726 True-Up Pre-Funded Warrant Shares.
30. Assuming exercise or conversion of the warrants held by George Benashvili or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Benashvili may be deemed to have beneficial ownership of 29,612 shares of Common Stock, which includes the following: (i) 1,288 Bridge Shares; (ii) 9,012 True-Up Shares; (iii) 2,575 Common Warrant Shares; and (iv) 9,012 True-Up Pre-Funded Warrant Shares.
31. Assuming exercise or conversion of the warrants held by Dan Armstrong or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Armstrong may be deemed to have beneficial ownership of 209,091 shares of Common Stock, which includes the following: (i) 9,091 Bridge Shares; (ii) 63,636 True-Up Shares; (iii) 18,182 Common Warrant Shares; and (iv) 63,636 True-Up Pre-Funded Warrant Shares.
32. Assuming exercise or conversion of the warrants held by CNP Consulting or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, CNP Consulting may be deemed to have beneficial ownership of 40,250 shares of Common Stock, which includes the following: (i) 1,750 Bridge Shares; (ii) 12,250 True-Up Shares; (iii) 3,500 Common Warrant Shares; and (iv) 12,250 True-Up Pre-Funded Warrant Shares.
33. Assuming exercise or conversion of the warrants held by Ivan Chi Vei Tong or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Tong may be deemed to have beneficial ownership of 57,500 shares of Common Stock, which includes the following: (i) 2,500 Bridge Shares; (ii) 17,500 True-Up Shares; (iii) 5,000 Common Warrant Shares; and (iv) 17,500 True-Up Pre-Funded Warrant Shares.

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34. Assuming exercise or conversion of the warrants held by Genmark Holdings or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Genmark Holdings may be deemed to have beneficial ownership of 209,091 shares of Common Stock, which includes the following: (i) 9,091 Bridge Shares; (ii) 63,636 True-Up Shares; (iii) 18,182 Common Warrant Shares; and (iv) 63,636 True-Up Pre-Funded Warrant Shares.
35. Assuming exercise or conversion of the warrants held by Stephen Ross or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Ross may be deemed to have beneficial ownership of 52,275 shares of Common Stock, which includes the following: (i) 2,273 Bridge Shares; (ii) 15,909 True-Up Shares; (iii) 4,546 Common Warrant Shares; and (iv) 15,909 True-Up Pre-Funded Warrant Shares.

36. Assuming exercise or conversion of the warrants held by Efrat Investments or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Efrat Investments may be deemed to have beneficial ownership of 104,546 shares of Common Stock, which includes the following: (i) 4,546 Bridge Shares; (ii) 31,818 True-Up Shares; (iii) 9,091 Common Warrant Shares; and (iv) 31,818 True-Up Pre-Funded Warrant Shares.
37. Assuming exercise or conversion of the warrants held by Daniel Shalhoub or his affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Shalhoub may be deemed to have beneficial ownership of 52,275 shares of Common Stock, which includes the following: (i) 2,273 Bridge Shares; (ii) 15,909 True-Up Shares; (iii) 4,546 Common Warrant Shares; and (iv) 15,909 True-Up Pre-Funded Warrant Shares.
38. Assuming exercise or conversion of the warrants held by Jeffrey and Shiela Negus or their affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Mr. Negus and Mrs. Negus may be deemed to have beneficial ownership of 52,275 shares of Common Stock, which includes the following: (i) 2,273 Bridge Shares; (ii) 15,909 True-Up Shares; (iii) 4,546 Common Warrant Shares; and (iv) 15,909 True-Up Pre-Funded Warrant Shares.
39. Assuming exercise or conversion of the warrants held by Maxim or its affiliates as of June 19, 2024 and disregarding any limitations on exercise or conversion applicable to such warrants or convertible notes, Maxim may be deemed to have beneficial ownership of 821 shares of Common Stock, which consists of the following: (i) 821 2022 Placement Agent Warrant Shares.

PLAN OF DISTRIBUTION

Each selling stockholder of the securities and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their securities covered hereby on the principal Trading Market or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling stockholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker dealer solicits purchasers;
- block trades in which the broker dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker dealer as principal and resale by the broker dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- in transactions through broker dealers that agree with the selling stockholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell securities under Rule 144 or any other exemption from registration under the Securities Act, if available, rather than under this prospectus.

Broker dealers engaged by the selling stockholders may arrange for other brokers dealers to participate in sales. Broker dealers may receive commissions or discounts from the selling stockholders (or, if any broker dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

In connection with the sale of the securities or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The selling stockholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling stockholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling stockholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the securities. The Company has agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the securities may be resold by the selling stockholders without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, without the requirement for the Company to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect or (ii) all of the securities have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the common stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

USE OF PROCEEDS

We will not receive proceeds from the sale of Common Stock under this prospectus. We may, however, receive proceeds upon exercise for cash of the Resale Warrants, in which case such proceeds will be used for general working capital purposes. However, each of the aforementioned warrants contains a cashless exercise provision.

The selling stockholders may (i) convert their 2022 Notes and 2024 Notes at any time at their own discretion, if at all, subject to conversion, prepayment, and acceleration under the terms of the 2022 Notes and 2024 Notes, (ii) exercise their Resale Warrants at any time at their own discretion, if at all; in each instance in accordance with the terms thereof until their expiration.

For further information, see the descriptions under “**Prospectus Summary-The Transactions**” beginning at page 8 of this prospectus and “**Description of Securities**” beginning at page 53 of this prospectus. Additionally, if there is no effective registration statement registering the resale of the shares of Common Stock underlying the Resale Warrants as of certain time periods, then the selling stockholders may choose to exercise the Resale Warrants on a “cashless exercise” or “net exercise” basis. If they do so, we will not receive any proceeds from the exercise of such warrants. As a result, we cannot plan on receiving any proceeds from the exercise of any of such warrants, nor can we plan on any specific uses of any proceeds we may receive beyond the purposes described herein. We have agreed to bear the expenses (other than any underwriting discounts or commissions or agent’s commissions) in connection with the registration of the Common Stock being offered hereby by the selling stockholders.

DESCRIPTION OF SECURITIES

Authorized Capital Stock

Pursuant to our amended and restated articles of incorporation, as amended, as of September 21, 2023, our authorized capital stock consists of 350,000,000 shares of Common Stock. The following description summarizes the material terms of our capital stock. Because it is only a summary, it may not contain all the information that is important to you. In connection with the Primary Offering, we intend to effect a reverse stock split of our Common Stock at a ratio of 1-for-8 prior to the pricing of the Primary Offering.

Preferred Stock

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

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

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

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

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

Common Stock Issued and Outstanding; Common Stock Registered Hereby

As of June 19, 2024, there were issued and outstanding 555,562 shares of Common Stock.

Transfer Agent

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

Anti-Takeover Provisions of Nevada State Law

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

Acquisition of Controlling Interest

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

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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.

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MARKET PRICE OF AND DIVIDENDS ON COMMON STOCK AND RELATED MATTERS

Market Information

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

Dividends

We have never declared or paid any cash dividends or distributions on our capital stock. We currently intend to retain our future earnings, if any, to support operations and to finance expansion and therefore we do not anticipate paying any cash dividends on our Common Stock in the foreseeable future.

Holders

As of June 19, 2024, there were approximately 124 holders of record of our Common Stock.

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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”) is a biotechnology company developing and marketing products based on our innovative AC5® self-assembling technology platform. Arch arose from the June 26, 2013 merger (the “Merger”) of three entities previously known as Arch Biosurgery, Inc., Almah, Inc., and Arch Acquisition Corporation, respectively.

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

Almah, Inc., was incorporated under the laws of the State of Nevada on September 16, 2009 and, as part of the Merger transaction, changed its name to Arch Therapeutics, Inc.

and abandoned both its prior business plan and operations in order to adopt those of ABS.

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

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

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

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

Our Company

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

Commercial Update

During its fourth fiscal quarter ended September 30, 2023, the Company experienced a significant increase in AC5 orders, posting record monthly order volumes during both August and September. Taken together, orders from August and September represented more than half of total fiscal year volume, and September orders more than doubled August orders. The Company also observed favorable coverage and reimbursement decisions from multiple payors in different regions of the country with a commensurate increase in paid claims. Early in the fourth fiscal quarter, the Company received its first payment from a provider as a result of a paid claim for reimbursement of AC5 using A2020, and the number of paid claims across different payor networks increased throughout the quarter. Throughout the first fiscal quarter ended December 31, 2023 and second fiscal quarter ending March 31, 2024, the number of providers using AC5 and the number of related coverage and reimbursement decisions continued to expand. While numbers remain expectedly modest, the Company is optimistic that its ongoing efforts will result in contracted pricing opportunities with several regional Medicare Administrator Contractors, which management believes is the next important milestone in the Company’s comprehensive strategic commercialization plan.

Core Technology

Our flagship product 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 (US) and the European Union (EU), respectively, and which are intended for skin applications, such as management of complicated chronic wounds and acute surgical wounds. Marketing for AC5 Topical Hemostat in the EU has not initiated. Other products are in development for use in minimally invasive or open surgical procedures and include, for example, AC5-G™ for gastrointestinal endoscopic procedures and AC5-V® and AC5 Surgical Hemostat for hemostasis inside the body, all of which are currently investigational devices limited by law to investigational use.

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

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

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

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

Sales and marketing efforts for our AC5 Advanced Wound System, which has received 510(k) marketing clearance from the FDA, address the demand for improved solutions to treat challenging chronic and acute surgical wounds, with a particular early focus on diabetic foot ulcers, venous leg ulcers and pressure ulcers. Chronic wounds are typically defined as wounds that have not healed after four weeks of standard care. Approximately 4 million to 6.5 million new onset chronic wounds are estimated to occur in the U.S.

annually, including approximately 700,000 to 2 million diabetic foot ulcers, 2.5 million pressure ulcers, and 1.2 million venous leg ulcers. If untreated, improperly treated or unresponsive to treatment, these wounds can ultimately lead to amputation. The 5-year mortality rate among patients with chronic wounds, especially after an amputation, is significant.

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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.

Operations

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

Our long-term business plan includes the following goals:

- growing revenues and building upon recent commercial momentum by driving product awareness, continued adoption and favorable payment policies for AC5 Advanced Wound System with the now-effective CMS Level II HCPCS code dedicated to AC5;
- conducting biocompatibility, pre-clinical, and clinical studies on our products and product candidates;
- obtaining additional marketing authorization for products in the United States, Europe, and other jurisdictions as we may determine;
- continuing to develop third party relationships to manufacture, distribute, market and otherwise commercialize our products;
- continuing to develop third party 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.

To support our long-term business goals, we expect to focus on the following activities during the next twelve months:

- further develop our product clinical profile;

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- enhance product packaging features;
- identify and address opportunities for supply chain efficiencies;
- assess our technology platform in order to identify and select product candidates for potential advancement into development;
- seek additional funding as required to support the previously described milestones necessary to support our operations;
- 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, maintaining granted patents in desired jurisdictions, and/or adding to our trade secrets in self-assembly, manufacturing, analytical methods and formulation, as appropriate.

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 future capital. We will require significant additional financing to fund our planned operations, including, but not limited to, further research and development relating to AC5; seeking regulatory approval for any product we may choose to develop, launch or license; commercializing any product for which we are able to obtain regulatory approval or certification; seeking to license or acquire new assets or business; supporting our intellectual property rights; pursuing new technologies; and financing the investor relations and incremental administrative costs associated with being a public corporation. We do not presently have, nor do we expect in the near future to have, sufficient revenue to fund our business from operations, and we will need to obtain substantially all of our necessary funding from external sources for the foreseeable future. We may not be able to obtain additional financing on commercially reasonable or acceptable terms when needed, or at all. If we cannot raise the money that we need in order to continue to develop our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations. If any of these were to occur, there is a substantial risk that our business would fail, and our stockholders could lose all of their investments.

The estimated capital requirements could potentially 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*”. 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 June 19, 2024, we do not believe that our current cash on hand is sufficient to meet our anticipated cash requirements through the end of June 2024, and we must obtain additional financing in order to continue to operate our business. Even if this offering is successful, we could spend our financial resources much faster than we expect, in which case we would need to raise additional capital.

Research and Development

Preclinical and clinical testing is required in order to receive regulatory marketing authorizations for our products and to support those products upon and after commercialization, and we anticipate continuing such testing as appropriate.

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

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Before initiating our clinical trials and submitting marketing applications for a given product in most jurisdictions, we complete a biocompatibility assessment using a battery of standard in vitro and in vivo tests. Examples of such tests may include the following, as set forth in ISO 10993 issued by the International Organization for Standardization:

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

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 plan to 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 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 both 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' AC5 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.

The AC5 technology has also 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.

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The AC5 technology 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/or 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 other collaborators.

In order to enroll patients in a clinical trial, we are required to obtain each patient's informed consent in a form and substance that complies with the FDA and/or other regulatory authority requirements as well as state and federal privacy and human subject protection regulations.

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We have completed two randomized controlled clinical studies to date. The first study, which met its primary and secondary endpoints, assessed the safety and performance of AC5 in 46 patients with bleeding skin wounds, including a group of patients taking anti-platelet medications (i.e., a blood thinner) that resulted from excision of skin lesions and followed for 30 days. The second study assessed AC5 on skin, determining that it was neither an irritant nor a sensitizer, and no immunogenic response or other adverse events attributable to this product were reported in any of the approximately 50 enrolled volunteers. The AC5 product candidate in these studies subsequently received marketing authorization and is presently known as AC5 Advanced Wound System in the US and AC5 Topical Hemostat in the EU.

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

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 US.

Commercialization

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.

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.

For at least the near term future, in order to maximize operational efficiencies and to account for changing landscapes since the COVID-19 pandemic during which both marketing authorizations were received, 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.

We expect the commercialization ramp to be gradual through 2024 and into 2025, while we encourage product use among key opinion leaders and early adopters in developing market channels, and then moderately accelerate.

We recently started to commercialize AC5 Advanced Wound System. We rely on both an internal commercial team and independent sales distributors to drive 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 (VA) hospitals and military 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.

We anticipate that material growth in the physician office setting will require product reimbursement. To that end, we applied to the Centers for Medicare and Medicaid Services (CMS) for a dedicated Healthcare Common Procedure Coding System (HCPCS) Level II reimbursement code specific to AC5 Advanced Wound System to better enable providers to bill third party payors for AC5 that is used in doctors' offices. The unique HCPCS code, A2020, was granted and made effective on April 1, 2023. A dedicated HCPCS code is an important step toward, although not a guarantee of, coverage and reimbursement, and we intend it to 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.

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In support of the government market, we partnered with Lovell Government Services (LGS), a service-disabled veteran-owned small business, to be our government channel distributor. As a direct result of our relationship with LGS, AC5 Advanced Wound System has been added to the four major government contracting vehicles: Federal Supply Schedule (FSS), General Services Administration (GSA) schedule, Defense Logistics Agency's Medical Electronic Catalog Program (ECAT), and Distribution and Pricing Agreement (DAPA). This listing enables purchase by federal government agencies, including the Department of Veterans Affairs (VA), Indian Health Services (IHS), and Department of Defense (DOD) Medical Treatment Facilities, and it allows doctors in government channels to order AC5 Advanced Wound System.

Our internal core team oversees AC5 Advanced Wound System sales, marketing, and inventory distribution from the warehouse to the customer. We envision hiring additional internal sales representatives to support commercialization.

We have partnerships with reputable, value-added independent sales representatives and distributors, and we expect to add more collaborative agreements on a case-by-case basis to expand the overall reach and footprint of the sales organization. Such collaborations may include strategic partners. We anticipate that we will also 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 both 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.

The COVID-19 Pandemic Impact on Commercialization

The COVID-19 pandemic environment introduced significant challenges related to product launch, marketing and sales. While the overall environment has improved, negative direct and indirect effects may variously wax and wane. Some effects that we periodically observe include curtailed access to non-US surgeons, facilities, and potential strategic partners, as well as to some US medical facilities.

The pandemic brought additional attention to the tendency for interventions for wounds to be too often considered elective procedures instead of essential or emergent, as National Pressure Ulcer Advisory Panel guidelines and others recommend, resulting in a projected increased risk to limb and life. 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 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 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.

We believe that these challenges may present an opportunity for new technology, such as ours, to address poorly met needs and limited healthcare overall resources.

Manufacturing

We work with contract manufacturing and related organizations, including those operating under cGMP, as is required by applicable regulatory agencies for production of products 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. 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 research, development, and commercialization.

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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 products.

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.

Industry and Competition

Arch is developing technology for Dermal Sciences and BioSurgery applications. 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 AC5 self-assembling peptide technology and Arch's 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 many 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 (www.ncbi.nlm.nih.gov/books/NBK442035), 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 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 (https://www.facs.org/media/buthal55/nonhealing_wounds.pdf; www.doi.org/10.1111/wrr.12994; www.doi.org/10.1186/s13643-016-0400-8; www.doi.org/10.19080/ARR.2020.06.555678).

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Diabetic foot ulcers develop in approximately 2 million Americans each year, according to The Health Innovation Program, University of Wisconsin (<https://hip.wisc.edu/DiabeticFootUlcers>), while the annual incidence across developed countries is estimated to be 2-4%, according to Woods et al in 2020 (www.doi.org/10.1371/journal.pone.0232395). Pressure ulcers develop in over 2.5 million Americans each year, according to the United States Agency for Healthcare Research & Quality (www.ahrq.gov/topics/pressure-ulcers.html).

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 (www.doi.org/10.3111/13696998.2014.903258), while Qiu et al in 2021 provided an estimated prevalence of 2-4% (www.doi.org/10.3389/fmed.2021.614059). 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 (www.doi.org/10.1186/s13643-016-0400-8). Woods et al in 2020 stated that only 2/3 of diabetic foot ulcers heal within 12 months (www.doi.org/10.1371/journal.pone.0232395). 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 (www.doi.org/10.1186/s13643-016-0400-8).

The Health Innovation Program, University of Washington, cited that of patients with diabetic foot ulcers in the United States, more than 50% will die within five years and 5% will have an amputation (<https://hip.wisc.edu/DiabeticFootUlcers>). A common phrase in medicine, which we often cite, is, “Save a limb, save a life.” Even the amputations that are required to save a patient from a non-healing, progressing chronic wound are associated with additional significant morbidity and mortality. In an examination of mortality rates after amputations from a chronic wound, Meshkin et al performed a systematic literature review and found that of the sixty-one studies yielding approximately 36,000 patients who previously received a nontraumatic major lower extremity amputation, approximately 34% died by year one, 55% died by year two, and 64% died by year five (<http://www.doi.org/10.1053/j.jfas.2020.06.027>). Stern et al in 2017 reported an even higher mortality rate one year after amputation of approximately 48% (www.doi.org/10.1016/j.avsg.2016.12.015).

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 (<https://www.doi.org/10.1016/j.jval.2017.07.007>). 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 (<https://www.doi.org/10.12968/jowc.2017.26.sup4.s4>). 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 (www.doi.org/10.1371/journal.pone.0232395). 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 (<https://www.doi.org/10.1007/s12325-017-0478-y>).

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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 (<https://www.researchgate.net/publication/340950761>). 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, will complement other products and procedures by potentially enabling the wound bed to be ready sooner, and will 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 wounds;
- conforms to irregularly shaped wound geometry;
- may be used in either lower acuity (e.g., doctor’s offices) 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 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.

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 (NOTES), and other procedures.

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While developing our products, we engaged commercial strategy and marketing consultants and communicated directly with care providers to understand the needs of potential customers and to assess product feature preferences. Surgeons, operating room managers, sales representatives and hospital decision-makers identified several characteristics deemed desirable, including that a product is:

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

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

- a persistent drive to migrate the site of surgical care from inpatient hospital operating room to progressively lower acuity same-day ambulatory settings due to cost and other potential negative impacts of unnecessary hospitalizations, such as infection risk or occupying scarce resources that may be more usefully deployed elsewhere;
- increased use of anticoagulants and other anti-thrombotic agents (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 in performing more types of procedures in less expensive outpatient settings.

Since the early days of modern MIS in the 1990s, the percent of minimally invasive surgeries 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.

In a trend to make traditional minimally invasive surgery even less invasive, known as NOTES, a procedure is performed through an endoscope that 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.

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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 have 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 and 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.

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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.

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.
- Reimbursement for some competing products and product categories may be more established, and reimbursement for advanced wound care products, in general, is being re-evaluated by payers, raising potential barriers to use.

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 US and foreign government agencies have broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on our business. Additionally, if we are able to successfully obtain approvals for, and commercialize our product candidates, then the Company and our products may become subject to various federal, state and local laws targeting fraud, abuse, privacy and security in the healthcare industry.

Intellectual Property

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

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As of March 31, 2024, we either own or license from others a number of US patents, US patent applications, foreign patents and foreign patent applications.

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

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

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

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

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

to our business and our lead product candidate. Our loss of any of the rights granted to us under our license agreement with MIT could materially harm our product development efforts and could cause our business to fail.

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

Employees

We presently have eight full-time employees, and we 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.

On December 5, 2023, Daniel Yrigoyen resigned, effective as of such date, from his position as an executive officer and as Vice President of Sales of the Company. Effective December 5, 2023 Shawn Carlson was appointed to serve as the Company's Vice President of Sales.

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Recent Events

Charter Amendments

On July 18, 2023, the board of directors of the Company (the "**Board**") adopted resolutions by unanimous written consent, pursuant to which the Board determined that it is advisable and in the best interests of the Company to amend the Articles of Incorporation of the Company (the "**Amendment**") to (i) increase the total number of authorized shares of Common Stock from 12,000,000 to 350,000,000 (the "**Authorized Share Increase**"), (ii) authorize 5,000,000 shares of "blank check" preferred stock of the Company, thereby giving the Board the authority to designate from time to time one or more series of preferred stock (the "**Blank Check Preferred**"), and (iii) provide for a reverse stock split of the outstanding Common Stock, at a ratio within a range of 1-for-1.5 to 1-for-20, with the exact ratio to be determined by the Board subsequent to the applicable approval by the Company's stockholders, within 1 year following the date of such approval, and without correspondingly decreasing the number of authorized shares of Common Stock (the "**Reverse Split**" and, together with the Authorized Share Increase and the Blank Check Preferred, the "**Charter Amendments**"). On August 22, 2023, stockholders representing a majority of the voting power of the then outstanding shares of voting stock of the Company (the "**Majority Stockholders**") executed a written consent approving the Charter Amendments and the Company filed a preliminary Information Statement with the SEC with respect to the transactions contemplated hereby. The Company filed a definitive Information Statement with the SEC and mailed the definitive Information Statement to the Company's stockholders notifying them of the action taken by written consent on September 1, 2023. Accordingly, the Company filed the Amendment with respect to the Authorized Share Increase and the Blank Check Preferred with the Secretary of State of Nevada on September 21, 2023. The Company intends to effect the Reverse Split at a ratio of 1-for-8 prior to the pricing of the Primary Offering. All share and per share information in this prospectus, other than the historical financial statements included herein, has been adjusted to give effect to the Reverse Split.

Reverse Stock Split

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

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

PIPE, Bridge and Note Financings

Uplist PIPE

On November 8, 2023, the Company and certain institutional and accredited individual investors (collectively, the "**PIPE Investors**") entered into a Securities Purchase Agreement, as subsequently amended on June 19, 2024 (as amended, the "**PIPE SPA**"), pursuant to which the Company has agreed to issue and sell to the PIPE Investors, and the PIPE Investors have agreed to purchase from the Company, an aggregate of (i) warrants (the "**PIPE Pre-Funded Warrants**") to purchase an aggregate of 1,430,650 shares of Common Stock (the "**PIPE Pre-Funded Warrant Shares**") and (ii) warrants (the "**PIPE Investor Warrants**") and together with the PIPE Pre-Funded Warrants, the "**PIPE Warrants**") to purchase an aggregate 1,430,650 shares of Common Stock (the "**PIPE Investor Warrant Shares**") and together with the PIPE Pre-Funded Warrant Share, the "**PIPE Warrant Shares**"), at a purchase price of \$4.124 per PIPE Pre-Funded Warrant to purchase one share of Common Stock and accompanying PIPE Investor Warrant to purchase one share of Common Stock, for aggregate gross proceeds of \$5.9 million, before deducting the placement agent's fees and estimated offering expenses, and expected net proceeds of \$5.4 million after deducting the placement agent's fees and estimated offering expenses payable by the Company. The PIPE Pre-Funded Warrants and PIPE Investor Warrants will be issued as part of a private placement offering authorized by the Company's board of directors (the "**Uplist PIPE**"). The Company currently intends to use the net proceeds it receives from the Uplist PIPE for product marketing and for general working capital purposes. The purpose of the Uplist PIPE is mainly to assist the Company in meeting the initial listing requirements of Cboe, including for purposes of the minimum stockholders' equity requirement and the requirement of the Company to achieve its listing in connection with a firm commitment underwritten public offering.

Between December 13, 2023 and March 28, 2024, certain of the PIPE Investors advanced the Company an aggregate of \$1.25 million as partial prepayment of their respective purchase price under the PIPE SPA, which funds were advanced outside of the escrow provided for in the PIPE SPA, and which funds have been available to the Company in support of its operations (the "**PIPE Advances**"). On May 15, 2024, the 2024 Notes Investors (as defined below) purchased an aggregate of \$2,220,000 in principal amount of 2024 Notes (as defined below) for an aggregate purchase price of \$1,850,000, which amount was paid through the surrender and cancellation of the PIPE Advances by the 2024 Notes Investors and an incremental amount of \$600,000 in cash. Under the PIPE SPA, a PIPE Investor's obligation to purchase PIPE Pre-Funded Warrants and PIPE Investor Warrants is reduced by the purchase price paid by such PIPE Investor for 2024 Notes under the 2024 Notes SPA (as defined below). Accordingly, it is currently anticipated that PIPE Pre-Funded Warrants to purchase an aggregate of 982,056 shares of Common Stock and PIPE Investor Warrants to purchase an aggregate of 982,056 shares of Common Stock will be issued in the Uplist PIPE, for gross proceeds of \$4,050,000, and expected net proceeds of \$3,528,000, while the \$2,220,000 in principal amount of 2024 Notes will automatically convert at the closing of the Primary Offering into (i) 2024 Note Conversion Pre-Funded Warrants to purchase an aggregate of 538,182 shares of Common Stock and (ii) 2024 Note Uplist Conversion Warrants to purchase an aggregate of 538,182 shares of Common Stock, reflecting a net addition for the benefit of the PIPE Investors that are 2024 Notes Investors of an aggregate of 89,700 shares underlying the 2024 Note Conversion Pre-Funded Warrants and 2024 Note Uplist Conversion Warrants, respectively, that is the result of the premium of the principal amount of \$2,220,000 of the 2024 Notes over their purchase price of \$1,850,000 (which purchase price, as stated above, has reduced the aggregate purchase price of the securities sold in the PIPE SPA).

The closing of the Uplist PIPE is contingent upon, among other conditions, the registration statement of which this prospectus forms a part being declared effective by the SEC and the approval of the listing of the Common Stock on any securities exchange registered with the SEC as a “national securities exchange” under Section 6 of the Exchange Act (a “**National Exchange**”), and the closing is expected to occur immediately prior to the pricing of the Primary Offering.

The Company retained Dawson James Securities, Inc. (“**DJ**”), pursuant to a placement agency agreement, dated November 8, 2023, as placement agent in connection with the Uplist PIPE. The Company will pay DJ a cash fee equal to 8.0% of the aggregate gross proceeds of the Uplist PIPE (expected to be \$472,000), will reimburse DJ for legal and other expenses of up to \$150,000 and will issue to DJ, or its designees, warrants (the “**PIPE Placement Agent Warrants**”) to purchase an aggregate of 71,533 shares of Common Stock. The PIPE Placement Agent Warrants will be exercisable at any time and from time to time, in whole or in part, during the five-year period commencing upon issuance, at a price per share equal to \$5.15625 (which is 125% of the price per Unit sold in the Primary Offering).

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PIPE Pre-Funded Warrants

The PIPE Pre-Funded Warrants (i) will have a nominal exercise price of \$0.001 per share; (ii) will be exercisable immediately upon issuance; (iii) will be exercisable until all of the PIPE Pre-Funded Warrants are exercised in full; and (iv) will have a provision preventing the exercisability of such PIPE Pre-Funded Warrants if, as a result of the exercise of the PIPE Pre-Funded Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than either 4.99% or 9.99% of the Common Stock (the “**Ownership Limitation**”) immediately after giving effect to the exercise of the PIPE Pre-Funded Warrants.

PIPE Investor Warrants

The PIPE Investor Warrants (i) will have an exercise price of \$4.00 per share; (ii) will have a term of exercise equal to 5 years after their issuance date; (iii) will be exercisable immediately upon issuance; and (iv) will have a provision preventing the exercisability of such PIPE Investor Warrants if, as a result of the exercise of the PIPE Investor Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than the Ownership Limitation immediately after giving effect to the exercise of the PIPE Investor Warrants.

Pursuant to the PIPE SPA, the Company has agreed to file no later than sixty (60) days after the closing date of an offering conducted in conjunction with an uplist of the Common Stock to, and in compliance with the rules of, any National Exchange (the “**Uplist Transaction**”), which the Primary Offering is intended to be, a registration statement on Form S-4, or other appropriate form, registering the offer by the Company to exchange, on a one-for-one basis, all outstanding PIPE Investor Warrants, 2022 Warrants (as defined below), Uplist Conversion Warrants (as defined below) and Exchange Investor Warrants (as defined below) for newly issued warrants identical to the Investor Warrants being sold in the Primary Offering, which warrants are expected to be listed on Cboe under the symbol “**ARTHW**.”

Registration Rights Agreement

The Company also entered into a registration rights agreement with the PIPE Investors dated November 8, 2023 (the “**PIPE Registration Rights Agreement**”), pursuant to which the Company is obligated, subject to certain conditions, to file with the SEC within the earlier of (i) the closing date of the Uplist Transaction and (ii) the 60th calendar day following the date of the PIPE Registration Rights Agreement one or more registration statements to register the PIPE Warrant Shares, the Uplist Conversion Warrant Shares (as defined below) and the 2022 Note Conversion Pre-Funded Warrant Shares (as defined below) for resale under the Securities Act of 1933, as amended (the “**Securities Act**”). The Company’s failure to satisfy certain filing and effectiveness deadlines and certain other requirements set forth in the PIPE Registration Rights Agreement may subject the Company to payment of monetary penalties. The Resale Prospectus currently covers the resale of the PIPE Warrant Shares, the Uplist Conversion Warrant Shares and the 2022 Note Conversion Pre-Funded Warrant Shares.

PIPE Advances

Under the terms of the PIPE Advances, since the Common Stock has not been approved for listing on the Nasdaq Capital Market by March 31, 2024, with respect to a portion of the PIPE Advances, or April 30, 2024, with respect to the remainder of the PIPE Advances, the Company has issued to the advancing parties (A) additional pre-funded warrants (the “**PIPE Advance Penalty Pre-Funded Warrants**”) to purchase up to an aggregate of 75,776 shares of Common Stock (which represents a 25% addition) and (B) additional investor warrants (the “**PIPE Advance Penalty Common Warrants**”) to purchase up to an aggregate of 75,776 shares of Common Stock. The Resale Prospectus currently covers the resale of the shares of Common Stock underlying the PIPE Advance Penalty Pre-Funded Warrants (the “**PIPE Advance Penalty Pre-Funded Warrant Shares**”) and the PIPE Advance Penalty Common Warrants (the “**PIPE Advance Penalty Common Warrant Shares**”).

Backstop Agreement

On June 19, 2024, certain of the PIPE Investors (the “**Backstop Buyers**”) agreed that in the event that as of the close of business on the date that is 10 calendar days prior to the date that the Company reasonably expects the closing of the Uplist PIPE to occur (the “**Escrow Date**”) there is not an amount of funds in escrow for the PIPE equal to \$5,900,000 less the aggregate purchase price paid for the 2024 Notes (the “**Escrow Minimum Amount**”) (such circumstance, an “**Escrow Deficiency**”), then each of the Backstop Buyers will deposit in escrow the purchase price for a pro rata share of an amount, no greater than \$1,500,000, equal to (A) \$320,000 plus (B) (i) \$5,900,000, minus (ii) the amount of funds in escrow on the Escrow Date, minus (iii) the aggregate purchase price paid by PIPE Investors for the 2024 Notes (the “**Backstop Amount**”) of additional PIPE Pre-Funded Warrants and PIPE Investor Warrants under the PIPE SPA (such agreement, the “**Backstop Agreement**”), and shall purchase such additional PIPE Pre-Funded Warrants and PIPE Investor Warrants at the Uplist PIPE closing. In consideration for the execution by the Backstop Buyers of the Backstop Agreement, the Company agreed to issue to the Backstop Buyers, as soon as practicable, pre-funded warrants (the “**Execution Backstop Pre-Funded Warrants**”), in form and substance substantially similar to the PIPE Pre-Funded Warrants, to purchase an aggregate of 225,000 shares of Common Stock. The Company also agreed to issue to the Backstop Buyers (i) additional pre-funded warrants (the “**Funding Backstop Pre-Funded Warrants**”) and, together with the Execution Backstop Pre-Funded Warrants, the “**Backstop Pre-Funded Warrants**”) to purchase an amount of shares of Common Stock equal to 0.5 shares per dollar of funding deposited under the Backstop Agreement, or up to an aggregate of 750,000 shares, and (ii) investor warrants (the “**Backstop Common Warrants**”), in form and substance substantially similar to the PIPE Investor Warrants, to purchase an amount of shares of Common Stock equal to 0.65 shares per dollar of funding deposited under the Backstop Agreement, or up to an aggregate of 975,000 shares. The Resale Prospectus currently covers the resale of the shares of Common Stock underlying the Backstop Pre-Funded Warrants (the “**Backstop Pre-Funded Warrant Shares**”) and the Backstop Common Warrants (the “**Backstop Common Warrant Shares**”).

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2024 Notes

On May 15, 2024, the Company entered into a Securities Purchase Agreement (the “**2024 Notes SPA**”) with certain institutional and accredited individual investors who are also PIPE Investors (collectively, the “**2024 Notes Investors**”) providing for the issuance and sale by the Company to the 2024 Notes Investors certain Secured Promissory Notes (each a “**2024 Note**” and collectively, the “**2024 Notes**”) convertible into shares of Common Stock. On June 12, 2024, an additional investor, which is not a PIPE Investor (the “**Additional 2024 Notes Investor**”) purchased 2024 Notes in the principal amount of \$180,000, including an original issue discount of \$30,000. The 2024 Notes were issued as part of a convertible notes offering authorized by the Company’s board of directors (the “**2024 Notes Financing**”).

In connection with the 2024 Notes Financing, the Company issued and sold to the 2024 Notes Investors and Additional 2024 Notes Investor the 2024 Notes in the aggregate

principal amount of \$2,400,000, which includes an aggregate \$370,000 original issue discount in respect of the 2024 Notes. The aggregate net proceeds for the sale of the 2024 Notes was approximately \$2,000,000, after deducting issuance discounts. The closing of the sales of the 2024 Notes to the 2024 Notes Investors under the 2024 Notes SPA occurred on May 15, 2024 (the “**2024 Notes Closing Date**”). The Company is using the net proceeds from the 2024 Notes Financing primarily for working capital and general corporate purposes, and has not allocated specific amounts for any specific purposes.

The 2024 Notes become due and payable on June 30, 2024 (the “**2024 Notes Maturity Date**”) and may be prepaid provided that an Event of Default (as defined therein) has not occurred. The 2024 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 their issuance date until the 2024 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 2024 Notes. Any amount of principal or interest on the 2024 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 “**Default Interest**”).

The 2024 Notes are convertible into an aggregate of 600,000 shares of Common Stock (such shares of Common Stock, the “**2024 Conversion Shares**”) at the option of each holder of the 2024 Notes from their issuance date at the 2024 Conversion Price (as defined below) through the later of (i) the 2024 Notes Maturity Date and (ii) the date of payment of the Default Amount (as defined in the 2024 Note); *provided, however*, the 2024 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 (the “**2024 Notes Ownership Limitation**”) immediately after giving effect to the conversion; and *provided further*, the holder, upon notice to the Company, may increase or decrease the 2024 Notes Ownership Limitation; *provided that* (i) the 2024 Notes 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 2024 Notes Ownership Limitation will not become effective until the 61st day after delivery of such waiver notice.

The initial conversion price of the 2024 Notes (the “**2024 Conversion Price**”) shall be equal to \$4.00 per share and may be reduced or increased proportionately as a result of any stock dividends, recapitalizations, reorganizations, and similar transactions. If the Company fails to deliver the shares of Common Stock issuable upon a conversion by the Deadline (as defined in the 2024 Notes), then the Company is obligated to pay such 2024 Note holder \$5,000 per day in cash for each day beyond the Deadline.

The 2024 Notes contain customary events of default, which include, among other things, (i) the Company’s failure to pay when due any principal or interest payment under the 2024 Notes; (ii) the insolvency of the Company; (iii) delisting of the Common Stock; (iv) the Company’s breach of any material covenant or other material term or condition under the 2024 Notes; and (v) the Company’s breach of any representations or warranties under the 2024 Notes which cannot be cured within five days. Further, Events of Default under the 2024 Notes also include (i) the unavailability of Rule 144 on or after six months from the Issue Date (as defined therein); (ii) the Company’s failure to deliver the shares of Common Stock to the 2024 Note holder upon exercise by such holder of its conversion rights under the 2024 Note; (iii) the Company’s 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) the Company’s failure to complete an uplist to a National Exchange by June 30, 2024.

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Upon an Event of Default, the 2024 Notes shall become immediately due and payable and the Company shall pay to each 2024 Note holder an amount equal to 125% (the “**Default Premium**”) multiplied by the sum of the outstanding principal amount of the 2024 Notes plus any accrued and unpaid interest on the unpaid principal amount of the 2024 Notes to the date of payment, plus any Default Interest and any other amounts owed to the holder under the 2024 Notes 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 five percent (5%) to the Default Premium for each subsequent Event of Default. At the election of each 2024 Note holder, the Default Amount may be paid in cash or shares of Common Stock equal to the Default Amount divided by the 2024 Conversion Price at the time of payment.

Upon the closing of the Primary Offering, 100% of the then outstanding principal amount of the 2024 Notes shall automatically convert (the “**2024 Notes Automatic Conversion**”) into shares of Common Stock (the “**2024 Notes Automatic Conversion Shares**”), with the conversion price for purposes of such 2024 Notes Automatic Conversion being \$4.125. Upon the 2024 Notes Automatic Conversion and to the extent that the beneficial ownership of a holder of 2024 Notes (a “**2024 Notes Holder**”) and, all holders of 2024 Notes together, the “**2024 Notes Holders**”) would increase over the applicable 2024 Notes Ownership Limitation, the 2024 Notes Holder will receive pre-funded warrants (the “**2024 Note Conversion Pre-Funded Warrants**”), and the shares issuable upon exercise thereof, the “**2024 Note Conversion Pre-Funded Warrant Shares**”) in lieu of shares of Common Stock otherwise issuable to the 2024 Notes Holder in connection with the 2024 Notes Automatic Conversion, which 2024 Note Conversion Pre-Funded Warrants shall have an exercise price of \$0.001 per share, may be exercised on a cashless basis, shall be exercisable immediately upon issuance and shall contain a customary beneficial ownership limitation provision.

In addition, upon the 2024 Notes Automatic Conversion, the 2024 Notes Holder shall receive a warrant (the “**2024 Notes Uplist Conversion Warrant**”), and the shares issuable upon exercise thereof, the “**2024 Notes Uplist Conversion Warrant Shares**”) to purchase a number of shares of Common Stock equal to the number of shares of Common Stock (or shares of Common Stock underlying 2024 Note Conversion Pre-Funded Warrants, if any) issued upon the 2024 Notes Automatic Conversion. The 2024 Notes Uplist Conversion Warrant shall have an exercise price per share of \$4.00 and shall otherwise be identical to the PIPE Investor Warrants. The Company also agreed in the 2024 Notes to file no later than sixty (60) days after the closing of the Primary Offering a registration statement on Form S-4, or other appropriate form, registering the offer by the Company to exchange, on a one-for-one basis, all outstanding PIPE Investor Warrants, 2024 Notes Uplist Conversion Warrants and Exchange Investor Warrants for newly issued warrants identical to the Investor Warrants being sold in the Primary Offering, which warrants are expected to be listed on Cboe under the symbol “ARTHW.”

Registration Rights Agreement

On the 2024 Notes Closing Date, the Company entered into a Registration Rights Agreement with the 2024 Notes Investors (the “**2024 Notes Registration Rights Agreement**”), pursuant to which the Company is obligated, subject to certain conditions, to file with the Securities and Exchange Commission within 60 days after the 2024 Notes Closing Date one or more registration statements (any such registration statement, a “**2024 Notes Resale Registration Statement**”) to register the 2024 Conversion Shares for resale under the Securities Act. The Company’s failure to satisfy certain filing and effectiveness deadlines with respect to a 2024 Notes Resale Registration Statement and certain other requirements set forth in the 2024 Notes Registration Rights Agreement may subject the Company to payment of monetary penalties.

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Security Agreement

In connection with the issuance of the 2024 Notes, the Company entered into a Security Agreement with the Collateral Agent (as defined therein) on behalf of the 2024 Notes Investors on the 2024 Notes Closing Date (the “**2024 Notes Security Agreement**”), pursuant to which the Company and each of its subsidiaries (together with any persons who execute a joinder to the 2024 Notes Security Agreement, the “**2024 Notes Debtors**”) provided as collateral to the 2024 Notes holders a security interest in, and a lien on, substantially all of the 2024 Notes Debtors. Upon an Event of Default under the 2024 Notes, each 2024 Notes holder may exercise its rights to the collateral pursuant to the terms of the 2024 Notes Security Agreement.

Accordingly, it is currently anticipated that at the closing of the Primary Offering: (i) (A) 2024 Note Conversion Pre-Funded Warrants with an exercise price of \$0.001 to purchase an aggregate of 538,182 shares of Common Stock and (B) 43,637 2024 Notes Automatic Conversion Shares will be issued upon the 2024 Note Automatic Conversion of the \$2,400,000 of principal amount outstanding under the 2024 Notes; and (ii) the 2024 Note Holders will be issued 2024 Note Uplist Conversion Warrants to purchase an aggregate of 581,819 shares of Common Stock. The expected allocation between shares of Common Stock and 2024 Note Conversion Pre-Funded Warrants in the previous sentence is only an initial estimate based on indications of interest and is subject to change based on the ultimate ownership of

the 2024 Note Holders after the Uplist PIPE and the Primary Offering. The maximum number of shares of Common Stock and 2024 Note Conversion Pre-Funded Warrants that may be issued, individually and in the aggregate is 581,819.

Bridge Offering

Between July 7, 2023 and September 11, 2023, pursuant to a Securities Purchase Agreement dated July 7, 2023, as subsequently amended (the “**Bridge SPA**”), among the Company and certain institutional and accredited individual investors (collectively, the “**Bridge Investors**”) the Company issued and sold to the Bridge Investors an aggregate of (i) 418,051 shares (the “**Bridge Shares**”) of Common Stock; (ii) warrants (the “**Bridge Pre-Funded Warrants**”) to purchase an aggregate of 756,871 shares of Common Stock (the “**Bridge Pre-Funded Warrant Shares**”); and (iii) warrants (the “**Common Warrants**”) and together with the Bridge Pre-Funded Warrants, the “**Bridge Warrants**”) to purchase an aggregate 2,349,826 shares of Common Stock (the “**Common Warrant Shares**”) and together with the Bridge Pre-Funded Warrant Share, the “**Bridge Warrant Shares**”), at a purchase price of \$2.20 per Bridge Share and accompanying Common Warrant to purchase two shares of Common Stock, and \$2.192 per Bridge Pre-Funded Warrant to purchase one share of Common Stock and accompanying Common Warrant to purchase two shares of Common Stock. The Bridge Shares, Bridge Pre-Funded Warrants, and Common Warrants were issued as part of a private placement offering authorized by the Company’s board of directors (the “**Bridge Offering**”).

Pursuant to the Bridge SPA, the Bridge Investors agreed not to sell or otherwise transfer any of the Bridge Shares or Bridge Warrant Shares prior to the one-year anniversary of the Bridge Closing Date. In the event that a Bridge Investor purchases securities in connection with an Uplist Transaction, which the Primary Offering is intended to be, and/or in the Uplist PIPE, with an aggregate purchase price equal to at least 4.3 multiplied by the aggregate purchase price paid by the Bridge Investor for the Bridge Shares and Bridge Warrants under the Bridge SPA, the one-year lock-up period will no longer apply to the Bridge Shares and Bridge Warrants. The aggregate gross proceeds for the sale of the Bridge Shares, Bridge Pre-Funded Warrants, and Common Warrants was approximately \$2.6 million, before deducting the placement agent’s fees and other estimated fees and offering expenses payable by the Company. The first closing of the sales of these securities under the Bridge SPA occurred on July 7, 2023 (the “**Bridge Closing Date**”).

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Under the Bridge SPA, the Company also agreed that upon the closing of the next underwritten public offering of Common Stock (a “**Qualifying Offering**”), which the Company agreed is the Primary Offering, if the effective offering price to the public per share of Common Stock (the “**Qualifying Offering Price**”) is lower than \$32.00 per share, then the Company shall issue additional Bridge Pre-Funded Warrants (the “**True-Up Pre-Funded Warrants**”, and the shares issuable upon exercise thereof, the “**True-Up Pre-Funded Warrant Shares**”), or shares of Common Stock (the “**True-Up Shares**”) in lieu thereof to the extent necessary to cause the Company to meet the listing requirements of the Company’s proposed trading market in the Uplist Transaction, in an amount reflecting a reduction in the purchase price paid for the Bridge Shares and Bridge Pre-Funded Warrants that equals the proportion by which the Qualifying Offering Price is less than \$32.00. The Company also agreed that the Qualifying Offering Price as a result of the Primary Offering is \$4.00. **Accordingly, at the closing of the Primary Offering, based on the sale of the Units and Pre-Funded Units at an assumed public offering price of \$4.125 per Unit and \$4.124 per Pre-Funded Unit, which represents the minimum bid price of \$4.00 per share under the initial listing requirements of Cboe in Cboe Listing Rule 14.9(b) plus a value of \$0.125 attributed to the accompanying Investor Warrant, the Company expects to issue (i) True-Up Pre-Funded Warrants with an exercise price of \$0.001 to purchase an aggregate of 6,330,422 shares of Common Stock and (ii) an aggregate of 1,893,919 True-Up Shares to the Bridge Investors.** The expected allocation between True-Up Shares and True-Up Pre-Funded Warrants in the previous sentence is only an initial estimate based on indications of interest and is subject to change based on the ultimate ownership of the Bridge Investors after the Uplist PIPE and the Primary Offering. The maximum amount of True-Up Pre-Funded Warrants and True-Up Shares that may be issued, individually and in the aggregate is 8,224,341. The Resale Prospectus currently covers the resale of the True-Up Pre-Funded Warrant Shares and True-Up Shares.

The Company retained DJ as placement agent in connection with the Bridge Offering. The Company paid DJ a cash fee equal to 8.0% of the aggregate gross proceeds of the Bridge Offering and reimbursement of expenses of \$50,000. Additionally, on September 7, 2023 the Company issued to DJ, or its designees, warrants, as subsequently amended (the “**Placement Agent Warrants**”) to purchase an aggregate of 55,242 shares of Common Stock. The Placement Agent Warrants are exercisable at any time and from time to time, in whole or in part, until September 7, 2028, at a price per share equal to \$2.20 (which will increase to \$5.15625 at the closing of the Uplist Transaction, representing 125% of the assumed price per share of Common Stock in the Uplist Transaction, as required by FINRA).

Bridge Pre-Funded Warrants

The Bridge Pre-Funded Warrants (i) have a nominal exercise price of \$0.008 per share; (ii) are exercisable after the earlier of (A) the six-month anniversary after the date of issuance, (B) 120 days after the closing date of an Uplist Transaction, and (C) the date that a registration statement registering the Bridge Pre-Funded Warrant Shares is declared effective; (iii) are exercisable until all of the Bridge Pre-Funded Warrants are exercised in full; and (iv) have a provision preventing the exercisability of such Bridge Pre-Funded Warrants if, as a result of the exercise of the Bridge Pre-Funded Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than the Ownership Limitation immediately after giving effect to the exercise of the Bridge Pre-Funded Warrants.

Common Warrants

The Common Warrants (i) have an exercise price of \$8.00 per share; (ii) have a term of exercise equal to 5 years after their issuance date; (iii) are exercisable after the earlier of (A) the six-month anniversary after the date of issuance and (B) the date that a registration statement registering the Common Warrant Shares is declared effective; (iv) have a provision permitting voluntary adjustments to the exercise price by the Company, subject to the prior written consent of the Common Warrant holder; (v) are automatically exchanged upon the closing of an Uplist Transaction for a new warrant that is identical to the warrants (other than any pre-funded warrants), if any, being issued to investors in such Uplist Transaction, with the number of shares underlying such new warrant being equal to the number of Common Warrant Shares then underlying the Common Warrant multiplied by three and (vi) have a provision preventing the exercisability of such Common Warrants if, as a result of the exercise of the Common Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Company Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than the Ownership Limitation immediately after giving effect to the exercise of the Common Warrants. **Accordingly, at the closing of the Primary Offering, the Common Warrants will be cancelled and exchanged for newly issued warrants identical to the Investor Warrants to purchase an aggregate of 7,049,478 shares of Common Stock at an exercise price per share equal to the exercise price per share of the Investor Warrants (the “Exchange Investor Warrants”).**

In addition, as noted above, pursuant to the PIPE SPA, the Company has agreed to file no later than sixty (60) days after the closing date of the Uplist Transaction, a registration statement on Form S-4, or other appropriate form, registering the offer by the Company to exchange, on a one-for-one basis, all outstanding Exchange Investor Warrants for newly issued warrants identical to the Investor Warrants being sold in the Primary Offering, which warrants are expected to be listed on Cboe under the symbol “ARTH.W.”

Registration Rights Agreement

The Company also entered into a registration rights agreement with the Bridge Investors dated July 7, 2023, as subsequently amended (the “**Registration Rights Agreement**”), pursuant to which the Company is obligated, subject to certain conditions, to file with the SEC within the earlier of (i) 30 days following the closing date of the Uplist Transaction and (ii) January 31, 2024 one or more registration statements (any such registration statement, a “**Resale Registration Statement**”) to register the Bridge Shares, the Bridge Warrant Shares and the shares of Common Stock issuable upon exercise in full of the Exchange Investor Warrants (the “**Exchange Investor Warrant Shares**”) for resale under the Securities Act of 1933, as amended (the “**Securities Act**”). The Company’s failure to satisfy certain filing and effectiveness deadlines with respect to a Resale Registration Statement and certain other requirements set forth in the Registration Rights Agreement may subject the Company to payment of monetary penalties. The Resale Prospectus currently covers the resale of the Bridge Shares and the Bridge Warrant Shares.

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On April 30, 2024, the Company entered into an amendment (“**Amendment No. 16 to the First Notes**”) with the holders of the Company’s outstanding Senior Secured Convertible Promissory Notes, as separately amended on February 14, 2023, March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023, September 30, 2023, November 8, 2023, November 15, 2023, January 5, 2024 and March 15, 2024 (as amended, the “**First Notes**”), issued in connection with a private placement financing the Company completed on July 6, 2022 (the “**First Closing**”). On April 30, 2024, the Company also entered into an amendment (“**Amendment No. 16 to the Second Notes**”) with the holders of the Company’s outstanding Unsecured Convertible Promissory Notes, as separately amended on February 14, 2023, March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023, September 30, 2023, November 8, 2023, November 15, 2023, January 5, 2024 and March 15, 2024 (as amended, the “**Second Notes**”), issued in connection with a private placement financing the Company completed on January 18, 2023 (the “**Second Closing**”). On April 30, 2024, the Company also entered into an amendment (“**Amendment No. 11 to the Third Notes**”) with the holders of the Company’s outstanding Unsecured Convertible Promissory Notes, as separately amended on June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023, September 30, 2023, November 8, 2023, November 15, 2023, January 5, 2024 and March 15, 2024 (as amended, the “**Third Notes**”), issued in connection with a private placement financing the Company completed on May 15, 2023 (the “**Third Closing**”). On April 30, 2024, the Company also entered into an amendment (“**Amendment No. 2 to the Fourth Notes**” and, together with Amendment No. 16 to the First Notes, Amendment No. 16 to the Second Notes and Amendment No. 11 to the Third Notes, the “**Amendments to the 2022 Notes**”) with the holders of the Company’s outstanding Unsecured Convertible Promissory Notes, as separately amended on March 15, 2024 (the “**Fourth Notes**” and, together with the First Notes, the Second Notes and the Third Notes, the “**2022 Notes**”), issued in connection with a private placement financing the Company completed on March 12, 2024 (the “**Fourth Closing**”).

Under the Amendments to the 2022 Notes, the following amendments to the 2022 Notes will be simultaneously effective upon the closing of the Uplist Transaction. 95% of the then outstanding principal amount of the 2022 Notes shall automatically convert (the “**Automatic Conversion**”) into shares of Common Stock (the “**Automatic Conversion Shares**”), with the conversion price for purposes of such Automatic Conversion being \$4.00. Upon the Automatic Conversion and to the extent that the beneficial ownership of a holder of 2022 Notes (a “**Holder**” and, all holders of 2022 Notes together, the “**Holder**”) would increase over the applicable Ownership Limitation, the Holder will receive pre-funded warrants (the “**2022 Note Conversion Pre-Funded Warrants**”, and the shares issuable upon exercise thereof, the “**2022 Note Conversion Pre-Funded Warrant Shares**”) in lieu of shares of Common Stock otherwise issuable to the Holder in connection with the Automatic Conversion, which 2022 Note Conversion Pre-Funded Warrants shall have an exercise price of \$0.001 per share, may be exercised on a cashless basis, shall be exercisable immediately upon issuance and shall contain a customary beneficial ownership limitation provision.

In addition, upon the Automatic Conversion, the Holder shall receive a warrant (the “**Uplist Conversion Warrant**”, and the shares issuable upon exercise thereof, the “**Uplist Conversion Warrant Shares**”) to purchase a number of shares of Common Stock equal to 10 times the dollar amount under the 2022 Notes that was converted in the Automatic Conversion. The Uplist Conversion Warrant shall have an exercise price per share of \$4.00 and shall otherwise be identical to the PIPE Investor Warrants. The Company also agreed in the Amendments to the 2022 Notes to file no later than sixty (60) days after the closing of the Primary Offering a registration statement on Form S-4, or other appropriate form, registering the offer by the Company to exchange, on a one-for-one basis, all outstanding PIPE Investor Warrants, 2022 Warrants, Uplist Conversion Warrants and Exchange Investor Warrants for newly issued warrants identical to the Investor Warrants being sold in the Primary Offering, which warrants are expected to be listed on Cboe under the symbol “ARTHW” (the “**Uplist Conversion Warrants Exchange Offer Obligation**”).

The Amendments to the 2022 Notes also prohibit the Company from engaging in any capital raising transactions, subject to certain exceptions, until the earlier of (A) July 7, 2027, and (B) the first date on which all Holders hold less than 20% of the original amount of the Uplist Conversion Warrants received by each Holder, respectively, in connection with the Automatic Conversion.

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Accordingly, it is currently anticipated that at the closing of the Primary Offering: (i) an aggregate of (A) 1,454,034 shares of Common Stock and (B) 2022 Note Conversion Pre-Funded Warrants with an exercise price of \$0.001 to purchase an aggregate of 184,296 shares of Common Stock will be issued upon the Automatic Conversion of an aggregate of \$6,553,310 of principal amount under the 2022 Notes, representing 95% of the \$6,898,221 in principal amount currently outstanding under the 2022 Notes, based on the assumed exercise price of the Investor Warrants being offered as part of the Units and Pre-Funded Units in the Primary Offering of \$4.00 per share; and (ii) the Holders will be issued Uplist Conversion Warrants to purchase an aggregate of 65,533,100 shares of Common Stock, representing 10 multiplied by the \$6,553,310 of principal amount converted in the Automatic Conversion. The expected allocation between shares of Common Stock and 2022 Note Conversion Pre-Funded Warrants in the previous sentence is only an initial estimate based on indications of interest and is subject to change based on the ultimate ownership of the Holders after the Uplist PIPE and the Primary Offering. The maximum number of shares of Common Stock and 2022 Note Conversion Pre-Funded Warrants that may be issued, individually and in the aggregate is 1,638,330.

Additionally, on July 7, 2023, the Company entered into an amendment (the “**Omnibus Amendment to Notes and Warrants**”) with the Holders of the 2022 Notes, amending the 2022 Notes and related warrants issued at each of the First Closing, Second Closing, and Third Closing (the “**First Warrants**”, “**Second Warrants**” and “**Third Warrants**”, respectively, and collectively with the related warrants issued at the Fourth Closing, the “**2022 Warrants**”). Under the Omnibus Amendment to Notes and Warrants, the 2022 Notes and 2022 Warrants were amended to modify the Most Favored Nation provisions therein to exclude the Bridge Offering.

2022 Notes

The 2022 Notes bear interest on the unpaid principal balance at a rate equal to ten percent (10%) (computed on the basis of the actual number of days elapsed in a 360-day year) per annum accruing from the issuance date until the 2022 Notes become due and payable at maturity or upon their conversion, acceleration or by prepayment, and may become due and payable upon the occurrence of an event of default under the 2022 Notes. The 2022 Notes mature June 30, 2024. Any amount of principal or interest on the 2022 Notes which is not paid when due shall bear interest at the rate of the lesser of (i) eighteen percent (18%) per annum or (ii) the maximum amount allowed by law from the due date thereof until payment in full. As of June 19, 2024, the outstanding unpaid principal balance including all accrued interest under the 2022 Notes totaled \$8,015,282.

The 2022 Notes are convertible into shares of Common Stock at the option of each Holder from the date of issuance at \$73.12 (which will automatically change to \$4.00 as of the closing of the Uplist PIPE through the operation of the Most Favored Nation Provision (as defined below)), subject to adjustment, through the later of (i) June 30, 2024 (the “**Maturity Date**”) or (ii) the date of payment of the Default Amount (as defined in the 2022 Notes).

The 2022 Notes contain events of default, which include, among other things, (i) the Company’s failure to pay when due any principal or interest payment under the 2022 Notes; (ii) our failure to complete an Uplist Transaction by June 30, 2024 and (iii) our default on the Uplist Conversion Warrant Exchange Offer Obligation.

The 2022 Warrants (i) have an exercise price of \$79.52 (which will automatically change to \$4.00 as of the closing of the Uplist PIPE through the operation of the Most Favored Nation Provision) per share; (ii) have a term of exercise equal to 5 years after their issuance date; (iii) became exercisable immediately after their issuance; and (iv) have a provision preventing the exercisability of such 2022 Warrants if, as a result of the exercise of the 2022 Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of our Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than the Ownership Limitation. Pursuant to the “**Most Favored Nation Provision**” contained in the 2022 Notes and the 2022 Warrants, 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.

As discussed above, it is currently anticipated that 95% of the \$6,898,221 unpaid principal balance currently outstanding under the 2022 Notes will convert into (A) 1,454,034 shares of Common Stock and (B) 2022 Note Conversion Pre-Funded Warrants with an exercise price of \$0.001 to purchase an aggregate of 184,296 shares of Common Stock in connection with the Automatic Conversion, such allocation between shares and 2022 Note Conversion Pre-Funded Warrants being subject to change, as described above.

Under the Third Amended and Restated Registration Rights Agreement, dated as of March 12, 2024, as amended, the Company is required to file a registration statement registering the securities issued in the Second Closing, Third Closing and Fourth Closing, including the applicable 2022 Notes and 2022 Warrants, no later than 45 days following the closing of the Uplist Transaction. The Resale Prospectus currently covers the resale of the shares of Common Stock issuable upon the Automatic Conversion, the shares of Common Stock issuable upon conversion of the 2022 Notes at their regular conversion price and the shares of Common Stock issuable upon exercise of the 2022 Warrants.

Series 1 and 2 Convertible Notes

On June 4, 2020 and November 6, 2020, the Company issued unsecured 10% Series 1 Convertible Notes (“**Series 1 Notes**”) and Series 2 Convertible Notes, as amended (“**Series 2 Notes**”, and collectively with the Series 1 Notes, the “**Series Convertible Notes**”). The maturity dates of the Series 1 Notes and Series 2 Notes are June 30, 2023 and November 30, 2023, respectively. On July 12, 2023, the Company secured countersigned notices of conversion from all remaining holders of the Series 1 Convertible Notes and provided instructions to its transfer agent to issue a total of 7,489 shares of Common Stock in full satisfaction of all previously outstanding Series 1 Convertible Notes, which had an aggregate of \$718,918 of principal and interest outstanding at the time of conversion.

On November 30, 2023, the Series 2 Notes of \$450,000 principal and outstanding accrued interest of \$137,946 were converted into 6,615 shares of Common Stock.

Insurance Financing

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

Warrant Exchange Agreement

On March 10, 2023, the Company entered into exchange agreements (the “**Exchange Agreements**”) with each holder (the “**Warrantholders**”) of the Company’s outstanding Series G Warrants to purchase shares of the Company’s Common Stock at an exercise price of \$1,120.00 per share and the Company’s outstanding Series H Warrants to purchase shares of Common Stock at an exercise price of \$640.00 per share. Pursuant to the Exchange Agreements, the Warrantholders exchanged 4,252 Series G Warrants for 426 shares of Common Stock and 5,385 Series H Warrants for 1,078 shares of Common Stock.

Reimbursements and Support Program

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

Results of Operations

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

Six Months Ended March 31, 2024 Compared to Six Months Ended March 31, 2023

	March 31, 2024	March 31, 2023	Increase (Decrease) \$
Revenue	\$ 77,733	\$ 22,914	54,819
Operating expenses:			
Cost of revenues	45,161	36,353	8,808
Selling, general and administrative	1,994,534	2,355,701	(361,167)
Research and development	409,449	332,087	77,362
Loss from operations	(2,371,411)	(2,701,227)	329,816
Other Expense	(1,779,380)	(1,306)	(1,778,074)
Net loss	\$ (4,150,791)	\$ (2,702,533)	(1,448,258)

Revenue

Revenue for the six months ended March 31, 2024 was \$77,733 an increase of \$54,819 compared to revenue of \$22,914 for the six months ended March 31, 2023. Revenue for the six months ended March 31, 2024 was the result of several transactions into a single hospital, transactions into VA Hospitals through LGS, and transactions leveraging the dedicated HCPCS code (A2020) that went effective April 1, 2023 through a growing number of providers and offices working with the Company to submit reimbursement claims with numerous payors.

Cost of Revenues

Cost of revenue during the six months ended March 31, 2024 was \$45,161, an increase of \$8,808, compared to cost of revenue of \$36,353 for the six months ended March 31, 2023. The increase in cost of revenues corresponds to the increase in revenues. Cost of revenue includes product costs, third party warehousing, overhead allocation, royalty and shipping costs. An increase in revenue for the six months ended March 31, 2024 led to higher cost of revenues as a result.

Selling, General and Administrative Expense

Selling, general and administrative expense during the six months ended March 31, 2024 was \$1,994,534, a decrease of \$361,167, compared to \$2,355,701 for the six months ended March 31, 2023. The decrease in selling, general and administrative expense for the six months ended March 31, 2024 is primarily attributable to a decrease in professional service costs, most notably legal costs related to financing activities.

Research and Development Expense

Research and development expense during the six months ended March 31, 2024 was \$409,449, an increase of \$77,362, compared to \$332,087 for the six months ended March 31, 2023. The increase in research and development expense is primarily attributable to an increase in payroll costs.

Other (Expense) Income

Other expense during the six months ended March 31, 2024 was \$1,779,380, an increase of \$1,778,074, compared to other expense of \$1,306 for the six months ended March 31, 2023. The increase in other expense is primarily attributed to an increase in interest expense related to the amortization of debt discount and debt issuance costs for 2022 Notes, Second Notes, Third, and Fourth Notes as well as increase in related interest expense. Additionally, the increase in other expense is primarily attributable to the gain on extinguishment of derivative liabilities that was recognized during the six months ended March 31, 2023 of approximately \$1,200,000 income and did not occur during the six months ended March 31, 2024.

Year Ended September 30, 2023 Compared to Year Ended September 30, 2022

	September 30, 2023 (\$)	September 30, 2022 (\$)	Increase (Decrease) (\$)
Revenue	75,724	15,652	60,072
Operating Expenses			
Cost of revenues	78,163	51,489	26,674
Selling, general and administrative	4,371,164	4,519,636	148,472
Research and development	670,880	1,153,333	(482,453)
Loss from Operations	(5,044,483)	(5,708,806)	(664,323)
Other (expense) income	(1,938,353)	432,952	(2,371,305)
Net loss	(6,982,836)	(5,275,854)	(1,706,982)

Revenue

Revenue for the year ended September 30, 2023 was \$75,724, an increase of \$60,072 compared to \$15,652 for the year ended September 30, 2022. Revenue for the year ended September 30, 2023 was the result of multiple transactions into a single hospital as well as transactions into multiple Veterans Administration Hospitals (*the "VA"*) consisting of twenty (20) total units through our distribution partner, Lovell Government Services (*"LGS"*). 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.

Cost of revenues

Cost of revenues during the year ended September 30, 2023 was \$78,163, an increase of \$26,674 compared to \$51,489 for the year ended September 30, 2022. 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, 2023 was \$4,371,164 a decrease of \$148,472 compared to \$4,519,636 for the year ended September 30, 2022. The decrease in selling, general and administrative expense for the year ended September 30, 2023 is primarily attributable to an increase in legal and consulting costs, which were more than offset by a decrease in compensation costs and patent costs.

Research and Development Expense

Research and development expense during the year ended September 30, 2023 was \$670,880 a decrease of \$482,453 compared to \$1,153,333 for the year ended September 30, 2022. The decrease in research and development expense is primarily attributable to a decrease in compensation costs and consulting costs.

Other (Expense) Income

Other expense during the year ended September 30, 2023 was \$1,938,353, an increase of \$2,371,305 compared to total other income of \$432,952 for the year ended September 30, 2022. The increase in other (expense) income is attributable to interest expense partially offset by gain for the extinguishment of derivative liabilities.

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.

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Working Capital

At March 31, 2024, we had total current assets of \$1,533,177 (including cash of \$26,426) and a working capital deficit of \$10,844,374. Our working capital as of March 31, 2024 and September 30, 2023 are summarized as follows:

	March 31, 2024	September 30, 2023
Total Current Assets	\$ 1,533,177	\$ 1,950,090
Total Current Liabilities	12,417,551	9,465,921
Working Capital Deficit	\$ (10,884,374)	\$ (7,515,831)

Total current assets as of March 31, 2024 were \$1,533,177, a decrease of \$416,913, compared to \$1,950,090, as of September 30, 2023. The decrease in current assets is primarily attributable to a decrease in cash and prepaid expenses. Our total current assets as of March 31, 2024 and September 30, 2023 were comprised primarily of cash, inventory and prepaid expenses and other current assets.

Total current liabilities as of March 31, 2024 were \$12,417,551, an increase of \$2,951,630, compared to \$9,465,921 as of September 30, 2023. The increase is primarily due to an increase in shareholder advances and accounts payable, new notes issued during the period, and amortization of the debt discount and debt issuance costs for the notes partially offset by a decrease to the amount owed in connection with the financing of certain insurance premiums and the conversion of the Series 2 and certain Senior Secured convertible note into shares.

Cash Flow for the Six Months Ended March 31, 2024 Compared to the Six Months Ended March 31, 2023

	<u>March 31, 2024</u>	<u>March 31, 2023</u>
Cash Used in Operating Activities	\$ (1,562,764)	\$ (1,249,931)
Cash Provided by Financing Activities	1,366,470	532,486
Net decrease in Cash	\$ (196,294)	\$ (717,445)

Cash Used in Operating Activities

Cash used in operating activities increased by \$312,833 to \$1,562,764 during the six months ended March 31, 2024, compared to \$1,249,931 during the six months ended March 31, 2023. The increase in cash used in operating activities is primarily attributable to an increase in net loss partially offset by an increase in non-cash accretion of debt discounts and issuance costs on convertible notes payable.

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Cash Provided by Financing Activities

Cash provided by financing activities increased by \$833,984 to \$1,366,470 during the six months ended March 31, 2024, compared to \$532,486 cash used in financing activities during the six months ended March 31, 2023. For the six months ended March 31, 2024, the increase in cash provided by financing activities was attributable to an increase in Shareholder and third-party advances related to bridge financing.

Cash Flow for the Year Ended September 30, 2023 Compared to the Year Ended September 30, 2022

	<u>September 30, 2023</u>	<u>September 30, 2022</u>
Cash Used in Operating Activities	\$ (3,374,216)	\$ (4,456,075)
Cash Used in Investing Activities	(4,521)	-
Cash Provided by Financing Activities	2,854,517	2,936,376
Net decrease in cash	\$ (524,220)	\$ (1,519,699)

Cash Used in Operating Activities

Cash used in operating activities decreased \$1,081,859 to \$3,374,216 during the fiscal year ended September 30, 2023 compared to \$4,456,075 for the fiscal year ended September 30, 2022. The decrease in cash used in operating activities is primarily attributable to the accretion of the debt discount, partially offset by a reduction in inventory.

Cash Used in Investing Activities

Cash used in investing activities increased \$4,521 to \$4,521 during the fiscal year ended September 30, 2023, compared to \$0 during the fiscal year ended September 30, 2022. For the fiscal year ended September 30, 2023, cash used in investing activities increased due to the purchase of computer hardware.

Cash Provided by Financing Activities

Cash provided by financing activities decreased \$81,859, to \$2,854,517 for the fiscal year ended September 30, 2023, compared to \$2,936,376 for the fiscal year ended September 30, 2022. For the year ended September 30, 2023, the cash provided by financing activities increased as a result from net proceeds of \$2,209,839 raised from bridge equity financing and proceeds of \$995,000 received from the issuance of unsecured convertible notes partially offset by repayment of financed insurance premium of \$350,332. For the year ended September 30, 2022, the cash provided by financing activities resulted from net proceeds of \$2,936,376 raised from the issuance of senior secured convertible notes, warrants and inducement shares partially offset by repayment of financed insurance premium.

Cash Requirements

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

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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 2022 SPA (see Note 8) and 2023 SPA (see Notes 2 and 12) 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. 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.

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. The continuation

of our business as a going concern is dependent upon raising additional capital and eventually attaining and maintaining profitable operations. As of March 31, 2024, there is substantial doubt about the Company's ability to continue as a going concern. The financial statements included in this registration statement do not include any adjustments that might be necessary should operations discontinue.

Critical Accounting Policies and Significant Judgments and Estimates

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

Derivative Liabilities

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

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Inventories

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

Complex Financial Instruments

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

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

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

Recent Accounting Guidance

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

Off-Balance Sheet Arrangements

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

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OUR BUSINESS

Corporate Overview

Arch Therapeutics, Inc. (together with its subsidiary, the "Company" or "Arch") is a biotechnology company developing and marketing products based on our innovative AC5® self-assembling technology platform. Arch arose from the June 26, 2013 merger (the "Merger") of three entities previously known as Arch Biosurgery, Inc., Almah, Inc., and Arch Acquisition Corporation, respectively.

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

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

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

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

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

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

Our Company

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

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Core Technology

Our flagship product 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 (US) and the European Union (EU), respectively, and which are intended for skin applications, such as management of complicated chronic wounds and acute surgical wounds. Marketing for AC5 Topical Hemostat in the EU has not initiated. Other products are in development for use in minimally invasive or open surgical procedures and include, for example, AC5-G™ for gastrointestinal endoscopic procedures and AC5-V® and AC5 Surgical Hemostat for hemostasis inside the body, all of which are currently investigational devices limited by law to investigational use.

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

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

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

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

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Sales and marketing efforts for our AC5 Advanced Wound System, which has received 510(k) marketing clearance from the United States Food and Drug Administration (“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 US 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.

Operations

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

Our long-term business plan includes the following goals:

- growing revenues and building upon recent commercial momentum by driving product awareness, continued adoption and favorable payment policies for AC5 Advanced Wound System with the now-effective CMS Level II HCPCS code dedicated to AC5;
- conducting biocompatibility, pre-clinical, and clinical studies on our products and product candidates;

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- 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 third party 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.

To support our long-term business goals, we expect to focus on the following activities during the next twelve months:

- further develop our product clinical profile;
- enhance product packaging features;
- identify and address opportunities for supply chain efficiencies;
- assess our technology platform in order to identify and select product candidates for potential advancement into development;
- seek additional funding as required to support the previously described milestones necessary to support our operations;
- 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, maintaining granted patents in desired jurisdictions, and/or adding to our trade secrets in self-assembly, manufacturing, analytical methods and formulation, as appropriate.

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 future capital. We will require significant additional financing to fund our planned operations, including, but not limited to, further research and development relating to AC5; seeking regulatory approval for any product we may choose to develop, launch or license; commercializing any product for which we are able to obtain regulatory approval or certification; seeking to license or acquire new assets or business; supporting our intellectual property rights; pursuing new technologies; and financing the investor relations and incremental administrative costs associated with being a public corporation. We do not presently have, nor do we expect in the near future to have, sufficient revenue to fund our business from operations, and we will need to obtain substantially all of our necessary funding from external sources for the foreseeable future. We may not be able to obtain additional financing on commercially reasonable or acceptable terms when needed, or at all. If we cannot raise the money that we need in order to continue to develop our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations. If any of these were to occur, there is a substantial risk that our business would fail, and our stockholders could lose all of their investments.

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The estimated capital requirements could potentially 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*”. 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, we do not believe that our current cash on hand as of June 19, 2024 is sufficient to meet our anticipated cash requirements through the end of June 2024, and we must obtain additional financing in order to continue to operate our business. Even if this offering is successful, we could spend our financial resources much faster than we expect, in which case we would need to raise additional capital.

Research and Development

Preclinical and clinical testing is required in order to receive regulatory marketing authorizations for our products and to support those products upon and after commercialization, and we anticipate continuing such testing as 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 and related activities, typically with assistance from our team. These third parties can include contract research organizations, academic institutions, consultants, advisors, scientists, clinicians, and 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 complete a biocompatibility assessment using a battery of standard in vitro and in vivo tests. Examples of such tests may include the following, as set forth in ISO 10993 issued by the International Organization for Standardization:

- in vitro cytotoxicity;
- in vitro blood compatibility;
- irritation/intracutaneous reactivity;

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- sensitization (allergic reaction);
- implantation (performed on devices that contact the body's interior);
- pyrogenicity (causing fever or inflammation); and
- systemic toxicity.

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 plan to 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 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 both 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' AC5 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.

The AC5 technology has also 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.

The AC5 technology 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.

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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/or 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 other collaborators.

In order to enroll patients in a clinical trial, we are required to obtain each patient's informed consent in a form and substance that complies with the FDA and/or other regulatory authority requirements as well as state and federal privacy and human subject protection regulations.

We have completed two randomized controlled clinical studies to date. The first study, which met its primary and secondary endpoints, assessed the safety and performance of AC5 in 46 patients with bleeding skin wounds, including a group of patients taking anti-platelet medications (i.e., a blood thinner) that resulted from excision of skin lesions and followed for 30 days. The second study assessed AC5 on skin, determining that it was neither an irritant nor a sensitizer, and no immunogenic response or other adverse events attributable to this product were reported in any of the approximately 50 enrolled volunteers. The AC5 product candidate in these studies subsequently received marketing authorization and is presently known as AC5 Advanced Wound System in the US and AC5 Topical Hemostat in the EU.

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

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 US.

Regulatory

We have engaged and continue to engage third parties in the US 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.

The research, development and clinical programs, as well as manufacturing and marketing operations that may be performed by us or third-parties on our behalf, are subject to extensive regulation in the US and other countries. Notably, for example, AC5 Advanced Wound System is subject to regulation as a medical device under the US Food Drug and Cosmetic Act (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, or others on our behalf, do or will perform, 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 manufacturing;
- 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 US and AC5 Topical Hemostat in EU 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. AC5 self-assembly, which is the desired effect, is consistent with the medical device definition.

Medical devices in the US and EU 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 those that have a new intended use or that use advanced technology not substantially equivalent to that of a legally marketed device.

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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 devices in these jurisdictions, depending upon the intended use. Specifically, AC5 Advanced Wound System is a Class II medical device in the US, and AC5 Topical Hemostat is a Class IIb medical device in EU.

In the US, 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; and
- 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 or European Union Medical Device Regulation 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 (defined below under the section entitled “*European Union Marketing Authorization (CE Mark) Process*”);
- 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.

US Class III and certain Class II medical device approvals and EU Class III and certain Class IIa and IIb medical device approvals may require the successful completion of human clinical trials.

US 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 (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 US. The FDA ultimately determines the appropriate regulatory path. For purposes herein, references to regulatory approval and marketing authorization may be used interchangeably.

AC5 Advanced Wound System, which is intended for external use, received marketing authorization through the 510(k) process. To obtain 510(k) 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 US. 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. 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.

We believe that our product candidates for internal use will require a PMA approval prior to commercialization. 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 IRB for the relevant clinical trial sites and comply with applicable FDA regulations, including those relating to good clinical practices (GCP).

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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 appropriate 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 EU member state as being competent to make independent judgments about whether a medical device complies with applicable regulatory requirements in the EU (a “Notified Body” or “Notified Bodies”). 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 *Conformité Européenne* mark (CE 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 or newer European Medical Device Regulations, a CE mark symbol that is placed on a product 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.

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While there are many similarities between the processes required to obtain marketing authorization in the US and EU, 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 510(k) or a 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 EU regulatory bodies implemented a Medical Device Regulation, which revises several aspects of the existing regulatory framework, such as clinical data requirements, and introduces new ones, such as Unique Device Identification. We, and the Notified Bodies who will oversee compliance to the new Medical Device Regulation, face uncertainties in the upcoming years as it is rolled out and enforced, creating risks in several areas, including the CE mark process, data transparency and application review timetables. The Medical Device Regulation became effective on May 26, 2021, although the European Commission has allowed an implementation period to facilitate transition from the Medical Device Directives. This transition period extends until the end of 2027 for high-risk devices and until the end of 2028 for medium and low risk devices.

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 US and EU member states and include:

- product listing and establishment registration;
- compliance by us and/or third-parties upon whom we depend with stringent design, testing, control, documentation and other quality assurance processes and procedures related to product design, manufacturing and commercialization;
- 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, revocation of certificates, criminal prosecution or other sanctions.

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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 (510)k 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 had been reviewed and cleared by the FDA, allowing for the product to be marketed. In line with plans to better harmonize our US and EU 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 US 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 had been reviewed and cleared by the FDA, allowing for the product to be marketed in the US with the aforementioned additions. AC5 Topical Gel was subsequently renamed AC5 Advanced Wound System in the US.

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

During November 2018, we submitted the required documents for AC5 Topical Hemostat to the Notified Body seeking a CE mark.

During April 2020, we received the CE 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 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.

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.

For at least the near term future, in order to maximize operational efficiencies and to account for changing landscapes since the COVID-19 pandemic during which both marketing authorizations were received, 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.

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We expect the commercialization ramp to be gradual through 2024 and into 2025, while we encourage product use among key opinion leaders and early adopters in developing market channels, and then moderately accelerate.

We recently started to commercialize AC5 Advanced Wound System. We rely on both an internal commercial team and independent sales distributors to drive 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 (VA) hospitals and military 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.

We anticipate that material growth in the physician office setting will require product reimbursement. To that end, we applied to the Centers for Medicare and Medicaid Services (CMS) for a dedicated Healthcare Common Procedure Coding System (HCPCS) Level II reimbursement code specific to AC5 Advanced Wound System to better enable providers to bill third party payors for AC5 that is used in doctors' offices. The unique HCPCS code, A2020, was granted and made effective on April 1, 2023. A dedicated HCPCS code is an important step toward, although not a guarantee of, coverage and reimbursement, and we intend it to 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.

In support of the government market, we partnered with Lovell Government Services (LGS), a service-disabled veteran-owned small business, to be our government channel distributor. As a direct result of our relationship with LGS, AC5 Advanced Wound System has been added to the four major government contracting vehicles: Federal Supply Schedule (FSS), General Services Administration (GSA) schedule, Defense Logistics Agency's Medical Electronic Catalog Program (ECAT), and Distribution and Pricing Agreement (DAPA). This listing enables purchase by federal government agencies, including the Department of Veterans Affairs (VA), Indian Health Services (IHS), and Department of Defense (DOD) Medical Treatment Facilities, and it allows doctors in government channels to order AC5 Advanced Wound System.

Our internal core team oversees AC5 Advanced Wound System sales, marketing, and inventory distribution from the warehouse to the customer. We envision hiring additional internal sales representatives to support commercialization.

We have partnerships with reputable, value-added independent sales representatives and distributors, and we expect to add more collaborative agreements on a case-by-case basis to expand the overall reach and footprint of the sales organization. Such collaborations may include strategic partners. We anticipate that we will also 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 both 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.

The COVID-19 Pandemic Impact on Commercialization

The COVID-19 pandemic environment introduced significant challenges related to product launch, marketing and sales. While the overall environment has improved, negative direct and indirect effects may variously wax and wane. Some effects that we periodically observe include curtailed access to non-US surgeons, facilities, and potential strategic partners, as well as to some US medical facilities.

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The pandemic brought additional attention to the tendency for interventions for wounds to be too often considered elective procedures instead of essential or emergent, as National Pressure Ulcer Advisory Panel guidelines and others recommend, resulting in a projected increased risk to limb and life. 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 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 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.

We believe that these challenges may present an opportunity for new technology, such as ours, to address poorly met needs and limited healthcare overall resources.

Manufacturing

We work with contract manufacturing and related organizations, including those operating under cGMP, as is required by applicable regulatory agencies for production of products 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. 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 research, development, and 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 products.

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.

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The manufacturing methods that we use to produce our current products 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. Our current products are synthesized from naturally occurring [ingredients amino acids] that, while not sourced from humans or other animals, 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. 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 AC5 self-assembling peptide technology and Arch’s 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 many 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 (www.ncbi.nlm.nih.gov/books/NBK442035), 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 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 (https://www.facs.org/media/buthal55/nonhealing_wounds.pdf; www.doi.org/10.1111/wrr.12994; www.doi.org/10.1186/s13643-016-0400-8; www.doi.org/10.19080/ARR.2020.06.555678).

Diabetic foot ulcers develop in approximately 2 million Americans each year, according to The Health Innovation Program, University of Wisconsin (<https://hip.wisc.edu/DiabeticFootUlcers>), while the annual incidence across developed countries is estimated to be 2-4%, according to Woods et al in 2020 (www.doi.org/10.1371/journal.pone.0232395). Pressure ulcers develop in over 2.5 million Americans each year, according to the United States Agency for Healthcare Research & Quality (www.ahrq.gov/topics/pressure-ulcers.html).

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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 (www.doi.org/10.3111/13696998.2014.903258), while Qiu et al in 2021 provided an estimated prevalence of 2-4% (www.doi.org/10.3389/fmed.2021.614059). 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 (www.doi.org/10.1186/s13643-016-0400-8). Woods et al in 2020 stated that only 2/3 of diabetic foot ulcers heal within 12 months (www.doi.org/10.1371/journal.pone.0232395). 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 (www.doi.org/10.1186/s13643-016-0400-8).

The Health Innovation Program, University of Washington, cited that of patients with diabetic foot ulcers in the United States, more than 50% will die within five years and 5% will have an amputation (<https://hip.wisc.edu/DiabeticFootUlcers>). A common phrase in medicine, which we often cite, is, “Save a limb, save a life.” Even the amputations that are required to save a patient from a non-healing, progressing chronic wound are associated with additional significant morbidity and mortality. In an examination of mortality rates after amputations from a chronic wound, Meshkin et al performed a systematic literature review and found that of the sixty-one studies yielding approximately 36,000 patients who previously received a nontraumatic major lower extremity amputation, approximately 34% died by year one, 55% died by year two, and 64% died by year five (<http://www.doi.org/10.1053/j.jfas.2020.06.027>). Stern et al in 2017 reported an even higher mortality rate one year after amputation of approximately 48% (www.doi.org/10.1016/j.avsg.2016.12.015).

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 (<https://www.doi.org/10.1016/j.jval.2017.07.007>). 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 (<https://www.doi.org/10.12968/jowc.2017.26.sup4.s4>). 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 (www.doi.org/10.1371/journal.pone.0232395). 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 (<https://www.doi.org/10.1007/s12325-017-0478-y>).

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 (<https://www.researchgate.net/publication/340950761>). 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, less 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, will complement other products and procedures by potentially enabling the wound bed to be ready sooner, and will 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 wounds;
- conforms to irregularly shaped wound geometry;
- may be used in either lower acuity (e.g., doctor's offices) 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 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 (NOTES), and other procedures.

While developing our products, we engaged commercial strategy and marketing consultants and communicated directly with care providers to understand the needs of potential customers and to assess product feature preferences. Surgeons, operating room managers, sales representatives and hospital decision-makers identified several characteristics deemed desirable, including that a product is:

- reliable;

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

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

- a persistent drive to migrate the site of surgical care from inpatient hospital operating room to progressively lower acuity same-day ambulatory settings due to cost and other potential negative impacts of unnecessary hospitalizations, such as infection risk or occupying scarce resources that may be more usefully deployed elsewhere;
- increased use of anticoagulants and other anti-thrombotic agents (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 in performing more types of procedures in less expensive outpatient settings.

Since the early days of modern MIS in the 1990s, the percent of minimally invasive surgeries 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.

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In a trend to make traditional minimally invasive surgery even less invasive, known as NOTES, a procedure is performed through an endoscope that 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 have 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 and 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.

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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.

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.
- Reimbursement for some competing products and product categories may be more established, and reimbursement for advanced wound care products, in general, is being re-evaluated by payers, raising potential barriers to use.

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 US and foreign government agencies have broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of

which could have a material adverse effect on our business. Additionally, if we are able to successfully obtain approvals for, and commercialize our product candidates, then the Company and our products may become subject to various federal, state and local laws targeting fraud, abuse, privacy and security in the healthcare industry.

Intellectual Property

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

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As of March 31, 2024, we either own or license from others a number of US patents, US patent applications, foreign patents and foreign patent applications.

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

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

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

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

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

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

Employees

We presently have eight full-time employees, and we 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.

On December 5, 2023, Daniel Yrigoyen resigned, effective as of such date, from his position as an executive officer and as Vice President of Sales of the Company. Effective December 5, 2023 Shawn Carlson was appointed to serve as the Company's Vice President of Sales.

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Auditor Appointment

On January 9, 2024, the Audit Committee of the Board of Directors of the Company (the "Audit Committee") dismissed Baker Tilly US, LLP ("Baker Tilly") as the Company's independent registered public accounting firm, effectively immediately. Also on January 9, 2024, the Audit Committee approved the appointment of Weinberg & Company, P.A. ("Weinberg") as the Company's new independent registered public accounting firm, effective immediately. Additional information related to all such matters can be found in the Form 8-K filed by the Company with SEC on January 12, 2024.

Properties

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

Legal Proceedings

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

Dr. Avtar Dhillon served as our Chairman of the Board from April 2013 through July 2018, and as an advisor to us from July 2018 until his termination on August 6, 2021. Dr. Avtar Dhillon was not a director, officer, or control person at the time of his termination. 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 was scheduled for May 23, 2024. At the same time, the SEC charged Dr. Avtar Dhillon with violations of the antifraud and certain other provisions of federal securities laws in connection with the sales of securities of certain public companies, including his sale of shares of the Company. On October 20, 2022, the United States District Court for the Central District of California entered a final judgment as to Dr. Avtar Dhillon, in favor of the SEC, pursuant to which he is (1) prohibited from acting as an officer or director of any issuer that has a class of securities registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or that

is required to file reports pursuant to Section 15(d) of the Exchange Act and (2) permanently restrained and enjoined from violating, directly or indirectly, (i) Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, (ii) Section 17(a) of the Securities Act, and (iii) Section 17(b) of the Securities Act. The Company has fully cooperated with the DOJ and the SEC and has not been implicated in or charged with any wrongdoing.

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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
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 a 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.

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.

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

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

Board of Director Composition

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

Term of Office of Directors

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

Involvement in Certain Legal Proceedings

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

Director Independence

Our Board of Directors has determined that Mr. Punit Dhillon, Mr. Laurence Hicks and Dr. Guy Fish would qualify as “independent” as that term is defined by Cboe Listing Rule 14.10(c)(1)(B). 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 Cboe Listing Rules applicable to all such board committees. Dr. Terrence W. Norchi would not qualify as

“independent” under Cboe 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, Cboe Listing Rule 14.10(c)(1)(B) 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 Cboe Listing Rule 14.10(c)(1)(B) and subject to certain exceptions, a director will not be deemed to be independent if (a) the director is, or at any time during the past three years was, an employee of ours; (b) the director or a member of the director’s immediate family or a person living with such director (collectively, a “**Related Party**”) has received more than \$120,000 in compensation from us during any twelve-month period within the preceding three years, other than compensation for service as a director or as a non-executive employee (in the case of Related Party), benefits under a tax-qualified retirement plan or non-discretionary compensation; (c) a Related Party is, or in the past three years has been, an executive officer of ours; (d) the director or a Related Party is an executive officer, partner or controlling shareholder of a company that makes payments to, or receives payments from, us in an amount which, in any twelve-month period during our past three fiscal years, exceeds the greater of 5% of the recipient’s consolidated gross revenues for that year or \$200,000 (except for payments arising solely from investments in our securities or payments under non-discretionary charitable contribution matching programs); (e) the director or a Related Party is employed as an executive officer of another company where at any time during the preceding three years one of our executive officers served on the compensation committee of such company; and (f) the director or a Related Party is a current partner of our independent public accounting firm, or has worked for such firm in any capacity on our audit at any time during the past three years.

Committees of the Board of Directors

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

Audit Committee

On August 15, 2022, our Board of Directors established a separate standing audit committee within the meaning of Section 3(a)(58)(A) of the Exchange Act. The Audit Committee consists of Mr. Punit Dhillon, serving as the Chairman of the Audit Committee, Mr. Laurence Hicks, and Dr. Guy Fish. Our Board has determined that the three directors currently serving on our Audit Committee are independent within the meaning of the Cboe Listing 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 SEC rules.

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

Compensation Committee

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

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

Nominating and Corporate Governance Committee

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

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EXECUTIVE COMPENSATION

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

Summary Compensation Table

Name	Fiscal Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards \$(1)	All other Compensation (\$)	Total (\$)
Dr. Terrence W. Norchi, <i>President and Chief Executive Officer</i>	2023	450,500	-	-	40,500	-	491,000
	2022	450,500	-	-	-	-	450,500
Michael S. Abrams <i>Chief Financial Officer</i>	2023	325,000	-	-	29,160	-	354,160
	2022	325,000	-	-	-	-	325,000
Daniel Yrigoyen(2) <i>VP of Sales</i>	2023	325,000	-	-	16,200	-	341,200
	2022	316,667	-	-	9,075	-	325,742

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

(2) On December 5, 2023, Daniel Yrigoyen resigned, effective as of such date, from his position as an executive officer and as Vice President of Sales.

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.

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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.

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Daniel M. Yrigoyen

On July 12, 2021, we entered into an executive employment agreement with Mr. Yrigoyen, our former 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.

On December 5, 2023, Daniel Yrigoyen resigned, effective as of such date, from his position as an executive officer and as Vice President of Sales of the Company.

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Outstanding Equity Awards At Fiscal Year-End

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

Name	Option Awards				Stock Awards	
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)
Dr. Terrence W. Norchi	312	(-1)	560.00	03/23/2024		0
	250	(-2)	304.00	01/21/2025		
	221	(-3)	448.00	08/17/2025		
	781	(-4)	624.00	05/02/2026		
	406	(-5)	1,040.00	02/02/2027		
	225	(-6)	680.00	07/18/2028		
	625	(-7)	366.72	12/19/2029		
	625	(-8)	164.48	09/26/2031		

	417	208(9)	164.48	09/26/2031		
	217	564(10)	64.16	11/9/2032		
Michael S. Abrams	260	52(11)	212.64	05/02/2031		
	145	72(12)	164.48	09/26/2031		
	156	406(13)	64.16	11/9/2032		
Daniel M. Yrigoyen	67	26(14)	144.00	06/29/2031		
	83	41(15)	164.48	09/26/2031	93(16)	19,500
	41	52(17)	96.8	05/23/2032		
	86	225(18)	64.16	11/9/2032		

- (1) Represents an option to purchase 312 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 250 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 221 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.

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- (4) Represents an option to purchase 781 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 406 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 225 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 625 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 625 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 625 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 781 shares of Common Stock with a grant date of November 10, 2022. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.
- (11) Represents an option to purchase 312 shares of Common Stock with a grant date of May 3, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with 30% of the shares vested immediately on the date of grant and the remaining shares to vest in 24 equal installments commencing on the first anniversary on the date of grant.
- (12) Represents an option to purchase 218 shares of Common Stock with a grant date of September 27, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.
- (13) Represents an option to purchase 562 shares of Common Stock with a grant date of November 10, 2022. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.
- (14) Represents an option to purchase 93 shares of Common Stock with a grant date of July 30, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant and the remaining shares to vest in 24 equal installments commencing on the first anniversary on the date of grant.
- (15) Represents an option to purchase 125 shares of Common Stock with a grant date of September 27, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.
- (16) Represents an option to purchase 93 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.

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- (17) Represents an option to purchase 93 shares of Common Stock with a grant date of May 24, 2022. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.
- (18) Represents an option to purchase 312 shares of Common Stock with a grant date of November 10, 2022. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.

Compensation of Directors

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

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

Director Compensation Table

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

- (1) Mr. Dhillon was appointed as a member of the Board on July 19, 2018. The aggregate number of shares of Common Stock underlying option awards outstanding as of September 30, 2023 held by Mr. Dhillon was 781.
- (2) Mr. Hicks was appointed as a member of the Board on September 27, 2021. The aggregate number of shares of Common Stock underlying option awards outstanding as of September 30, 2023 held by Mr. Hicks was 312.
- (3) Dr. Fish was appointed as a member of the Board on December 31, 2021. The aggregate number of shares of Common Stock underlying option awards outstanding as of September 30, 2023 held by Dr. Fish was 312.

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CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Related Party Transactions

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

On June 22, 2020, the Company entered into a Series J Warrant Issuance Agreement (the "**Keyes Sulat Agreement**") with the Keyes Sulat Revocable Trust (the "**Trust**"), also a holder of outstanding Series D Warrants, resulting in approximately \$82,000 of proceeds as a result of the full exercise of the Trust's Series D Warrants. Under the terms of the Keyes Sulat Agreement, in exchange for fully exercising the Trust's remaining Series D Warrants for 284 shares of Common Stock on June 22, 2020, the Trust was issued Series J Warrants to purchase 213 shares of Common Stock at an exercise price of \$400.00 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 October 25, 2023, no Series J Warrants remain outstanding.

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

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

Review, Approval or Ratification of Transactions with Related Persons

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

Subject to some exceptions, Cboe Listing Rule 14.10(c)(1)(B) 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 Cboe Listing Rule 14.10(c)(1)(B) 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.

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SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth certain information regarding the beneficial ownership of our Common Stock by (i) each person who, to our knowledge, beneficially owns more than 5% of our Common Stock; (ii) each of our directors and named executive officers; and (iii) all of our directors and executive officers as a group. Unless otherwise indicated in the footnotes to the following table, the address of each person named in the table is: c/o Arch Therapeutics, Inc., 235 Walnut St., Suite #6, Framingham, Massachusetts 01702. The information set forth in the table below is based on 555,562 shares of our Common Stock outstanding on June 19, 2024. Shares of our Common

Stock subject to options, warrants, or other rights currently exercisable or exercisable within 60 days of June 19, 2024 are deemed to be beneficially owned and outstanding for computing the share ownership and percentage of the person holding such options, warrants or other rights, but are not deemed outstanding for computing the percentage of any other person.

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

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned (1)
<i>5%+ Stockholders:</i>		
Bigger Capital Fund, LP & District 2 Capital Fund LP (2)	37,500	6.75%
Walleye Opportunities Master Fund Ltd (3)	37,500	6.75%
Cavalry Fund I LP (4)	37,500	6.75%
Brandt & Mona Wilson (5)	37,500	6.75%
Ana and Michael Parker (6)	37,500	6.75%
Andrew Stahl (7)	37,500	6.75%
Sixth Borough Capital Fund, LP (8)	37,500	6.75%
<i>Named Executive Officers and Directors:</i>		
Terrence Norchi (9)	19,826	3.50%
Punit Dhillon (10)	773	*
Laurence Hicks (11)	11,129	1.79%
Michael Abrams (12)	11,327	2.00%
Daniel Yrigoyen (13)	94	*
Guy Fish (14)	291	*
Named Officers and Directors as a Group	43,744	7.45%

* Less than 1%.

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

Shares of our Common Stock subject to options, warrants, or other rights currently exercisable or convertible or exercisable or convertible within 60 days of June 19, 2024, 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.

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- (2) Represents 37,500 shares of Common Stock owned by, and split evenly between, Bigger Capital Fund, LP and District 2 Capital Fund LP with a common control person. Excludes (a) 362,500 Conversion Shares; (b) 138,750 2024 Notes Conversion Shares; (c) 18,944 PIPE Advance Penalty Pre-Funded Warrants; (d) 56,250 Execution Backstop Pre-Funded Warrants; (e) 18,944 PIPE Advance Penalty Common Warrants; (f) 21,379 2022 Warrants; (g) 123,683 Bridge Pre-Funded Warrants with unsatisfied exercise restrictions; and (h) 319,082 Common Warrants with unsatisfied exercise restrictions held in the aggregate by Bigger Capital Fund, LP and District 2 Capital Fund LP, all of which are subject to conversion or exercise restrictions that prohibit conversion or exercise until such time as the holder would not beneficially own, after such conversion or exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of June 19, 2024, neither Bigger Capital Fund, LP, nor District 2 Capital Fund LP has waived such limitation.
- (3) Represents 37,500 shares of Common Stock owned by Walleye Opportunities Master Fund Ltd. Excludes (a) 122,035 Bridge Pre-Funded Warrants with unsatisfied exercise restrictions; and (b) 319,070 Common Warrants with unsatisfied exercise restrictions, all of which are subject to exercise restrictions that prohibit exercise until such time as the holder would not beneficially own, after such exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of June 19, 2024, Walleye Opportunities Master Fund Ltd has not waived such limitation.
- (4) Represents 37,500 shares of Common Stock owned by Cavalry Fund I LP. Excludes (a) 145,000 Conversion Shares; (b) 138,750 2024 Notes Conversion Shares; (c) 18,944 PIPE Advance Penalty Pre-Funded Warrants; (d) 56,250 Execution Backstop Pre-Funded Warrants; (e) 18,944 PIPE Advance Penalty Common Warrants; (f) 8,552 2022 Warrants; (g) 123,133 Bridge Pre-Funded Warrants with unsatisfied exercise restrictions; and (h) 319,078 Common Warrants with unsatisfied exercise restrictions, all of which are subject to conversion or exercise restrictions that prohibit conversion or exercise until such time as the holder would not beneficially own, after such conversion or exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of June 19, 2024, Cavalry Fund I LP has not waived such limitation.

- (5) Represents 37,500 shares of Common Stock owned individually by Brandt and Mona Wilson. Excludes (a) 138,750 2024 Notes Conversion Shares; (b) 18,944 PIPE Advance Penalty Pre-Funded Warrants; (c) 56,250 Execution Backstop Pre-Funded Warrants; (d) 18,944 PIPE Advance Penalty Common Warrants; (e) 122,035 Bridge Pre-Funded Warrants with unsatisfied exercise restrictions; and (f) 319,070 Common Warrants with unsatisfied exercise restrictions, all of which are subject to exercise restrictions that prohibit exercise until such time as the holder would not beneficially own, after such exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of June 19, 2024, neither Brandt Wilson nor Mona Wilson had waived such limitation.
- (6) Represents (i) 29,431 shares of Common Stock owned individually by Ana Parker, Michael A. Parker's spouse; (ii) 4,757 shares of Common Stock owned individually by Mr. Parker; (iii) 3,125 shares of Common Stock owned through Tungsten, of which Mr. Parker is the sole manager and (iv) 188 shares of restricted stock granted to Mr. Parker on September 27, 2021. Excludes (a) 10,308 Bridge Pre-Funded Warrants with unsatisfied exercise restrictions; (b) 68,686 Common Warrants with unsatisfied exercise restrictions; (c) 236,631 Conversion Shares; (d) 6,036 First Warrant Shares; (e) any of the 2,143 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 2,930 shares that may be acquired upon the exercise of Series K Warrants (which expire on August 11, 2026), since such warrants cannot be exercised until such time as the holder would not beneficially own, after such exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case such waiver will become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of June 19, 2024, neither Ms. Parker nor Mr. Parker have waived such limitation.

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- (7) Represents 37,500 shares of Common Stock owned individually by Andrew Stahl. Excludes (a) 138,750 2024 Notes Conversion Shares; (b) 18,944 PIPE Advance Penalty Pre-Funded Warrants; (c) 56,250 Execution Backstop Pre-Funded Warrants; (d) 18,944 PIPE Advance Penalty Common Warrants; (e) 122,035 Bridge Pre-Funded Warrants with unsatisfied exercise restrictions; and (f) 319,070 Common Warrants with unsatisfied exercise restrictions, all of which are subject to exercise restrictions that prohibit exercise until such time as the holder would not beneficially own, after such exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of June 19, 2024, Mr. Stahl had not waived such limitation.
- (8) Represents 37,500 shares of Common Stock owned by Sixth Borough Capital Fund, LP. Excludes (a) 7,984 Bridge Pre-Funded Warrants with unsatisfied exercise restrictions; and (b) 90,968 Common Warrants with unsatisfied exercise restrictions, all of which are subject to exercise restrictions that prohibit exercise until such time as the holder would not beneficially own, after such exercise, more than 4.99% or 9.99% (as the case may be) of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case any waiver would become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of June 19, 2024, Sixth Borough Capital Fund, LP has not waived such limitation.
- (9) Represents (a) 6,250 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) 887 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) 706 shares of restricted stock granted to Dr. Norchi on May 3, 2016; (d) 406 shares of restricted stock granted to Dr. Norchi on February 3, 2017; (e) 225 shares of restricted stock granted to Dr. Norchi on July 19, 2018; (f) 6,000 First Conversion Shares; (g) 302 First Warrants; (h) 45 First Inducement Shares; and (i) 4,146 shares subject to options exercisable within 60 days after June 19, 2024; and (j) 858 shares of common stock purchased. Excludes 1,716 Common Warrants with unsatisfied exercise restrictions. Dr. Norchi disclaims beneficial ownership of the securities held by Twelve Pins Partners, LLC except to the extent of his pecuniary interest therein
- (10) Represents 773 shares of Common Stock subject to options exercisable within 60 days after June 19, 2024.
- (11) Represents 304 shares of Common Stock subject to options exercisable within 60 days after June 19, 2024. Includes (i) 17 shares of Common Stock, (ii) 9,000 First Conversion Shares, (iii) 453 First Warrant Shares, (iv) 68 First Inducement Shares; and (v) 1,287 shares of common stock held by Drake Partners Equity LLC, in which Mr. Hicks has an ownership interest. Excludes 2,573 Common Warrants with unsatisfied exercise restrictions held by Drake Partners Equity LLC, in which Mr. Hicks has an ownership interest.
- (12) Represents (i) 492 First Conversion Shares; (ii) 453 First Warrant Shares; (iii) 68 First Inducement Shares; (iv) 1,287 shares of common stock purchased, and (v) 519 shares of Common Stock subject to options exercisable within 60 days after June 19, 2024. Excludes 2,573 Common Warrants with unsatisfied exercise restrictions.
- (13) Represents 94 shares of restricted stock granted to Mr. Yrigoyen on July 30, 2021.
- (14) Represents 291 shares of Common Stock subject to options exercisable within 60 days after June 19, 2024.

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LEGAL MATTERS

The validity of the Common Stock being offered hereby has been passed upon for us by McDonald Carano LLP, Reno, Nevada.

EXPERTS

Weinberg & Company, P.A., an independent registered public accounting firm, has audited our consolidated financial statements as of and for the year ended September 30, 2023, 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.

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, 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

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Arch Therapeutics, Inc.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Arch Therapeutics, Inc. and Subsidiary (the Company) as of September 30, 2023, the related consolidated statements of operations, changes in stockholders’ deficit, and cash flows for the year then ended, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of September 30, 2023, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, during the year ended September 30, 2023, the Company incurred a net loss and utilized cash flows in operations, and has had recurring losses since inception. These conditions raise substantial doubt about the Company’s ability to continue as a going concern. Management’s plans in regards to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audit. 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 audit 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 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 audit, 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 audit included performing procedures to assess the risks of material misstatement of the 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 financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides 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 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 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.

Convertible note transactions

As described in Note 7 to the financial statements, during the year ended September 30, 2023, the Company issued unsecured convertible promissory notes totaling \$1.3 million. In connection with the issuance of the convertible notes, the Company granted noteholders shares of the Company’s common stock, and warrants to acquire shares of the Company’s common stock. The Company allocated the proceeds received to the convertible notes, shares of common stock, and warrants based upon their relative fair value. The Company used a Black Scholes model to determine the fair value of the warrants issued.

We identified the accounting for the issuance of the convertible notes, shares of common stock, and warrants as a critical audit matter because of the significance of the account balances, and due to the complexity involved in assessing the classification and presentation of the convertible notes and warrants. The auditing for these transactions required a high degree of audit judgement including evaluating the reasonableness of the significant judgements made by management in determining the appropriate accounting.

The primary audit procedures we performed to address this critical audit matter included the following, among others:

- We read the convertible note and warrant agreements, and relevant documentation.
- We obtained the Company’s analysis of the accounting of the convertible note and warrants issued in accordance with relevant accounting standards.
- We evaluated the reasonableness of the Company’s methodology for allocation of proceeds including the Company’s consideration of relevant accounting standards.
- We developed independent estimates for the relative fair value of the warrants and shares of common stock issued based on the assumptions and data used by management.

We have served as the Company’s auditor since 2024.

/s/ Weinberg & Company, P.A.
Los Angeles, California
February 14, 2024

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Arch Therapeutics Inc. and Subsidiary

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Arch Therapeutics, Inc. and Subsidiary (the “Company”) as of September 30, 2022, the related consolidated statements of operations, changes in stockholders’ deficit, and cash flows for the year 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 the results of its operations and its cash flows for the year ended September 30, 2022, in conformity with accounting principles generally accepted in the United States of America.

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 audit. 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 audit 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 audit, 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ Baker Tilly US, LLP

We served as the Company’s auditor from 2013 to 2024.

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

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Arch Therapeutics, Inc. and Subsidiary Consolidated Balance Sheets As of September 30, 2023 and 2022

	September 30, 2023	September 30, 2022
ASSETS		
Current assets:		
Cash	\$ 222,720	\$ 746,940
Inventory	1,364,504	1,414,848
Prepaid expenses and other current assets	362,866	436,407
Total current assets	<u>1,950,090</u>	<u>2,598,195</u>
Long-term assets:		
Property and equipment, net	4,599	2,044
Other assets	3,500	3,500
Total long-term assets	<u>8,099</u>	<u>5,544</u>
Total assets	<u>\$ 1,958,189</u>	<u>\$ 2,603,739</u>
LIABILITIES AND STOCKHOLDERS’ DEFICIT		

Balance at September 30, 2022	—	\$ —	1,252,734	\$ 1,252	\$ 50,878,718	\$ (55,072,773)	\$ (4,192,803)
Net loss	—	—	—	—	—	(6,982,836)	(6,982,836)
Issuance of common stock and warrants for cash, net	—	—	3,344,321	3,345	2,206,495	—	2,209,840
Issuance of common stock upon conversion of convertible notes	—	—	59,912	60	718,858	—	718,918
Issuance of common stock and warrants with convertible notes	—	—	20,210	20	440,297	—	440,317
Exchange of warrants into common stock	—	—	12,019	12	49,265	—	49,277
Stock-based compensation expense	—	—	250	—	249,555	—	249,555
Balance at September 30, 2023	—	\$ —	4,689,446	\$ 4,689	\$ 54,543,188	\$ (62,055,609)	\$ (7,507,732)
<i>Fiscal Year Ended</i>	<u>Preferred Stock</u>		<u>Common Stock</u>		<u>Additional</u>	<u>Accumulated</u>	<u>Total</u>
<i>September 30, 2022</i>	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Paid-in</u>	<u>Deficit</u>	<u>Stockholders'</u>
					<u>Capital</u>		<u>Deficit</u>
Balance at September 30, 2021	—	\$ —	1,186,901	\$ 1,186	\$ 48,770,059	\$ (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	—	\$ —	1,252,734	\$ 1,252	\$ 50,878,718	\$ (55,072,773)	\$ (4,192,803)

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

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Arch Therapeutics, Inc. and Subsidiary
Consolidated Statements of Cash Flows
For the Years Ended September 30, 2023 and 2022

	Fiscal Year Ended September 30, 2023	Fiscal Year Ended September 30, 2022
Cash flows from operating activities:		
Net loss	\$ (6,982,836)	\$ (5,275,854)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	1,966	3,196
Stock-based compensation	249,555	499,583
Change in fair value of derivative liability	(1,158,197)	(1,000,000)
Inventory obsolescence charge	—	248,073
Amortization of debt discount	2,310,860	302,049
Changes in operating assets and liabilities:		
(Increase) decrease in:		
Inventory	50,344	(569,156)
Prepaid expenses and other current assets	421,091	225,124
Increase (decrease) in:		
Accounts payable	976,207	846,869
Accrued interest	659,690	265,000
Accrued expenses and other liabilities	97,104	(959)
Net cash used in operating activities	<u>(3,374,216)</u>	<u>(4,456,075)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(4,521)	—
Net cash used in investing activities	<u>(4,521)</u>	<u>—</u>
Cash flows from financing activities:		
Repayment of insurance premium financing	(350,322)	(106,257)
Proceeds received from senior secured convertible notes, net of financing costs	—	3,042,633
Proceeds from unsecured convertible notes	995,000	—
Proceeds from issued common stock and warrants, net of financing costs	2,209,839	—
Net cash provided by financing activities	<u>2,854,517</u>	<u>2,936,376</u>
Net (decrease) increase in cash	(524,220)	(1,519,699)
Cash, beginning of year	<u>746,940</u>	<u>2,266,639</u>

Cash, end of year	\$ 222,720	\$ 746,940
Non-cash financing activities:		
Financing of insurance premium	\$ 347,550	\$ 354,190
Issuance of restricted stock	\$ —	\$ 8,959
Fair value of 2022 Warrants issued	\$ —	\$ 1,470,133
Fair value of 2022 Inducement Shares issued	\$ —	\$ 314,523
Relative fair value of common stock and warrants issued with notes payable	\$ 1,159,247	\$ —
Fair value of commons stock issued for warrants	\$ 49,277	\$ —
Exchange of Series 2 Convertible Notes into Senior Secured Notes (See Note 6)	\$ —	\$ 699,781
Issuance of restricted stock in consideration for services performed	\$ —	\$ 30,840
Fair Value of 2022 Placement Agent Warrants (see Note 6)	\$ —	\$ 219,894
Unpaid issuance costs in accounts payable	\$ 110,576	\$ 73,048

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

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Arch Therapeutics, Inc. and Subsidiary
Notes to the Consolidated Financial Statements
For the Years Ended September 30, 2023 and 2022

1. DESCRIPTION OF BUSINESS

Arch Therapeutics, Inc. (together with its subsidiary, the “Company” or “Arch”) is a biotechnology company developing and marketing a products based on our innovative AC5® self-assembling technology platform. Arch is the result of the merger (the “Merger”) of three entities on June 26, 2013, previously known as Arch Biosurgery, Inc., Almah, Inc., and Arch Acquisition Corporation, respectively.

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

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

Arch Acquisition Corporation, or Merger Sub, was a wholly owned subsidiary of Almah, Inc., formed for the purpose of the Merger transaction, pursuant to which Merger Sub merged with and into ABS, and ABS thereafter became the wholly owned subsidiary of the Company. The ticker symbol under which its Common Stock trades changed from “AACH” to “ARTH”, accordingly.

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

We believe these that our products can be important advances in the field of stasis and barrier applications, which includes managing wounds created during surgery, trauma or interventional care, or from disease; stopping bleeding (hemostasis); and controlling leaking (sealant). We have recently devoted a substantial part of our operational effort to the market adoption and commercial sales of AC5 Advanced Wound System, our first product. Our goal is to make care faster and safer for patients by providing 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.

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Going Concern

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The Company has not yet generated sufficient revenues to fund operations and relies on issuance of debt and equity instruments to generate working capital. As reflected in the accompanying financial statements, for the year ended September 30, 2023, the Company recorded a net loss of \$6,982,836 and used cash in operations of \$3,374,216. These factors raise substantial doubt about the Company’s ability to continue as a going concern within one year of the date that the financial statements are issued. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

In evaluating the going concern position of the Company, management has considered potential funding providers and believes that financing to fund future operations could be provided by equity and/or debt financing. Even if the Company is able to obtain additional financing, it may contain undue restrictions on our operations, in the case of debt financing, or cause substantial dilution for our stockholders, in the case of equity financing.

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 1:200, effective January 17, 2023 (the “Reverse Share Split”). All information included in these consolidated financial statements has been adjusted, on a retrospective basis, to reflect the Reverse Share Split, unless otherwise stated. All outstanding securities entitling their holders to purchase shares of Common Stock or acquire shares of Common Stock, including stock options, restricted stock units, and warrants, were adjusted as a result of the Reverse Stock Split, as required by the terms of those securities.

In accordance with the “Segment Reporting” Topic of the Accounting Standards Codification, the Company’s chief operating decision maker (the Company’s President and Chief Executive Officer) determined that the Company has only one reporting unit.

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. Significant estimates include the assumptions used in the accrual for potential liabilities, the net realizable value of inventory, the valuation of debt and equity instruments, the fair value of derivative liabilities, valuation of equity instruments issued for services, and deferred tax valuation allowances. Actual results could differ from those estimates.

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[Revenue recognition](#)

In accordance with Financial Accounting Standard Board's ("FASB") Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers*, 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 upon shipment from the Company's third-party warehouse which is when control of the product is transferred to the customers. In circumstances where the transaction price is not able to be determined at the time of shipment, the Company does not recognize revenue or any receivable amount until such time that the final transaction price is established and shipped to customer.

[Cost of Revenues](#)

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

[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, 2023 and 2022.

[Inventories](#)

Inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out ("FIFO") basis. 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 Company records adjustments to its inventory for estimated obsolescence or diminution in net realizable value equal to the difference between the cost of the inventory and the estimated net realizable value. When evidence exists that the net realizable value of inventory is lower than its cost, the difference is recognized as a loss in the period in which it occurs. Once inventory has been written down, it creates a new cost basis for inventory that may not subsequently be written up. For the year ended September 30, 2023 there was no write-downs of inventories. For the year ended September 30, 2022, the Company recorded write-down of inventories of \$248,073.

[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. For the years ended September 30, 2023 and 2022 there has not been any impairment of long-lived assets.

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[Leases](#)

The Company determines whether a contract is, or contains, a lease at inception. Operating lease right-of-use ("ROU") assets and liabilities are recognized at lease commencement based on the present value of unpaid 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.

The Company leases its office facility on a month to month basis with a monthly lease of approximately \$3,500. The terms of the lease provide break options allowing both landlord and tenant to terminate on provision of not less than one month's prior written notice.

[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.

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[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.

[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.

[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.

[Loss per Common Share](#)

Basic earnings (loss) per share is computed by dividing the net income (loss) applicable to common stockholders by the weighted average number of shares of common stock outstanding during the year, excluding shares of unvested restricted common stock. Shares of restricted stock are included in the basic weighted average number of common shares outstanding from the time they vest. Diluted earnings (loss) per share is computed by dividing the net income applicable to common stockholders by the weighted average number of common shares outstanding plus the number of additional common shares that would have been outstanding if all dilutive potential common shares had been issued, using the treasury stock method. Shares of restricted stock are included in the diluted weighted average number of common shares outstanding from the date they are granted. Potential common shares are excluded from the computation when their effect is antidilutive.

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For the years ended September 30, 2023 and 2022, the calculations of basic and diluted loss per share are the same because potential dilutive securities would have had an antidilutive effect. The potentially dilutive securities consisted of the following:

	<u>September 30, 2023</u>	<u>September 30, 2022</u>
Stock Options	102,125	98,626
Stock Warrants	26,284,002	806,452
Convertible notes payable	738,763	652,202
Unvested restricted common stock	-	250
Total	<u><u>27,124,890</u></u>	<u><u>1,557,530</u></u>

[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, 2023 and 2022, the carrying amounts of cash, accounts payables and accrued expense and other liabilities approximate fair value because of their short-term nature. The carrying amounts for the Company’s convertible notes (see Notes 6, 7, and 8) approximate fair value because borrowing rates and terms are similar to comparable

market participants.

Financial Statement Reclassification

Certain balances in the prior year consolidated financial statements have been reclassified for comparison purposes to conform to the presentation in the current period consolidated financial statements. During the year ended September 30, 2023, the Company reclassified the carrying amount of Exchange Notes of \$699,781 (see Notes 7 and 8) that were previously included in the Convertible Notes Payable, Senior Secured to Convertible notes payable, unsecured.

Recent Accounting Pronouncements

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt — Modifications and Extinguishments (Subtopic 470-50), Compensation — Stock Compensation (Topic 718), and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options ("ASU 2021-04"). ASU 2021-04 provides guidance as to how an issuer should account for a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option (i.e., a warrant) that remains classified after modification or exchange as an exchange of the original instrument for a new instrument. An issuer should measure the effect of a modification or exchange as the difference between the fair value of the modified or exchanged warrant and the fair value of that warrant immediately before modification or exchange and then apply a recognition model that comprises four categories of transactions and the corresponding accounting treatment for each category (equity issuance, debt origination, debt modification, and modifications unrelated to equity issuance and debt origination or modification). ASU 2021-04 is effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply the guidance provided in ASU 2021-04 prospectively to modifications or exchanges occurring on or after the effective date. The Company adopted ASU 2021-04 effective October 1, 2022. The adoption of ASU 2021-04 did not have any impact on the Company's consolidated financial statement presentation or disclosures.

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Other recent accounting pronouncements and guidance issued by the FASB, its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the Securities and Exchange Commission did not or are not believed by management to have a material impact on the Company's present or future financial statements.

3. INVENTORIES

Inventories consist of the following:

	September 30, 2023	September 30, 2022
Finished Goods	\$ 40,969	\$ 9,063
Goods-in-process	1,323,535	1,405,785
Total	\$ 1,364,504	\$ 1,414,848

4. INSURANCE PREMIUM FINANCING

During July 2023 and 2022, the Company entered into a financing agreement with First Insurance Funding to fund a portion of its insurance policies. As part of the agreement, First Insurance Funding agreed to finance the insurance policies of the Company of approximately \$395,000 and \$354,000, respectively and with an average interest rate per annum of 8.7% and 2.99%, respectively. The Company is required to make monthly payments of approximately \$35,000 through April 2024.

The outstanding balance as of September 30, 2023 and 2022 was \$243,285 and \$247,933, respectively.

5. DERIVATIVE LIABILITIES

In June 2018 and May 2019, the Company issued its Series F Warrants, Series G Warrants, and Series H Warrants. Pursuant to the terms of the respective warrant agreements, the Company was required to purchase its Series F Warrants, Series G Warrants and Series H Warrants for an amount of cash equal to \$36.00, \$22.00 and \$10.66, respectively, (the "Minimum Value"). As a result, the Company accounted for the Series F Warrants, Series G Warrants and the Series H Warrants in accordance with ASC 815-10 and were recorded as liabilities at the greater of the Minimum Value or fair value. These warrants were marked to fair value each reporting period using the Black Scholes Model and the corresponding change in the fair value of the warrants were reported in the Consolidated Statement of Operations.

As of September 30, 2021, the estimated fair value of the derivative liabilities was \$2,207,475. During the year ended September 30, 2022, certain Series F and Series H warrants expired unexercised. As a result, the Company recognized a gain of \$1,000,000 to account the expiration of the corresponding derivative liability. As of September 30, 2022, the estimated fair value of the derivative liabilities was \$1,207,475.

On March 10, 2023, the Company entered into exchange agreements with the holders of the Series G Warrants and the Series H Warrants. Pursuant to the exchange agreements, the warrant holders exchanged 34,013 Series G Warrants for 3,402 shares of Common Stock and 43,077 Series H Warrants for 8,617 shares of Common Stock. As a result, the Company recorded \$49,277 to account the fair value of the common stock issued and recorded a change in fair value of \$1,158,197 to account for extinguishment of the corresponding derivative liability. As of September 30, 2023, there are no instruments accounted as derivative liability.

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Fair Value Measurements Using Significant Unobservable Inputs - Year Ended September 30, 2023

(Level 3)

	Series G	Series H	Total
Beginning balance at September 30, 2022	\$ 748,275	\$ 459,200	\$ 1,207,475
Exchange of warrants into common stock	(13,947)	(35,330)	(49,277)
Extinguishment of derivative liabilities	(734,328)	(423,870)	(1,158,197)
Ending balance at September 30, 2023	\$ —	\$ —	\$ —

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
Expiration of derivative liability	(1,000,000)	—	—

Ending balance at September 30, 2022	\$ —	\$ 748,275	\$ 459,200
--------------------------------------	------	------------	------------

As of March 10, 2023 and September 30, 2022, the derivative liabilities were valued at the greater of their minimum value or by using the Black Scholes option pricing model with the following assumptions:

Date of valuation	Series G		Series H	
	March 10, 2023		September 30, 2022	
Closing price per share of Common Stock	\$ 4.10	\$ 4.10	\$ 3.84	\$ 3.84
Exercise price per share	\$ 140.00	\$ 80.00	\$ 140.00	\$ 80.00
Expected volatility	179.41%	141.03%	132.97%	122.50%
Risk-free interest rate	4.91%	4.75%	4.05%	4.14%
Dividend yield	—	—	—	—
Remaining expected term of underlying securities (years)	0.24	1.31	0.69	1.57

6. CONVERTIBLE NOTES PAYABLE, SENIOR SECURED

	September 30, 2023	September 30, 2022
Senior Secured Convertible Promissory Notes (the “2022 Notes”, includes \$96,000 of related party notes)	\$ 4,230,000	\$ 4,230,000
Unamortized debt discount	(710,897)	(2,567,508)
Net Balance	3,519,103	1,662,492
Current Balance	(3,519,103)	-
Non-Current Balance	-	1,662,492

In July 2022, the Company entered into a Securities Purchase Agreement (the “SPA”) with certain institutional and accredited individual investors and issued Senior Secured Convertible Promissory Notes (the “2022 Notes”) in the aggregate of \$4,230,000 in exchange for cash proceeds of \$3,525,000, net of original issue discount (OID) of \$705,000.

The 2022 Notes are secured by tangible and intangible assets of the Company, bears interest at a rate of 10% per annum payable at maturity or upon conversion, originally matured January 6, 2024 (which was subsequently extended to March 15, 2024), and are convertible into shares of the Company’s common stock at a conversion price of \$9.14 per share. The 2022 Notes contain customary events of default. Further, events of default under the 2022 Notes also include (i) the unavailability of Rule 144 on or after January 6, 2023; (ii) our failure to deliver the shares of common stock to the 2022 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 March 15, 2024 (the “Uplist Transaction”). During the year ended September 2023, for no additional consideration, the 2022 Notes were amended several times in order to allow the Company to issue additional notes payable, extend the completion date for the Uplist Transaction, and amend certain provisions with regards to mandatory conversion of the notes upon the Uplist Transaction.

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In connection with the issuance of the 2022 Notes, the Company granted the 2022 Notes noteholders 425,562 warrants to purchase shares of common stock. The warrants are fully vested, exercisable at \$9.94 per share and expire in 5 years. The Company estimated the relative fair value of the warrants to be \$1,470,000 using the Black Scholes option pricing model. The Company also issued note holders 63,842 shares of the Company’s common stock with a relative fair value of \$315,000. The Company also issued 31,510 warrants to purchase shares of common stock to the placement agent that assisted in the 2022 Notes offering. The placement agent warrants are fully vested, exercisable at \$10.06 per share and will expire in 5 years. The Company estimated the relative fair value of the placement agent warrants to be \$219,894 using the Black Scholes option pricing model. The Company incurred direct legal and professional fees of \$555,414 as part of this offering.

The Company recorded 2022 Notes with total principal of \$4,230,000. In addition, total debt discount of \$2,870,000 was recorded to account for the 2022 Notes OID of \$705,000, the relative fair value of the warrants of \$1,470,000, the relative fair value of common stock issued of \$315,000, and direct legal and professional fees incurred in the 2022 Notes offering of \$555,414. The debt discount is being amortized over the term of the notes using the effective interest rate method. During the year ended September 30, 2022, the Company amortized debt discount of \$302,000.

As of September 30, 2022, outstanding balance of the 2022 Notes payable was \$4,230,000 and unamortized debt discount was \$2,567,508, or a net balance of \$1,662,492. During the year ended September 2023, the Company amortized debt discount of \$1,857,000. As of September 30, 2023, outstanding balance of the 2022 Notes payable amounted to \$4,230,000 and unamortized debt discount was \$710,897, or a net balance of \$3,519,103. As of September 30, 2023 and 2022, notes payable in the aggregate of \$96,000, respectively, are issued to two officers and a member of the Board of Directors of the Company.

7. CONVERTIBLE NOTES PAYABLE, UNSECURED

	September 30, 2023	September 30, 2022
Exchanged notes (July 2022)	\$ 699,781	\$ 699,781
Second closing notes (January 2023)	636,000	-
Third closing notes (March, April, May, 2023)	702,720	-
Total	2,038,501	\$ 699,781
Unamortized debt discount	(379,799)	-
Net Balance	1,658,702	699,781
Current Balance	(1,658,702)	-
Non-Current Balance	-	699,781

[Exchanged Notes \(July 2022\)](#)

In relation to the issuance of the 2022 Notes (see Note 6), certain noteholders of the Company’s Series 2 note payable (see Note 8) agreed to exchange their Series 2 notes payable consisting of \$600,000 principal and accrued interest of \$99,781 for \$699,781 of Unsecured Convertible Promissory Notes (the “Exchanged Notes”) on substantially the same terms as the 2022 Notes, except that the Exchanged Notes are subordinate to the 2022 Notes and are unsecured. The notes bear interest at a rate of 10% per annum payable at maturity or upon conversion, originally matured January 6, 2024 (which was subsequently extended to March 15, 2024), and are convertible into shares of the Company’s common stock at a conversion price of \$9.14 per share. At September 30, 2022, there was no discount recorded for the Exchanged Notes.

[Second Closing Notes \(January 2023\)](#)

In January 2023, pursuant to the SPA (see Note 6), as amended, investors agreed to purchase Unsecured Convertible Promissory Notes (the “Second Closing Notes”) in the aggregate of \$636,000 in exchange for cash proceeds of \$530,000, net of original issue discount (OID) of \$106,000. The notes are unsecured, bear interest at a rate of 10% per

annum, originally matured January 6, 2024 (which was subsequently extended to March 15, 2024), and are convertible into shares of the Company's common stock with a conversion price of \$9.14 per share.

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In connection with the issuance of the Second Closing Notes, the Company granted the Second Closing Notes noteholders (i) 127,968 warrants to purchase shares of common stock. The warrants are fully vested, exercisable at \$9.94 per share and expire in 5 years. The Company determined the relative fair value of the warrants to be \$256,000 using the Black Scholes option pricing model; and (ii) 9,598 shares of common stock with a relative fair value of \$26,000. The Company also issued 6,565 warrants to purchase shares of the Company's common stock to the placement agent who assisted in the Second Closing offering. The placement agent warrants are fully vested, exercisable at \$10.06 per share and will expire in 5 years. The Company determined the relative fair value of the placement agent warrants to be \$13,000 using the Black Scholes option pricing model. Furthermore, the Company also incurred direct legal and professional fees of \$31,000 as part of this offering.

Third Closing Notes (March, April and May 2023)

In March, April and May 2023, pursuant to the SPA, as amended, investors agreed to purchase Unsecured Convertible Promissory Notes (the "Third Closing Notes") in the aggregate of \$703,000 in exchange for cash proceeds of \$488,000, net of original issue discount (OID) of \$215,000. The notes are unsecured, bear interest at a rate of 10% per annum, originally matured January 6, 2024 (which was subsequently extended to March 15, 2024), and are convertible into shares of the Company's common stock with a conversion price of \$9.14 per share.

In connection with the issuance of the Third Closing Notes, the Company granted the Third Closing Notes noteholders (i) 141,396 warrants to purchase shares of common stock. The warrants are fully vested, exercisable at \$9.94 per share and expire in 5 years. The Company determined the relative fair value of the warrants to be \$164,000 using the Black Scholes option pricing model; and (ii) 10,608 shares of common stock with a relative fair value of \$18,000. The Company also incurred direct legal and professional fees of \$5,000 as part of this offering.

The Second Closing Notes and Third Closing Notes contain events of default similar to the 2022 Notes (See Note 6). Subsequent to issuance, for no additional consideration, the Second Closing Notes and Third Closing Notes were amended several times in order to allow the Company to issue additional notes payable, extend the completion date of the Uplist Transaction, and amend certain provisions with regards mandatory conversion of the notes upon the Uplist Transaction.

Debt discount on unsecured convertible promissory notes

As a result of the issuance of the Second Closing and the Third Closing Notes, the Company recorded debt discount in the aggregate of \$834,000 to account for the Second Closing and the Third Closing Notes OID of \$321,000, the relative fair value of the warrants issued of \$433,000, the relative fair value of common stock issued of \$44,000, and direct legal and professional fees incurred of \$36,000. The debt discount is being amortized over the term of the notes using the effective interest rate method.

During the year ended September 30, 2023, the Company amortized debt discount of \$454,000. As of September 30, 2023, outstanding balance of the Exchange notes, Second Closing Notes, and Third Closing Notes was \$2,039,000 and unamortized debt discount of \$380,000, or a net balance of \$1,659,000.

The warrants issued with the 2022 Notes, the Second Closing Notes, and the Third Closing Notes were valued using the Black Scholes option pricing model with the following assumptions:

Date of valuation	First closing		Second Closing		Third Closing
	Note holders	Placement Agent	Note holders	Placement Agent	Note holders
	July 6, 2022		January 18, 2023		May 15, 2023
Closing price per share of Common Stock	\$ 9.98	\$ 9.98	\$ 5.76	\$ 5.76	\$ 2.77
Exercise price per share	\$ 9.94	\$ 10.06	\$ 9.94	\$ 10.06	\$ 9.94
Expected volatility	88.44%	88.44%	111.31%	111.31%	114.33%
Risk-free interest rate	2.96%	2.96%	3.43%	3.43%	3.46%
Dividend yield	—	—	—	—	—
Remaining expected term of underlying securities (years)	5.0	5.0	5.0	5.0	5.0

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8. CONVERTIBLE NOTES PAYABLE, SERIES 1 AND 2

	2023	2022
Series 1 Convertible Notes (converted in July 2023)	\$ -	\$ 550,000
Series 2 Convertible Notes (converted in November 2023)	450,000	450,000
Total	450,000	1,000,000
Current Balance	(450,000)	(550,000)
Non-Current Balance	\$ -	\$ 450,000

Series 1 Convertible Notes

On June 4, 2020, the Company issued unsecured 10% Series 1 Convertible Notes in the aggregate principal amount of \$550,000. The maturity dates of the Series 1 Notes was June 30, 2023, and all were converted in July 2023.

The Series 1 Convertible Notes provide, among other things:

- (i) interest at a rate of 10% per annum;
- (ii) term of approximately three years;
- (iii) allow for the Company's ability to prepay the Series Convertible Notes, in whole or in part, at any time;
- (iv) allow the automatic conversion of the Series 1 Convertible Notes upon a change of control into shares of the Company's common stock, at a conversion price of \$54.00 per share;
- (v) allow the holders to convert the principal of the Series 1 Convertible Notes, along with accrued interest, in whole or in part, into shares of common stock at the conversion price of \$54.00 per share;

- (vi) allow for the Company's ability to convert all note obligations outstanding upon a qualified equity financing into shares of common stock at the corresponding price per share of the qualified equity financing;
- (vii) the Company's ability to convert the principal of the Series 1 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;
- (viii) 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, subject to a conversion multiplier of 4.5, as amended.

As of September 30, 2022, outstanding balance of the Series 1 Convertible Notes amounted to \$550,000.

During the year ended September 30, 2023, pursuant to the terms of the convertible notes agreement, the Company issued 59,912 shares of common stock to convert the outstanding notes payable of \$550,000 and accrued interest of \$168,918 for a total of \$718,918. There are no Series 1 convertible notes payable outstanding as of September 30, 2023.

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[Series 2 Convertible Notes](#)

On November 6, 2020, the Company issued its unsecured Series 2 10% Convertible Notes Payable in exchange for cash proceeds of \$1,050,000. The Series 2 Convertible Notes have similar terms and provisions with the Series 1 Convertible Notes (see above), except the maturity dates of the Series 2 Notes was November 30, 2023, and the notes were all converted in November 2023.

As of September 30, 2021, outstanding balance of the Series 2 Convertible Notes amounted to \$1,050,000. During the year ended September 30, 2022, as a part of a separate 2022 Convertible Note Offering (see Note 6), certain holders of the Series 2 Notes agreed to exchange their Series 2 Notes with an aggregate principal amount of \$600,000 and accrued interest of approximately \$100,000 for promissory notes of the Company on substantially similar terms to those of the 2022 Notes (the "Exchange Notes", see Note 7).

As of September 30, 2023 and 2022, outstanding balance of the Series 2 Convertible Notes amounted to \$450,000 and \$1,000,000, respectively.

9. INCOME TAXES

The principal components of the Company's net deferred tax assets consisted of the following at September 30:

	2023	2022
Net operating loss & charitable contribution carryforwards	\$ 12,905,738	\$ 11,485,524
Capitalized expenditures	1,396,415	1,535,736
Research and experimentation credit carryforwards	1,014,466	946,246
Stock based compensation	1,491,338	1,427,946
Property and Equipment	1,531	2,616
Accrued expenses	746,143	162,191
Inventory allowance	51,463	70,805
Gross deferred tax assets	17,607,094	15,631,061
Deferred tax asset valuation allowance	(17,607,094)	(15,631,061)
Net deferred tax assets	\$ -	\$ -

The provision (benefit) for income taxes differs from the tax computed with the statutory federal income tax rate as follows:

	2023	2022
Expected income tax (benefit) at federal statutory rate	21.00%	21.00%
<u>Increase due to:</u>		
State income taxes – net of federal benefit	0.24%	3.65%
<u>Permanent Differences:</u>		
Stock based compensation	-%	(18.10)%
R&D, taken as a credit	(0.16)%	(0.23)%
Adjustment to fair value of derivative	3.48%	3.98%
Other	-%	(1.14)%
Change in Valuation Allowance	(24.56)%	(9.16)%
Total Income Tax Provision (Benefit)	-%	-%

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As of September 30, 2023 and 2022, the Company had federal net operating loss carryforwards totaling approximately \$48,200,000 and \$42,700,000, 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, 2023 and 2022, the Company has federal net operating loss carryforwards with an indefinite life of \$26,444,000 and \$20,945,000. As of September 30, 2023 and 2022, the Company had federal research and experimentation credit carryforwards of \$679,000 and \$626,000, respectively, which may be available to offset future income tax liabilities and which would begin to expire in 2028.

As of September 30, 2023 and 2022, the Company had state net operating loss carryforwards of approximately \$44,570,000 and \$40,367,000, respectively, which may be available to offset future taxable income and which would begin to expire in 2030. As of September 30, 2023 and 2022, the Company had state research and experimentation credit carryforwards of \$425,000 and \$406,000, respectively, which may be able to offset future income tax liabilities and which begin to expire in 2023.

As the Company has not yet achieved profitable operations, management believes the tax benefits as of September 30, 2023 and 2022 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 2023 by approximately \$1,976,000 and increased in 2022 by approximately \$483,000. The Company's effective income tax rate differed from the federal statutory rate due to state taxes

and the Company's full valuation allowance, 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, 2023, the Company is open to examination in the U.S. federal and certain state jurisdictions for tax years ended September 30, 2023, 2022, 2021 and 2020. In addition, any loss years remain open to the extent that losses are available for carryover to future years. Therefore, the tax years ended 2010 through 2021 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, 2023 and continues to evaluate the impact of the CARES act on the business.

10. STOCKHOLDERS DEFICIT

Common Stock

During the year ended September 30, 2023, the Company issued 3,436,712 shares of Common Stock, par value \$0.001, as follows: (i) 250 shares issued in connection with the vesting of a restricted stock grant; (ii) 3,344,321 shares issued in connection with certain financing activities involving the sale of Common Stock and warrants to certain accredited investors in exchange for the net cash proceeds of \$2,209,839 (the "Bridge Offering"); (iii) 20,210 inducement shares issued in connection with the closing of the Second Notes and Third Notes; (iv) 12,019 shares issued in connection with the exchange of Series G and Series H warrants for Common Stock; and (v) 59,912 shares issued in connection with the conversion of the Company's outstanding Series 1 Notes into Common stock.

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Common Stock Options

Common Stock Options activity under the 2013 Plan for the year ended September 30, 2023 and 2022 follows:

	Option Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at September 30, 2021	124,495	\$ 58.00	1.86	\$ 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
Awarded	24,500	\$ 8.00		
Forfeited/Cancelled	(21,001)	\$ 68.00		
Outstanding at September 30, 2023	102,125	\$ 38.00	3.9	\$ —
Vested at September 30, 2023	82,940	\$ 44.00	4.89	\$ —
Vested and expected to vest at September 30, 2023	102,125	\$ 38.00	3.9	\$ —

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. The stock options issued to employees and directors vest over a period of 36 months, and options issued to consultants vest over a period of 12 months. The weighted average exercise price for all options was \$10.02. Options issued to employees and consultants expire in 5 years. Options issued to management and directors expire after 10 years. Total fair value of the stock options issued was \$47,609 using the Black-Scholes Option Pricing Model. The following assumptions were used to calculate the fair value - expected volatility, 86.8% - 98.5%, risk-free interest rate, 1.5% - 3.5%, expected dividend yield, 0%, expected term, 3.6 - 5.8 years.

During the year ended September 30, 2023, the Company granted 20,875 options to employees and directors and 3,625 options to consultants to purchase shares of common stock under the 2013 Plan. The stock options issued to employees vest over a period of 36 months, and options issued to consultants and directors vest over a period of 12 months. The exercise price for all options granted was \$8.02. Options issued to employees and consultants expire in 5 years. Options issued to management and directors expire after 10 years. Total fair value of the stock options issued \$156,275 using the Black-Scholes Option Pricing Model. The following assumptions were used to calculate the fair value - expected volatility, 102.8% - 103.4 %, risk-free interest rate, 3.8% - 4.0%, expected dividend yield, 0%, expected term, 4.1 - 5.8 years.

Pursuant to the vesting terms of the stock options, Share-based compensation expense recorded in the Company's Consolidated Statements of Operations for the year ended September 30, 2023 and 2022 resulting from stock options awarded to the Company's employees, directors and consultants was approximately \$246,000 and \$459,000, respectively. Of this amount during the years ended September 30, 2023 and 2022, \$57,000 and \$148,000, respectively, were recorded as research and development expenses, and \$189,000 and \$311,000, respectively were recorded as general and administrative expenses in the Company's Consolidated Statements of Operations.

As of September 30, 2023, there is approximately \$162,000 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 1.80 years. As of September 30, 2023, 0 shares are available for future grants under the 2013 Plan as the plan is now expired.

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Common Stock Warrants

Common Stock Warrants activity for the year ended September 30, 2023 and 2022 follows:

	Warrants Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at September 30, 2021	349,380	\$ 53.28	1.8	\$ -
Awarded	457,072	\$ 9.95	3.8	-
Forfeited/Cancelled	-	\$ -	-	-

Outstanding at September 30, 2022	806,452	\$ 28.72	2.9	\$ -
Awarded	25,572,245	\$ 0.85	4.8	13,958,846
Exchanged	(77,090)	\$ 106.47	-	-
Forfeited/Cancelled	(17,605)	\$ 50.20	-	-
Outstanding at September 30, 2023	26,284,002	\$ 0.85	4.8	\$ 13,958,846
Vested at September 30, 2023	26,284,002	\$ -	-	\$ -
Vested and expected to vest at September 30, 2023	26,284,002	\$ -	-	\$ -

Restricted Stock

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 vested in three separate tranches on January 12, 2022, July 12, 2022 and January 12, 2023.

Restricted stock activity in shares under the 2013 Plan for the years ended September 30, 2023 and 2022 follows:

	<u>2023</u>	<u>2022</u>
Non Vested at September 30, 2022 and 2021	250	2,250
Awarded	—	—
Vested	(250)	(2,000)
Forfeited	—	—
Non Vested at September 30, 2023 and 2022	<u>—</u>	<u>250</u>

The weighted average restricted stock award date fair value information for the years ended September 30, 2023 and 2022 follows:

	<u>2023</u>	<u>2022</u>
Non Vested at September 30, 2022 and 2021	\$ 18.00	\$ 19.76
Awarded	—	—
Vested	(18.00)	(19.90)
Forfeited	—	—
Non Vested at September 30, 2023 and 2022	<u>\$ —</u>	<u>\$ 18.00</u>

For the years ended September 30, 2023 and 2022 compensation expense recorded for the restricted stock awards was approximately \$3,000 and \$40,000, respectively. As of September 30, 2023, there is no unrecognized compensation expense related to unvested stock-based compensation arrangements granted under the 2013 Plan.

11. 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, 2023 and 2022, no amounts have been accrued related to such indemnification provisions.

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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, 2023 and 2022. For the years ended September 30, 2023 and 2022, 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, 2023.

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 US 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.

12. SUBSEQUENT EVENTS

In October and November 2023, the Company received shareholder advances in the aggregate of \$450,000 to support the operations of the Company.

On November 8, 2023, the Company entered into a Securities Purchase Agreement (the "PIPE SPA") with certain institutional and accredited individual investors (collectively, the "Investors") providing for the issuance and sale by the Company to the Investors of (i) pre-funded warrants (the "PIPE Pre-Funded Warrants") and (ii) warrants (the "PIPE Common Warrants" and together with the PIPE Pre-Funded Warrants, the "PIPE Warrants"). The PIPE Warrants will be issued as part of a private placement offering authorized by the Company's Board of Directors (the "PIPE Offering"). The estimated aggregate gross proceeds for the sale of the PIPE Warrants will be approximately \$7.1 million, before deducting the placement agent's fees and other estimated fees and offering expenses payable by the Company. The closing of the PIPE Offering is contingent upon, among other conditions, a registration statement that registers the PIPE Warrant shares for resale being declared effective by the SEC, and the approval of the listing of

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In November 2023, certain provisions of the Company’s Convertible Notes Payable, Senior Secured (See Note 6) and Exchange Notes (see Note 7) were amended to extend the date of the completion of an Uplist Transaction to March 15, 2024. In addition, upon effectivity of the Uplist Transaction, 50% of the then outstanding principal amount of the Convertible Notes Payable, Senior Secured and Exchange Notes shall automatically convert (the “Automatic Conversion”) into shares of Common Stock, with the conversion price for purposes of such Automatic Conversion of \$4.00. Upon the Automatic Conversion and to the extent that the beneficial ownership of a holder of Convertible Notes Payable, Senior Secured and Convertible Notes Payable, Unsecured would increase over the applicable Ownership Limitation, the Holder will receive pre-funded warrants in lieu of shares of Common Stock otherwise issuable to the Holder in connection with the Automatic Conversion, which may be exercised on a cashless basis, shall be exercisable immediately upon issuance and shall contain a customary beneficial ownership limitation provision. In addition, upon the Automatic Conversion, the Holder shall receive a warrant (the “Uplist Conversion Warrant”) to purchase a number of shares of Common Stock equal to 6.3812 times the dollar amount under the Convertible Notes Payable, Senior Secured and Convertible Notes Payable, Unsecured that was converted in the Automatic Conversion. The Uplist Conversion Warrant shall have an exercise price per share of \$4.00 and shall otherwise be identical to the PIPE Common Warrant.

In November 2023, the Company amended the Second A&R Registration Rights Agreement to that certain Second Amended and Restated Registration Rights Agreement, dated as of May 15, 2023 to (I) extend the filing deadline by which the Company is obligated to file with the SEC a registration statement under the Securities Act of 1933, as amended, registering certain securities issued in the 2022 Convertible Note Offering to the earlier of (i) the date that is 30 days following the Uplist Transaction and (ii) January 31, 2024 (such date was subsequently extended to March 15, 2024), and (II) to provide for the inclusion of the Registerable Securities (as defined therein) in the Uplist S-1 (as defined therein).

In November 2023, the Company also entered into an amendment to the Bridge SPA, with certain institutional and accredited individual investors that participated in the Bridge Offering. Under amendment, upon the closing of the next underwritten public offering of Common Stock (the “Qualifying Offering”), which the Company agreed is the Uplist Transaction, if the effective offering price to the public per share of Common Stock (the “Qualifying Offering Price”) is lower than \$4.00 per share, then the Company shall issue additional Bridge Pre-Funded Warrants, or shares of Common Stock in lieu thereof to the extent necessary to cause the Company to meet the listing requirements of the Company’s proposed trading market in the Uplist Transaction, in an amount reflecting a reduction in the purchase price paid for the Bridge Shares and Bridge Pre-Funded Warrants that equals the proportion by which the Qualifying Offering Price is less than \$4.00.

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Arch Therapeutics, Inc. and Subsidiary

Condensed Consolidated Balance Sheets

As of March 31, 2024 (Unaudited) and September 30, 2023

	March 31, 2024	September 30, 2023
	(unaudited)	
ASSETS		
Current assets:		
Cash	\$ 26,426	\$ 222,720
Inventory	1,329,593	1,364,504
Prepaid expenses and other current assets	177,158	362,866
Total current assets	<u>1,533,177</u>	<u>1,950,090</u>
Long-term assets:		
Property and equipment, net	3,390	4,599
Other assets	3,500	3,500
Total long-term assets	<u>6,890</u>	<u>8,099</u>
Total assets	<u>\$ 1,540,067</u>	<u>\$ 1,958,189</u>
LIABILITIES AND STOCKHOLDERS’ DEFICIT		
Current liabilities:		
Accounts payable	\$ 2,969,520	\$ 2,304,207
Accrued interest	1,026,963	823,128
Shareholders advances related to bridge financing	1,125,000	-
Accrued expenses and other liabilities	363,092	467,496
Insurance premium financing	34,755	243,285
Convertible notes payable, senior secured, current portion, net of discount	4,211,720	3,519,103
Convertible notes payable, unsecured, current portion, net of discount	2,686,501	1,658,702
Convertible notes payable, Series 2, unsecured, current portion	-	450,000
Total current liabilities	<u>12,417,551</u>	<u>9,465,921</u>
Commitments and contingencies		
Stockholders’ deficit:		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized, none issued and outstanding as of March 31, 2024 and September 30, 2023	-	-
Common stock, \$0.001 par value, 350,000,000 authorized as of March 31, 2024 and September 30, 2023; 4,444,364 and 4,689,446 shares issued and outstanding as of March 31, 2024 and September 30, 2023	4,444	4,689
Additional paid-in capital	55,324,472	54,543,188
Accumulated deficit	<u>(66,206,400)</u>	<u>(62,055,609)</u>
Total stockholders’ deficit	<u>(10,877,484)</u>	<u>(7,507,732)</u>
Total liabilities and stockholders’ deficit	<u>\$ 1,540,067</u>	<u>\$ 1,958,189</u>

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

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Arch Therapeutics, Inc. and Subsidiary

Condensed Consolidated Statements of Operations (Unaudited)

For the Three and Six Months Ended March 31, 2024 and 2023

	For the three months ended		For the six months ended	
	March 31, 2024	March 31, 2023	March 31, 2024	March 31, 2023
Revenue	\$ 31,866	\$ 16,654	\$ 77,733	\$ 22,914
Operating expenses:				
Cost of revenues	21,555	18,718	45,161	36,353
Selling, general and administrative expenses	683,184	1,252,786	1,994,534	2,355,701
Research and development expenses	203,869	170,634	409,449	332,087
Total operating expenses	908,608	1,442,138	2,449,144	2,724,141
Loss from operations	(876,742)	(1,425,484)	(2,371,411)	(2,701,227)
Other (expense) income:				
Interest expense	(592,397)	(635,190)	(1,779,380)	(1,159,503)
Gain on extinguishment of derivative liabilities	-	1,158,197	-	1,158,197
Total other (expense) income, net	(592,397)	523,007	(1,779,380)	(1,306)
Net loss	\$ (1,469,139)	\$ (902,477)	\$ (4,150,791)	\$ (2,702,533)
Net loss per common share - basic and diluted	\$ (0.33)	\$ (0.71)	\$ (0.90)	\$ (2.15)
Weighted common shares - basic and diluted	4,497,111	1,263,585	4,602,623	1,258,099

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

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Arch Therapeutics, Inc. and Subsidiary

Condensed Consolidated Statements of Changes in Stockholders' Deficit (Unaudited)
For the Three and Six Months Ended March 31, 2024 and 2023

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at September 30, 2023	-	\$ -	4,689,446	\$ 4,689	\$ 54,543,188	\$ (62,055,609)	\$ (7,507,732)
Net loss	-	-	-	-	-	(2,681,652)	(2,681,652)
Issuance of common stock upon conversion of convertible notes	-	-	52,918	53	587,906	-	587,959
Stock-based compensation expense	-	-	-	-	25,909	-	25,909
Balance at December 31, 2023	-	-	4,742,364	4,742	55,157,003	(64,737,261)	(9,575,516)
Net loss	-	-	-	-	-	(1,469,139)	(1,469,139)
Issuance of common stock upon conversion of convertible notes	-	-	2,000	2	18,278	-	18,280
Issuance of warrants, net of financing costs	-	-	-	-	148,891	-	148,891
Exchange of common stock into warrants	-	-	(300,000)	(300)	300	-	-
Balance at March 31, 2024	-	\$ -	4,444,364	\$ 4,444	\$ 55,324,472	\$ (66,206,400)	\$ (10,877,484)
Balance at September 30, 2022	-	\$ -	1,252,734	\$ 1,252	\$ 50,878,718	\$ (55,072,773)	\$ (4,192,803)
Net loss	-	-	-	-	-	(1,800,056)	(1,800,056)
Stock-based compensation expense	-	-	-	-	104,026	-	104,026
Balance at December 31, 2022	-	-	1,252,734	1,252	50,982,744	(56,872,829)	(5,888,833)
Net loss	-	-	-	-	-	(902,477)	(902,477)
Vesting of restricted stock	-	-	250	-	-	-	-
Issuance of common stock and warrants, net of financing costs	-	-	9,598	10	287,410	-	287,420
Exchange of warrants into common stock	-	-	12,019	13	49,265	-	49,278
Stock-based compensation expense	-	-	-	-	68,524	-	68,524
Balance at March 31, 2023	-	\$ -	1,274,601	\$ 1,275	\$ 51,387,943	\$ (57,775,306)	\$ (6,386,088)

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

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Arch Therapeutics, Inc. and Subsidiary

Condensed Consolidated Statements of Cash Flows (Unaudited)
For the Six Months Ended March 31, 2024 and 2023

	For the Six Months Ended	
	March 31, 2024	March 31, 2023
Cash flows from operating activities:		
Net loss	\$ (4,150,791)	\$ (2,702,533)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	1,209	1,043
Stock-based compensation	25,909	172,550
Gain on extinguishment of derivative liabilities	-	(1,158,197)
Accretion of discount and debt issuance costs on convertible notes payable	1,437,588	846,147
Changes in operating asset and liabilities:		
Inventory	34,911	12,464

Prepaid expenses and other current assets	185,707	280,058
Accounts payable	665,314	1,097,894
Accrued interest	341,793	313,356
Accrued expenses and other liabilities	(104,404)	(112,713)
Net cash used in operating activities	(1,562,764)	(1,249,931)
Cash flows from financing activities:		
Repayment of insurance premium financing	(208,530)	(212,514)
Shareholder advances related to bridge financing	1,125,000	230,000
Proceeds from unsecured convertible notes	450,000	515,000
Net cash provided by financing activities	1,366,470	532,486
Net decrease in cash	(196,294)	(717,445)
Cash, beginning of period	222,720	746,940
Cash, end of period	\$ 26,426	\$ 29,495
Non-cash financing activities:		
Exchange of Senior Secured and Series 2 Convertible notes and accrued interest into common stock	\$ 606,239	\$ -
Relative fair value of warrants issued – fourth close	\$ 148,891	\$ -
Conversion of convertible notes and accrued interest to common stock, net	\$ 606,239	\$ -
Exchange of Series G and Series H warrants for common stock	\$ -	\$ 49,278
Issuance of restricted stock	\$ -	\$ 3,019
Fair value of warrants issued - second close	\$ -	\$ 256,439
Fair value of inducement shares issued - second close	\$ -	\$ 25,840
Fair value of placement agent warrants - second close	\$ -	\$ 28,093

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

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ARCH THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
THREE AND SIX-MONTHS ENDED MARCH 31, 2024 AND 2023
(Unaudited)

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Arch Therapeutics, Inc. (together with its subsidiary, the “Company” or “Arch”) is a biotechnology company developing and marketing products based on our innovative AC5® self-assembling technology platform. The Company’s products are in the field of stasis and barrier applications, which includes managing wounds created during surgery, trauma or interventional care, or from disease; stopping bleeding (hemostasis); and controlling leaking (sealant).

Basis of presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) and the applicable rules and regulations of the Securities and Exchange Commission (the “SEC”) regarding interim financial reporting. Certain information and note disclosures normally included in the financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. These condensed financial statements should be read in conjunction with the financial statements contained in the Company’s Annual Report on Form 10-K for the year ended September 30, 2023, filed with the SEC. The accompanying condensed financial statements are unaudited, but in the opinion of management contain all adjustments, including normal recurring adjustments, necessary to present fairly the Company’s financial position as of March 31, 2024, and the results of its operations and its cash flows for the three and six months ended March 31, 2024 and 2023. The balance sheet as of September 30, 2023 is derived from the Company’s audited financial statements. The results of operations for the three and six months ended March 31, 2024 are not necessarily indicative of the results of operations to be expected for the full fiscal year ending September 30, 2024.

In accordance with the “Segment Reporting” Topic of the Accounting Standards Codification, the Company’s chief operating decision maker (the Company’s President and Chief Executive Officer) determined that the Company has only one reporting unit.

The condensed 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.

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Going Concern

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The Company has not yet generated sufficient revenues to fund operations and relies on issuance of debt and equity instruments to generate working capital. As reflected in the accompanying financial statements, for the six months ended March 31, 2024, the Company recorded a net loss of \$4,150,791 and used cash in operations of \$1,562,764. These factors raise substantial doubt about the Company’s ability to continue as a going concern within one year of the date that the financial statements are issued. In addition, the Company’s independent registered public accounting firm, in its report on the Company’s September 30, 2023, financial statements, raised substantial doubt about the Company’s ability to continue as a going concern. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

The Company expects to incur substantial expenses for the foreseeable future relating to research, development and commercialization of its current and its potential future products. The Company has not yet generated sufficient revenues to fund operations and relies on issuance of debt and equity instruments to generate working capital. In evaluating the going concern position of the Company, management has considered potential funding providers and believes that financing to fund future operations could be provided by equity and/or debt financing. Even if the Company is able to obtain additional financing, it may contain undue restrictions on our operations, in the case of debt financing, or cause substantial dilution for our stockholders, in the case of equity financing.

Reverse stock split

On January 6, 2023, the directors of the Company authorized a reverse share split of the issued and outstanding Common Shares in a ratio of 1:200, effective January 17, 2023. Accordingly, all share and per share amounts presented herein with respect to common stock have been retroactively adjusted to reflect the above-described reverse stock split for all periods presented.

Use of Estimates

Management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenue and expense during the reporting periods. Significant estimates include the assumptions used in the accrual for potential liabilities, the net realizable value of inventory, the valuation of debt and equity instruments, the fair value of derivative liabilities, valuation of equity instruments issued for services, and deferred tax valuation allowances. Actual results could differ from those estimates.

Revenue

The Company recognizes revenue in accordance with Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers* (“ASC 606”), through a five-step process: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) a performance obligation is satisfied.

The Company’s source of revenue is product sales. Contracts with customers contain a single performance obligation and the Company recognizes revenue from product sales when the Company has satisfied our performance obligation by transferring control of the product to the customers. Control of the product transfers to the customer upon shipment from the Company’s third-party warehouse. In circumstances where the transaction price is not able to be determined at the time of shipment, the Company does not recognize revenue or any receivable amount until such time that the final transaction price is established.

Cost of Revenue

Cost of revenue includes product costs, warehousing, overhead allocation and royalty expense.

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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 condensed consolidated financial statements based on their fair values. In accordance with ASC 718, the Company has elected to use the Black-Scholes Option Pricing Model (the “*Black-Scholes Model*”) to determine the fair value of options granted and recognizes the compensation cost of share-based awards on a straight-line basis over the vesting period of the award.

The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by the fair value of the Common Stock and a number of other assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. The expected life for awards uses the simplified method for all “plain vanilla” options, as defined in ASC 718-10-S99, and the contractual term for all other employee and non-employee awards. The risk-free interest rate assumption is based on observed interest rates appropriate for the terms of the Company’s awards. The dividend yield assumption is based on history and the expectation of paying no dividends. Stock-based compensation expense, when recognized in the condensed 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 condensed 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 March 31, 2024 and September 30, 2023, the carrying amounts of cash, accounts payables and accrued expense and other liabilities approximate fair value because of their short-term nature. The carrying amounts for the Series Convertible Notes, 2022 Notes, Second Notes, Third Notes and the Fourth Notes approximate fair value because borrowing rates and terms are similar to comparable market participants.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant’s specific terms and applicable authoritative guidance in Accounting Standards Codification (“ASC”) 480, *Distinguishing Liabilities from Equity* (“ASC 480”), and ASC 815, *Derivatives and Hedging* (“ASC 815”). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company’s own common stock and whether the warrant holders could potentially require “net cash settlement” in a circumstance outside of the Company’s control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted when the warrants are issued and at the end each subsequent quarterly period while the warrants are outstanding. For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be liability classified and recorded at their initial fair value on the date of issuance and remeasured at fair value at each balance sheet date thereafter. Changes in the estimated fair value of the warrants are recognized as a non-cash gain or loss on the statements of operations. The Company has determined that the warrants issued in June 2018 and May 2019 equity financing (see Note 3) meet the requirements for liability classification. During the three months ended March 31, 2023, \$1,158,197 was recorded to gain on extinguishment of derivative liability for the exchange of the Series G warrants and Series H warrants to 12,019 shares of common stock with a fair value of \$49,278.

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Loss per Common Share

Basic earnings (loss) per share is computed by dividing the net income (loss) applicable to common stockholders by the weighted average number of shares of common stock outstanding during the year, excluding shares of unvested restricted common stock. Shares of restricted stock are included in the basic weighted average number of common shares outstanding from the time they vest. Diluted earnings (loss) per share is computed by dividing the net income applicable to common stockholders by the weighted average number of common shares outstanding plus the number of additional common shares that would have been outstanding if all dilutive potential common shares had been issued, using the treasury stock method. Shares of restricted stock are included in the diluted weighted average number of common shares outstanding from the date they

are granted. Potential common shares are excluded from the computation when their effect is antidilutive.

For the periods ended March 31, 2024 and 2023, the calculations of basic and diluted loss per share are the same because potential dilutive securities would have had an anti-dilutive effect. The potentially dilutive securities consisted of the following:

	<u>March 31,</u> <u>2024</u>	<u>March 31,</u> <u>2023</u>
Stock options	88,275	104,325
Stock warrants	26,724,240	847,021
Convertible notes payable	754,744	721,790
Total	<u>27,567,259</u>	<u>1,673,136</u>

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.

Risks and uncertainties – 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 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. The extent to which recent events, including recent wars in Ukraine and Israel/Gaza, will impact the global economy and the Company is uncertain and cannot be reasonably measured.

2. INVENTORIES

Inventories consist of the following:

	<u>March 31,</u> <u>2024</u>	<u>September 30,</u> <u>2023</u>
Finished Goods	\$ 65,980	\$ 40,969
Goods-in-Process	1,263,613	1,323,535
Total	<u>\$ 1,329,593</u>	<u>\$ 1,364,504</u>

Inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out ("FIFO") basis. 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 Company records adjustments to its inventory for estimated obsolescence or diminution in net realizable value equal to the difference between the cost of the inventory and the estimated net realizable value. Once inventory has been written down, it creates a new cost basis for inventory that may not be subsequently written up. For the periods ended March 31, 2024 and 2023, the Company did not record any write-down of inventories.

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3. WARRANT DERIVATIVE LIABILITY

As of March 31, 2024 and September 30, 2023, there are no financial instruments accounted as a derivative liability.

The Company previously issued warrants (Series G and Series H warrants) that were accounted for in accordance with ASC 815-10 as the Company is required to purchase the Series G, and Series H warrants for an amount of cash per share equal to \$22.00 and \$10.66, respectively, (the "Minimum Value"). Accordingly, the warrants were recorded as liabilities at the greater of the Minimum Value or fair value at each reporting period.

During the three months ended March 31, 2023, the Company issued 12,019 shares of common stock with a fair value of \$49,278 in exchange for the cancellation of the Series G and Series H warrants. As a result, during the three month ended March 31, 2023, the Company recorded a gain of \$1,158,197 to account for the extinguishment of derivative liability.

4. CONVERTIBLE NOTES PAYABLE, SENIOR SECURED

	<u>March 31,</u> <u>2024</u>	<u>September 30,</u> <u>2023</u>
Senior Secured Convertible Promissory Notes (the "2022 Notes")	\$ 4,211,720	\$ 4,230,000
Unamortized debt discount	-	(710,897)
Net Balance	<u>\$ 4,211,720</u>	<u>\$ 3,519,103</u>

In July 2022, the Company entered into a Securities Purchase Agreement (the "SPA") with certain institutional and accredited individual investors and issued Senior Secured Convertible Promissory Notes (the "2022 Notes") in the aggregate of \$4,230,000 in exchange for cash proceeds of \$3,525,000, net of original issue discount (OID) of \$705,000.

The 2022 Notes are secured by tangible and intangible assets of the Company, bears interest at a rate of 10% per annum payable at maturity or upon conversion, matures on June 30, 2024, as amended, and are convertible into shares of the Company's common stock at a conversion price of \$9.14 per share.

The 2022 Notes contain customary events of default. Further, events of default under the 2022 Notes also include (i) the unavailability of Rule 144 on or after January 6, 2023; (ii) our failure to deliver the shares of common stock to the 2022 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 April 30, 2024 (the "Uplisting Transaction"). During the year ended September 2023, for no additional consideration, the 2022 Notes were amended several times in order to allow the Company to issue additional notes payable, extend the completion date for the Uplisting Transaction, and amend certain provisions with regards to mandatory conversion of the notes upon the Uplisting Transaction.

In connection with the issuance of the 2022 Notes, the Company granted the 2022 Notes noteholders 425,555 warrants to purchase shares of common stock. The warrants are fully vested, exercisable at \$9.94 per share and expire in 5 years. The Company estimated the relative fair value of the warrants to be \$1,470,000 using the Black Scholes option pricing model. The Company also issued note holders 63,834 shares of the Company's common stock with a relative fair value of \$315,000. The Company also issued 31,510 warrants to purchase shares of common stock to the placement agent that assisted in the 2022 Notes offering. The placement agent warrants are fully vested, exercisable at

\$10.06 per share and will expire in 5 years. The Company estimated the relative fair value of the placement agent warrants to be \$108,000 using the Black Scholes option pricing model. The Company incurred direct legal and professional fees of \$271,000 as part of this offering.

The Company recorded 2022 Notes with total principal of \$4,230,000. In addition, total debt discount of \$2,870,000 was recorded to account for the 2022 Notes OID of \$705,000, the relative fair value of the warrants of \$1,578,000, the relative fair value of common stock issued of \$315,000, and direct legal and professional fees incurred in the 2022 Notes offering of \$271,000. The debt discount was amortized over the term of the notes using the effective interest rate method.

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As of September 30, 2023, outstanding balance of the 2022 Notes payable was \$4,230,000 and unamortized debt discount was \$710,897, or a net balance of \$3,519,103.

On December 26, 2023, the Company issued a total of 2,000 shares of Common Stock in partial satisfaction of the outstanding Senior Secured Convertible Promissory Notes with the principal balance of \$18,280.

On February 14, 2024, the Company entered into an amendment to the 2022 Notes, under which 95% of the principal amount of the Notes shall automatically convert, upon the closing of an Uplist Transaction, as defined, with a conversion price of \$0.50 per share, into pre-funded warrants with an exercise price of \$0.000125 per share, exercisable immediately. In addition, the note holder shall receive a warrant to purchase 80 times the dollar amount of the notes that are converted, with an exercise price per share of \$0.50. There is no impact to the amendment until the Uplist transaction is completed.

During the three and six months ended March 31, 2024, the Company amortized debt discount of \$46,965 and \$710,897, respectively. As of March 31, 2024, the outstanding balance of the 2022 Notes payable amounted to \$4,211,720 and no unamortized debt discount was remaining. On April 30, 2024, the convertible notes payable was amended in order to extend the maturity date to June 30, 2024. There were no compensation provided to the note holder nor any changes in the other terms of the notes payable.

5. CONVERTIBLE NOTES PAYABLE, UNSECURED

	March 31, 2024	September 30, 2023
Exchanged notes (July 2022)	\$ 699,781	\$ 699,781
Second closing notes (January 2023)	636,000	636,000
Third closing notes (March, April, May, 2023)	702,720	702,720
Fourth closing notes (March, 2024)	648,000	-
Total	<u>2,686,501</u>	<u>2,038,501</u>
Unamortized debt discount	-	(379,799)
Net balance	<u>\$ 2,686,501</u>	<u>\$ 1,658,702</u>

Exchanged Notes (July 2022)

In relation to the issuance of the 2022 Notes (see Note 4), certain noteholders of the Company's Series 2 note payable agreed to exchange their Series 2 notes payable consisting of \$600,000 principal and accrued interest of \$99,781 for \$699,781 of Unsecured Convertible Promissory Notes (the "Exchanged Notes") on substantially the same terms as the 2022 Notes, except that the Exchanged Notes are subordinate to the 2022 Notes and are unsecured. The notes bear interest at a rate of 10% per annum payable at maturity or upon conversion, mature June 30, 2024, as amended, and are convertible into shares of the Company's common stock at a conversion price of \$9.14 per share. At March 31, 2024 and September 30, 2023, there was no unamortized discount for the Exchanged Notes.

Second Closing Notes (January 2023)

In January 2023, the Company issued Unsecured Convertible Promissory Notes (the "Second Closing Notes") in the aggregate of \$636,000 in exchange for cash proceeds of \$530,000, net of original issue discount (OID) of \$106,000. The notes are unsecured, bear interest at a rate of 10% per annum, matures on June 30, 2024, as amended, and are convertible into shares of the Company's common stock with a conversion price of \$9.14 per share.

In connection with the issuance of the Second Closing Notes, the Company granted the Second Closing Notes noteholders 127,968 warrants to purchase shares of common stock and 9,598 shares of common stock. The warrants are fully vested, exercisable at \$9.94 per share and expire in 5 years. The Company determined the relative fair value of the warrants to be \$256,000 and the relative fair value of the 9,598 shares of common stock to be \$26,000. The Company also issued 6,565 placement agent warrants to purchase shares of the Company's common stock. The placement agent warrants are fully vested, exercisable at \$10.06 per share and will expire in 5 years. The Company determined the relative fair value of the placement agent warrants to be \$13,000. Furthermore, the Company also incurred direct legal and professional fees of \$31,000 as part of this offering.

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On February 14, 2024, the Company entered into an amendment to the Second Closing Notes, under which 95% of the principal amount of the Notes shall automatically convert, upon the closing of an Uplist Transaction, as defined, with a conversion price of \$0.50 per share, into pre-funded warrants with an exercise price of \$0.000125 per share, exercisable immediately. In addition, the note holder shall receive a warrant to purchase 80 times the dollar amount of the notes that are converted, with an exercise price per share of \$0.50.

Third Closing Notes (March, April and May 2023)

In March, April and May 2023, the Company issued Unsecured Convertible Promissory Notes (the "Third Closing Notes") in the aggregate of \$703,000 in exchange for cash proceeds of \$488,000, net of original issue discount (OID) of \$215,000, and. The notes are unsecured, bear interest at a rate of 10% per annum, matures on June 30, 2024, as amended, and are convertible into shares of the Company's common stock with a conversion price of \$9.14 per share.

In connection with the issuance of the Third Closing Notes, the Company granted the Third Closing Notes noteholders 141,396 warrants to purchase shares of common stock and 10,608 shares of common stock. The warrants are fully vested, exercisable at \$9.94 per share and expire in 5 years. The Company determined the relative fair value of the warrants to be \$164,000, and the relative fair value of the 10,608 shares of common stock to be \$18,000. The Company also incurred direct legal and professional fees of \$5,000 as part of this offering.

The Second Closing Notes and Third Closing Notes contain events of default similar to the 2022 Notes. Subsequent to issuance, for no additional consideration, the Second Closing Notes and Third Closing Notes were amended several times in order to allow the Company to issue additional notes payable, extend the completion date of the Uplist Transaction, and amend certain provisions with regards mandatory conversion of the notes upon the Uplist Transaction.

On February 14, 2024, the Company entered into an amendment to the Third Closing Notes, under which 95% of the principal amount of the Notes shall automatically convert, upon the closing of an Uplist Transaction, as defined, with a conversion price of \$0.50 per share, into pre-funded warrants with an exercise price of \$0.000125 per share, exercisable immediately. In addition, the note holder shall receive a warrant to purchase 80 times the dollar amount of the notes that are converted, with an exercise price per share of \$0.50.

On March 12, 2024, investors agreed to purchase Unsecured Convertible Promissory Notes (the “Fourth Closing Notes”) in the aggregate principal amount of \$648,000 in exchange for cash proceeds of \$450,000, net of an OID of \$198,000. The notes are unsecured, bears interest at a rate of 10% per annum, and matures June 30, 2024, as amended, and are convertible into shares of the Company’s common stock with a conversion price of \$9.14 per share.

In connection with the issuance of the Fourth Closing Notes, the Company granted the Fourth Closing Notes noteholders 130,383 warrants to purchase shares of common stock and 9,782 pre-funded warrants. The warrants are fully vested, exercisable at \$9.94 per share, and expire in 5 years, and prefunded warrants have similar terms, however, are exercisable at \$0.001 per share. The Company determined the relative fair value of the warrants and pre-funded warrants to be approximately \$148,891.

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On February 14, 2024, the Company entered into an amendment to the Fourth Closing Notes, under which 95% of the principal amount of the Notes shall automatically convert, upon the closing of an Uplist Transaction, as defined, with a conversion price of \$0.50 per share, into pre-funded warrants with an exercise price of \$0.000125 per share, exercisable immediately. In addition, the note holder shall receive a warrant to purchase 80 times the dollar amount of the notes that are converted, with an exercise price per share of \$0.50.

6. CONVERTIBLE NOTES PAYABLE, SERIES 2

	March 31, 2024	September 30, 2023
Series 2 Convertible Notes (converted in November 2023)	\$ -	\$ 450,000

On November 6, 2020, the Company issued its unsecured Series 2 10% Convertible Notes Payable in exchange for cash proceeds of \$450,000. The notes matured on November 30, 2023, and the notes were all converted in November 2023. As of September 30, 2023, outstanding balance of the Series 2 Convertible Notes amounted to \$450,000.

On November 30, 2023, the Series 2 Convertible Notes of \$450,000 and outstanding accrued interest of \$137,946, were converted into 52,918 shares of the Company’s common stock.

7. STOCKHOLDERS DEFICIT

Common Stock

In January 2024 certain shareholders of the Company exchanged a total of 300,000 shares of Company’s Common Stock for 300,073 of pre-funded warrants to purchase shares of Common Stock. At the date of the exchange, the fair value of the common stock received approximates the fair value of the warrants issued. The pre-funded warrants are fully vested, exercisable at \$0.001 per share, and expire in 5 years.

2013 Stock Incentive Plan

On September 1, 2023, a majority of shareholders approved the 2023 Stock Plan with 455,169 common shares reserved to be issued under the plan. As of March 31, 2024, there were no issuances under the new plan.

On June 18, 2013, the Company established the 2013 Stock Incentive Plan (the “2013 Plan”). Under the 2013 Plan, the Company can issue or grant a total of 185,571 shares, as amended. On June 18, 2023, the 2013 Stock Incentive Plan expired, and no shares are available for grants under the 2013 Plan.

Common Stock Options

Stock compensation activity under the 2013 Plan for the six months ended March 31, 2024 follows:

	Option Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at September 30, 2023	102,125	\$ 38.00	5.58	\$ -
Awarded	-	-	-	-
Forfeited/Cancelled	(1,825)	(67.00)	-	-
Outstanding at December 31, 2023	100,300	38.00	4.00	11,000
Awarded	-	-	-	-
Forfeited/Cancelled	(12,025)	(58.00)	-	-
Outstanding at March 31, 2024	88,275	\$ 35.00	5.00	-
Vested at March 31, 2024	74,769	\$ 39.00	3.50	-
Vested and expected to vest at March 31, 2024	88,275	\$ 35.00	5.00	-

During the six months ended March 31, 2024 and 2023, the Company recorded stock compensation expense of \$25,909 and \$172,550 to account the fair value of the stock options that vested.

As of March 31, 2024, there is approximately \$45,000 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 1.34 years.

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Restricted Stock

For the three months ended March 31, 2024 and 2023, compensation expense recorded for the restricted stock awards was approximately \$0 and \$1,000, respectively. For the six months ended March 31, 2024 and 2023, compensation expense recorded for the restricted stock awards was approximately \$0 and \$3,000, respectively.

As of March 31, 2023, there was no unrecognized compensation expense related to unvested stock-based compensation arrangements granted under the 2013 Plan.

8. SHAREHOLDER ADVANCES RELATED TO BRIDGE FINANCING

During the period ended March 31, 2024, the Company received \$1,125,000 in shareholder advances provided as a partial prepayment of securities to be issued pursuant to a Securities Purchase Agreement dated November 8, 2023 (the “PIPE SPA”). If the transaction underlying the PIPE SPA, with respect to \$1,000,000 of these advances, was not consummated by March 31, 2024, as amended, the Company would be obligated to repay all of the advances within three business days thereafter, provided, however, that in lieu of repayment each investor may in its sole discretion elect to receive, by notice to the Company, prefunded warrants and common warrants in lieu of repayment as if the PIPE SPA transaction had closed. If the transaction underlying the PIPE SPA, with respect to \$125,000 of these advances, was not consummated by April 30, 2024, as amended, the Company would be obligated to repay all of the advances within three business days thereafter, provided, however, that in lieu of repayment each investor may in its sole discretion elect to receive, by notice to the Company, prefunded warrants and common warrants in lieu of repayment as if the PIPE SPA transaction had closed.

With respect to \$1,000,000 of the above referenced shareholder advances, if the Company’s Common Stock had not been approved to be listed on a qualifying national exchange by April 2, 2024, as amended, then the amount of prefunded warrants and common warrants that would otherwise be issuable in connection with the PIPE SPA specific to those advances shall be increased by twenty-five percent. With respect to \$125,000 of the above referenced shareholder advances, if the Company’s Common Stock had not been approved to be listed on a qualifying national exchange by May 2, 2024, as amended, then the amount of prefunded warrants and common warrants that would otherwise be issuable in connection with the PIPE SPA specific to those advances shall be increased by twenty-five percent.

As of May 9, 2024, the Company had not been approved to be listed on a qualifying national exchange, had not repaid any advances, and had not received notice from any investors to receive pre-funded warrants and common warrants in lieu of prepayment.

9. SUBSEQUENT EVENTS

From April 1, 2024 through April 3, 2024, the Company raised an additional \$125,000 from three investors in the form of shareholder advances provided as a partial prepayment of each investor’s purchase price set forth on their respective signature pages to the PIPE SPA. If the transaction underlying the PIPE SPA, with respect to these advances, was not consummated by April 30, 2024, as amended, the Company would be obligated to repay all of the advances within three business days thereafter, provided, however, that in lieu of repayment each investor may in its sole discretion elect to receive, by notice to the Company, prefunded warrants and common warrants in lieu of repayment as if the PIPE SPA transaction had closed.

With respect to the \$125,000 of the above referenced shareholder advances received in April 2024, if the Company’s Common Stock had not been approved to be listed on a qualifying national exchange by May 2, 2024, as amended, then the amount of prefunded warrants and common warrants that would otherwise be issuable in connection with the PIPE SPA specific to these advances shall be increased by twenty-five percent.

As of May 9, 2024, the Company had not been approved to be listed on a qualifying national exchange, had not repaid any advances, and had not received notice from any investors to receive pre-funded warrants and common warrants in lieu of prepayment.

From April 12, 2024 through May 1, 2024, the Company raised an additional \$600,000 in shareholder advances from five investors. Such amounts are expected to be exchanged into a new senior secured note with 20% OID. Upon closing, all prior shareholder advances are expected to be applied toward or exchanged into the new senior note with a maturity date of June 30, 2024.

In May 2024, the Company issued its convertible notes payable totaling \$2,220,000, in exchange for cash of \$1,850,000, net of original issue discount of \$370,000. The convertible notes payable are secured by the Company’s tangible and intangible assets, bears interest at a rate of 10% per annum, convertible to common stock at a conversion price of \$0.50 per share and will mature on June 30, 2024. In addition, upon the closing of a transaction that results in the uplist of the Company’s common stock to a National Exchange, 100% of the then outstanding principal amount shall automatically convert into shares of common stock at a conversion price of \$0.515625 per share, subject beneficial ownership limitation.

On June 12, 2024, the Company completed a second closing of its convertible notes payable totaling \$180,000, in exchange for cash of \$150,000, net of original issue discount of \$30,000. All other terms were identical to the convertible notes payable issued by the Company in May 2024.

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PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

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

Item 13. Other Expenses of Issuance and Distribution.

The estimated expenses payable by us in connection with the offering described in this registration statement (other than the underwriting discount and commissions) will be as follows:

EXPENSE	AMOUNT
SEC/FINRA Expenses	\$ 9,881
Nasdaq listing and filing fees	\$ 50,000
Reimbursement to underwriters for expenses	\$ 150,000
Legal fees and expenses	\$ 400,000
Accounting fees and expenses	\$ 60,000
Printing and engraving expenses	\$ 100,000
Miscellaneous expenses	\$ 5,119
	<u>\$ 775,000</u>

Item 14. Indemnification of Directors and Officers.

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

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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.

Uplist PIPE

On November 8, 2023, the Company and certain institutional and accredited individual investors (collectively, the "**PIPE Investors**") entered into a Securities Purchase Agreement, as subsequently amended on June 19, 2024 (as amended, the "**PIPE SPA**"), pursuant to which the Company has agreed to issue and sell to the PIPE Investors, and the PIPE Investors have agreed to purchase from the Company, an aggregate of (i) warrants (the "**PIPE Pre-Funded Warrants**") to purchase an aggregate of 1,430,650 shares of Common Stock (the "**PIPE Pre-Funded Warrant Shares**") and (ii) warrants (the "**PIPE Investor Warrants**") and together with the PIPE Pre-Funded Warrants, the "**PIPE Warrants**") to purchase an aggregate 1,430,650 shares of Common Stock (the "**PIPE Investor Warrant Shares**") and together with the PIPE Pre-Funded Warrant Share, the "**PIPE Warrant Shares**"), at a purchase price of \$4.124 per PIPE Pre-Funded Warrant to purchase one share of Common Stock and accompanying PIPE Investor Warrant to purchase one share of Common Stock, for aggregate gross proceeds of \$5.9 million, before deducting the placement agent's fees and estimated offering expenses, and expected net proceeds of \$5.4 million after deducting the placement agent's fees and estimated offering expenses payable by the Company. The PIPE Pre-Funded Warrants and PIPE Investor Warrants will be issued as part of a private placement offering authorized by the Company's board of directors (the "**Uplist PIPE**"). The Company currently intends to use the net proceeds it receives from the Uplist PIPE for product marketing and for general working capital purposes. The purpose of the Uplist PIPE is mainly to assist the Company in meeting the initial listing requirements of Cboe, including for purposes of the minimum stockholders' equity requirement and the requirement of the Company to achieve its listing in connection with a firm commitment underwritten public offering.

Between December 13, 2023 and March 28, 2024, certain of the PIPE Investors advanced the Company an aggregate of \$1.25 million as partial prepayment of their respective purchase price under the PIPE SPA, which funds were advanced outside of the escrow provided for in the PIPE SPA, and which funds have been available to the Company in support of its operations (the "**PIPE Advances**"). On May 15, 2024, the 2024 Notes Investors (as defined below) purchased an aggregate of \$2,220,000 in principal amount of 2024 Notes (as defined below) for an aggregate purchase price of \$1,850,000, which amount was paid through the surrender and cancellation of the PIPE Advances by the 2024 Notes Investors and an incremental amount of \$600,000 in cash. Under the PIPE SPA, a PIPE Investor's obligation to purchase PIPE Pre-Funded Warrants and PIPE Investor Warrants is reduced by the purchase price paid by such PIPE Investor for 2024 Notes under the 2024 Notes SPA (as defined below). Accordingly, it is currently anticipated that PIPE Pre-Funded Warrants to purchase an aggregate of 982,056 shares of Common Stock and PIPE Investor Warrants to purchase an aggregate of 982,056 shares of Common Stock will be issued in the Uplist PIPE, for gross proceeds of \$4,050,000, and expected net proceeds of \$3,528,000, while the \$2,220,000 in principal amount of 2024 Notes will automatically convert at the closing of the Primary Offering into (i) 2024 Note Conversion Pre-Funded Warrants to purchase an aggregate of 538,182 shares of Common Stock and (ii) 2024 Note Uplist Conversion Warrants to purchase an aggregate of 538,182 shares of Common Stock, reflecting a net addition for the benefit of the PIPE Investors that are 2024 Notes Investors of an aggregate of 89,700 shares underlying the 2024 Note Conversion Pre-Funded Warrants and 2024 Note Uplist Conversion Warrants, respectively, that is the result of the premium of the principal amount of \$2,220,000 of the 2024 Notes over their purchase price of \$1,850,000 (which purchase price, as stated above, has reduced the aggregate purchase price of the securities sold in the PIPE SPA).

The closing of the Uplist PIPE is contingent upon, among other conditions, the registration statement of which this prospectus forms a part being declared effective by the SEC and the approval of the listing of the Common Stock on any securities exchange registered with the SEC as a "national securities exchange" under Section 6 of the Exchange Act (a "**National Exchange**"), and the closing is expected to occur immediately prior to the pricing of the Primary Offering.

The Company retained Dawson James Securities, Inc. ("**DJ**"), pursuant to a placement agency agreement, dated November 8, 2023, as placement agent in connection with the Uplist PIPE. The Company will pay DJ a cash fee equal to 8.0% of the aggregate gross proceeds of the Uplist PIPE (expected to be \$472,000), will reimburse DJ for legal and other expenses of up to \$150,000 and will issue to DJ, or its designees, warrants (the "**PIPE Placement Agent Warrants**") to purchase an aggregate of 71,533 shares of Common Stock. The PIPE Placement Agent Warrants will be exercisable at any time and from time to time, in whole or in part, during the five-year period commencing upon

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PIPE Pre-Funded Warrants

The PIPE Pre-Funded Warrants (i) will have a nominal exercise price of \$0.001 per share; (ii) will be exercisable immediately upon issuance; (iii) will be exercisable until all of the PIPE Pre-Funded Warrants are exercised in full; and (iv) will have a provision preventing the exercisability of such PIPE Pre-Funded Warrants if, as a result of the exercise of the PIPE Pre-Funded Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder's, would be deemed to beneficially own more than either 4.99% or 9.99% of the Common Stock (the "**Ownership Limitation**") immediately after giving effect to the exercise of the PIPE Pre-Funded Warrants.

PIPE Investor Warrants

The PIPE Investor Warrants (i) will have an exercise price of \$4.00 per share; (ii) will have a term of exercise equal to 5 years after their issuance date; (iii) will be exercisable immediately upon issuance; and (iv) will have a provision preventing the exercisability of such PIPE Investor Warrants if, as a result of the exercise of the PIPE Investor Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder's, would be deemed to beneficially own more than the Ownership Limitation immediately after giving effect to the exercise of the PIPE Investor Warrants.

Pursuant to the PIPE SPA, the Company has agreed to file no later than sixty (60) days after the closing date of an offering conducted in conjunction with an uplist of the Common Stock to, and in compliance with the rules of, any National Exchange (the "**Uplist Transaction**"), which the Primary Offering is intended to be, a registration statement on Form S-4, or other appropriate form, registering the offer by the Company to exchange, on a one-for-one basis, all outstanding PIPE Investor Warrants, 2022 Warrants (as defined below), Uplist Conversion Warrants (as defined below) and Exchange Investor Warrants (as defined below) for newly issued warrants identical to the Investor Warrants being sold in the Primary Offering, which warrants are expected to be listed on Cboe under the symbol "ARTHW."

Registration Rights Agreement

The Company also entered into a registration rights agreement with the PIPE Investors dated November 8, 2023 (the "**PIPE Registration Rights Agreement**"), pursuant to which the Company is obligated, subject to certain conditions, to file with the SEC within the earlier of (i) the closing date of the Uplist Transaction and (ii) the 60th calendar day following the date of the PIPE Registration Rights Agreement one or more registration statements to register the PIPE Warrant Shares, the Uplist Conversion Warrant Shares (as defined below) and the 2022 Note Conversion Pre-Funded Warrant Shares (as defined below) for resale under the Securities Act of 1933, as amended (the "Securities Act"). The Company's failure to satisfy certain filing and effectiveness deadlines and certain other requirements set forth in the PIPE Registration Rights Agreement may subject the Company to payment of monetary penalties.

PIPE Advances

Under the terms of the PIPE Advances, since the Common Stock has not been approved for listing on the Nasdaq Capital Market by March 31, 2024, with respect to a portion of the PIPE Advances, or April 30, 2024, with respect to the remainder of the PIPE Advances, the Company has issued to the advancing parties (A) additional pre-funded warrants (the "**PIPE Advance Penalty Pre-Funded Warrants**") to purchase up to an aggregate of 75,776 shares of Common Stock (which represents a 25% addition) and (B) additional investor warrants (the "**PIPE Advance Penalty Common Warrants**") to purchase up to an aggregate of 75,776 shares of Common Stock. The Resale Prospectus currently covers the resale of the shares of Common Stock underlying the PIPE Advance Penalty Pre-Funded Warrants (the "**PIPE Advance Penalty Pre-Funded Warrant Shares**") and the PIPE Advance Penalty Common Warrants (the "**PIPE Advance Penalty Common Warrant Shares**").

Backstop Agreement

On June 19, 2024, certain of the PIPE Investors (the "**Backstop Buyers**") agreed that in the event that as of the close of business on the date that is 10 calendar days prior to the date that the Company reasonably expects the closing of the Uplist PIPE to occur (the "**Escrow Date**") there is not an amount of funds in escrow for the PIPE equal to \$5,900,000 less the aggregate purchase price paid for the 2024 Notes (the "**Escrow Minimum Amount**") (such circumstance, an "**Escrow Deficiency**"), then each of the Backstop Buyers will deposit in escrow the purchase price for a pro rata share of an amount, no greater than \$1,500,000, equal to (A) \$320,000 plus (B) (i) \$5,900,000, minus (ii) the amount of funds in escrow on the Escrow Date, minus (iii) the aggregate purchase price paid by PIPE Investors for the 2024 Notes (the "**Backstop Amount**") of additional PIPE Pre-Funded Warrants and PIPE Investor Warrants under the PIPE SPA (such agreement, the "**Backstop Agreement**"), and shall purchase such additional PIPE Pre-Funded Warrants and PIPE Investor Warrants at the Uplist PIPE closing. In consideration for the execution by the Backstop Buyers of the Backstop Agreement, the Company agreed to issue to the Backstop Buyers, as soon as practicable, pre-funded warrants (the "**Execution Backstop Pre-Funded Warrants**"), in form and substance substantially similar to the PIPE Pre-Funded Warrants, to purchase an aggregate of 225,000 shares of Common Stock. The Company also agreed to issue to the Backstop Buyers (i) additional pre-funded warrants (the "**Funding Backstop Pre-Funded Warrants**") and, together with the Execution Backstop Pre-Funded Warrants, the "**Backstop Pre-Funded Warrants**") to purchase an amount of shares of Common Stock equal to 0.5 shares per dollar of funding deposited under the Backstop Agreement, or up to an aggregate of 750,000 shares, and (ii) investor warrants (the "**Backstop Common Warrants**"), in form and substance substantially similar to the PIPE Investor Warrants, to purchase an amount of shares of Common Stock equal to 0.65 shares per dollar of funding deposited under the Backstop Agreement, or up to an aggregate of 975,000 shares. The Resale Prospectus currently covers the resale of the shares of Common Stock underlying the Backstop Pre-Funded Warrants (the "**Backstop Pre-Funded Warrant Shares**") and the Backstop Common Warrants (the "**Backstop Common Warrant Shares**").

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2024 Notes

On May 15, 2024, the Company entered into a Securities Purchase Agreement (the "**2024 Notes SPA**") with certain institutional and accredited individual investors who are also PIPE Investors (collectively, the "**2024 Notes Investors**") providing for the issuance and sale by the Company to the 2024 Notes Investors certain Secured Promissory Notes (each a "**2024 Note**" and collectively, the "**2024 Notes**") convertible into shares of Common Stock. On June 12, 2024, an additional investor, which is not a PIPE Investor (the "**Additional 2024 Notes Investor**") purchased 2024 Notes in the principal amount of \$180,000, including an original issue discount of \$30,000. The 2024 Notes were issued as part of a convertible notes offering authorized by the Company's board of directors (the "**2024 Notes Financing**").

In connection with the 2024 Notes Financing, the Company issued and sold to the 2024 Notes Investors and Additional 2024 Notes Investor the 2024 Notes in the aggregate principal amount of \$2,400,000, which includes an aggregate \$370,000 original issue discount in respect of the 2024 Notes. The aggregate net proceeds for the sale of the 2024 Notes was approximately \$2,000,000, after deducting issuance discounts. The closing of the sales of the 2024 Notes to the 2024 Notes Investors under the 2024 Notes SPA occurred on May 15, 2024 (the "**2024 Notes Closing Date**"). The Company is using the net proceeds from the 2024 Notes Financing primarily for working capital and general corporate purposes, and has not allocated specific amounts for any specific purposes.

The 2024 Notes become due and payable on June 30, 2024 (the "**2024 Notes Maturity Date**") and may be prepaid provided that an Event of Default (as defined therein) has not occurred. The 2024 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 their issuance date until the 2024 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 2024 Notes. Any amount of principal or interest on the 2024 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 “**Default Interest**”).

The 2024 Notes are convertible into an aggregate of 600,000 shares of Common Stock (such shares of Common Stock, the “**2024 Conversion Shares**”) at the option of each holder of the 2024 Notes from their issuance date at the 2024 Conversion Price (as defined below) through the later of (i) the 2024 Notes Maturity Date and (ii) the date of payment of the Default Amount (as defined in the 2024 Note); *provided, however*, the 2024 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 (the “**2024 Notes Ownership Limitation**”) immediately after giving effect to the conversion; and *provided further*, the holder, upon notice to the Company, may increase or decrease the 2024 Notes Ownership Limitation; *provided that* (i) the 2024 Notes 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 2024 Notes Ownership Limitation will not become effective until the 61st day after delivery of such waiver notice.

The initial conversion price of the 2024 Notes (the “**2024 Conversion Price**”) shall be equal to \$4.00 per share and may be reduced or increased proportionately as a result of any stock dividends, recapitalizations, reorganizations, and similar transactions. If the Company fails to deliver the shares of Common Stock issuable upon a conversion by the Deadline (as defined in the 2024 Notes), then the Company is obligated to pay such 2024 Note holder \$5,000 per day in cash for each day beyond the Deadline.

The 2024 Notes contain customary events of default, which include, among other things, (i) the Company’s failure to pay when due any principal or interest payment under the 2024 Notes; (ii) the insolvency of the Company; (iii) delisting of the Common Stock; (iv) the Company’s breach of any material covenant or other material term or condition under the 2024 Notes; and (v) the Company’s breach of any representations or warranties under the 2024 Notes which cannot be cured within five days. Further, Events of Default under the 2024 Notes also include (i) the unavailability of Rule 144 on or after six months from the Issue Date (as defined therein); (ii) the Company’s failure to deliver the shares of Common Stock to the 2024 Note holder upon exercise by such holder of its conversion rights under the 2024 Note; (iii) the Company’s 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) the Company’s failure to complete an uplist to a National Exchange by June 30, 2024.

Upon an Event of Default, the 2024 Notes shall become immediately due and payable and the Company shall pay to each 2024 Note holder an amount equal to 125% (the “**Default Premium**”) multiplied by the sum of the outstanding principal amount of the 2024 Notes plus any accrued and unpaid interest on the unpaid principal amount of the 2024 Notes to the date of payment, plus any Default Interest and any other amounts owed to the holder under the 2024 Notes 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 five percent (5%) to the Default Premium for each subsequent Event of Default. At the election of each 2024 Note holder, the Default Amount may be paid in cash or shares of Common Stock equal to the Default Amount divided by the 2024 Conversion Price at the time of payment.

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Upon the closing of an Uplist Transaction, which the Primary Offering is intended to be, 100% of the then outstanding principal amount of the 2024 Notes shall automatically convert (the “**2024 Notes Automatic Conversion**”) into shares of Common Stock (the “**2024 Notes Automatic Conversion Shares**”), with the conversion price for purposes of such 2024 Notes Automatic Conversion being \$4.125. Upon the 2024 Notes Automatic Conversion and to the extent that the beneficial ownership of a holder of 2024 Notes (a “**2024 Notes Holder**” and, all holders of 2024 Notes together, the “**2024 Notes Holders**”) would increase over the applicable 2024 Notes Ownership Limitation, the 2024 Notes Holder will receive pre-funded warrants (the “**2024 Note Conversion Pre-Funded Warrants**”), and the shares issuable upon exercise thereof, the “**2024 Note Conversion Pre-Funded Warrant Shares**”) in lieu of shares of Common Stock otherwise issuable to the 2024 Notes Holder in connection with the 2024 Notes Automatic Conversion, which 2024 Note Conversion Pre-Funded Warrants shall have an exercise price of \$0.001 per share, may be exercised on a cashless basis, shall be exercisable immediately upon issuance and shall contain a customary beneficial ownership limitation provision.

In addition, upon the 2024 Notes Automatic Conversion, the 2024 Notes Holder shall receive a warrant (the “**2024 Notes Uplist Conversion Warrant**”, and the shares issuable upon exercise thereof, the “**2024 Notes Uplist Conversion Warrant Shares**”) to purchase a number of shares of Common Stock equal to the number of shares of Common Stock (or shares of Common Stock underlying 2024 Note Conversion Pre-Funded Warrants, if any) issued upon the 2024 Notes Automatic Conversion. The 2024 Notes Uplist Conversion Warrant shall have an exercise price per share of \$4.00 and shall otherwise be identical to the PIPE Investor Warrants. The Company also agreed in the 2024 Notes to file no later than sixty (60) days after the closing of the Primary Offering a registration statement on Form S-4, or other appropriate form, registering the offer by the Company to exchange, on a one-for-one basis, all outstanding PIPE Investor Warrants, 2024 Notes Uplist Conversion Warrants and Exchange Investor Warrants for newly issued warrants identical to the Investor Warrants being sold in the Primary Offering, which warrants are expected to be listed on Cboe under the symbol “ARTHW.”

Registration Rights Agreement

On the 2024 Notes Closing Date, the Company entered into a Registration Rights Agreement with the 2024 Notes Investors (the “**2024 Notes Registration Rights Agreement**”), pursuant to which the Company is obligated, subject to certain conditions, to file with the Securities and Exchange Commission within 60 days after the 2024 Notes Closing Date one or more registration statements (any such registration statement, a “**2024 Notes Resale Registration Statement**”) to register the 2024 Conversion Shares for resale under the Securities Act. The Company’s failure to satisfy certain filing and effectiveness deadlines with respect to a 2024 Notes Resale Registration Statement and certain other requirements set forth in the 2024 Notes Registration Rights Agreement may subject the Company to payment of monetary penalties.

Security Agreement

In connection with the issuance of the 2024 Notes, the Company entered into a Security Agreement with the Collateral Agent (as defined therein) on behalf of the 2024 Notes Investors on the 2024 Notes Closing Date (the “**2024 Notes Security Agreement**”), pursuant to which the Company and each of its subsidiaries (together with any persons who execute a joinder to the 2024 Notes Security Agreement, the “**2024 Notes Debtors**”) provided as collateral to the 2024 Notes holders a security interest in, and a lien on, substantially all of the 2024 Notes Debtors. Upon an Event of Default under the 2024 Notes, each 2024 Notes holder may exercise its rights to the collateral pursuant to the terms of the 2024 Notes Security Agreement.

Accordingly, it is currently anticipated that at the closing of the Primary Offering: (i) (A) 2024 Note Conversion Pre-Funded Warrants with an exercise price of \$0.001 to purchase an aggregate of 538,182 shares of Common Stock and (B) 43,637 2024 Notes Automatic Conversion Shares will be issued upon the 2024 Note Automatic Conversion of the \$2,400,000 of principal amount outstanding under the 2024 Notes; and (ii) the 2024 Note Holders will be issued 2024 Note Uplist Conversion Warrants to purchase an aggregate of 581,819 shares of Common Stock. The expected allocation between shares of Common Stock and 2024 Note Conversion Pre-Funded Warrants in the previous sentence is only an initial estimate based on indications of interest and is subject to change based on the ultimate ownership of the 2024 Note Holders after the Uplist PIPE and the Primary Offering. The maximum number of shares of Common Stock and 2024 Note Conversion Pre-Funded Warrants that may be issued, individually and in the aggregate is 581,819.

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We are registering for resale by the selling shareholders named herein (i) up to 2,861,300 PIPE Warrant Shares, (ii) up to 75,776 PIPE Advance Penalty Pre-Funded Warrant Shares, (iii) up to 75,776 PIPE Advance Penalty Common Warrant Shares, (iv) up to 975,000 Backstop Pre-Funded Warrant Shares, (v) up to 975,000 Backstop Common Warrant Shares, (vi) up to 555,000 2024 Conversion Shares, (vii) up to 538,182 2024 Notes Automatic Conversion Shares, (viii) up to 538,182 2024 Note Conversion Pre-Funded Warrant Shares and (ix) up to 538,182 2024 Notes Uplist Conversion Warrant Shares.

Bridge Offering

Between July 7, 2023 and September 11, 2023, pursuant to a Securities Purchase Agreement dated July 7, 2023, as subsequently amended (the “**Bridge SPA**”), among the Company and certain institutional and accredited individual investors (collectively, the “**Bridge Investors**”) the Company issued and sold to the Bridge Investors an aggregate of (i) 418,051 shares (the “**Bridge Shares**”) of Common Stock; (ii) warrants (the “**Bridge Pre-Funded Warrants**”) to purchase an aggregate of 756,871 shares of Common Stock (the “**Bridge Pre-Funded Warrant Shares**”); and (iii) warrants (the “**Common Warrants**”) and together with the Bridge Pre-Funded Warrants, the “**Bridge Warrants**”) to purchase an aggregate 2,349,826 shares of Common Stock (the “**Common Warrant Shares**”) and together with the Bridge Pre-Funded Warrant Share, the “**Bridge Warrant Shares**”), at a purchase price of \$2.20 per Bridge Share and accompanying Common Warrant to purchase two shares of Common Stock, and \$2.192 per Bridge Pre-Funded Warrant to purchase one share of Common Stock and accompanying Common Warrant to purchase two shares of Common Stock. The Bridge Shares, Bridge Pre-Funded Warrants, and Common Warrants were issued as part of a private placement offering authorized by the Company’s board of directors (the “**Bridge Offering**”).

Pursuant to the Bridge SPA, the Bridge Investors agreed not to sell or otherwise transfer any of the Bridge Shares or Bridge Warrant Shares prior to the one-year anniversary of the Bridge Closing Date. In the event that a Bridge Investor purchases securities in connection with an Uplist Transaction, which the Primary Offering is intended to be, and/or in the Uplist PIPE, with an aggregate purchase price equal to at least 4.3 multiplied by the aggregate purchase price paid by the Bridge Investor for the Bridge Shares and Bridge Warrants under the Bridge SPA, the one-year lock-up period will no longer apply to the Bridge Shares and Bridge Warrants. The aggregate gross proceeds for the sale of the Bridge Shares, Bridge Pre-Funded Warrants, and Common Warrants was approximately \$2.6 million, before deducting the placement agent’s fees and other estimated fees and offering expenses payable by the Company. The first closing of the sales of these securities under the Bridge SPA occurred on July 7, 2023 (the “**Bridge Closing Date**”).

Under the Bridge SPA, the Company also agreed that upon the closing of the next underwritten public offering of Common Stock (a “**Qualifying Offering**”), which the Company agreed is the Primary Offering, if the effective offering price to the public per share of Common Stock (the “**Qualifying Offering Price**”) is lower than \$32.00 per share, then the Company shall issue additional Bridge Pre-Funded Warrants (the “**True-Up Pre-Funded Warrants**”), and the shares issuable upon exercise thereof, the “**True-Up Pre-Funded Warrant Shares**”), or shares of Common Stock (the “**True-Up Shares**”) in lieu thereof to the extent necessary to cause the Company to meet the listing requirements of the Company’s proposed trading market in the Uplist Transaction, in an amount reflecting a reduction in the purchase price paid for the Bridge Shares and Bridge Pre-Funded Warrants that equals the proportion by which the Qualifying Offering Price is less than \$32.00. The Company also agreed that the Qualifying Offering Price as a result of the Primary Offering is \$4.00. **Accordingly, at the closing of the Primary Offering, based on the sale of the Units and Pre-Funded Units at an assumed public offering price of \$4.125 per Unit and \$4.124 per Pre-Funded Unit, which represents the minimum bid price of \$4.00 per share under the initial listing requirements of Cboe in Cboe Listing Rule 14.9(b) plus a value of \$0.125 attributed to the accompanying Investor Warrant, the Company expects to issue (i) True-Up Pre-Funded Warrants with an exercise price of \$0.001 to purchase an aggregate of 6,330,422 shares of Common Stock and (ii) an aggregate of 1,893,919 True-Up Shares to the Bridge Investors.** The expected allocation between True-Up Shares and True-Up Pre-Funded Warrants in the previous sentence is only an initial estimate based on indications of interest and is subject to change based on the ultimate ownership of the Bridge Investors after the Uplist PIPE and the Primary Offering. The maximum amount of True-Up Pre-Funded Warrants and True-Up Shares that may be issued, individually and in the aggregate is 8,224,341.

The Company retained DJ as placement agent in connection with the Bridge Offering. Pursuant to an engagement agreement, the Company paid DJ a cash fee equal to 8.0% of the aggregate gross proceeds of the Bridge Offering and reimbursement of expenses of \$50,000. Additionally, on September 7, 2023 the Company issued to DJ, or its designees, warrants, as subsequently amended (the “**Bridge Placement Agent Warrants**”) to purchase an aggregate of 55,242 shares of Common Stock (the “**Bridge Placement Agent Warrant Shares**”). The Bridge Placement Agent Warrants are exercisable at any time and from time to time, in whole or in part, until September 7, 2028, at a price per share equal to \$2.20 (which will increase to \$5.15625 at the closing of the Uplist Transaction, representing 125% of the assumed price per share of Common Stock in the Uplist Transaction, as required by FINRA).

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Bridge Pre-Funded Warrants

The Bridge Pre-Funded Warrants (i) have a nominal exercise price of \$0.008 per share; (ii) are exercisable after the earlier of (A) the six-month anniversary after the date of issuance, (B) 120 days after the closing date of an Uplist Transaction, and (C) the date that a registration statement registering the Bridge Pre-Funded Warrant Shares is declared effective; (iii) are exercisable until all of the Bridge Pre-Funded Warrants are exercised in full; and (iv) have a provision preventing the exercisability of such Bridge Pre-Funded Warrants if, as a result of the exercise of the Bridge Pre-Funded Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than the Ownership Limitation immediately after giving effect to the exercise of the Bridge Pre-Funded Warrants.

Common Warrants

The Common Warrants (i) have an exercise price of \$8.00 per share; (ii) have a term of exercise equal to 5 years after their issuance date; (iii) are exercisable after the earlier of (A) the six-month anniversary after the date of issuance and (B) the date that a registration statement registering the Common Warrant Shares is declared effective; (iv) have a provision permitting voluntary adjustments to the exercise price by the Company, subject to the prior written consent of the Common Warrant holder; (v) are automatically exchanged upon the closing of an Uplist Transaction for a new warrant that is identical to the warrants (other than any pre-funded warrants), if any, being issued to investors in such Uplist Transaction, with the number of shares underlying such new warrant being equal to the number of Common Warrant Shares then underlying the Common Warrant multiplied by three and (vi) have a provision preventing the exercisability of such Common Warrants if, as a result of the exercise of the Common Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of Company Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than the Ownership Limitation immediately after giving effect to the exercise of the Common Warrants. **Accordingly, at the closing of the Primary Offering, the Common Warrants will be cancelled and exchanged for newly issued warrants (the “Exchange Investor Warrants”) identical to the Investor Warrants to purchase an aggregate of 7,049,478 shares of Common Stock (the “Exchange Investor Warrant Shares”) at an exercise price per share equal to the exercise price per share of the Investor Warrants.**

In addition, as noted above, pursuant to the PIPE SPA, the Company has agreed to file no later than sixty (60) days after the closing date of the Uplist Transaction, a registration statement on Form S-4, or other appropriate form, registering the offer by the Company to exchange, on a one-for-one basis, all outstanding Exchange Investor Warrants for newly issued warrants identical to the Investor Warrants being sold in the Primary Offering, which warrants are expected to be listed on Cboe under the symbol “ARTHW.”

Registration Rights Agreement

The Company also entered into a registration rights agreement with the Bridge Investors dated July 7, 2023, as subsequently amended (the “**Registration Rights Agreement**”), pursuant to which the Company is obligated, subject to certain conditions, to file with the SEC within the earlier of (i) 30 days following the closing date of the Uplist Transaction and (ii) January 31, 2024 one or more registration statements (any such registration statement, a “**Resale Registration Statement**”) to register the Bridge Shares, the Bridge Warrant Shares and the Exchange Investor Warrant Shares for resale under the Securities Act of 1933, as amended (the “**Securities Act**”). The Company’s failure to satisfy certain filing and effectiveness deadlines with respect to a Resale Registration Statement and certain other requirements set forth in the Registration Rights Agreement may subject the Company to payment of monetary penalties.

We are registering for resale by the selling shareholders named herein (i) 384,159 Bridge Shares (which is less than the 418,051 total Bridge Shares originally issued because a former stockholder exchanged 33,892 Bridge Shares for a near equivalent amount of Legacy Pre-Funded Warrants, as discuss below), (ii) up to 8,224,341 True-Up Shares, (iii) up to 8,224,341 True-Up Pre-Funded Warrant Shares and (iii) up to 3,106,697 Bridge Warrant Shares.

2022 Private Placement Financing

On July 7, 2022, the Company announced that it had entered into a Securities Purchase Agreement, as subsequently amended (the “**2022 SPA**”) with certain institutional and accredited individual investors (collectively, the “**2022 Investors**”) providing for the issuance and sale by the Company to the 2022 Investors of (i) Senior Secured Convertible Promissory Notes (the “**First Notes**”); (ii) warrants (the “**First Warrants**”) to purchase 53,195 shares of Common Stock (the “**First Warrant Shares**”); and (iii) 7,980 shares

of Common Stock (the “**First Inducement Shares**”), equal to 15% of the principal amount of the Senior Secured Convertible Promissory Notes divided by the closing price of the Common Stock immediately prior to the First Closing Date (as defined below). The securities were issued as part of a convertible note offering authorized by the Company’s board of directors (the “**2022 Private Placement Financing**”). The first closing of the sales of these securities under the 2022 SPA (the “**First Closing**”) occurred on July 6, 2022 (the “**First Closing Date**”). The Company retained Maxim Group LLC (“**Maxim**”) as placement agent in connection with the First Closing. Pursuant to an engagement agreement the Company entered into with Maxim (the “**2022 Engagement Letter**”), that we entered into with Maxim, we agreed, among other things, to (i) pay Maxim 10% of the gross proceeds in the First Closing from certain institutional investors, or \$240,000, and (ii) issue Maxim, or its designees, warrants (“**First Placement Agent Warrants**”) to purchase up to 10% of the aggregate number of shares sold to the institutional investors in the First Closing, or warrants to purchase up to 3,939 shares of Common Stock.

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On January 18, 2023, the Company entered into Amendment No. 1 to the 2022 SPA (the “**Amendment**”), with certain Investors in connection with the second closing of the 2022 Private Placement Financing (the “**Second Closing**”) for the issuance and sale by the Company to such Investors of an aggregate of (i) Unsecured Convertible Promissory Notes (each a “**Second Note**” and collectively, the “**Second Notes**”) in the aggregate principal amount of \$636,000, which includes an aggregate \$106,000 original issue discount in respect of the Second Notes; (ii) warrants (the “**Second Warrants**”) to purchase an aggregate of 15,996 shares of Common Stock at an exercise price of \$79.52 (which will automatically change to \$4.00 as of the closing of the Uplist PIPE through the operation of the Most Favored Nation Provision) per share (the “**Second Warrant Shares**”); and (iii) 1,200 shares of Common Stock (the “**Second Inducement Shares**”). The aggregate gross proceeds for the sale of the Second Notes, Second Warrants, and Second Inducement Shares was approximately \$530,000, before deducting the placement agent’s fees and other estimated fees and offering expenses payable by the Company of approximately \$15,000. The Second Closing of the sales of these securities under the 2022 SPA, as amended, occurred on January 18, 2023 (the “**Second Closing Date**”). The Company retained Maxim as placement agent in connection with the private placement of \$500,000 of the Second Notes to the institutional investors. Pursuant to the 2022 Engagement Letter, the Company agreed, among other things, to (i) pay Maxim 10% of the gross proceeds in the Second Closing of the 2022 Private Placement Financing from the institutional investors, or \$50,000, and (ii) issue to Maxim, or its designees, warrants (the “**2022 Placement Agent Warrants**”) to purchase up to 10% of the aggregate number of shares sold to the institutional investors in the Second Closing of the Convertible Notes Offering, or warrants to purchase up to 821 shares of Common Stock at a price per share equal to \$80.48 (which will automatically change to \$4.00 as of the closing of the Uplist PIPE through the operation of the Most Favored Nation Provision) (the “**2022 Placement Agent Warrant Shares**”).

On May 15, 2023, the Company entered into Amendment No. 2 to the 2022 SPA related to the 2022 Private Placement Financing (the “**Second Amendment**”) with an Investor in connection with the third closing of the 2022 Private Placement Financing (the “**Third Closing**”) for the issuance and sale by the Company to an Investor of an aggregate of (i) Unsecured Convertible Promissory Notes (each a “**Third Note**” and collectively, the “**Third Notes**”) in the aggregate principal amount of \$703,000, which includes an aggregate \$215,000 original issue discount in respect of the Third Notes; (ii) warrants (the “**Third Warrants**”) to purchase an aggregate of 17,675 shares of Common Stock at an exercise price of \$79.52 (which will automatically change to \$4.00 as of the closing of the Uplist PIPE through the operation of the Most Favored Nation Provision) per share (the “**Third Warrant Shares**”); and (iii) 1,326 shares of Common Stock (the “**Third Inducement Shares**” and together with the Second Inducement Shares, the “**2022 Inducement Shares**”). The aggregate gross proceeds for the sale of the Third Notes, Third Warrants, and Third Inducement Shares was approximately \$488,000, before deducting any estimated fees and offering expenses payable by the Company. The Company did not engage a placement agent in connection with the issuance of the Third Notes, Third Warrants, and Third Inducement Shares. The Third Closing of the sales of these securities under the 2022 SPA, as amended, occurred on May 15, 2023 (the “**Third Closing Date**”).

On March 12, 2024, the Company entered into Amendment No. 3 to the 2022 SPA (the “**Third Amendment**”), with certain Investors in connection with the fourth closing of the 2022 Private Placement Financing (the “**Fourth Closing**”) for the issuance and sale by the Company to such Investors of an aggregate of (i) Unsecured Convertible Promissory Notes (each a “**Fourth Note**” and collectively, the “**Fourth Notes**”) in the aggregate principal amount of \$648,000, which includes an aggregate \$108,000 original issue discount in respect of the Fourth Notes; (ii) Warrants (the “**Fourth Warrants**”) to purchase an aggregate of 16,298 shares (the “**Fourth Warrant Shares**”) and, together with the Second Warrant Shares and Third Warrant Shares, the “**2022 Warrant Shares**”) at an exercise price of \$79.52 (which will automatically change to \$4.00 as of the closing of the Uplist PIPE through the operation of the Most Favored Nation Provision) per share of Common Stock; and (iii) Pre-Funded Warrants (the “**Inducement Pre-Funded Warrants**”) to purchase an aggregate of 1,223 shares of Common Stock (the “**Inducement Pre-Funded Warrant Shares**”) at an exercise price of \$0.008 per share, in lieu of shares of Common Stock otherwise issuable under the 2022 SPA. The aggregate net proceeds for the sale of the Fourth Notes, Fourth Warrants and Inducement Pre-Funded Warrants was approximately \$450,000, after deducting issuance discounts. The fourth closing of the sales of these securities under the 2022 SPA occurred on March 12, 2024 (the “**Fourth Closing Date**”).

2022 Notes

The First Notes, Second Notes, Third Notes and Fourth Notes (collectively, the “**2022 Notes**”) bear interest on the unpaid principal balance at a rate equal to ten percent (10%) (computed on the basis of the actual number of days elapsed in a 360-day year) per annum accruing from the issuance date until the 2022 Notes become due and payable at maturity or upon their conversion, acceleration or by prepayment, and may become due and payable upon the occurrence of an event of default under the 2022 Notes. The 2022 Notes mature on June 30, 2024. Any amount of principal or interest on the 2022 Notes that is not paid when due shall bear interest at the rate of the lesser of (i) eighteen percent (18%) per annum or (ii) the maximum amount allowed by law from the due date thereof until payment in full.

The 2022 Notes are convertible into shares of Common Stock at the option of each Holder from the date of issuance at \$73.12 (which will automatically change to \$4.00 as of the closing of the Uplist PIPE through the operation of the Most Favored Nation Provision) (the “**Conversion Price**”), subject to adjustment, through the later of (i) June 30, 2024 (the “**Maturity Date**”) or (ii) the date of payment of the Default Amount (as defined in the 2022 Notes).

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The 2022 Notes contain events of default, which include, among other things, (i) the Company’s failure to pay when due any principal or interest payment under the 2022 Notes; (ii) our failure to complete an Uplist Transaction by June 30, 2024 and (iii) our default on the Uplist Conversion Warrant Exchange Offer Obligation (as defined below).

The First Warrants, Second Warrants, Third Warrants and Fourth Warrants (collectively, the “**2022 Warrants**”) (i) have an exercise price of \$79.52 (which will automatically change to \$4.00 as of the closing of the Uplist PIPE through the operation of the Most Favored Nation Provision) per share; (ii) have a term of exercise equal to 5 years after their issuance date; (iii) became exercisable immediately after their issuance; and (iv) have a provision preventing the exercisability of such 2022 Warrants if, as a result of the exercise of the 2022 Warrants, the holder, together with its affiliates and any other persons whose beneficial ownership of our Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than the Ownership Limitation. Pursuant to the “**Most Favored Nation Provision**” contained in the 2022 Notes and the 2022 Warrants, as long as the 2022 Notes and 2022 Warrants remain outstanding, upon the issuance of any security in connection with any potential future financing activity on terms more favorable than the existing terms, the Company has an obligation to notify the holders of the 2022 Notes and 2022 Warrants of such more favorable terms, and to use best efforts to effect such terms in the 2022 Notes and 2022 Warrants.

Note Modification Agreements

On April 30, 2024, the Company entered into (i) an amendment (“**Amendment No. 16 to the First Notes**”) with the holders of the First Notes, (ii) an amendment (“**Amendment No. 16 to the Second Notes**”) with the holders of the Second Notes, (iii) an amendment (“**Amendment No. 11 to the Third Notes**”) with the holders of the Third Notes and (iv) an amendment (“**Amendment No. 2 to the Fourth Notes**”) and, together with Amendment No. 16 to the First Notes, Amendment No. 16 to the Second Notes and Amendment No. 11 to the Third Notes, the “**Amendments to the 2022 Notes**”).

Under the Amendments to the 2022 Notes, the following amendments to the 2022 Notes will be simultaneously effective upon the closing of the Uplist Transaction. 95% of the

then outstanding principal amount of the 2022 Notes shall automatically convert (the “**Automatic Conversion**”) into shares of Common Stock (the “**Automatic Conversion Shares**”), with the conversion price for purposes of such Automatic Conversion being \$4.00. Upon the Automatic Conversion and to the extent that the beneficial ownership of a holder of 2022 Notes (a “**Holder**” and, all holders of 2022 Notes together, the “**Holders**”) would increase over the applicable Ownership Limitation, the Holder will receive pre-funded warrants (the “**2022 Note Conversion Pre-Funded Warrants**”, and the shares issuable upon exercise thereof, the “**2022 Note Conversion Pre-Funded Warrant Shares**”) in lieu of shares of Common Stock otherwise issuable to the Holder in connection with the Automatic Conversion, which 2022 Note Conversion Pre-Funded Warrants shall have an exercise price of \$0.001 per share, may be exercised on a cashless basis, shall be exercisable immediately upon issuance and shall contain a customary beneficial ownership limitation provision.

In addition, upon the Automatic Conversion, the Holder shall receive a warrant (the “**Uplist Conversion Warrant**”, and the shares issuable upon exercise thereof, the “**Uplist Conversion Warrant Shares**”) to purchase a number of shares of Common Stock equal to 10 times the dollar amount under the 2022 Notes that was converted in the Automatic Conversion. The Uplist Conversion Warrant shall have an exercise price per share of \$4.00 and shall otherwise be identical to the PIPE Investor Warrants. The Company also agreed in the Amendments to the 2022 Notes to file no later than sixty (60) days after the closing of the Uplist Transaction a registration statement on Form S-4, or other appropriate form, registering the offer by the Company to exchange, on a one-for-one basis, all outstanding PIPE Investor Warrants, 2022 Warrants, Uplist Conversion Warrants and Exchange Investor Warrants for newly issued warrants identical to the Investor Warrants being sold in the Uplist Transaction, which warrants are expected to be listed on Cboe under the symbol “ARTHW” (the “**Uplist Conversion Warrants Exchange Offer Obligation**”).

The Amendments to the 2022 Notes also prohibit the Company from engaging in any capital raising transactions, subject to certain exceptions, until the earlier of (A) July 7, 2027, and (B) the first date on which all Holders hold less than 20% of the original amount of the Uplist Conversion Warrants received by each Holder, respectively, in connection with the Automatic Conversion.

Accordingly, it is currently anticipated that at the closing of the Primary Offering: (i) an aggregate of (A) 1,454,034 shares of Common Stock and (B) 2022 Note Conversion Pre-Funded Warrants with an exercise price of \$0.001 to purchase an aggregate of 184,296 shares of Common Stock will be issued upon the Automatic Conversion of an aggregate of \$6,553,310 of principal amount under the 2022 Notes, representing 95% of the \$6,898,221 in principal amount currently outstanding as of May 15, 2024 under the 2022 Notes, based on the assumed exercise price of the Investor Warrants being offered as part of the Units and Pre-Funded Units in the Primary Offering of \$4.00 per share; and (ii) the Holders will be issued Uplist Conversion Warrants to purchase an aggregate of 65,533,100 shares of Common Stock, representing 10 multiplied by the \$6,553,310 of principal amount converted in the Automatic Conversion. The expected allocation between shares of Common Stock and 2022 Note Conversion Pre-Funded Warrants in the previous sentence is only an initial estimate based on indications of interest and is subject to change based on the ultimate ownership of the Holders after the Uplist PIPE and the Primary Offering. The maximum number of shares of Common Stock and 2022 Note Conversion Pre-Funded Warrants that may be issued, individually and in the aggregate is 1,638,330.

Additionally, on July 7, 2023, the Company entered into an amendment (the “**Omnibus Amendment to Notes and Warrants**”) with the Holders of the 2022 Notes, amending the 2022 Notes and 2022 Warrants. Under the Omnibus Amendment to Notes and Warrants, the 2022 Notes and 2022 Warrants were amended to modify the Most Favored Nation provisions therein to exclude the Bridge Offering.

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Under the registration rights agreement, dated as of March 12, 2024, as amended, (as amended, the “**Third Amended and Restated Registration Rights Agreement**”) the Company is required to file a registration statement registering the securities issued in the Second Closing, Third Closing and Fourth Closing, including the applicable 2022 Notes and 2022 Warrants, no later than 45 days following the closing of the Uplist Transaction. Due to the operation of the Most Favored Nation Provision, the number of Conversion Shares underlying the First Notes will increase due to the Uplist PIPE, and thus we are also registering for resale the Conversion Shares underlying the First Notes.

We are registering for resale by the selling shareholders named herein (i) up to 1,724,557 Conversion Shares, (ii) up to 1,638,330 Automatic Conversion Shares; (iii) up to 1,638,330 2022 Note Conversion Pre-Funded Warrant Shares; (iv) 730 2022 Inducement Shares; (v) up to 1,223 Inducement Pre-Funded Warrant Shares; (vi) up to 49,971 2022 Warrant Shares; (vii) up to 65,533,100 Uplist Conversion Warrant Shares; and (viii) up to 821 2022 Placement Agent Warrant Shares.

Legacy Pre-Funded Warrants

During March 2024, one of the selling shareholders acquired pre-funded warrants (the “**Legacy Pre-Funded Warrants**”) to purchase an aggregate of 37,510 shares (the “**Legacy Pre-Funded Warrant Shares**”) of Common Stock, with an exercise price of \$0.008 per share, from a former stockholder of the Company. Some of the Legacy Pre-Funded Warrants were issued to such former stockholder in exchange for the surrender by the former stockholder to the Company of Bridge Shares, First Inducement Shares and 2022 Inducement Shares, previously held by such former stockholder. We are registering for resale by the selling shareholder named herein up to 37,510 Legacy Pre-Funded Warrant Shares.

All of the securities described thus far in this Item 15 were issued and sold (or are issuable) in reliance upon an exemption from registration afforded by Section 4(a)(2) of the Securities Act.

Series G and Series H Warrant Exchange

On March 10, 2023, we entered into Exchange Agreements with each of the holders of Series G Warrants and Series H Warrants, pursuant to which we exchanged 4,252 Series G Warrants for 425 shares of Common Stock and 5,385 Series H Warrants for 1,077 shares of Common Stock. The shares of Common Stock were issued in reliance upon an exemption from registration pursuant to Section 3(a)(9) of the Securities Act.

2021 Offering

On February 11, 2021, we entered into a Securities Purchase Agreement, or the 2021 SPA, with certain institutional and accredited investors providing for the issuance and sale of an aggregate of (i) 26,953 shares of our Common Stock (the “**2021 SPA Shares**”); and (ii) Series K Warrants to purchase an aggregate of 20,215 shares of Common Stock, at a combined offering price of \$256.00 per share and related Series K Warrant. The Series K Warrants (i) have an exercise price of \$272.00 per share; (ii) have a term of exercise equal to 5.5 years after their issuance date; (iii) were exercisable immediately after their issuance; and (iv) have a provision preventing the exercisability of such Series K Warrant if, as a result of the exercise of the Series K Warrant, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more the Ownership Limitation (all capitalized terms in this paragraph not otherwise defined to have the meaning ascribed to such terms in the 2021 SPA) immediately after giving effect to the exercise of the Series K Warrant. The holder, upon notice to the Company, may increase or decrease the Ownership Limitation; provided that (i) the Ownership Limitation may only be increased to a maximum of 9.99% of the outstanding shares of the Company’s Common Stock; and (ii) any increase in the Ownership Limitation will not become effective until the 61st day after delivery of such waiver notice. The number of shares of the Company’s Common Stock into which each of the Series K Warrants is exercisable and the exercise price therefor are subject to adjustment as set forth in the Series K Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise).

Pursuant to an engagement agreement that we entered into with H.C. Wainwright & Co., or the 2021 Placement Agent, we agreed, among other things, to issue the 2021 Placement Agent, or its designees, warrants to purchase up to 7.5% of the aggregate number of shares sold to investors in the 2021 Private Placement Financing, or warrants to purchase up to 2,022 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 \$320.00 per share.

The issuance and sale of the 2021 SPA Shares, Series K Warrants, 2021 Placement Agent Warrants, Exchanged Notes, and the shares of Common Stock issuable upon conversion of the Exchanged Notes and upon the exercise of the Series K Warrants and the 2021 Placement Agent Warrants were issued and sold in reliance upon an exemption from registration afforded by Section 4(a)(2) of the Securities Act and Rule 506(b) promulgated under Securities Act.

2020 Offering

On June 4, 2020 and June 22, 2020, we issued Series J Warrants to purchase up to an aggregate of 2,429 shares of Common Stock at an exercise price of \$400.00 per share to certain holders of our Series D Warrants as an inducement for those holders to exercise their Series D Warrants. The Series J Warrants were exercisable immediately upon their issuance and, as originally issued, had a term of exercise equal to one year after their issuance date; *however*, on November 6, 2020, the Series J Warrant to purchase up to 2,109 shares of Common Stock was amended to extend the term by an additional eighteen (18) months. The number of shares of our Common Stock into which each of the Series J Warrants were exercisable and the exercise price thereof were subject to adjustment as set forth in the Series J Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise). In addition, the Series J Warrants provided that they would not be exercisable in the event and to the extent that the exercise thereof would have resulted in the holder of the Series J Warrant, together with any person whose beneficial ownership would have been aggregated with the holder, beneficially owning more than 4.99% of the outstanding shares of our Common Stock; however, the holder could have increased such ownership limitation to 9.99% of the outstanding shares of our Common Stock, in which case the ownership limitation increase would have become effective 61 days after the holder requested such increase. In addition, each Series J Warrant provided the holder with “piggy back” registration rights under certain circumstances. The Series J Warrant and the shares of Common Stock issuable thereunder were issued and sold in reliance upon an exemption from registration afforded by Section 4(a)(2) of the Securities Act.

Series 1 and 2 Convertible Notes

On June 4, 2020 and November 6, 2020, the Company issued unsecured 10% Series 1 Convertible Notes (“**Series 1 Notes**”) and Series 2 Convertible Notes, as amended (“**Series 2 Notes**”, and collectively with the Series 1 Notes, the “**Series Convertible Notes**”). The maturity dates of the Series 1 Notes and Series 2 Notes are June 30, 2023 and November 30, 2023, respectively. On July 12, 2023, the Company secured countersigned notices of conversion from all remaining holders of the Series 1 Convertible Notes and provided instructions to its transfer agent to issue a total of 7,489 shares of Common Stock in full satisfaction of all previously outstanding Series 1 Convertible Notes, which had an aggregate of \$718,918 of principal and interest outstanding at the time of conversion.

On November 30, 2023, the Series 2 Notes of \$450,000 principal and outstanding accrued interest of \$137,946 were converted into 6,615 shares of Common Stock. The Series Convertible Notes, and the shares of Common Stock issued upon conversion thereunder were issued and sold in reliance upon an exemption from registration afforded by Section 4(a)(2) of the Securities Act.

Item 16. Exhibits and Financial Statement Schedules

Exhibits

EXHIBIT INDEX

Exhibit No.	Exhibit Title	Filed Herewith	Incorporated By Reference			
			Form	Exhibit No.	File No.	Filing Date
1.1*	Form of Underwriting Agreement					
1.2*	Form of Warrant Agency 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
3.3	Amendment No. 1 to the Amended and Restated Bylaws, as adopted on July 18, 2023		8-K	3.1	000-54986	7/24/2023
4.1	Description of Securities		10-K	4.1	000-54986	12/11/2020
4.2*	Form of Investor Warrant					
4.3*	Form of Pre-Funded Warrant					
4.4	Form of Bridge Pre-Funded Warrant		10-Q	4.1	000-54986	8/11/2023
4.5	Form of Bridge Common Warrant		10-Q	4.2	000-54986	8/11/2023
4.6	Form of Bridge Placement Agent Warrant		8-K	4.3	000-54986	09/07/2023
4.7*	Form of PIPE Pre-Funded Warrant					
4.8*	Form of PIPE Investor Warrant					
4.9*	Form of PIPE Placement Agent Warrant					
4.10*	Form of True-Up Pre-Funded Warrant					
4.11*	Form of 2022 Note Conversion Pre-Funded Warrant					
4.12*	Form of Uplist Conversion Warrant					
4.13*	Form of Exchange Investor Warrant					
5.1**	Opinion of McDonald Carano LLP					

5.2**	Opinion of Lowenstein Sandler LLP				
10.1#	Executive Employment Agreement dated June 26, 2013 between Arch Therapeutics, Inc. and Terrence W. Norchi	8-K	10.8	333-178883	6/26/2013
10.2#	First Amendment to Executive Employment Agreement, dated March 23, 2014, by and between Arch Therapeutics, Inc. and Terrence W. Norchi Stock	8-K	10.1	000-54986	3/27/2014
10.3#	Arch Therapeutics, Inc. 2013 Stock Incentive Plan	8-K	10.1	333-178883	6/24/2013

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10.4#	Form of Stock Option Award Agreement under Arch Therapeutics, Inc. 2013 Stock Incentive Plan	10-Q	10.13	000-54986	8/14/2013
10.5#	Form of Restricted Stock Unit Award Agreement under Arch Therapeutics, Inc. 2013 Stock Incentive Plan	10-Q	10.14	000-54986	8/14/2013
10.6#	Form of Restricted Stock Bonus Award Agreement under Arch Therapeutics, Inc. 2013 Stock Incentive Plan	10-Q	10.15	000-54986	8/14/2013
10.7#	Form of Restricted Stock Award Agreement	8-K	10.2	000-54986	5/6/2016
10.8	Amended and Restated Exclusive Patent License Agreement dated May 23, 2011 between ABS and the Massachusetts Institute of Technology, as amended by the First Amendment to Amended and Restated Exclusive Patent License Agreement dated May 15, 2012 between ABS and the Massachusetts Institute of Technology, and further amended by the Second Amendment to Amended and Restated Exclusive Patent License Agreement dated February 1, 2013 between ABS and the Massachusetts Institute of Technology, as further amended by the Third Amendment to Amended and Restated Exclusive Patent License Agreement dated April 30, 2013 between ABS and the Massachusetts Institute of Technology, and as further amended by the Letter Agreement dated June 10, 2013 between ABS and the Massachusetts Institute of Technology	8-K	10.6	333-178883	6/26/2013
10.9	Form of Warrant to Purchase Shares of Common Stock dated September 30, 2013 issued by Arch Therapeutics, Inc. to the Massachusetts Life Sciences Center ((included as Exhibit B in Exhibit 10.22)	8-K	10.2	000-54986	10/4/2013
10.10	Form of MLSC Subordination Agreement	8-K	10.1	000-54986	09/09/2013
10.11	Amendment Agreement to Arch Therapeutics, Inc. Accelerator Funding Agreement dated September 28, 2016 by and between Arch Therapeutics, Inc. and Massachusetts Life Sciences Center	8-K	10.1	000-54986	09/29/2016
10.12	Form of Subscription Agreement	8-K	10.1	000-54986	3/13/2015
10.13†	Project Agreement by and between Arch Therapeutics, Inc. and the National University of Ireland Galway dated May 28, 2015	8-K	10.1	000-54986	08/07/2015
10.14	2018 Securities Purchase Agreement	8-K	10.1	000-54986	06/29/2018
10.15	Form of Series G Warrants	8-K	10.2	000-54986	06/29/2018

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10.16#	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 I Convertible Notes	8-K	10.3	000-54986	06/05/2020
10.25.1	Form of Amendment No. 1 to Series I Notes, dated March 10, 2023	8-K	10.6	000-54986	03/17/2023

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
10.27.1	Form of Amendment No. 1 to Series 2 Notes, dated March 10, 2023	8-K	10.7	000-54986	03/17/2023
10.28	Form of 2021 Securities Purchase Agreement	8-K	10.1	000-54986	02/12/2021
10.29	Form of Series K Warrant	8-K	10.2	000-54986	02/12/2021
10.30	2021 Engagement Agreement	8-K	10.3	000-54986	02/12/2021
10.31	Form of 2021 Placement Agent Warrant	8-K	10.4	000-54986	02/12/2021
10.32	Form of Registration Rights Agreement	8-K	10.5	000-54986	02/12/2021

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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	05/3/2021
10.34	Employment Agreement, effective June 30, 2021, by and between Arch Therapeutics, Inc. and Dan M. Yrigoyen	8-K	10.1	000-54986	08/11/2021
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	08/11/2021
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	07/8/2022
10.37	Form of First Notes	8-K	10.2	000-54986	07/8/2022
10.37.1	Form of First Notes Amendment	8-K	10.1	000-54986	02/16/2023
10.37.2	Form of Amendment No. 2 to First Notes, dated March 10, 2023	8-K	10.2	000-54986	03/17/2023
10.37.3	Form of Amendment No. 3 to First Notes, dated March 15, 2023	8-K	10.4	000-54986	03/17/2023
10.37.4	Form of Amendment No. 4 to First Notes, dated April 15, 2023	8-K	10.1	000-54986	04/20/2023
10.37.5	Form of Amendment No. 5 to First Notes	10-Q	10.5	000-54986	05/23/2023
10.37.6	Form of Amendment No. 6 to First Notes, dated June 15, 2023	8-K	10.1	000-54986	06/22/2023
10.37.7	Form of Amendment No. 7 to First Notes, dated July 1, 2023	8-K	10.1	000-54986	07/07/2023
10.37.8	Form of Amendment No. 8 to First Notes	10-Q	10.17	000-54986	08/11/2023
10.37.9	Form of Amendment No. 9 to First Notes, dated July 31, 2023	8-K	10.1	000-54986	08/4/2023
10.37.10	Form of Amendment No. 10 to First Notes, dated August 30, 2023	8-K	10.1	000-54986	09/06/2023
10.37.11	Form of Amendment No. 11 to First Notes, dated September 30, 2023	8-K	10.1	000-54986	10/04/2023
10.37.12*	Form of Amendment No. 12 to First Notes				
10.37.13	Form of Amendment No. 13 to the First Notes, dated November 21, 2023	8-K	10.1	000-54986	11/22/2023
10.37.14	Form of Amendment No. 14 to the First Notes, dated January 5, 2024.	8-K	10.1	000-54986	1/11/2024
10.37.15	Form of Amendment No. 15 to the First Notes	8-K	10.4	000-54986	3/18/2024
10.37.16	Form of Amendment No. 16 to the First Notes	8-K	10.3	000-54986	5/6/2024
10.38	Form of First Warrant	8-K	10.3	000-54986	07/08/2022
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	07/08/2022
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	07/08/2022

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10.41	Form of Second Note	8-K	10.2	000-54986	01/20/2023
10.41.1	Form of Second Note Amendment	8-K	10.2	000-54986	02/16/2023
10.41.2	Form of Amendment No. 2 to Second Notes, dated March 10, 2023	8-K	10.3	000-54986	03/17/2023

10.41.3	Form of Amendment No. 3 to Second Notes, dated March 15, 2023	8-K	10.5	000-54986	03/17/2023
10.41.4	Form of Amendment No. 4 to Second Notes, dated April 15, 2023	8-K	10.2	000-54986	04/20/2023
10.41.5	Form of Amendment No. 5 to Second Notes	10-Q	10.6	000-54986	05/23/2023
10.41.6	Form of Amendment No. 6 to Second Notes, dated June 15, 2023	8-K	10.2	000-54986	06/22/2023
10.41.7	Form of Amendment No. 7 to Second Notes, dated July 1, 2023	8-K	10.2	000-54986	07/07/2023
10.41.8	Form of Amendment No. 8 to Second Notes	10-Q	10.18	000-54986	08/11/2023
10.41.9	Form of Amendment No. 9 to Second Notes, dated July 31, 2023	8-K	10.2	000-54986	08/4/2023
10.41.10	Form of Amendment No. 10 to Second Notes, dated August 30, 2023	8-K	10.2	000-54986	09/06/2023
10.41.11	Form of Amendment No. 11 to Second Notes, dated September 30, 2023	8-K	10.2	000-54986	10/04/2023
10.41.12*	Form of Amendment No. 12 to Second Notes				
10.41.13	Form of Amendment No. 13 to the Second Notes, dated November 21, 2023	8-K	10.2	000-54986	11/22/2023
10.41.14	Form of Amendment No. 14 to the Second Notes, dated January 5, 2024.	8-K	10.2	000-54986	1/11/2024
10.41.15	Form of Amendment No. 15 to the Second Notes	8-K	10.5	000-54986	3/18/2024
10.41.16	Form of Amendment No. 16 to the Second Notes	8-K	10.4	000-54986	5/6/2024
10.42	Form of Second Warrant	8-K	10.3	000-54986	01/20/2023
10.43	Form of Amended and Restated Registration Rights Agreement, dated January 18, 2023, by and among the Company and the signatories thereto	8-K	10.4	000-54986	01/20/2023
10.43.1	Form of Amendment No. 1 to the A&R Registration Rights Agreement	8-K	10.3	000-54986	04/20/2023
10.44^	Form of Amendment No. 1 to Securities Purchase Agreement, dated January 18, 2023, by and among the Company and the signatories thereto	8-K	10.1	000-54986	01/20/2023
10.45^	Form of Amendment No. 2 to Securities Purchase Agreement, dated May 15, 2023, by and among the Company and the signatories thereto	10-Q	10.1	000-54986	05/23/2023
10.46	Form of Exchange Agreement, dated March 10, 2023	8-K	10.1	000-54986	03/17/2023

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10.47	Form of Third Note	10-Q	10.2	000-54986	05/23/2023
10.47.1	Form of Amendment No. 1 to Third Notes, dated June 15, 2023	8-K	10.3	000-54986	06/22/2023
10.47.2	Form of Amendment No. 2 to Third Notes, dated July 1, 2023	8-K	10.3	000-54986	07/07/2023
10.47.3	Form of Amendment No. 3 to Third Notes	10-Q	10.19	000-54986	08/11/2023
10.47.4	Form of Amendment No. 4 to Third Notes, dated July 31, 2023	8-K	10.3	000-54986	08/04/2023
10.47.5	Form of Amendment No. 5 to Third Notes, dated August 30, 2023	8-K	10.3	000-54986	09/06/2023
10.47.6	Form of Amendment No. 6 to Third Notes, dated September 30, 2023	8-K	10.3	000-54986	10/04/2023
10.47.7*	Form of Amendment No. 7 to Third Notes				
10.47.8	Form of Amendment No. 8 to the Third Notes, dated November 21, 2023	8-K	10.3	000-54986	11/22/2023
10.47.9	Form of Amendment No. 9 to the Third Notes, dated January 5, 2024.	8-K	10.3	000-54986	1/11/2024
10.47.10	Form of Amendment No. 10 to the Third Notes	8-K	10.6	000-54986	3/18/2024
10.47.11	Form of Amendment No. 11 to the Third Notes	8-K	10.5	000-54986	5/6/2024
10.48	Form of Third Warrant	10-Q	10.3	000-54986	05/23/2023
10.49	Form of Second A&R Registration Rights Agreement	10-Q	10.4	000-54986	05/23/2023
10.49.1	Form of Amendment No. 1 to Second A&R Registration Rights Agreement	8-K	10.4	000-54986	09/06/2023
10.49.2*	Form of Amendment No. 2 to Second A&R Registration Rights Agreement				
10.49.3	Form of Amendment No. 3 to Second A&R Registration Rights Agreement	8-K	10.4	000-54986	11/22/2023
10.50#	Arch Therapeutics, Inc. Amended and Restated 2023 Omnibus Equity Incentive Plan	8-K	10.1	000-54986	08/23/2023
10.51	Form of Omnibus Amendment to Notes and Warrants	10-Q	10.20	000-54986	08/11/2023

10.52^	Form of Securities Purchase Agreement, dated July 7, 2023, by and among the Company and the signatories thereto	10-Q	10.24	000-54986	08/11/2023
10.52.1	Form of Amendment No. 1 to Securities Purchase Agreement	8-K	10.5	000-54986	09/06/2023
10.52.2*	Form of Amendment No. 2 to Securities Purchase Agreement				
10.52.3	Form of Amendment No. 3 to Securities Purchase Agreement	8-K	10.1	000-54986	3/18/2024

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10.53	Form of Registration Rights Agreement, dated July 7, 2023, by and among the Company and the signatories thereto	10-Q	10.25	000-54986	08/11/2023
10.53.1	Form of Amendment No. 1 to Registration Rights Agreement	10-K	10.6	000-54986	09/06/2023
10.53.2*	Form of Amendment No. 2 to Registration Rights Agreement				
10.53.3	Form of Amendment No. 3 to the Bridge Registration Rights Agreement	8-K	10.5	000-54986	11/22/2023
10.53.4	Form of Amendment No. 4 to Registration Rights Agreement	8-K	10.2	000-54986	5/6/2024
10.54*	Form of PIPE Securities Purchase Agreement				
10.55*	Form of PIPE Registration Rights Agreement				
10.56*	PIPE Placement Agency Agreement				
10.57*	Form of Bridge Lock-Up Agreement				
10.58	Form of Fourth Warrant	8-K	4.1	000-54986	3/18/2024
10.59	Form of Third A&R Registration Rights Agreement	8-K	10.2	000-54986	3/18/2024
10.60	Form of Fourth Note	8-K	10.3	000-54986	3/18/2024
10.61.1	Form of Amendment No. 1 to the Fourth Notes	8-K	10.7	000-54986	3/18/2024
10.61.2	Form of Amendment No. 2 to the Fourth Notes	8-K	10.6	000-54986	5/6/2024
10.62	Form of Amendment No. 1 to Third A&R Registration Rights Agreement	8-K	10.1	000-54986	5/6/2024
10.63	Form of Securities Purchase Agreement	8-K	10.1	000-54986	5/21/2024
10.64	Form of 2024 Note	8-K	10.2	000-54986	5/21/2024
10.65	Form of Registration Rights Agreement	8-K	10.3	000-54986	5/21/2024
10.66	Form of Security Agreement	8-K	10.4	000-54986	5/21/2024
10.67	Form of IP Security Agreement	8-K	10.5	000-54986	5/21/2024
21.1	List of Subsidiaries	8-K	21.1	333-178883	06/26/2013
23.1	Consent of Baker Tilly US, LLP, Independent Registered Public Accounting Firm				X
23.2	Consent of Weinberg & Company, P.A.				X
23.3**	Consent of McDonald Carano LLP (included in Exhibit 5.1)				
23.4**	Consent of Lowenstein Sandler LLP (included in Exhibit 5.2)				
24.1*	Power of Attorney	S-1	24.1	333-268008	10/26/2022
101.INS	Inline XBRL Instance Document				
101.SCH	Inline XBRL Taxonomy Extension Schema Document				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document and included in Exhibit 101)				
107	Filing fee table				X

* Previously filed.

** To be filed by amendment.

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

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

Management contract or compensatory plan or arrangement.

Financial Statement Schedules

All financial statement schedules are omitted because they are not applicable or the required information is shown in the consolidated financial statements or notes thereto.

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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.

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- (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.

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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 June 20, 2024.

Arch Therapeutics, Inc.

By: /s/ Terrence W. Norchi, MD
Terrence W. Norchi, MD
President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

<u>SIGNATURE</u>	<u>TITLE</u>	<u>DATE</u>
<u>/s/ Terrence W. Norchi, MD</u> Terrence W. Norchi, MD	President, Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	June 20, 2024
<u>/s/ Michael S. Abrams</u> Michael S. Abrams	Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	June 20, 2024
<u>*</u> Punit Dhillon	Director	June 20, 2024
<u>*</u> Guy Fish, MD	Director	June 20, 2024
<u>*</u> Laurence Hicks	Director	June 20, 2024
<u>*By: /s/ Terrence W. Norchi, Attorney-in-Fact</u>		

Consent of Independent Registered Public Accounting Firm

We consent to the use in this amendment to the Registration Statement (No. 333-268008) on Form S-1 of Arch Therapeutics, Inc and Subsidiary (collectively, the “Company”) of our report dated December 28, 2022, except for the effects of the 1-for-200 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 year ended September 30, 2022. Our report includes an explanatory paragraph relating to 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

June 20, 2024

Consent of Independent Registered Public Accounting Firm

We consent to the inclusion in this Registration Statement (Amendment No. 5 to Form S-1 No. 333-268008) of our report dated February 14, 2024, which includes an explanatory paragraph regarding the Company's ability to continue as a going concern, relating to the consolidated financial statements of Arch Therapeutics, Inc. and Subsidiary as of and for the year ended September 30, 2023. We also consent to the reference to our firm under the caption "Experts" in such Registration Statement and related Prospectus.

/s/ Weinberg & Company, P.A.

Los Angeles, California
June 20, 2024

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) (i) Common Stock, par value \$0.001 per share(4)	Rule 457(o)	—	—	\$ 4,600,000.00	0.0001476	\$ 678.96
Fees to Be Paid	Equity	(ii) one Investor Warrant to purchase one share of Common Stock(4)	—	—	—	—	—	—
Fees to Be Paid	Equity	Pre-Funded Units consisting of:(3)(6)	Rule 457(o)	—	—	—	0.0001476	—
Fees to Be Paid	Equity	(i) one Pre-Funded Warrant to purchase one share of Common Stock(4)	—	—	—	—	—	—
Fees to Be Paid	Equity	(ii) one Investor Warrant to purchase one share of Common Stock(4)	—	—	—	—	—	—
Fees to Be Paid	Equity	Common Stock issuable upon exercise of Pre-Funded Warrants (3)(5)	Rule 457(o)	—	—	—	0.0001476	—
Fees to Be Paid	Equity	Common Stock issuable upon exercise of the Investor Warrants(3)(5)	Rule 457(o)	—	—	\$ 4,600,000.00	0.0001476	\$ 678.96
Fees to Be Paid	Equity	Shares of Common Stock offered by the Selling Stockholders in the Resale Prospectus(7)	Rule 457(c)	98,444,466	\$ 1.09	\$ 107,304,468	0.0001476	\$ 15,838.14
Fees Previously Paid	—	—	—	—	—	—	—	\$ 22,934.78
Carry Forward Securities	—	—	—	—	—	—	—	—
Total Offering Amounts						\$ 116,504,468		\$ 17,196.06
Total Fees Previously Paid								\$ 22,934.78
Total Fee Offsets								\$ 0.00
Net Fee Due								\$ 0.00

- (1) Pursuant to Rule 416 under the Securities Act of 1933, as amended (the “**Securities Act**”), there is also being registered hereby such indeterminate number of additional shares of common stock, par value \$0.001 per share (the “**Common Stock**”), of Arch Therapeutics, Inc. (the “**Company**”), as may be issued or issuable because of stock splits, stock dividends stock distributions, and similar transactions.
- (2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act.
- (3) Includes any additional shares of Common Stock and/or warrants to purchase shares of Common Stock (the “**Investor Warrants**”) that may be issued upon exercise of the option granted to the underwriters to cover over-allotments, if any.
- (4) No separate registration fee is payable pursuant to Rule 457(g) under the Securities Act.
- (5) The Investor Warrants are exercisable at a per share price of 100% of the price per Unit in this offering.
- (6) The proposed maximum aggregate offering price of the Units will be reduced on a dollar-for-dollar basis based on the offering price of any Pre-Funded Units issued in the offering, and the proposed maximum aggregate offering price of the Pre-Funded Units to be issued in the offering will be reduced on a dollar-for-dollar basis based on the offering price of any Units issued in the offering. Accordingly, the proposed maximum aggregate offering price of the Units and Pre-Funded Units, if any, is \$4,600,000.
- (7) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act based on a per share price of \$1.09, the average of the high and low reported sales prices of the registrant’s common stock on the OTCQB on June 18, 2024.