

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

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended September 30, 2022

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 000-54986

ARCH THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of incorporation or organization)

46-0524102

(I.R.S. Employer Identification No.)

235 Walnut Street, Suite 6

Framingham, MA

(Address of principal executive offices)

01702

(Zip Code)

Registrant's telephone number, including area code **(617) 431-2313**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
N/A	N/A	N/A

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value \$0.001 per share  
(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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 13(a) of the Securities Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates as of the last business day of the registrant's most recently completed second fiscal quarter, computed by reference to the average of the bid and asked price of such common equity, was approximately \$22,000,000. For purposes of this calculation, it has been assumed that shares of common stock held by each director, each officer and each person who owns 10% or more of the registrant's outstanding common stock are held by affiliates.

As of December 28, 2022, 249,936,370 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None



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*This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements.* We make forward-looking statements, as defined by the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, as amended, and in some cases, you can identify these statements by forward-looking words 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 and other comparable terminology. Such forward-looking statements contained in this Form 10-K are based on various underlying assumptions and expectations and are subject to risks, uncertainties and other unknown factors, may include projections of our future financial performance based on our growth strategies and anticipated trends in our business and include risks and uncertainties relating to Arch's current cash position and its need to raise additional capital in order to be able to continue to fund its operations; the stockholder dilution that may result from future capital raising efforts and the exercise or conversion, as applicable of Arch's outstanding options and warrants; Arch's limited operating history which may make it difficult to evaluate Arch's business and future viability; Arch's ability to timely and successfully commercialize and generate revenues or profits from our anticipated products; Arch's ability to achieve and maintain regulatory approvals or marketing authorizations in the United States or elsewhere; Arch's ability to retain its managerial personnel and to attract additional personnel; the strength of Arch's intellectual property, the intellectual property of others and any asserted claims of infringement; and other risk factors identified in the documents Arch has filed, or will file with the Securities and Exchange Commission ("SEC"). Copies of Arch's filings with the SEC may be obtained from the SEC Internet site at <http://www.sec.gov>. We undertake no duty to update any of these forward-looking statements after the date of filing of this report to conform such forward-looking statements to actual results or revised expectations, except as otherwise required by law.

As used in this Annual Report unless otherwise indicated, the "Company", "we", "us", "our", and "Arch" refer to Arch Therapeutics, Inc. and its consolidated subsidiary, Arch Biosurgery, Inc.

*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 Annual Report are the property of their respective owners.*

## PART I

### ITEM 1. BUSINESS

*The following discussion should be read in conjunction with our consolidated financial statements and the related notes and other financial information included in this Annual Report.*

#### Corporate Overview

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

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

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

The Company expects to incur substantial expenses for the foreseeable future relating to research, development and commercialization of its potential 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.

#### Business Overview

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

#### Core Technology

Our flagship products and product candidates are derived from our AC5® self-assembling peptide (“SAP”) technology platform and are sometimes referred to as AC5® or the “AC5® Devices.” These include AC5® Advanced Wound System and AC5 Topical Hemostat, which have received marketing authorization as medical devices in the United States (“US”) and the Europe Union (“EU”), respectively, and which are intended for skin applications, such as management of complicated chronic wounds or acute surgical wounds. Other products are in development for use in minimally invasive or open surgical procedures and include, for example, AC5-G™ for gastrointestinal endoscopic procedures and AC5-V® and AC5® Surgical Hemostat for hemostasis inside the body, all of which are currently investigational devices limited by law to investigational use.

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

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

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

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

## Operations

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

Our long-term business plan includes the following goals:

- conducting biocompatibility, pre-clinical, and clinical studies on our products and product candidates;
- obtaining additional marketing authorization for products in the United States, Europe, and other jurisdictions as we may determine;
- continuing to develop third party relationships to manufacture, distribute, market and otherwise commercialize our products;
- continuing to develop academic, scientific and institutional relationships to collaborate on product research and development;
- expanding and maintaining protection of our intellectual property portfolio; and
- developing additional product candidates in Dermal Sciences, BioSurgery, and other areas.

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

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

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

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

Since inception, we have funded our operations primarily through debt borrowings, the issuance of convertible debt and the issuance of units consisting of Common Stock and warrants, and we may continue to seek to do so in the future. If we obtain additional financing by issuing equity securities, our existing stockholders’ ownership will be diluted. The terms of securities we may issue in future capital-raising transactions may be more favorable for our new investors. Further, newly issued securities may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have additional dilutive effects. If we obtain additional financing by incurring debt, we may become subject to significant limitations and restrictions on our operations pursuant to the terms of any loan or credit agreement governing the debt. Further, obtaining any loan, assuming a loan on acceptable terms would be available when needed, would increase our liabilities and future cash commitments. We may also seek funding from additional collaboration or licensing arrangements in the future, which may require that we relinquish potentially valuable rights to our product candidates or proprietary technologies or grant licenses on terms that are not favorable to us. Moreover, regardless of the manner in which we seek to raise capital, we may incur substantial costs in those pursuits, including investment-banking fees, legal fees, accounting fees, printing and distribution expenses and other related costs.

## Merger with ABS and Related Activities

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

## Recent Developments

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

On July 6, 2022 (the “Closing Date”), we entered into a Securities Purchase Agreement (the “SPA”) with certain institutional and accredited individual investors providing for the issuance and sale of an aggregate of (i) 12,766,600 of shares of common stock, par value \$0.001 per share, (ii) Senior Secured Convertible Promissory Notes (each a “2022 Note” and collectively, the “2022 Notes”) in the aggregate principal amount of \$4.23 million, which included an aggregate \$0.705 million original issue discount in respect of the 2022 Notes; (iii) warrants (the “2022 Warrants”) to purchase an aggregate of 85,110,664 shares of Common Stock (the “Warrant Shares”); and (iv) a warrant (the “Placement Agent Warrant”) to purchase 6,301,969 shares of Common Stock (the “Placement Agent Warrant Shares”) (collectively the “2022 Note Financing”). The 2022 Notes may be prepaid by the Company, in whole or in part, at any time with the written consent of the lead investor, with such prepayment amounts subject to adjustment as a result of certain time-based prepayment premiums set forth in the 2022 Notes; provided, that, the written consent of the lead investor is not required in connection with a prepayment made from the proceeds of an Uplist Transaction (as defined below). The 2022 Notes bear interest on the unpaid principal balance at a rate equal to ten percent (10%) (computed on the basis of the actual number of days elapsed in a 360-day year) per annum accruing from the Closing Date until the 2022 Notes become due and payable at maturity or upon their conversion, acceleration or by prepayment, and may become due and payable upon the occurrence of an event of default under the 2022 Notes. Any amount of principal or interest on the 2022 Notes which is not paid when due shall bear interest at the rate of the lesser of (i) eighteen percent (18%) per annum or (ii) the maximum amount allowed by law from the due date thereof until payment in full.

The 2022 Notes are convertible into shares of Common Stock at the option of each holder of the 2022 Notes from the date of issuance at \$0.0457 (the “Conversion Price”) through the later of (i) the Maturity Date and (ii) the date of payment of the Default Amount (as defined in the 2022 Note); *provided, however*, certain 2022 Notes include a provision preventing such conversion if, as a result, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than 4.99% of the Common Stock (as applicable, the “Ownership Limitation”) immediately after giving effect to the Conversion; and *provided further*, the holder, upon notice to us, may increase or decrease the Ownership Limitation; *provided that* (i) the Ownership Limitation may only be increased to a maximum of 9.99% of the Common Stock; and (ii) any increase in the Ownership Limitation will not become effective until the 61st day after delivery of such waiver notice. The Conversion Price is subject to adjustment as set forth in the 2022 Notes.

The 2022 Notes contain customary events of default, which include, among other things, (i) our failure to pay when due any principal or interest payment under the 2022 Notes; (ii) our insolvency; (iii) delisting of our Common Stock; (iv) our breach of any material covenant or other material term or condition under the 2022 Notes; and (v) our breach of any representations or warranties under the 2022 Notes which cannot be cured within five (5) days. Further, events of default under the 2022 Notes also include (i) the unavailability of Rule 144 on or after January 6, 2023; (ii) our failure to deliver the shares of Common Stock to the 2022 Note holder upon exercise by such holder of its conversion rights under the 2022 Note; (iii) our loss of the “bid” price for its Common Stock and/or a market and such loss is not cured during the specified cure periods; and (iv) our failure to complete an uplisting of our Common Stock to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American by February 15, 2023 (an “Uplist Transaction”).

The 2022 Warrants (i) have an exercise price of \$0.0497 per share; (ii) have a term of exercise equal to 5 years after their issuance date; (iii) became exercisable immediately after their issuance; and (iv) have a provision preventing the exercisability of such 2022 Warrant if, as a result of the exercise of the 2022 Warrant, the holder, together with its affiliates and any other persons whose beneficial ownership of our Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than the Ownership Limitation. The holder, upon notice to us, may increase or decrease the Ownership Limitation; provided that (i) the Ownership Limitation may only be increased to a maximum of 9.99% of our Common Stock; and (ii) any increase in the Ownership Limitation will not become effective until the 61st day after delivery of such waiver notice. The number of shares of Common Stock into which each of the 2022 Warrants is exercisable and the exercise price therefor are subject to adjustment as set forth in the 2022 Warrants, including 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 Maxim Group LLC (the “2022 Placement Agent”), we agreed, among other things, to (i) pay the 2022 Placement Agent 10% of the gross proceeds in the 2022 Placement Agent from certain institutional investors, or \$240,000, and (ii) issue the 2022 Placement Agent, or its designees, warrants to purchase up to 10% of the aggregate number of shares sold to the institutional investors in the 2022 Note Financing, or warrants to purchase up to 6,301,969 shares of Common Stock (the “2022 Placement Agent Warrants”). The 2022 Placement Agent Warrants have substantially the same terms as the 2022 Warrants, except that the exercise price of the 2022 Placement Agent Warrants is \$0.0503 per share and (ii) are not exercisable until six (6) months from the date of issuance. We also reimbursed the 2022 Placement Agent approximately \$58,000 for non-accountable banking fees, legal fees and other expenses.

On September 29, 2022, the Company held its annual meeting of stockholders (the “Annual Meeting”). The following matters were voted upon at the Annual Meeting: i) election of directors, ii) reverse stock split of not less than 1-for-100 and not greater than 1-for-200 at any time prior to September 29, 2023 with the exact timing and final ratio to be determined by the Board of Directors of the Company, iii) increase the number of authorized shares of Common Stock resulting following the consummation of the reverse stock split by three times, iv) advisory vote to approve executive compensation, v) advisory vote to approve the frequency of advisory votes on executive compensation, vi) authority to adjourn the meeting, and vii) ratification of Baker Tilly US, LLP as the Company’s independent auditors for the fiscal year ended September 30, 2022. In connection with proposal No.1, Dr. Terrence Norchi, Dr. Guy Fish, Punit Dhillon and Laurence Hicks were elected to serve on the board until the next annual meeting of stockholders by a plurality of votes cast. Proposal Nos. 2, 3, 4, 6, and 7 were approved. In connection with Proposal No. 5, stockholders voted to support an advisory vote on executive compensation every three years. The Company filed a Current Report on Form 8-K with detailed voting results, ratified by the inspector of the election, for all seven proposals on September 30, 2022.

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

## Research and Development

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

### *Preclinical Testing*

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

### *Clinical Testing*

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

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

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

### **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.

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

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

#### *Medical Device Classification in the United States and Europe*

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

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

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

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

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

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

- Class IIa, which are considered low-medium risk devices and require certification by a Notified Body (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.

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

### *U.S. Regulatory Marketing Authorization Process*

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

We believe that the products we are currently pursuing for internal use will require a PMA approval prior to commercialization. However, we are commercializing an initial product for external use that has been cleared through the 510(k) process. To obtain 510(k) marketing clearance for a medical device, an applicant must submit a premarket notification to the FDA demonstrating that the device is “substantially equivalent” to a predicate device or devices, which is typically a legally marketed Class II device in the 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 finding substantial equivalence. Depending upon a product’s underlying technology and intended use, as well as on FDA processes and procedures, seeking and obtaining a 510(k) marketing clearance can be a lengthy process.

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

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

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

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

### *European Union Marketing Authorization (CE Mark) Process*

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

While there are many similarities between the processes required to obtain marketing authorization in the 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 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. We, and the Notified Bodies who will oversee compliance to the new MDR, face uncertainties in the upcoming years as the MDR is rolled out and enforced, creating risks in several areas, including the CE mark process, data transparency and application review timetables.

#### *Post-Approval Regulation*

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

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

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

#### *Regulation by Other Foreign Agencies*

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

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

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

In line with plans to better harmonize our 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 for AC5 Topical Gel 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 to 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 its Notified Body seeking a CE mark. During August 2019, we received and responded to customary written and verbal questions related to the technical file, and that BSI had provided and assessed during the review period were acceptable so far. In that announcement, we further expressed our belief that the delay by the regulatory authority in completing the CE mark technical file review appeared to be due to a backlog of work for EU Notified Bodies related to both the United Kingdom's exit from the EU, and the implementation of the EU's new MDR.

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

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

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

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

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

Securing reimbursement for AC5 Advanced Wound System in ambulatory settings, such as doctor's offices, is an important part of our commercial strategy. Consequently, we applied to the Centers for Medicare and Medicaid Services ("CMS") for a dedicated Healthcare Common Procedure Coding System ("HCPCS") Level II billing code specific to AC5® Advanced Wound System on June 29, 2022, which if granted, would better enable providers to bill third party payors for AC5 that is used in doctors' offices. We believe that there is a growing trend toward the use of synthetic wound care products, including those that have been commonly referred to as synthetic skin substitutes.

A dedicated HCPCS code is an important step toward, although not a guarantee of, coverage and reimbursement, and it would enhance our ability to work directly with payors as we expand access in outpatient settings and continue to advocate for clinically appropriate usage of our technology for patients. A final decision, which we anticipate, but cannot guarantee, will be positive, is expected during the first calendar quarter of 2023 with a "go live" date of April 1, 2023. In the meantime, CMS has established a new and temporary coding option to facilitate the reimbursement of doctor's offices and wound clinics, and certain providers have begun to submit claims under this new code as we pursue a dedicated HCPCS code.

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

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

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

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

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

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

#### *The COVID-19 Pandemic Impact on Commercialization*

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

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

We believe that these challenges may present an opportunity for our new technology to address certain poorly met needs.

Wound interventions are too often considered to be elective procedures instead of being treated essentially or emergently as National Pressure Ulcer Advisory Panel guidelines and others recommend, resulting in a projected increased risk to limb and life while elective procedures are delayed and not prioritized. Furthermore, the implications of these delays are a growing backlog of chronic wounds awaiting care and a worsening of such wounds, leading to greater morbidity, such as infection, necrosis, and amputation, and potentially mortality.

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

## **Manufacturing**

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

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



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

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

## Industry and Competition

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

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

### *Dermal Sciences*

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

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

The incidence and prevalence of both acute surgical and chronic wounds is noteworthy. According to a 2020 report by Steiner et al for The Healthcare Cost and Utilization Project ([www.ncbi.nlm.nih.gov/books/NBK442035](http://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 additional greater challenges due to the prolonged duration of the healing period, the frequency of interventions needed to help the wound heal, and the often-underlying medical problem that placed the patient at risk for the wound in the first place, which is itself a hindrance to the healing process.

Chronic wounds affect approximately 2% of the United States Population, accounting for an estimated 6-7 million people ([https://www.facs.org/media/buthal55/nonhealing\\_wounds.pdf](https://www.facs.org/media/buthal55/nonhealing_wounds.pdf); [www.doi.org/10.1111/wrr.12994](http://www.doi.org/10.1111/wrr.12994); [www.doi.org/10.1186/s13643-016-0400-8](http://www.doi.org/10.1186/s13643-016-0400-8); [www.doi.org/10.19080/ARR.2020.06.555678](http://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](http://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](http://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](http://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](http://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](http://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](http://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](http://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](http://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 total Medicare alone spends 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](http://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, lessen expensive non-product-related treatment costs for insurers (e.g., skin grafts, dressing changes, etc.), and deliver improved outcomes more quickly and in lower acuity settings.

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

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

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

*BioSurgery*

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

While developing our products, we engaged commercial strategy and marketing consultants and communicated directly with care providers to understand the needs of potential customers and to assess product feature preferences. Surgeons, operating room managers, sales representatives and hospital decision-makers identified several characteristics deemed desirable, including that a product is:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

### **Other Governmental Regulations and Environmental Matters**

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

### **Intellectual Property**

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

As of November 7, 2022, we either own or license from others several U.S. patents, U.S. patent applications, foreign patents and foreign patent applications.

Six patent portfolios assigned to Arch Biosurgery, Inc. include a total of 55 patents and pending applications in a total of 22 jurisdictions, including eleven patents and pending applications in the US. These portfolios cover self-assembling peptides, formulations and methods of use thereof and self-assembling peptidomimetics and methods of use thereof, including eight issued US patents (US 9,415,084; US 9,162,005; US 9,789,157; US 9,821,022; US 9,339,476; US 10,314,886; US 10,682,386, and 10,869,907) that expire between 2026 and 2034 (absent patent term extension), as well as thirty-three patents that have been either allowed, issued or granted in foreign jurisdictions.

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

The two portfolios exclusively licensed from MIT include a total of 34 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 21 jurisdictions. The portfolios include five issued US patents (US 9,511,113; US 9,084,837; US 10,137,166; US 9,327,010; and US 9,364,513) that expire between 2026 and 2027 (absent patent term extension), as well as twenty-six patents that have been either allowed, issued or granted in foreign jurisdictions.

The three portfolios non-exclusively licensed from MIT include a number of US and foreign applications, including three issued US patents (US 7,846,891; US 7,713,923; and US 8,901,084) that expire not before 2024 (absent patent term extension), as well as four patents that have been either allowed, issued or granted in foreign jurisdictions.

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

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

## **Employees**

We presently have eight employees, all of whom are full-time, and make extensive use of third-party contractors, consultants, and advisors to perform many of our present activities. We expect to increase the number of our employees as we increase our operations.

## **ITEM 1A. RISK FACTORS**

*Investment in our Common Stock 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 before making an investment decision. If any of the following risks and uncertainties actually occur, our business, financial condition, and results of operations could be negatively impacted, and you could lose all or part of your investment.*

### **Risk Factor Summary**

- There is substantial doubt about our ability to continue as a going concern, and we believe that our current cash on hand will only meet our anticipated cash requirements into the second quarter of fiscal 2023.
- We have incurred significant losses since inception, we expect to continue to incur losses for the foreseeable future, and we may not generate sufficient revenue to achieve or maintain profitability.
- We will need to raise additional capital, which may not be available to us on acceptable terms, or at all. In addition, the terms of our previous financings could impose additional challenges on our ability to raise funding in the future.
- Our obligations under the 2022 Notes are secured by security interests in substantially all of our assets and our failure to comply with the terms and covenants of the 2022 Notes could result in our loss of substantially all of our assets.
- The 2022 Note holders have certain additional rights upon an event of default under such 2022 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 business may be materially adversely affected by the coronavirus (COVID-19) pandemic. Should the pandemic or its aftereffects continue, our business operations could and will likely be delayed or interrupted.
- If we do not receive a dedicated HCPCS code for AC5 Advanced Wound System or if private or government insurers elect to not reimburse providers at all or at lower than anticipated rates, our ability to commercialize the product will be significantly impaired; receipt of the dedicated HCPCS code is not a guarantee of product coverage and reimbursement.
- Applications for regulatory marketing authorization for commercialization of our 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 principal product and product candidates are inherently risky because they are based on novel technologies and thus create significant challenges with respect to product development and optimization, engineering, manufacturing, scale-up, quality systems, pre-clinical in vitro and in vivo testing, government regulation and approval, third-party reimbursement and market acceptance.
- Any changes in our supply chain, including to the third-party contract manufacturers, service providers, or other vendors, or in the processes that they employ, could adversely affect us.

- If the FDA or similar foreign agencies or intermediaries impose requirements or an alternative product classification 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 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 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.
- Any product for which we obtain required regulatory marketing authorization could be subject to post-approval regulation, and we may be subject to penalties if we fail to comply with such post-approval requirements.
- Use of third parties to manufacture our product 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 who 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.
- The market price of our Common Stock is and is expected to continue to be in the near term, less than \$5.00 per share and is therefore a “penny stock.” Brokers and dealers effecting transactions in “penny stock” must disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities.

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

#### **Risks Related to our Business, Financial Position and Capital Requirements**

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

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. As of December 28, 2022, we believe that our current cash will meet anticipated requirements into the second quarter of fiscal 2023 and we will need to raise additional capital before then.

During the first and second quarters of fiscal 2021 and the fourth fiscal quarter of 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 U.S. and Europe. Even with the additional funds received from these financings, there exists substantial doubt about our ability to continue as a going concern.



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

As noted above under the risk factor entitled “*There is substantial doubt about our ability to continue as a going concern,*” we have only recently commenced commercial sales of our first product, AC5® Advanced Wound System and we have incurred substantial net losses as a result. Consequently, we have incurred losses in each year since our inception and we expect that losses will continue to be incurred in the foreseeable future in the operation of our business. To date, we have financed our operations primarily through equity and debt investments by founders, other investors and third parties, and we expect to continue to rely on these sources of funding, to the extent available in the foreseeable future. Losses from operations have resulted principally from costs incurred in research and development programs and from general and administrative expenses, including significant costs associated with establishing and maintaining intellectual property rights, significant legal and accounting costs incurred in connection with both the closing of the Merger and complying with public company reporting and control obligations, and personnel expenses. 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 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.

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.

***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, as of December 28, 2022, we believe that our current cash on hand will meet our anticipated cash requirements into the second quarter of fiscal 2023. Notwithstanding that, depending upon additional input from EU and US regulatory authorities, we may need to raise additional capital before then. For example, on December 18, 2017, we voluntarily withdrew a 510(k) notification for AC5 Topical Gel 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. While on October 1, 2018, we announced that we both completed the necessary steps required to refile our 510(k) submission for AC5 Topical Gel and filed a 510(k) submission during the third calendar quarter of 2018, the resubmission process required us to expend a minimum of \$100,000 that we had not anticipated spending and delayed the clearance of our 510(k) submission.

During the first and second quarters of fiscal 2021 and the fourth quarter of fiscal 2022, we obtained additional cash to continue operations and fund our planned future operations, including the continuation of our ongoing research and development efforts, the licensing or acquisition of new assets, and researching and developing any potential patents, the related compounds and any further intellectual property that we may acquire. 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 commercialization efforts;
- the scope, progress and results of our research and development collaborations;
- the extent of potential direct or indirect grant funding for our research and development activities;
- the scope, progress, results, costs, timing and outcomes of any regulatory process and clinical trials conducted for any of our product candidates;
- the timing of entering into, and the terms of, any collaboration agreements with third parties relating to any of our product candidates;
- the timing of and the costs involved in obtaining regulatory marketing authorization for our product candidates;
- the costs of operating, expanding and enhancing our operations to support our clinical activities and, if our product candidates are approved, commercialization activities;
- the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities;
- the costs associated with maintaining and expanding our product pipeline;
- the costs associated with expanding our geographic focus;
- operating revenues, if any, received from sales of our product candidates, if any are approved by the FDA or other applicable regulatory agencies;
- the cost associated with being a public company, including obligations to regulatory agencies, and increased investor relations and corporate communications expenses; and
- the costs of additional general and administrative personnel, including accounting and finance, legal and human resources employees.

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

In addition, we are bound by certain contractual terms and obligations that may limit or otherwise impact our ability to raise additional funding in the near-term including, but not limited to, provisions in the 2018 SPA in connection with the 2018 Financing, and the SPA that we entered into in connection with the 2022 Note Financing, in each case as described in greater detail in the risk factor entitled **“The terms of the 2018 Financing and 2022 Note 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 2018 Financing and 2022 Note Financing could impose additional challenges on our ability to raise funding in the future.***

The 2018 SPA contains provisions that provide that until such time as the three lead investors in the 2018 Financing collectively own less than 20% of the warrants purchased by them pursuant to the 2018 SPA (“*Series G Warrants*”), the Company is prohibited from effecting or entering into an agreement to effect any issuance by the Company or its subsidiary of Common Stock or securities convertible, exercisable or exchangeable for Common Stock (or a combination of units thereof) involving a Variable Rate Transaction (as defined below) including, but not limited to, an equity line of credit or “At-the-Market” financing facility .

As of December 27, 2022, none of the lead investors for the 2018 Financing have exercised or transferred any of their Series G Warrants. As defined in the 2018 SPA, “*Variable Rate Transaction*” means a transaction in which the Company (a) issues or sells any debt or equity securities that are convertible into, exchangeable or exercisable for, or include the right to receive additional shares of Common Stock either (A) at a conversion price, exercise price or exchange rate or other price that is based upon and/or varies with the trading prices of or quotations for the shares of Common Stock at any time after the initial issuance of such debt or equity securities, or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such debt or equity security or upon the occurrence of specified or contingent events directly or indirectly related to the business of the Company or the market for the Common Stock (excluding adjustments under customary anti-dilution provisions) or (b) enters into, or effects a transaction under, any agreement, including, but not limited to, an equity line of credit, whereby the Company may issue securities at a future determined price. These provisions could make our securities less attractive to investors and could limit our ability to obtain adequate financing on a timely basis or on acceptable terms in the future, which could have significant harmful effects on our financial condition and business and could include substantial limitations on our ability to continue to conduct operations.

The SPA entered into in connection with the 2022 Note Financing contains certain restrictions on our ability to conduct subsequent sales of our equity securities and certain business activities. In particular, subject to certain customary exemptions, until 30 days after a resale registration statement goes effective, we are prohibited from filing any registration statement with respect to our Common Stock other than in respect to an offering conducted in conjunction with the uplisting of the Company’s Common Stock to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (an “*Uplist Transaction*”). Similarly, until January 6, 2023, we are prohibited from (i) changing the nature of business, (ii) selling, divesting, acquiring, or changing the structure of any material assets other than in the ordinary course of business; or (iii) negotiating or entering into any variable rate debt transactions that does not contain a floor price that is more than \$0.02485, or 50% the closing price of the Common Stock on the trading day immediately prior to the Closing Date; in each instance without each 2022 Note holder’s prior written consent, which shall not be unreasonably withheld.

In addition, under the 2022 Notes, we were restricted from consummating any capital raising transactions until October 4, 2022, except for the Uplist Transaction, without the lead investor’s consent.

***Our obligations under the 2022 Notes are secured by security interests in substantially all of our assets and our failure to comply with the terms and covenants of the 2022 Notes could result in our loss of substantially all of our assets.***

Our obligations under the 2022 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 2022 Notes, the 2022 Note holders could foreclose on the security interests and liquidate some or all of our assets, which would harm our business, financial condition and results of operations and could require us to reduce or cease operations.

In connection with the 2022 Note Financing, the 2022 Note holders were granted a security interest in substantially all of our assets pursuant to the terms of the Security Agreement. If we fail to make payments on the 2022 Notes when due or otherwise comply with the covenants contained in the 2022 Notes, the 2022 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.

The 2022 Notes contain customary events of default, which include, among other things, (i) our failure to pay when due any principal or interest payment under the 2022 Notes; (ii) our insolvency; (iii) delisting of our Common Stock; (iv) our breach of any material covenant or other material term or condition under the 2022 Notes; and (v) our breach of any representations or warranties under the 2022 Notes which cannot be cured within five (5) days. Further, events of default under the 2022 Notes also include (i) the unavailability of Rule 144 on or after 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 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 February 15, 2023.

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

Under the 2022 Notes, the holders have certain rights upon an event of default. Such rights include that, upon an event of default, the 2022 Notes will become immediately due and payable and we will be obligated to pay to each 2022 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 2022 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 SPA; *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 \$0.0457 (subject to adjustment as more specifically set forth in the 2022 Notes) at the time of payment.

In addition, the 2022 Notes are subject to prepayment penalties, subject to adjustment as a result of certain time-based prepayment premiums set forth in the 2022 Notes; provided, that, the written consent of the lead investor is not required in connection with a prepayment made from the proceeds of an Uplist Transaction. The 2022 Notes bear interest on the unpaid principal balance at a rate equal to ten percent (10%) (computed on the basis of the actual number of days elapsed in a 360-day year) per annum accruing from July 6, 2022 until the 2022 Notes become due and payable on January 6, 2024 or upon their conversion, acceleration or by prepayment. Any amount of principal or interest on the 2022 Notes which is not paid when due will bear interest at the 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.

***Our business may be materially adversely affected by the recent coronavirus (COVID-19) outbreak.***

COVID-19 is the disease caused by a coronavirus discovered in 2019 called SARS-CoV-2. It has evolved into a global pandemic, having spread to many regions of the world. The extent to which COVID-19 impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the COVID-19 and the actions to contain the COVID-19 or treat its impact, among others.

Should COVID-19 continue to spread, our business operations could and will likely be delayed or interrupted. For instance, clinical use may be delayed due to, among other items, availability of clinicians, follow-up by patients, availability of facility administrators to coordinate product evaluations and intake, and the inability to ship product to clinical sites. Site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis may be paused or delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. Some participants and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to conduct our clinical trials. Furthermore, if the spread of the COVID-19 pandemic continues and our operations are adversely impacted, we risk a delay, default and/or nonperformance under existing agreements which may increase our costs. These cost increases may not be fully recoverable or adequately covered by insurance.

Infections, deaths and resource constraints due to the pandemic have and may continue to disrupt the United States and/or other healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from evaluating and/or using our products, materially delay FDA and/or other regulatory agency review and/or approval with respect to our current and future preclinical development plans, clinical trials and requests for marketing authorizations. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could and will materially affect the development and study of our product candidates.

We currently utilize third parties to, among other things, manufacture raw materials. If any third-party involved in the production of our products, product candidates, or raw materials are adversely impacted by restrictions resulting from the COVID-19 outbreak, our supply chain may be disrupted, limiting our ability to manufacture products for research and development operations, clinical trials and, in the cases of AC5® Advanced Wound System and AC5 Topical Hemostat, commercialization.

Finally, while we believe that we currently have sufficient supply of our products to continue commercialization efforts, our products and product candidates or the materials contained therein (such as the Active Pharmaceutical Ingredients for our AC5 product line) are manufactured from facilities in areas impacted by the COVID-19, which could result in shortages due to ongoing efforts to address the outbreak. If any of the foregoing were to occur, it could materially adversely affect our future revenues, financial condition, profitability, and cash flows.

***In the event of a shelter-in-place order or other mandated local travel restrictions, our employees conducting research and development, or manufacturing activities may not be able to access their laboratory or manufacturing space, and our core activities may be significantly limited or curtailed, possibly for an extended period of time.***

The spread of COVID-19, which has had a broad negative global impact, including restrictions on travel and quarantine policies put into place by businesses and governments, may have a material economic effect on our business. This may also limit the ability of physicians to perform procedures in which our products could be used.

In addition, and as noted elsewhere, we believe that our current cash on hand will meet our anticipated cash requirements into the second quarter of fiscal 2023. Accordingly, while the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of COVID-19 could materially and adversely affect our business and the value of our common stock.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the situation closely.

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

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

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

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

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

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

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

***If we fail to maintain appropriate internal controls in the future, we may not be able to report our financial results accurately, which may adversely affect our stock price and our business.***

Our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and the related regulations regarding our required assessment of our internal controls over financial reporting requires the commitment of significant financial and managerial resources. Internal control over financial reporting has inherent limitations, including human error, the possibility that controls could be circumvented or become inadequate because of changed conditions, and fraud. If we are unable to maintain effective internal controls, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations as a publicly traded company or comply with the requirements of the SEC or the Sarbanes-Oxley Act of 2002. This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our stock, or investigation by regulatory authorities, all of which is exacerbated by the recent determination of a material weakness related to our internal controls over financial reporting as disclosed herein. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our stock and our business.

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

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

***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.

## 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 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 private managed care organizations and government payors and additional third-party payors. If we are unable to obtain adequate reimbursement from third-party payors, or acceptable prices, for AC5® Advanced Wound System, our revenues and prospects for profitability will suffer.***

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

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

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



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

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

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

On October 1, 2018 the Company announced that it submitted a 510(k) notification to the FDA for its AC5 Topical Gel (AC5) and received acknowledgement 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 US 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 or an alternative product classification 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 BSI, a Notified Body, confirming 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 US, 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 EU, 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 US, 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 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. We, and the Notified Bodies who will oversee compliance to the new MDR, face uncertainties in the upcoming years as the MDR is rolled out and enforced, creating risks in several areas, including the CE mark process, data transparency and application review timetables.

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

Our management has limited experience in conducting preclinical development activities and clinical trials. As a result, we have relied and will need to continue to rely on third-party research institutions, organizations and clinical investigators to conduct our preclinical and clinical trials and support our regulatory submissions. If we are unable to reach agreement with qualified research institutions, organizations and clinical investigators on acceptable terms, or if any resulting agreement is terminated prior to the completion of our clinical trials, then our product development efforts could be materially delayed or otherwise harmed. Further, our reliance on third parties to conduct our clinical trials and support our regulatory submissions will provide us with less control over the timing and cost of those trials, the ability to recruit suitable subjects to participate in the trials, and the timing, cost, and probability of success for the regulatory submissions. Moreover, the FDA and other regulatory authorities require that we comply with 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 products and 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 the Company has completed its 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 IRB or other applicable regulatory authorities find violations that require us to undertake corrective action, suspend or terminate one or more testing sites, or prohibit us from using some or all of the resulting data in support of our marketing applications with the FDA or other applicable agencies;
- manufacturing facilities of our third-party manufacturers are ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of cGMP or other applicable requirements;
- third-party contractors become debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements;

- the FDA or other regulatory authorities impose requirements on the design, structure or other features of the clinical trials for our product candidates that we and/or our third-party contractors are unable to satisfy;
- one or more IRB refuses to approve, suspends or terminates a trial at an investigational site, precludes enrollment of additional subjects, or withdraws its approval of the trial;
- the FDA or other regulatory authorities seek the advice of an advisory committee of physician and patient representatives that may view the risks of our product candidates as outweighing the benefits;
- the FDA or other regulatory authorities require us to expand the size and scope of the clinical trials, which we may not be able to do; or
- the FDA or other regulatory authorities impose prohibitive post-marketing restrictions on any of our product candidates that attain marketing authorization.

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

***We cannot market and sell any product candidate in the US 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 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 US 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 US for our lead product candidate for internal use will likely be classified as a Class III medical device and require the process of a 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 US, 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 commercialize 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 commercialize directly, such products' prospects will be harmed.

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

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

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

If any of our product candidates achieves 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 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 US. If we elect to expand our current relationships or seek additional collaborators in the future but are unable to reach agreements with such other collaborators, as applicable, then we may fail to meet our business objectives for the affected product or program. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement, and we may not be successful in our efforts, if any, to establish and implement additional collaborations or other alternative arrangements. The terms of any collaboration or other arrangements that we establish may not be favorable to us, and the success of any such collaboration will depend heavily on the efforts and activities of our collaborators. Any failure to engage successful collaborators could cause delays in our product development and/or commercialization efforts, which could harm our financial condition and operational results.

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

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

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

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

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

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

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

## Risks Related to our Intellectual Property

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

Our success will depend in large part on our ability to obtain and maintain protection in the US 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") 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, 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 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's decision is in relation to the granted European patent EP1879606 and the various national patents that are derived therefrom, and it has no legal significance outside of Europe except in Hong Kong. Further, we cannot be certain that we were the first to make the inventions claimed in the patents we own or license, or that protection of the inventions set forth in those patents was the first to be filed in the US. 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 US 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 US 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 November 7, 2022, we either own or license from others several US patents, US patent applications, foreign patents and foreign patent applications.

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

The two portfolios exclusively licensed from MIT include a total of 34 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 21 jurisdictions. The portfolios include five issued US patents (US 9,511,113; US 9,084,837; US 10,137,166; US 9,327,010; and US 9,364,513) that expire between 2026 and 2027 (absent patent term extension), as well as twenty-six patents that have been either allowed, issued or granted in foreign jurisdictions.

The three portfolios non-exclusively licensed from MIT include a number of US and foreign applications, including three issued US patents (US 7,846,891; US 7,713,923; and US 8,901,084) that expire not before 2024 (absent patent term extension), as well as four patents that have been 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 US 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**

***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.***

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.

Under the 2022 Notes, we are obligated to complete an Uplist Transaction by February 15, 2023. The Company has applied to be listed for quotation on the NASDAQ Capital Market. We do not currently meet the initial listing standards of such national securities exchanges. In the event we are unable to consummate an Uplist Transaction, 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 or that we will be able to comply with such applicable listing standards.

A more active market for our Common Stock may never develop. As a result, investors must bear the economic risk of holding their shares of our Common Stock for an indefinite period of time.

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

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

***Substantial future sales of shares of our Common Stock could cause the market price of our Common Stock to decline.***

A substantial portion of outstanding shares of our Common Stock has been registered for resale by the holders thereof. The resale, or expected or potential resale, of a substantial number of shares of our Common Stock in the public market could adversely affect the market price for our Common Stock and make it more difficult for you to sell shares of our Common Stock at times and prices that you feel are appropriate. Furthermore, we expect that selling stockholders holding shares that have been registered by us for resale will continue to offer such shares of our Common Stock for a significant period of time, the precise duration of which cannot be predicted. Accordingly, the adverse market and price pressures resulting from these sales may continue for an extended period of time and continued negative pressure on the market price of our Common Stock could have a material adverse effect on our ability to raise additional equity capital.

***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 August 19, 2022, our articles of incorporation authorize the issuance of up to 800,000,000 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. On September 29, 2022, the shareholders approved a reverse stock split between 1 for 100 and 1 for 200. Simultaneous with the reverse stock split the shareholders approved an increase in the number of authorized shares equal to 3 times the number of shares outstanding at such time.

In connection with the 2022 Note Financing, we issued to the investors in the 2022 Note Financing an aggregate of (i) 12,766,600 Inducement Shares; (ii) 92,560,174 Conversion Shares issuable upon conversion of the 2022 Notes issued in the 2022 Note Financing; (iii) 85,110,664 2022 Warrant Shares issuable upon exercise of the 2022 Warrants issued in the 2022 Note Financing at an exercise price of \$0.0497 per share; and (iv) 6,301,969 2022 Placement Agent Warrant Shares issuable upon exercise of the 2022 Placement Agent Warrants issued in the 2022 Note Financing at an exercise price of \$0.0503 per share. As of December 28, 2022, up to 92,560,174 Conversion Shares may be acquired upon the conversion of the 2022 Notes, up to 85,110,664 Warrant Shares may be acquired upon the exercise of the 2022 Warrants and up to 6,301,969 Placement Agent Warrant Shares may be acquired upon the exercise of the 2022 Placement Agent Warrants. As of December 28, 2022, there have been no conversions in connection with the 2022 Note Financing and none of the 2022 Warrants and 2022 Placement Agent Warrants have been exercised.

In connection with the financing that closed on February 11, 2021 (the “2021 Financing”), we issued to the investors in the 2021 Financing an aggregate of 43,125,004 shares of Common Stock and warrants to acquire up to an additional 32,343,754 shares of Common Stock at an exercise price of \$0.17 per share (“Series K Warrants”). In addition, we also issued designees of H.C. Wainwright (the “Placement Agent”), warrants to acquire up to 3,234,375 shares of Common Stock at an exercise price of \$0.20 per share (“2021 Placement Agent Warrants”). As of December 28, 2022, up to 32,343,754 shares may be acquired upon the exercise of the Series K Warrants and up to 3,234,375 shares may be acquired upon the exercise of the 2021 Placement Agent Warrants. See Note 9 to the Notes to the Consolidated Financial Statements included in this Annual Report for more information on the 2021 Financing.

In June 2020, we issued certain holders of our outstanding warrants classified as “Series D Warrants”, additional warrants to acquire up to 3,886,364 shares of our Common Stock at an initial exercise price of \$0.25 per share (“Series J Warrants”) as consideration for those holders exercising their Series D Warrants in full to acquire 5,181,819 shares of our Common Stock at \$0.18 per share. As of December 28, 2022, up to 3,375,000 shares may be acquired upon the exercise of the Series J Warrants. See Note 11 to the Notes to the Consolidated Financial Statements included in this Annual Report for more information on the Series D Warrants.

In connection with the financing that closed on October 18, 2019 (the “October 2019 Financing”), we issued an aggregate of 14,285,714 shares of our Common Stock, which equaled approximately 8% of the 173,577,233 shares of our Common Stock that were issued and outstanding immediately prior to the commencement of the October 2019 Financing. Upon the closing of the October 2019 Financing, we also issued warrants to acquire up to an additional 14,285,714 shares of our Common Stock at an initial exercise price of \$0.22 per share (“Series I Warrants”) and additional warrants to acquire up to an additional 1,071,429 shares of our Common Stock at an initial exercise price of \$0.21875 per share to designees of the Placement Agent (the “2019 Placement Agent Warrants”). As of December 28, 2022, up to 14,285,714 shares may be acquired upon the exercise of the Series I Warrants and up to 1,071,429 shares may be acquired upon the exercise of the 2019 Placement Agent Warrants. See Note 8 to the Notes to the Consolidated Financial Statements included in this Annual Report for more information on the October 2019 Financing.

In connection with the financing that closed on May 14, 2019 (the “May 2019 Financing”), we issued an aggregate of 8,615,384 shares of our Common Stock, which equaled approximately 5% of the 164,961,849 shares of our Common Stock that were issued and outstanding immediately prior to the commencement of the 2019 Financing. Upon the closing of the 2019 Financing, we also issued warrants to acquire up to an additional 8,615,384 shares of our Common Stock at an initial exercise price of \$0.40 per share (“Series H Warrants”). As of December 28, 2022, up to 8,615,384 shares may be acquired upon the exercise of the Series H Warrants. See Note 6 to the Notes to the Consolidated Financial Statements included in this Annual Report for more information on the May 2019 Financing.

In connection with the financing that closed on July 2, 2018 (the “2018 Financing”), we issued an aggregate of 9,070,000 shares of our Common Stock, which equaled approximately 6% of the 154,052,013 shares of our Common Stock that were issued and outstanding immediately prior to the commencement of the 2018 Financing. Upon the closing of the 2018 Financing, we also issued warrants to acquire up to an additional 6,802,500 shares of our Common Stock at an initial exercise price of \$0.70 per share (“Series G Warrants”). As of December 28, 2022, up to 6,802,500 shares may be acquired upon the exercise of the Series G Warrants. See Note 6 to the Notes to the Consolidated Financial Statements included in this Annual Report for more information on the 2018 Financing.

In addition to the aforementioned warrants, in June 2020 and November 2020, we issued \$550,000 and \$1,050,000 in aggregate principal amount of our Series 1 Convertible Notes and Series 2 Convertible Notes (collectively, the “Series Convertible Notes”), respectively. The Series Convertible Notes (i) have a three-year term; (ii) accrue interest on the unpaid principal balance at a rate equal to ten percent (10%), and (iii) the Series 1 Convertible Notes and Series 2 Convertible Notes can be converted into shares of our Common Stock at a conversion price of \$0.27 per share, and \$0.25 per share, respectively. At maturity, at our sole option, we may convert the principal and accrued interest under the Series Convertible Notes (the “Note Obligations”) into shares of our Common Stock at the applicable conversion price in lieu of repaying the Series Convertible Notes; provided, however, in the event we exercise this option, the Note Obligations will be deemed to equal the product of 1.35 (which was subsequently increased to 1.60 in connection with the July 2022 financing as holders of the Series Convertible Notes were required to execute subordination agreements as a condition to the July 2022 financing) and the outstanding Note Obligations. See Note 11 to the Notes to the Consolidated Financial Statements included in this Annual Report for more information on the Series Convertible Notes.

In connection with the 2022 Note Financing, we issued certain investors Series 3B Subordinated Notes in the aggregate principal amount of \$699,781 (the “Subordinated Notes”). The Subordinated Notes are convertible into 15,312,493 shares of Common Stock at a conversion price of \$0.0457 in exchange for their Series 2 Convertible Notes. The terms of the Subordinated Notes are substantially similar to those of the 2022 Notes. In connection with the 2022 Note Financing, the holders of the Series Convertible Notes entered into a subordination agreement on July 6, 2022 to subordinate their rights to the investors respect to the 2022 Notes. As of December 28, 2022, up to 15,312,493 shares may be acquired upon the conversion of the Subordinated Notes.

In connection with the 2022 Note Financing, we issued Senior Secured Convertible Notes in the aggregate principal amount of \$4.23 million, which includes an aggregate \$0.705 million original issue discount in respect of the 2022 Senior Secured Convertible Notes. The Senior Secured Convertible Notes (i) have an eighteen-month term; (ii) accrue interest on the unpaid principal balance at a rate equal to ten percent (10%), and (iii) can be converted into shares of our Common Stock at a conversion price of \$0.0457 per share. See Note 10 to the Notes to the Consolidated Financial Statements included in this Annual Report for more information on the Senior Secured Convertible Notes. As of December 28, 2022, up to 92,560,174 shares may be acquired upon the conversion of the Senior Secured Convertible Notes.

Additionally, as of December 28, 2022, 6,373,158 shares of Common Stock were reserved for future issuance under the 2013 Plan, of which 19,725,196 shares are subject to outstanding option awards granted under the 2013 Plan at exercise prices ranging from \$0.02 to \$0.65 per share and with a weighted average exercise price of \$0.26 per share and the numbers issuable under the 2013 Plan will increase by up to 3 million shares on the first business day of each following fiscal year as set forth in the 2013 Plan. Finally, there are currently outstanding warrants to acquire up to 145,985 shares of our Common Stock which are related to the Massachusetts Life Sciences Center (“MSLC”) note. 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 of Directors deems are in the Company’s best interest. By way of example, on September 27, 2021, we issued 300,000 shares of restricted stock in connection with our entrance into separate consulting agreement with Michael J. Parker, in consideration of the services to be provided under and in accordance with the terms of each consulting agreement. Additionally, shares of Common Stock could be used for anti-takeover purposes or to delay or prevent changes in control or management of the Company. We cannot provide assurances that any issuances of Common Stock will be consummated on favorable terms or at all, that they will enhance stockholder value, or that they will not adversely affect our business or the trading price of our Common Stock. The issuance of any such shares will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our Common Stock. If we issue any such additional shares, such issuance will reduce the proportionate ownership and voting power of all current shareholders. Further, such issuance may result in a change of control of our Company.

***Our Common Stock is a “penny stock.”***

The SEC has adopted regulations that generally define “penny stock” as an equity security that has a market price of less than \$5.00 per share, subject to specific exemptions. The market price of our Common Stock is and is expected to continue to be in the near term, less than \$5.00 per share and is therefore a “penny stock.” Brokers and dealers effecting transactions in “penny stock” must disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities. Those rules may restrict the ability of brokers or dealers to sell our Common Stock and may affect the ability of our stockholders to sell their shares of our Common Stock. In addition, if our Common Stock continues to be quoted on the OTCQB as we expect, then our stockholders may find it difficult to obtain accurate quotations for our stock and may find few buyers to purchase our stock and few market makers to support its price.

***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 have a public float of less than \$700 million and annual revenues of less than \$100 million during our most recently completed fiscal year. 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.

***Future sales of our Common Stock or rights to purchase Common Stock, or the perception that such sales could occur, could cause our stock price to fall.***

As noted above under the risk factor entitled, “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,” as of December 28, 2022, we believe that our current cash on hand will meet our anticipated cash requirements into the second quarter of fiscal 2023. To raise capital, we may sell Common Stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. Any such sales of our Common Stock by us or resale of our Common Stock by our existing stockholders could cause the market price of our Common Stock to decline.

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

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

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

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

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

Certain of our directors and executive officers own a significant percentage of our outstanding capital stock. As of December 28, 2022, Dr. Terrence W. Norchi, our Chairman of the Board, President and Chief Executive Officer beneficially owns (as determined under Section 13(d) of the Exchange Act and the rules and regulations thereunder) approximately 8% of our shares of Common Stock. Accordingly, this member of our Board of Directors and management team has substantial voting power to approve matters requiring stockholder approval, including without limitation the election of directors, and has significant influence over our affairs. This concentration of ownership could have the effect of delaying or preventing a change in control of our Company, even if such a change in control would be beneficial to our stockholders.

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

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

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

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

We are a public reporting company in the US, 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 of Directors.

***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.

#### **ITEM 1B. UNRESOLVED STAFF COMMENTS**

Not applicable.

#### **ITEM 2. 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.

#### **ITEM 3. 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.

#### **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.



## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

#### Market Information

Our common stock, par value \$0.001 per share ("*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 OTC Bulletin Board BB ("*OTCBB*") and the OTC Venture Market ("*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.

As of December 28, 2022, there were approximately 100 holders of record of our Common Stock.

#### 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.

### ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

### ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with our consolidated financial statements and notes thereto included elsewhere in this Annual Report on Form 10-K (this "*Annual Report*"). This discussion and analysis contains forward looking statements. We make forward-looking statements, as defined by the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, as amended, and in some cases, you can identify these statements by forward-looking words such as "if," "will," "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 and other comparable terminology. These forward-looking statements are based on various underlying assumptions and expectations and are subject to risks, uncertainties and other unknown factors, may include projections of our future financial performance based on our growth strategies and anticipated trends in our business and include risks and uncertainties relating to our current cash position and our need to raise additional capital in order to be able to continue to fund operations; the stockholder dilution that may result from future capital raising efforts and the exercise or conversion, as applicable of our outstanding convertible debt instruments, options, and warrants; our limited operating history which may make it difficult to evaluate our business and future viability; our ability to timely commercialize and generate revenues or profits from our AC5® Advanced Wound System and other potential product candidates; our ability to achieve the desired regulatory approvals in the United States or elsewhere; our ability to retain our managerial personnel and attract additional personnel; the strength of our intellectual property, the intellectual property of others and any asserted claims of infringement; and other risk factors identified under the caption "*Risk Factors*" in this Annual Report and in the documents we have filed, or will file, with the Securities and Exchange Commission ("*SEC*"). We undertake no duty to update any of these forward-looking statements after the date of filing of this Annual Report to conform such forward-looking statements to actual results or revised expectations, except as otherwise required by law.

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 its subsidiary. For purposes herein, references to regulatory approval and marketing authorization may be used interchangeably.

#### Corporate Overview

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

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

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

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

#### *Liquidity*

We devote a significant amount of our efforts on fundraising, planning and conducting clinical trials, activities in connection with obtaining regulatory approval, and product research. We have principally raised capital through borrowings, the issuance of convertible debt, and units consisting of Common Stock and warrants to fund our operations. For the year ended September 30, 2022, we had a net loss of \$5,275,854 versus a net loss of \$6,240,482 in the prior year. The losses for each of the years ended September 30, 2022 and 2021 can be attributable to research and development expense, including regulatory approval and product research, and general and administrative costs, primarily relating to legal costs associated with intellectual property and patent application, general corporate legal expense all of which were partially offset by adjustments to the derivative liabilities and, for the fiscal year ended September 30, 2021, a gain on the forgiveness of the loan issued by First Republic Bank under the Paycheck Protection Program, established under the Coronavirus Aid, Relief, and Economic Security Act. Cash used in operating activities decreased \$1,502,553 during the year ended September 30, 2022 to \$4,456,075, compared to \$5,958,628 for the year ended September 30, 2021. Cash at September 30, 2022 decreased by \$1,519,699 to \$746,940 compared to \$2,266,639 as of September 30, 2021.

#### **Business Overview**

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

#### *Core Technology*

Our flagship products and product candidates are derived from our AC5® self-assembling peptide ("*SAP*") technology platform and are sometimes referred to as AC5 or the "*AC5 Devices*." These include AC5® Advanced Wound System and AC5® Topical Hemostat, which have received marketing authorization as medical devices in the United States and Europe, respectively, and which are intended for skin applications, such as the management of complicated chronic wounds and acute surgical wounds. Other products are in development for use in minimally invasive or open surgical procedures, and include, for example, AC5-GTM for gastrointestinal endoscopic procedures, and AC5-V® and AC5® Surgical Hemostat for hemostasis inside the body, all of which are currently investigational devices limited by law to investigational use.

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

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



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

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

### *Operations*

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

Our long-term business plan includes the following goals:

- conducting biocompatibility, pre-clinical, and clinical studies on our products and product candidates;
- obtaining additional marketing authorization for products in the United States, Europe, and other jurisdictions as we may determine;
- continuing to develop third party relationships to manufacture, distribute, market and otherwise commercialize our products;
- continuing to develop academic, scientific and institutional relationships to collaborate on product research and development;
- expanding and maintaining protection of our intellectual property portfolio; and
- developing additional product candidates in Dermal Sciences, BioSurgery, and other areas.

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

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

We have no commitments for any future capital. We will require significant additional financing to fund our planned operations, including further research and development relating to AC5®, seeking regulatory approval of any product we may choose to develop, commercializing any product for which we are able to obtain regulatory approval or certification, seeking to license or acquire new assets or business, and maintaining our intellectual property rights, pursuing new technologies and for financing the investor relations and incremental administrative costs associated with being a public corporation.

The estimated capital requirements potentially could increase significantly if a number of risks relating to conducting these activities were to occur, including without limitation those set forth under the heading “*RISK FACTORS*” in this Annual Report. We anticipate that our operating and other expenses will continue to increase as we continue to implement our business plan and pursue and achieve these goals. After giving effect to the funds received in past equity and debt financings and assuming our use of that funding at the rate we presently anticipate, as of December 28, 2022 we believe that our current cash on hand will meet our anticipated cash requirements into the second quarter of fiscal 2023. We could spend our financial resources much faster than we expect, in which case we would need to raise additional capital as our current funds may not be sufficient to operate our business for the entire duration of that period.

#### *Preclinical Testing*

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

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

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

#### *Clinical Testing*

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

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

#### **Commercialization**

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

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

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

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

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

Securing reimbursement for AC5 Advanced Wound System in ambulatory settings, such as doctor's offices, is an important part of our commercial strategy. Consequently, we applied to the Centers for Medicare and Medicaid Services ("CMS") for a dedicated Healthcare Common Procedure Coding System ("HCPCS") Level II billing code specific to AC5® Advanced Wound System on June 29, 2022, which if granted, would better enable providers to bill third party payors for AC5 that is used in doctors' offices. We believe that there is a growing trend toward the use of synthetic wound care products, including those that have been commonly referred to as synthetic skin substitutes.

A dedicated HCPCS code is an important step toward, although not a guarantee of, coverage and reimbursement, and it would enhance our ability to work directly with payors as we expand access in outpatient settings and continue to advocate for clinically appropriate usage of our technology for patients. A final decision, which we anticipate, but cannot guarantee, will be positive, is expected during the first calendar quarter of 2023 with a "go live" date of April 1, 2023. In the meantime, CMS has established a new and temporary coding option to facilitate the reimbursement of doctor's offices and wound clinics, and certain providers have begun to submit claims under this new code as we pursue a dedicated HCPCS code.

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

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

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

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

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

#### *The COVID-19 Pandemic Impact on Commercialization*

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

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

We believe that these challenges may present an opportunity for our new technology to address certain poorly met needs.

Wound interventions are too often considered to be elective procedures instead of being treated essentially or emergently as National Pressure Ulcer Advisory Panel guidelines and others recommend, resulting in a projected increased risk to limb and life while elective procedures are delayed and not prioritized. Furthermore, the implications of these delays are a growing backlog of chronic wounds awaiting care and a worsening of such wounds, leading to greater morbidity, such as infection, necrosis, and amputation, and potentially mortality.

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

## **Manufacturing**

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

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

## **Merger with ABS and Related Activities**

On June 26, 2013, the Company completed the Merger with ABS, pursuant to which ABS became a wholly owned subsidiary of the Company. In contemplation of the Merger, effective May 24, 2013, the Company increased its authorized Common Stock, from 75,000,000 shares to 300,000,000 shares and effected a forward stock split, by way of a stock dividend, of its issued and outstanding shares of Common Stock at a ratio of 11 shares to each 1 issued and outstanding share. Also, in contemplation of the Merger, effective June 5, 2013, the Company changed its name from Almah, Inc. to Arch Therapeutics, Inc. and changed the ticker symbol under which its Common Stock trades on the OTC Bulletin Board from “AACH” to “ARTH”.

## **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.

## Recent Developments

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

On July 6, 2022 (the “Closing Date”), we entered into a Securities Purchase Agreement (the “SPA”) with certain institutional and accredited individual investors providing for the issuance and sale of an aggregate of (i) 12,766,600 of shares of common stock, par value \$0.001 per share, (ii) Senior Secured Convertible Promissory Notes (each a “2022 Note” and collectively, the “2022 Notes”) in the aggregate principal amount of \$4.23 million, which included an aggregate \$0.705 million original issue discount in respect of the 2022 Notes; (iii) warrants (the “2022 Warrants”) to purchase an aggregate of 85,110,664 shares of Common Stock (the “Warrant Shares”); and (iv) a warrant (the “Placement Agent Warrant”) to purchase 6,301,969 shares of Common Stock (the “Placement Agent Warrant Shares”) (collectively, the “2022 Note Financing”). The 2022 Notes may be prepaid by the Company, in whole or in part, at any time with the written consent of the lead investor, with such prepayment amounts subject to adjustment as a result of certain time-based prepayment premiums set forth in the 2022 Notes; provided, that, the written consent of the lead investor is not required in connection with a prepayment made from the proceeds of an Uplist Transaction (as defined below). The 2022 Notes bear interest on the unpaid principal balance at a rate equal to ten percent (10%) (computed on the basis of the actual number of days elapsed in a 360-day year) per annum accruing from the Closing Date until the 2022 Notes become due and payable at maturity or upon their conversion, acceleration or by prepayment, and may become due and payable upon the occurrence of an event of default under the 2022 Notes. Any amount of principal or interest on the 2022 Notes which is not paid when due shall bear interest at the rate of the lesser of (i) eighteen percent (18%) per annum or (ii) the maximum amount allowed by law from the due date thereof until payment in full.

The 2022 Notes are convertible into shares of Common Stock at the option of each holder of the 2022 Notes from the date of issuance at \$0.0457 (the “Conversion Price”) through the later of (i) the Maturity Date and (ii) the date of payment of the Default Amount (as defined in the 2022 Note); *provided, however*, certain 2022 Notes include a provision preventing such conversion if, as a result, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than 4.99% of the Common Stock (as applicable, the “Ownership Limitation”) immediately after giving effect to the Conversion; and *provided further*, the holder, upon notice to us, may increase or decrease the Ownership Limitation; *provided that* (i) the Ownership Limitation may only be increased to a maximum of 9.99% of the Common Stock; and (ii) any increase in the Ownership Limitation will not become effective until the 61<sup>st</sup> day after delivery of such waiver notice. The Conversion Price is subject to adjustment as set forth in the 2022 Notes.

The 2022 Notes contain customary events of default, which include, among other things, (i) our failure to pay when due any principal or interest payment under the 2022 Notes; (ii) our insolvency; (iii) delisting of our Common Stock; (iv) our breach of any material covenant or other material term or condition under the 2022 Notes; and (v) our breach of any representations or warranties under the 2022 Notes which cannot be cured within five (5) days. Further, events of default under the 2022 Notes also include (i) the unavailability of Rule 144 on or after 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 uplifting of our Common Stock to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American by February 15, 2023 (an “Uplist Transaction”).

The 2022 Warrants (i) have an exercise price of \$0.0497 per share; (ii) have a term of exercise equal to 5 years after their issuance date; (iii) became exercisable immediately after their issuance; and (iv) have a provision preventing the exercisability of such 2022 Warrant if, as a result of the exercise of the 2022 Warrant, the holder, together with its affiliates and any other persons whose beneficial ownership of our Common Stock would be aggregated with the holder’s, would be deemed to beneficially own more than the Ownership Limitation. The holder, upon notice to us, may increase or decrease the Ownership Limitation; provided that (i) the Ownership Limitation may only be increased to a maximum of 9.99% of our Common Stock; and (ii) any increase in the Ownership Limitation will not become effective until the 61<sup>st</sup> day after delivery of such waiver notice. The number of shares of Common Stock into which each of the 2022 Warrants is exercisable and the exercise price therefor are subject to adjustment as set forth in the 2022 Warrants, including 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 Maxim Group LLC (the “2022 Placement Agent”), we agreed, among other things, to (i) pay the 2022 Placement Agent 10% of the gross proceeds in the 2022 Placement Agent from certain institutional investors, or \$240,000, and (ii) issue the 2022 Placement Agent, or its designees, warrants to purchase up to 10% of the aggregate number of shares sold to the institutional investors in the 2022 Note Financing, or warrants to purchase up to 6,301,969 shares of Common Stock (the “2022 Placement Agent Warrants”). The 2022 Placement Agent Warrants have substantially the same terms as the 2022 Warrants, except that the exercise price of the 2022 Placement Agent Warrants is \$0.0503 per share and (ii) are not exercisable until six (6) months from the date of issuance. We also reimbursed the 2022 Placement Agent approximately \$58,000 for non-accountable banking fees, legal fees and other expenses.

On September 29, 2022, the Company held its annual meeting of stockholders (the “Annual Meeting”). The following matters were voted upon at the Annual Meeting: i) election of directors, ii) reverse stock split of not less than 1-for-100 and not greater than 1-for-200 at any time prior to September 29, 2023 with the exact timing and final ratio to be determined by the Board of Directors of the Company, iii) increase the number of authorized shares of Common Stock resulting following the consummation of the reverse stock split by three times, iv) advisory vote to approve executive compensation, v) advisory vote to approve the frequency of advisory votes on executive compensation, vi) authority to adjourn the meeting, and vii) ratification of Baker Tilly US, LLP as the Company’s independent auditors for the fiscal year ended September 30, 2022. In connection with Proposal No.1, Dr. Terrence Norchi, Dr. Guy Fish, Punit Dhillon and Laurence Hicks were elected to serve on the board until the next annual meeting of stockholders by a plurality of votes cast. Proposal Nos. 2, 3, 4, 6, and 7 were approved. In connection with Proposal No. 5, stockholders voted to support an advisory vote on executive compensation every three years. The Company filed a Current Report on Form 8-K with detailed voting results, ratified by the inspector of the election, for all seven proposals on September 30, 2022.

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

## Results of Operations

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

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

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

#### *Revenue*

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

#### *Cost of revenues*

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

#### *Selling, General and Administrative Expense*

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

#### *Research and Development Expense*

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

#### *Other Income*

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

## Liquidity and Capital Resources

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

### Working Capital

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

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

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

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

### Cash Flow

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

#### Cash Used in Operating Activities

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

#### Cash Provided by (Used in) Investing Activities

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

#### Cash Provided by Financing Activities

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

### Cash Requirements

We anticipate that our operating expenses, interest expense and other expenses will increase significantly as we continue to implement our business plan and pursue our operational goals. As of December 28, 2022, we believe that our current cash on hand will meet our anticipated cash requirements into the second quarter of fiscal 2023. Depending upon additional input from EU and US regulatory authorities, however, we do not expect to generate sufficient revenues from operations before we will need to raise additional capital. Further, our estimates regarding our use of cash could change if we encounter unanticipated difficulties or other issues arise, including without limitation those set forth under the heading “*RISK FACTORS*” in this Annual Report.



In the first quarter of 2021, the Company commenced commercial sales of our first product, AC5® Advanced Wound System. That revenue will not be sufficient to fund our business operations and we will need to obtain additional funding from external sources for the foreseeable future. We do not have any commitments for future capital. Significant additional financing will be required to fund our planned operations in the near term and in future periods, including research and development activities relating to our potential new product candidates, seeking regulatory approval of any other product candidates we may choose to develop, commercializing any product candidates for which we are able to obtain regulatory approval or certification, seeking to license or acquire new assets or businesses, and maintaining our intellectual property rights and pursuing rights to new technologies. We may not be able to obtain additional financing on commercially reasonable or acceptable terms when needed, or at all. We are bound by certain contractual terms and obligations that may limit or otherwise impact our ability to raise additional funding in the near-term including, but not limited to, provisions in the 2018 SPA (see Note 6) and the 2022 SPA (see Note 10) restricting our ability to effect or enter into an agreement to effect any issuance by the Company or any of its subsidiaries of Common Stock or securities convertible, exercisable or exchangeable for Common Stock (or a combination of units thereof) involving a Variable Rate Transaction (as defined in the 2018 SPA) including, but not limited to, an equity line of credit or “At-the-Market” financing facility until the three lead investors in the 2018 Financing collectively own less than 20% of the Series G Warrants (see Note 6) purchased by them pursuant to the 2018 SPA. These restrictions and provisions could make it more challenging for us to raise capital through the incurrence of debt or through equity issuances. If we cannot raise the money that we need in order to continue to develop our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations. If any of these were to occur, there is a substantial risk that our business would fail, and our stockholders could lose all of their investments.

As previously noted, since inception we have funded our operations primarily through equity and debt financings and we expect to continue to seek to do so in the future. If we obtain additional financing by issuing equity securities, our existing stockholders’ ownership will be diluted. Additionally, the terms of securities we may issue in future capital-raising transactions may be more favorable for our new investors, and in particular may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have additional dilutive effects. If we obtain additional financing by incurring debt, we may become subject to significant limitations and restrictions on our operations pursuant to the terms of any loan or credit agreement governing the debt. Further, obtaining any loan, assuming a loan would be available when needed on acceptable terms, would increase our liabilities and future cash commitments. We may also seek funding from collaboration or licensing arrangements in the future, which may require that we relinquish potentially valuable rights to our product candidates or proprietary technologies or grant licenses on terms that are not favorable to us. Moreover, regardless of the manner in which we seek to raise capital, we may incur substantial costs in those pursuits, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other related costs.

#### *Going Concern*

We have commenced commercial sales of our first product, AC5® Advanced Wound System. From inception, we have had recurring losses from operations. While the Company anticipates that it will have cash on hand into the second quarter of fiscal 2023, the continuation of our business as a going concern is dependent upon raising additional capital and eventually attaining and maintaining profitable operations. As of September 30, 2022, there is substantial doubt about the Company’s ability to continue as a going concern. The financial statements included in this Annual Report do not include any adjustments that might be necessary should operations discontinue.

#### **Critical Accounting Policies and Significant Judgments and Estimates**

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

#### *Derivative Liabilities*

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



## *Inventories*

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

## Complex Financial Instruments

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

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

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

## **Recent Accounting Guidance**

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

## **Off-Balance Sheet Arrangements**

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

## **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK**

Not applicable.

## **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The financial statements required by this item are set forth at the end of this Annual Report beginning on page F-1 and are incorporated herein by reference. We are not required to provide the supplementary data required by this item, as we are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the “*Exchange Act*”).

## **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

## **ITEM 9A. CONTROLS AND PROCEDURES**

### **Evaluation of Disclosure Controls and Procedures**

Our management carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer (who is our Principal Executive Officer) and our Chief Financial Officer (who is our Principal Financial Officer and Principal Accounting Officer), of the effectiveness of the design of our disclosure controls and procedures (as defined by Exchange Act Rules 13a-15(e) or 15d-15(e)) as of September 30, 2022, pursuant to Exchange Act Rule 13a-15(b). Due to the material weakness described below, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were not effective as of September 30, 2022.

## **Management's Annual Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Internal control over financial reporting is a process designed by, or under the supervision of, the Principal Executive Officer and Principal Financial Officer and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Under the supervision and with the participation of our Principal Executive Officer and Principal Financial Officer, management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control — Integrated Framework* issued in 2013 by the Committee of Sponsoring Organizations (“COSO”). We believe, that as of September 30, 2022 there existed a material weakness in our internal control over financial reporting. The deficiencies in the design of internal control over financial reporting related to a lack of sufficient resources with an understanding of the technical guidance under generally accepted accounting principles related to accounting for complex financial instruments within the 2022 Senior Secured Convertible Notes and certain accounting practices relating to the recording of the insurance premium advanced by a third party. Accordingly, the Audit Committee in consultation with management has determined that these matters may be best addressed by: (i) reviewing accounting literature and other technical materials to ensure that the appropriate personnel have a full awareness and understanding of the applicable accounting pronouncements and how they are to be implemented; (ii) additional education on new and existing accounting pronouncements and their application and (iii) requiring senior accounting staff and outside consultants with technical accounting experience to review complex transactions to evaluate and approve the accounting treatment of such transactions. Accordingly, the Board has recommended to management and management has agreed that the Company's accounting staff, including its Chief Financial Officer, undertake additional training on an accelerated basis and that such training, in view of the complexity of certain generally accepted accounting principles and other matters be ongoing and engage third party specialists on an as-needed basis to help supplement the Company's internal resources.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

### **Changes in Internal Control Over Financial Reporting**

During the year ended September 30, 2022, there have been no changes in our internal control over financial reporting that have materially affected or are reasonably likely to materially affect our internal controls over financial reporting. From time to time, we make changes to our internal control over financial reporting that are intended to enhance its effectiveness, and which do not have a material effect on our overall internal control over financial reporting.

### **ITEM 9B. OTHER INFORMATION**

None.

### **ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS**

Not applicable.

**PART III****ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

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

<b>Name</b>	<b>Position</b>	<b>Age</b>	<b>Director/Officer Since</b>
Dr. Terrence W. Norchi	President, Chief Executive Officer and Chairman of the Board of Directors	58	April 2013
Punit Dhillon	Director	42	July 2018
Laurence Hicks	Director	56	September 2021
Dr. Guy L. Fish	Director	62	December 2021
Michael S. Abrams	Chief Financial Officer	52	May 2021
Daniel M. Yrigoyen	Vice President of Sales	53	July 2021

**Business Experience**

The following is a brief account of the education and business experience of our current directors and executive officers during at least the past five years, indicating their principal occupation during the period, and the name and principal business of the organization by which they were employed:

*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-US 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 of Directors 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.

*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). Collectively, Mr. Dhillon has led and assisted in raising over \$500 million through financings, M&A deals, and several licensing and development transactions with large pharma including Merck, BMS, and Pfizer. 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.

*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. Mr. Abrams graduated with an MBA with Honors from the Booth School of Business at the University of Chicago and received his BBA with Honors from the University of Massachusetts at Amherst as a William F. Field Alumni scholar, an award given annually to the top finance student in the class.

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

#### **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.

#### **Audit Committee**

On August 15, 2022, our Board of Directors established a separate standing audit committee within the meaning of Section 3(a)(58)(A) of the Securities Exchange Act of 1934, as amended (the "*Exchange Act*"). Our Board of Directors has determined that Mr. Dhillon is an "audit committee financial expert" as defined by applicable Securities and Exchange Commission ("*SEC*") rules. Other members of the audit committee include Mr. Laurence Hicks and Dr. Guy Fish.

#### **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.

## Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act, requires our executive officers and directors, and persons who beneficially own more than 10% of our common stock to file with the SEC initial reports of ownership and reports of changes in ownership of common stock and other equity securities of our company. Officers, directors and greater than ten percent stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file. SEC regulations require us to identify in this report anyone who filed a required report late during our most recent fiscal year.

Based on our review of forms we received or written representations from reporting persons, we believe that all reports of securities ownerships and changes in such ownership required to be filed during the year ended September 30, 2022 were timely, except that Mr. Yrigoyen filed a late report on Form 4 on June 9, 2022, reporting one transaction.

## ITEM 11. EXECUTIVE COMPENSATION

The following table summarizes all compensation recorded by us in each of the fiscal years ended September 30, 2022 and September 30, 2021 for (i) our principal executive officer; (ii) our two next most highly compensated executive officers whose total compensation exceeded \$100,000 during our last completed fiscal year; and (iii) certain of our other executive officers, whose compensation is voluntarily provided.

### Summary Compensation Table

Name	Fiscal Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards \$(1)	All other Compensation (\$)	Total (\$)
Dr. Terrence W. Norchi	2022	450,500	—	—	—	—	450,500
<i>President and Chief Executive Officer</i>	2021	450,500	27,030	—	157,400	—	634,930
Michael S. Abrams	2022	325,000	—	—	—	—	325,000
<i>Chief Financial Officer</i>	2021	135,417	—	—	66,895	—	202,312
Daniel Yrigoyen	2022	316,667	—	—	9,075	—	325,742
<i>VP of Sales</i>	2021	64,299	—	13,500	27,545	—	105,344

- (1) Represents the aggregate grant date fair values of awards granted during the fiscal year ended September 30, 2022 under the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“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 included in this filing.

### 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 of Directors, 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 of Directors. 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 of Directors’ 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 of Directors’ annual review of Dr. Norchi’s base salary, Dr. Norchi’s annual base salary was increased to \$450,500 effective August 1, 2019.

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

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

*Michael S. Abrams*

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

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

*Daniel M. Yrigoyen*

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

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

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

### Outstanding Equity Awards At Fiscal Year-End

The following table summarizes the aggregate number of option and stock awards held by our named executive officers at September 30, 2022:

Name	Option Awards				Stock Awards	
	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	500,000	—(1)	0.35	03/23/2024		
	400,000	—(2)	0.19	01/21/2025		
	355,000	—(3)	0.28	08/17/2025		
	1,250,000	—(4)	0.39	05/02/2026		
	650,000	—(5)	0.65	02/02/2027		
	360,000	—(6)	0.425	07/18/2028		
	937,489	154,177(7)	0.2292	12/19/2029		
	665,000	335,000(8)	0.1028	09/26/2031		
	333,336	666,664(9)	0.1028	09/26/2031		
Michael S. Abrams	250,001	249,999(10)	0.1329	05/02/2031		
	116,664	233,336(11)	0.1028	09/26/2031		
Daniel M. Yrigoyen	58,334	91,666(12)	0.09	07/29/2031		
	66,672	133,328(14)	0.1028	09/26/2031	150,000(13)	19,500
	16,668	133,332 (15)	0.0605	05/23/2032		



- (1) Represents an option to purchase 500,000 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 1/24<sup>th</sup> 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 400,000 shares of Common Stock with a grant date of January 22, 2015. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, 25% of the shares shall vest 12 months following the date of grant and 1/24<sup>th</sup> 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 355,000 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 1/36<sup>th</sup> 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 1,250,000 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 650,000 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 360,000 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 1/36<sup>th</sup> 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 1,000,000 shares of Common Stock with a grant date of December 20, 2019. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, and 1/36<sup>th</sup> 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 1,000,000 shares of Common Stock with a grant date of September 27, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with 33% of the shares vested immediately on the date of grant and the remaining shares to vest in 24 equal installments commencing on the first anniversary on the date of grant.
- (9) Represents an option to purchase 1,000,000 shares of Common Stock with a grant date of September 27, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.
- (10) Represents an option to purchase 500,000 shares of Common Stock with a grant date of May 3, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with 30% of the shares vested immediately on the date of grant and the remaining shares to vest in 24 equal installments commencing on the first anniversary on the date of grant.
- (11) Represents an option to purchase 350,000 shares of Common Stock with a grant date of September 27, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.
- (12) Represents an option to purchase 150,000 shares of Common Stock with a grant date of July 30, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant and the remaining shares to vest in 24 equal installments commencing on the first anniversary on the date of grant.
- (13) Represents a stock award to receive 150,000 shares of Common Stock granted on July 30, 2021. The stock award vests as follows; 50,000 shares on January 12, 2022, 50,000 shares on July 12, 2022 and 50,000 shares on January 12, 2023.
- (14) Represents an option to purchase 200,000 shares of Common Stock with a grant date of September 27, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.
- (15) Represents an option to purchase 150,000 shares of Common Stock with a grant date of May 24, 2022. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.



## Compensation of Directors

On March 23, 2014, our Board of Directors 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 of Directors 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. Effective January 1, 2022, the person serving as the Chairman of our Board of Directors receives an aggregate annual cash fee of \$30,000 for that chairperson role, and all other non-employee directors receive an annual cash fee of \$25,000.

The following table summarizes all compensation paid to our non-employee directors during the fiscal year ended September 30, 2022:

### Director Compensation Table

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

- (1) Mr. Dhillon was appointed as a member of the Board on July 19, 2018. The aggregate number of shares of Common Stock underlying option awards outstanding as of September 30, 2022 held by Mr. Dhillon was 1,000,000.
- (2) Mr. Hicks was appointed as a member of the Board on September 27, 2021. The aggregate number of shares of Common Stock underlying option awards outstanding as of September 30, 2022 held by Mr. Hicks was 250,000.
- (3) Dr. Fish was appointed as a member of the Board on December 31, 2021. The aggregate number of shares of Common Stock underlying option awards outstanding as of September 30, 2022 held by Dr. Fish was 250,000.

## ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

### Securities Authorized for Issuance under Equity Compensation Plans

On June 18, 2013, our Board of Directors and the holders of a majority of our standing common stock approved and adopted the Arch Therapeutics, Inc. 2013 Stock Incentive Plan (the “Plan”). The Plan permits us 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 us to adapt our incentive compensation program to meet our needs. As of September 30, 2022, the Plan has reserved 34,114,256 shares of our Common Stock for issuance thereunder in awards granted to employees, directors and/or consultants. The Plan provides that on the first business day of each fiscal year commencing with fiscal year 2013, the number of shares of our Common Stock reserved for issuance under the Plan for all awards except for incentive stock option awards will be subject to increase by an amount equal to the lesser of (i) 3,000,000 shares, (ii) 4% of the number of shares outstanding on the last day of our immediately preceding fiscal year, or (iii) such lesser number of shares as determined by the administrator of the Plan, which is currently our Board of Directors. As a result of that provision, as of October 1, 2022, the number of shares reserved for issuance under the Plan increased by 3,000,000 to 37,114,256. The following table provides information as of September 30, 2022 with respect to our equity compensation plans:

### Equity Compensation Plan Information

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted- average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	19,725,196	\$ 0.26	8,273,158
Equity compensation plans not approved by security holders	—	—	—
Total	19,725,196	\$ 0.26	8,273,158

## 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 249,936,370 shares of our Common Stock outstanding on December 28, 2022. Shares of our Common Stock subject to options, warrants, or other rights currently exercisable or exercisable within 60 days of December 28, 2022 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 Series Convertible Notes, and all the holders of our 2022 Warrants, 2022 Placement Agent Warrants, 2022 Notes, Subordinated Notes, Series G Warrants, Series H Warrants, Series I Warrants, 2019 Placement Agent Warrants, Series J Warrants, Series K Warrants and 2021 Placement Agent Warrants are subject to the applicable ownership limitations. 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.

<b>Name of Beneficial Owner</b>	<b>Number of Shares Beneficially Owned</b>	<b>Percentage of Shares Beneficially Owned (1)</b>
<i>5%+ Stockholders:</i>		
Michael A. Parker (2)	22,419,392	8.97%
<i>Directors and Executive Officers</i>		
Terrence Norchi (3)	20,445,156	7.96%
Punit Dhillon (4)	846,941	0.340%
Laurence Hicks (5)	2,050,794	0.81%
Michael Abrams (6)	2,104,079	0.84%
Daniel Yrigoyen (7)	375,005	0.15%
Guy Fish (8)	131,938	0.05%
Current Directors and Named Executive Officers as a Group (6 persons)	25,953,913	10.15%

Shares of our Common Stock subject to options, warrants, or other rights currently exercisable or convertible or exercisable or convertible within 60 days of December 28, 2022, are deemed to be beneficially owned and outstanding for computing the share ownership and percentage of the person holding such options, warrants or other rights, but are not deemed outstanding for computing the percentage of any other person.

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

- (2) Represents (i) 9,488,501 shares of Common Stock owned individually by Ana Parker, Michael A. Parker's spouse; (ii) 7,630,891 shares of Common Stock owned individually by Mr. Parker; (iii) 5,000,000 shares of Common Stock owned through Tungsten, of which Mr. Parker is the sole manager and (iv) 300,000 shares of restricted stock granted to Mr. Parker on September 27, 2021. Excludes (a) 600,000 shares of Common Stock that may be acquired upon the exercise of Series G Warrants (which expire July 7, 2023); (b) any of the 1,230,769 shares of Common Stock that may be acquired upon the exercise of Series H Warrants (which expire May 14, 2024); (c) 20,711,609 Conversion Shares; (d) 9,567,948 Warrant Shares; (e) any of the 3,428,571 shares of Common Stock that may be acquired upon the exercise of Series I Warrants (which expire October 18, 2024); (f) 3,375,000 shares of Common Stock that may be acquired upon exercise of Series J Warrants (which expire on December 22, 2022); or (g) any of the 4,687,500 shares that may be acquired upon the exercise of Series K Warrants (which expire on August 11, 2026), since such warrants cannot be exercised until such time as the holder would not beneficially own, after such exercise, more than 4.9% of the outstanding shares of Common Stock; provided, however, that the holder may waive such ownership limitation, in which case such waiver will become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of December 28, 2022, neither Ms. Parker nor Mr. Parker have waived such limitation.
- (3) Represents (a) 10,000,000 shares of Common Stock held by Twelve Pins Partners, LLC, with respect to which Dr. Norchi is the sole member and holds sole voting and investment control; (b) 1,419,076 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) 1,130,000 shares of restricted stock granted to Dr. Norchi on May 3, 2016; (d) 650,000 shares of restricted stock granted to Dr. Norchi on February 3, 2017; (e) 360,000 shares of restricted stock granted to Dr. Norchi on July 19, 2018; (f) 525,164 Conversion Shares; (g) 482,897 Warrant Shares; and (h) 72,435 Inducement Shares; and (i) 5,805,584 shares subject to options exercisable within 60 days after December 28, 2022. Dr. Norchi disclaims beneficial ownership of the securities held by Twelve Pins Partners, LLC except to the extent of his pecuniary interest therein.
- (4) Represents 846,941 shares of Common Stock subject to options exercisable within 60 days after December 28, 2022.
- (5) Represents 402,777 shares of Common Stock subject to options exercisable within 60 days after December 28, 2022. Includes (i) 27,273 shares of Common Stock, (ii) 787,746 Conversion Shares, (iii) 724,346 Warrant Shares, and (iv) 108,652 Inducement Shares held by Drake Partners Equity LLC, in which Mr. Hicks has an ownership interest.
- (6) Represents (i) 787,746 Conversion Shares; (ii) 724,346 Warrant Shares; (iii) 108,652 Inducement Shares; and (iv) 483,335 shares of Common Stock subject to options exercisable within 60 days after December 28, 2022.
- (7) Represents 150,000 shares of restricted stock granted to Mr. Yrigoyen on July 30, 2021 and 225,005 shares of Common Stock subject to options exercisable within 60 days after December 28, 2022.
- (8) Represents 131,938 shares of Common Stock subject to options exercisable within 60 days after December 28, 2022.

### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

#### **Related Party Transactions**

During fiscal years 2022 and 2021, other than with respect to matters relating to the Company's compensation arrangements with its executive officers, there were no transactions between the Company or any of its subsidiaries and any "Related Person" (as that term is defined in Item 404 of Regulation S-K) that would be required to be reported pursuant to Item 404 of Regulation S-K other than the following:

On June 22, 2020, the Company entered into a Series J Warrant Issuance Agreement (the "*Keyes Sulat Agreement*") with the Keyes Sulat Revocable Trust (the "*Trust*"), also a holder of outstanding Series D Warrants, resulting in approximately \$82,000 of proceeds as a result of the full exercise of the Trust's Series D Warrants. Under the terms of the Keyes Sulat Agreement, in exchange for fully exercising the Trust's remaining Series D Warrants for 454,546 shares of Common Stock on June 22, 2020, the Trust was issued Series J Warrants to purchase 340,910 shares of Common Stock at an exercise price of \$0.25 over a 1 year term. James R. Sulat, a former member of the Board of Directors, 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 of Directors prior to its approval of the transaction and abstained from voting on the transaction.

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

## 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 of Directors to review related party transactions and identify and prevent conflicts of interest. Our Board of Directors 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 of Directors for approval before they are entered into or, if that is not possible, for ratification after the transaction has occurred. If our Board of Directors finds that a conflict of interest exists, then it will determine the appropriate remedial action, if any. Our Board of Directors 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 of Directors.

## Director Independence

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

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

## ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table presents the aggregate fees agreed to by the Company for the annual audits for the fiscal years ended September 30, 2022 and 2021 and all other fees paid by us for services rendered by Baker Tilly US, LLP (and Moody, Famiglietti & Andronico LLP before the two firms combined):

	2022	2021
Audit Fees	\$ 152,500	\$ 154,500
Audit-Related Fees	98,000	21,000
Tax Fees	—	—
All Other Fees	—	—
<b>Total</b>	<b>\$ 250,500</b>	<b>\$ 175,500</b>

*Audit Fees.* The fees identified under this caption were for professional services rendered by Baker Tilly US, LLP, our current principal accountant, during the fiscal year ended September 30, 2022 and Moody, Famiglietti & Andronico LLP for the fiscal year ended September 30, 2021 for the audit of our annual consolidated financial statements. The fees identified under this caption also include fees for professional services rendered by Baker Tilly and Moody, Famiglietti & Andronico LLP for the review of the condensed consolidated financial statements included in our quarterly reports on Forms 10-Q.

*Audit-Related Fees.* Audit-related fees consist principally of assurance and related services reasonably related to the performance of the audit or review of our financial statements that are not reported as audit fees.

*Tax Fees.* Tax fees consist principally of assistance related to tax compliance, tax advice, and tax planning. For the fiscal years ended September 30, 2022 and 2021 there were no tax fees paid to our principal accountant.

*All Other Fees.* These fees would consist of all fees paid to our principal accountant that are not reflected as audit, audit-related or tax fees. For the fiscal year ended September 30, 2022 and 2021 there were no other fees paid to our principal accountant.

## Pre-Approval Policy

The Board of Directors has established a separate standing audit committee effective August 15, 2022, all engagements entered into prior to that date with our independent registered public accounting firms for 2022 and 2021 were pre-approved by the full Board of Directors.

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

- (a)(1). The following consolidated financial statements of Arch Therapeutics, Inc. and subsidiary, are found beginning on Page F-1 immediately following the signature page hereto, are incorporated by reference into Item 8 — Financial Statements and Supplementary Data:

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

[Consolidated Balance Sheets as of September 30, 2022 and 2021](#)

[Consolidated Statements of Operations for the Years Ended September 30, 2022 and 2021](#)

[Consolidated Statements of Changes in Stockholders' Equity \(Deficit\) for the Years Ended September 30, 2022 and 2021](#)

[Consolidated Statements of Cash Flows for the Years Ended September 30, 2022 and 2021](#)

[Notes to Consolidated Financial Statements](#)

- (a)(2) Financial Statement Schedules

These schedules are omitted because they are not required, or are not applicable, or the required information is shown in the consolidated financial statements or notes thereto.

- (b) Exhibits. The required exhibits are filed as part of this Annual Report on Form 10-K or are incorporated herein by reference.

# EXHIBIT INDEX

Exhibit No.	Exhibit Title	Filed Herewith	Incorporated By Reference		
			Form	Exhibit No.	Filing Date
2.1	<a href="#">Agreement and Plan of Merger dated May 10, 2013, by and among Almah, Inc., Arch Acquisition Corporation, and Arch Therapeutics, Inc.</a>		8-K	2.1	333-178883 5/13/2013
2.2	<a href="#">Amendment No. 1 to Agreement and Plan of Merger, dated May 23, 2013, by and among Almah, Inc., Arch Acquisition Corporation, and Arch Therapeutics, Inc.</a>		10-Q	10.11	000-54986 8/14/2013
3.1	<a href="#">Restated Articles of Incorporation of Arch Therapeutics, Inc.</a>		10-Q	3.1	000-54986 07/23/2020
3.2	<a href="#">Amended and Restated Bylaws, as adopted on August 15, 2022</a>		8-K/A	3.1	000-54986 08/17/2022
4.1	<a href="#">Description of Securities</a>		10-K	4.1	000-54986 12/11/2020
10.1#	<a href="#">Termination Agreement and Release dated June 25, 2013, between ABS and Terrence W. Norchi</a>		8-K	10.7	333-178883 6/26/2013
10.2#	<a href="#">Executive Employment Agreement dated June 26, 2013 between Arch Therapeutics, Inc. and Terrence W. Norchi</a>		8-K	10.8	333-178883 6/26/2013
10.3#	<a href="#">First Amendment to Executive Employment Agreement, dated March 23, 2014, by and between Arch Therapeutics, Inc. and Terrence W. Norchi Stock</a>		8-K	10.1	000-54986 3/27/2014
10.4#	<a href="#">Executive Employment Agreement dated June 26, 2013 between Arch Therapeutics, Inc. and Alan T. Barber</a>		8-K	10.9	333-178883 6/26/2013
10.5#	<a href="#">Executive Employment Agreement, effective July 8, 2013, by and between Arch Therapeutics, Inc. and William M. Cotter</a>		8-K	10.1	000-54986 7/8/2013
10.6#	<a href="#">First Amendment to Executive Employment Agreement, dated March 23, 2014, by and between Arch Therapeutics, Inc. and William M. Cotter</a>		8-K	10.2	000-54986 3/27/2014
10.7#	<a href="#">Separation Agreement dated June 15, 2015 by and between Arch Therapeutics, Inc. and William M. Cotter</a>		10-Q	10.3	000-54986 8/7/2015
10.8#	<a href="#">Executive Employment Agreement, effective July 7, 2014, by and between Arch Therapeutics, Inc. and Richard E. Davis</a>		8-K	10.1	000-54986 7/7/2014
10.9#	<a href="#">First Amendment to Executive Employment Agreement, dated July 27, 2015, by and between Arch Therapeutics, Inc. and Richard E. Davis</a>		8-K	10.1	000-54986 7/31/2015
10.10#	<a href="#">Consulting Agreement dated October 15, 2015 by and between Arch Therapeutics, Inc. and Dr. Arthur Rosenthal</a>		S-1/A	10.40	333-206873 10/16/2015
10.11#	<a href="#">Arch Therapeutics, Inc. 2013 Stock Incentive Plan</a>		8-K	10.1	333-178883 6/24/2013
10.12#	<a href="#">Form of Stock Option Award Agreement under Arch Therapeutics, Inc. 2013 Stock Incentive Plan</a>		10-Q	10.13	000-54986 8/14/2013

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10.13#	<a href="#">Form of Restricted Stock Unit Award Agreement under Arch Therapeutics, Inc. 2013 Stock Incentive Plan</a>	10-Q	10.14	000-54986	8/14/2013
10.14#	<a href="#">Form of Restricted Stock Bonus Award Agreement under Arch Therapeutics, Inc. 2013 Stock Incentive Plan</a>	10-Q	10.15	000-54986	8/14/2013
10.15#	<a href="#">Form of Restricted Stock Award Agreement</a>	8-K	10.2	000-54986	5/6/2016
10.16	<a href="#">Binding Letter of Intent by and between Almah, Inc. and Arch Therapeutics, Inc. dated April 19, 2013</a>	8-K	10.1	333-178883	4/25/2013
10.17	<a href="#">Promissory Note by and between Almah, Inc. and Arch Therapeutics, Inc. dated April 19, 2013</a>	8-K	10.2	333-178883	4/25/2013
10.18	<a href="#">Financing Agreement by and between Almah, Inc. and Coldstream Summit Ltd. Dated April 19, 2013</a>	8-K	10.3	333-178883	4/25/2013
10.19	<a href="#">Form of Securities Purchase Agreement</a>	8-K	10.4	333-178883	4/25/2013
10.20	<a href="#">Form of Warrant</a>	8-K	10.5	333-178883	4/25/2013
10.21	<a href="#">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</a>	8-K	10.6	333-178883	6/26/2013
10.22	<a href="#">Life Sciences Accelerator Funding Agreement dated September 30, 2013 between Arch Therapeutics, Inc. and the Massachusetts Life Sciences Center</a>	8-K	10.1	000-54986	10/4/2013
10.23	<a href="#">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)</a>	8-K	10.2	000-54986	10/4/2013
10.24	<a href="#">Form of MLSC Subordination Agreement</a>	8-K	10.1	000-54986	9/9/2013
10.25	<a href="#">Amendment Agreement to Arch Therapeutics, Inc. Accelerator Funding Agreement dated September 28, 2016 by and between Arch Therapeutics, Inc. and Massachusetts Life Sciences Center</a>	8-K	10.1	000-54986	9/29/2016
10.26	<a href="#">Securities Purchase Agreement dated January 30, 2014, by and among Arch Therapeutics, Inc. and the investors listed on the Schedule of Buyers attached thereto</a>	8-K	10.1	000-54986	1/31/2014
10.27	<a href="#">Form of Series A Warrant to Purchase Common Stock</a>	8-K	4.1	000-54986	1/31/2014

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10.28	<a href="#">Form of Series B Warrant to Purchase Common Stock</a>	8-K	4.2	000-54986	1/31/2014
10.29	<a href="#">Form of Series C Warrant to Purchase Common Stock</a>	8-K	4.3	000-54986	1/31/2014
10.30	<a href="#">Amendment to Series A Warrants, Series B Warrants and Series C Warrants to Purchase Common Stock</a>	8-K	10.1	000-54986	12/2/2014
10.31	<a href="#">Amendment to Series C Warrants to Purchase Common Stock</a>	8-K	10.3	000-54986	3/13/2015
10.32	<a href="#">Amendment to Series C Warrants to Purchase Common Stock dated May 30, 2015</a>	8-K	10.1	000-54986	6/1/2015
10.33	<a href="#">Amendment to Series A and Series C Warrants to Purchase Common Stock dated June 22, 2015</a>	8-K	10.1	000-54986	6/23/2015
10.34	<a href="#">Form of Registration Rights Agreement dated January 30, 2014, by and among Arch Therapeutics, Inc. and the investors listed on the Schedule of Buyers attached thereto</a>	8-K	10.2	000-54986	1/31/2014
10.35	<a href="#">Form of Subscription Agreement</a>	8-K	10.1	000-54986	3/13/2015
10.36	<a href="#">Form of 8% Convertible Note</a>	8-K	10.2	000-54986	3/13/2015
10.37†	<a href="#">Project Agreement by and between Arch Therapeutics, Inc. and the National University of Ireland Galway dated May 28, 2015</a>	8-K	10.1	000-54986	8/7/2015
10.38	<a href="#">Form of Subscription Agreement</a>	8-K	10.1	000-54986	7/6/2015
10.39	<a href="#">Form of Series D Warrants</a>	8-K	10.2	000-54986	7/6/2015
10.40	<a href="#">Registration Rights Agreement dated June 30, 2015, by and among Arch Therapeutics, Inc. and the Purchasers set forth on the signature pages thereto</a>	8-K	10.3	000-54986	7/6/2015
10.41	<a href="#">2017 Securities Purchase Agreement</a>	8-K	10.1	000-54986	02/21/2017
10.42	<a href="#">Form of Series F Warrants</a>	8-K	10.2	000-54986	02/21/2017
10.43	<a href="#">2018 Securities Purchase Agreement</a>	8-K	10.1	000-54986	06/29/2018
10.44	<a href="#">Form of Series G Warrants</a>	8-K	10.2	000-54986	06/29/2018
10.45#	<a href="#">Advisory Agreement, effective July 19, 2018, by and between Arch Therapeutics, Inc. and Dr. Avtar Dhillon</a>	8-K	10.1	000-54986	07/20/2018
10.46#	<a href="#">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</a>	8-K	10.4	000-54986	07/20/2018
10.47	<a href="#">May 2019 Securities Purchase Agreement</a>	8-K	10.1	000-54986	05/13/2019



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10.48	<a href="#">Form of Series H Warrants</a>	8-K	10.2	000-54986	05/13/2019
10.49	<a href="#">Form of October 2019 Securities Purchase Agreement</a>	8-K	10.1	000-54986	10/18/2019
10.50	<a href="#">Form of Series I Warrants</a>	8-K	10.2	000-54986	10/18/2019
10.51	<a href="#">2019 Engagement Agreement</a>	8-K	10.3	000-54986	10/18/2019
10.52	<a href="#">Form of 2019 Placement Agent Warrant</a>	8-K	10.4	000-54986	10/18/2019
10.53	<a href="#">PPP Note</a>	8-K	10.1	000-54986	04/27/2020
10.54	<a href="#">Form of Amendment to Series D Warrants to Purchase Common Stock</a>	8-K	10.1	000-54986	06/05/2020
10.55	<a href="#">Form of Series J Warrant</a>	8-K	10.2	000-54986	06/05/2020
10.56	<a href="#">Form of Series 1 Convertible Notes</a>	8-K	10.3	000-54986	06/05/2020
10.57	<a href="#">Amendment to Series J Warrant to Purchase Common Stock</a>	8-K	10.1	000-54986	11/10/2020
10.58	<a href="#">Form of Series 2 Convertible Notes</a>	8-K	10.2	000-54986	11/10/2020
10.59#	<a href="#">Transition Agreement, dated December 31, 2020, by and between Arch Therapeutics, Inc. and Richard Davis</a>	S-1	10.62	333-234811	01/26/2021
10.60	<a href="#">Form of 2021 Securities Purchase Agreement</a>	8-K	10.1	000-54986	2/12/2021
10.61	<a href="#">Form of Series K Warrant</a>	8-K	10.2	000-54986	2/12/2021
10.62	<a href="#">2021 Engagement Agreement</a>	8-K	10.3	000-54986	2/12/2021
10.63	<a href="#">Form of 2021 Placement Agent Warrant</a>	8-K	10.4	000-54986	2/12/2021
10.64	<a href="#">Form of Registration Rights Agreement</a>	8-K	10.5	000-54986	2/12/2021
10.65	<a href="#">Amendment No. 1 to Transition Agreement, dated December 31, 2020, by and between Arch Therapeutics, Inc. and Richard Davis</a>	8-K	10.1	000-54986	5/3/2021
10.66	<a href="#">Executive Employment Agreement, effective May 3, 2021, by and between Arch Therapeutics, Inc. and Michael S. Abrams</a>	8-K	10.2	000-54986	5/3/2021
10.67	<a href="#">Employment Agreement, effective June 30, 2021, by and between Arch Therapeutics, Inc. and Dan M. Yrigoyen</a>	8-K	10.1	000-54986	8/11/2021
10.68	<a href="#">First Amendment to Employment Agreement, effective August 9, 2021, by and between Arch Therapeutics, Inc. and Dan M. Yrigoyen</a>	8-K	10.2	000-54986	8/11/2021
10.69	<a href="#">Form of Securities Purchase Agreement, dated July 6, 2022, by and among the Company and the signatories thereto</a>	8-K	10.1	000-54986	7/8/2022
10.70	<a href="#">Form of 2022 Notes</a>	8-K	10.2	000-54986	7/8/2022
10.71	<a href="#">Form of 2022 Warrant</a>	8-K	10.3	000-54986	7/8/2022
10.72	<a href="#">Form of Registration Rights Agreement, dated July 6, 2022, by and among the Company and the signatories thereto</a>	8-K	10.4	000-54986	7/8/2022
10.73	<a href="#">Form of Security Agreement, dated July 6, 2022, by and among the Company and the signatories thereto</a>	8-K	10.5	000-54986	7/8/2022

21.1	<a href="#">List of Subsidiaries</a>		8-K	21.1	333-178883	6/26/2013
23.1	<a href="#">Consent of Independent Registered Public Accounting firm</a>	X				
24.1	<a href="#">Power of Attorney (included on the signature page hereto)</a>	X				
31.1	<a href="#">Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities and Exchange Act of 1934</a>	X				
31.2	<a href="#">Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities and Exchange Act of 1934</a>	X				
32.1	<a href="#">Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, executed by Terrence W. Norchi, President and Chief Executive Officer, and Michael S. Abrams, Chief Financial Officer</a>	X				
101.INS	Inline XBRL Instance Document	X				
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X				
104	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit)	X				
†	Confidential treatment has been granted as to certain portions of these Exhibits					
#	Management contract or compensatory plan or arrangement.					

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Arch Therapeutics, Inc.

Date: December 28, 2022

By: /s/ Terrence W. Norchi, MD  
Terrence W. Norchi, MD  
*President and Chief Executive Officer*

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and 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>	December 28, 2022
<u>/s/ Michael S. Abrams</u> Michael S. Abrams	Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	December 28, 2022
<u>/s/ Punit Dhillon</u> Punit Dhillon	Director	December 28, 2022
<u>/s/ Laurence Hicks</u> Laurence Hicks	Director	December 28, 2022
<u>/s/ Guy Fish</u> Guy Fish	Director	December 28, 2022

**ARCH THERAPEUTICS, INC. AND SUBSIDIARY**  
**CONSOLIDATED FINANCIAL STATEMENTS**

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<a href="#">Consolidated Balance Sheets as of September 30, 2022 and 2021</a>	<a href="#">F-4</a>
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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

### Opinion on the Financial Statements

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

### Going Concern Uncertainty

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

### Basis for Opinion

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

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

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

### Critical Audit Matter

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

As described in Note 10, the Company entered a transaction (the 2022 Note Offering) that included the issuance of \$4.23 million in aggregate principal of senior secured convertible promissory notes, 12,766,600 shares of Common Stock, warrants to purchase 85,110,664 shares of the Company's common stock (the 2022 Warrants) and warrants to purchase 6,301,969 shares of the Company's common stock (the 2022 Placement Agent Warrants). In addition, in conjunction with the 2022 Note Offering, certain Series 2 note holders exchanged their notes in the aggregate amount of approximately \$700,000 of principal and interest (the Series 2 exchange), for senior secured convertible promissory notes of the Company.

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

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

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

/s/ Baker Tilly US, LLP

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

Tewksbury, Massachusetts  
December 28, 2022

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

	September 30, 2022	September 30, 2021
<b>ASSETS</b>		
Current assets:		
Cash	\$ 746,940	\$ 2,266,639
Inventory	1,414,848	1,093,765
Prepaid expenses and other current assets	436,407	307,341
Total current assets	<u>2,598,195</u>	<u>3,667,745</u>
Long-term assets:		
Property and equipment, net	2,044	5,240
Other assets	3,500	3,500
Total long-term assets	<u>5,544</u>	<u>8,740</u>
Total assets	<u>\$ 2,603,739</u>	<u>\$ 3,676,485</u>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 1,328,000	\$ 408,083
Accrued expenses and other liabilities	318,505	319,464
Insurance premium financing	247,933	—
Current portion of Series 1 convertible notes	550,000	—
Current portion of accrued interest	127,781	—
Current portion of derivative liability	748,275	1,000,000
Total current liabilities	<u>3,320,494</u>	<u>1,727,547</u>
Long-term liabilities:		
Series 1 convertible notes	—	550,000
Series 2 convertible notes	450,000	1,050,000
Senior secured convertible notes, net of discount and issuance costs	2,362,273	—
Accrued interest	204,575	167,137
Derivative liability	459,200	1,207,475
Total long-term liabilities	<u>3,476,048</u>	<u>2,974,612</u>
Total liabilities	<u>6,796,542</u>	<u>4,702,159</u>
Commitments and contingencies (Note 15)		
Stockholders' equity (deficit):		
Common stock, \$0.001 par value, 800,000,000 shares authorized as of September 30, 2022 and 2021, 249,886,370 and 237,169,770 shares issued as of September 30, 2022 and 2021, and 249,936,370 and 236,719,770 outstanding as of September 30, 2022 and 2021	249,886	236,720
Additional paid-in capital	50,630,084	48,534,525
Accumulated deficit	(55,072,773)	(49,796,919)
Total stockholders' deficit	<u>(4,192,803)</u>	<u>(1,025,674)</u>
Total liabilities and stockholders' deficit	<u>\$ 2,603,739</u>	<u>\$ 3,676,485</u>

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

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

	Fiscal Year Ended September 30, 2022	Fiscal Year Ended September 30, 2021
Revenue	\$ 15,652	\$ 11,565
Operating expenses:		
Cost of revenues	51,489	26,282
Selling, general and administrative expenses	4,519,636	5,009,323
Research and development expenses	1,153,333	1,353,084
Total costs and expenses	<u>5,724,458</u>	<u>6,388,689</u>
Loss from operations	<u>(5,708,806)</u>	<u>(6,377,124)</u>
Other (expense) income:		
Interest expense	(567,048)	(150,531)
Gain on forgiveness of loan	—	178,229
Decrease to fair value of derivative	1,000,000	108,944
Total other income	<u>432,952</u>	<u>136,642</u>
Net loss	<u>\$ (5,275,854)</u>	<u>\$ (6,240,482)</u>
Loss per share - basic and diluted		
Net loss per common share - basic and diluted	\$ (0.02)	\$ (0.03)
Weighted common shares - basic and diluted	239,914,846	220,001,412

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



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

<i><b>Fiscal Year Ended September 30, 2022</b></i>	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balance at September 30, 2021	236,719,770	\$ 236,720	\$ 48,534,525	\$ (49,796,919)	\$ (1,025,674)
Net loss	—	—	—	(5,275,854)	(5,275,854)
Issuance of common stock and warrants, net of financing costs	12,766,600	12,766	1,596,375	—	1,609,141
Vesting of restricted stock issued	400,000	400	(400)	—	—
Stock-based compensation expense	—	—	499,584	—	499,584
Balance at September 30, 2022	<u>249,886,370</u>	<u>\$ 249,886</u>	<u>\$ 50,630,084</u>	<u>\$ (55,072,773)</u>	<u>\$ (4,192,803)</u>
<i><b>Fiscal Year Ended September 30, 2021</b></i>	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balance at September 30, 2020	193,044,766	\$ 193,045	\$ 41,862,901	\$ (43,556,437)	(1,500,491)
Net loss	—	—	—	(6,240,482)	(6,240,482)
Issuance of common stock and warrants, net of financing costs	43,125,004	43,125	6,176,108	—	6,219,233
Vesting of restricted stock issued	550,000	550	(550)	—	—
Stock-based compensation expense	—	—	496,066	—	496,066
Balance at September 30, 2021	<u>236,719,770</u>	<u>\$ 236,720</u>	<u>\$ 48,534,525</u>	<u>\$ (49,796,919)</u>	<u>\$ (1,025,674)</u>

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

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

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

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

## Notes to the Consolidated Financial Statements

### 1. DESCRIPTION OF BUSINESS

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

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

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

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

### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

#### Basis of Presentation

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

#### Use of Estimates

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

#### Recently Issued and Adopted Accounting Guidance

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

### Cash and Cash Equivalents

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

### Inventories

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

### Concentration of Credit Risk

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

### Property and Equipment

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

### Impairment of Long-Lived Assets

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

### Leases

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

### Income Taxes

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

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

### Revenue

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

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

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### [Cost of Revenues](#)

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

### [Research and Development](#)

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

### [Accounting for Stock-Based Compensation](#)

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

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

### [Fair Value Measurements](#)

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

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

### [Derivative Liabilities](#)

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

### [Complex Financial Instruments](#)

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

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

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

### [Financial Statement Reclassification](#)

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

### [Subsequent Events](#)

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

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

### Going Concern Basis of Accounting

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

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

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

### 3. PROPERTY AND EQUIPMENT

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

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

For the years ended September 30, 2022 and 2021 depreciation expense recorded was \$3,196 and \$2,587, respectively.

#### 4. INVENTORIES

Inventories consist of the following:

	September 30, 2022	September 30, 2021
Finished Goods	\$ 9,063	\$ 249,571
Goods-in-process	1,405,785	844,194
Total	<u>\$ 1,414,848</u>	<u>\$ 1,093,765</u>

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

#### 5. INSURANCE PREMIUM FINANCING

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

#### 6. REGISTERED DIRECT OFFERINGS

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

On February 20, 2017, the Company entered into a Securities Purchase Agreement (the “*2017 SPA*”) with six accredited investors (collectively, the “*2017 Investors*”) providing for the issuance and sale by the Company to the 2017 Investors of an aggregate of 10,166,664 units at a purchase price of \$0.60 per unit in a registered offering (the “*2017 Financing*”). The securities comprising the units sold in the 2017 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant equal to 55% of the shares of Common Stock at an exercise price of \$0.75 per share (“*Series F Warrant*”) at any time prior to the fifth anniversary of the issuance date of the Series F Warrant subject to certain restrictions on exercise (the “*2017 Warrants*”) and the shares issuable upon exercise of the 2017 Warrants (the “*2017 Warrant Shares*”).

On June 28, 2018, the Company entered into a Securities Purchase Agreement (“*2018 SPA*”) with eight accredited investors (collectively, the “*2018 Investors*”) providing for the issuance and sale by the Company to the 2018 Investors of an aggregate of 9,070,000 units at a purchase price of \$0.50 per unit in a registered offering (“*2018 Financing*”). The securities comprising the units sold in the 2018 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant to purchase up to a number of shares of the Company’s Common Stock equal to 75% of the shares of Common Stock at an exercise price of \$0.70 per share (“*Series G Warrant*”) at any time prior to the fifth anniversary of the issuance date of the Series G Warrant subject to certain restrictions on exercise (the “*2018 Warrants*”) and the shares issuable upon exercise of the 2018 Warrants (the “*2018 Warrant Shares*”).

On May 12, 2019, the Company entered into a Securities Purchase Agreement (“*2019 SPA*”) with five accredited investors (collectively, the “*2019 Investors*”) providing for the issuance and sale by the Company to the 2019 Investors of an aggregate of 8,615,384 units at a purchase price of \$0.325 per unit in a registered offering (“*2019 Financing*”). The securities comprising the units sold in the 2019 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant to purchase one share of Common Stock at an exercise price of \$0.40 per share (“*Series H Warrant*”) at any time prior to the fifth anniversary of the issuance date of the Series H Warrant subject to certain restrictions on exercise (the “*2019 Warrants*”) and the shares issuable upon exercise of the 2019 Warrants (the “*2019 Warrant Shares*”).

During the years ended September 30, 2022 and 2021, no Series F, Series G or Series H Warrants had been exercised. As of September 30, 2022, up to 6,802,500 and 8,615,384 shares may be acquired upon the exercise of the Series G and Series H Warrants, respectively.

During the year ended September 30, 2022, all 5,591,664 remaining Series F Warrants expired.



## 7. Derivative Liabilities

The Company accounted for the Series F Warrants, Series G Warrants and the Series H Warrants in accordance with ASC 815-10. Since the Company may be required to purchase its Series F Warrants, Series G Warrants and Series H Warrants for an amount of cash equal to \$0.08, \$0.11 and \$0.0533, respectively, for each share of Common Stock (“*Minimum*”) they are recorded as liabilities at the greater of the Minimum or fair value. They are marked to market each reporting period through the Consolidated Statement of Operations. During the year ended September 30, 2022, the Company recognized income of \$1,000,000 for the expiration of the Series F Warrants.

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

### Fair Value Measurements Using Significant Unobservable Inputs - Year Ended September 30, 2022

(Level 3)

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

### Fair Value Measurements Using Significant Unobservable Inputs – Year Ended September 30, 2021

(Level 3)

	Series F	Series G	Series H
Beginning balance at September 30, 2020	\$ 1,000,000	\$ 748,275	\$ 568,144
Issuances	—	—	—
Adjustments to estimated fair value	—	—	(108,944)
Ending balance at September 30, 2021	\$ 1,000,000	\$ 748,275	\$ 459,200

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

	Series G	Series H
Closing price per share of Common Stock		
Exercise price per share	\$ 0.70	\$ 0.40
Expected volatility	132.97%	122.50%
Risk-free interest rate	4.05%	4.14%
Dividend yield	—	—
Remaining expected term of underlying securities (years)	0.69	1.57

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

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

	Series F	Series G	Series H
Closing price per share of Common Stock	\$ 0.12	\$ 0.12	\$ 0.12
Exercise price per share	\$ 0.75	\$ 0.70	\$ 0.40
Expected volatility	90.28%	87.40%	86.59%
Risk-free interest rate	0.04%	0.19%	0.41%
Dividend yield	—	—	—
Remaining expected term of underlying securities (years)	0.34	1.70	2.58

## 8. OCTOBER 2019 REGISTERED DIRECT OFFERING

On October 16, 2019, the Company entered into a Securities Purchase Agreement (the “*October 2019 SPA*”) with seven accredited investors (collectively, the “*October 2019 Investors*”) providing for the issuance and sale by the Company to the 2019 Investors of an aggregate of 14,285,714 units at a purchase price of \$0.175 per unit in a registered offering (“*October 2019 Financing*”). The securities comprising the units sold in the October 2019 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, a warrant to purchase one share of Common Stock at an exercise price of \$0.22 per share (“*Series I Warrant*”) at any time prior to the fifth anniversary of the issuance date of the Series I Warrant subject to certain restrictions on exercise and the shares issuable upon exercise of the Series I Warrants (collectively, the “*October 2019 Warrant Shares*”). As of October 18, 2019, the Company recorded the 14,285,714 shares as Common Stock. Pursuant to the Engagement Agreement (as defined below), the Company also agreed to issue to the Placement Agent, or its designees, warrants to purchase up to 1,071,429 shares (the “*Placement Agent Warrants*”). The 2019 Placement Agent Warrants have substantially the same terms as the Series I Warrants, except that the exercise price of the Placement Agent Warrants is \$0.21875 per share and the term of the Placement Agent Warrants is five years.

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

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

During the year ended September 30, 2022, no Series I Warrants or Placement Agent Warrants have been exercised. As of September 30, 2022, up to 14,285,714 and 1,071,429 shares may be acquired upon the exercise of the Series I Warrants and Placement Agent Warrants, respectively.

#### Common Stock

At October 18, 2019 the Closing Date of the October 2019 Financing, the Company issued 14,285,714 shares of Common Stock.

#### Equity Value of Warrants

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

### **9. 2021 REGISTERED DIRECT OFFERING**

On February 11, 2021, the Company entered into a Securities Purchase Agreement (the "*2021 SPA*") with certain institutional and accredited investors (collectively, "*2021 Investors*") providing for the issuance and sale by the Company to the 2021 Investors of an aggregate of 43,125,004 shares (the "*Shares*") of the Company's Common Stock, and warrants (the "*Series K Warrants*") to purchase an aggregate of 32,343,754 shares (the "*Warrant Shares*") of Common Stock, at a combined offering price of \$0.16 per share (the "*2021 Financing*"). The Series K Warrants have an exercise price of \$0.17 per share and are exercisable for a period of 5.5 years. The aggregate gross proceeds for the sale of the Shares and Series K Warrants were approximately \$6.9 million, before deducting the Placement Agent's fees and expenses and other offering expenses payable by the Company, of approximately \$700,000. Pursuant to an engagement agreement dated as of February 8, 2021 (the "*2021 Engagement Agreement*"), by and between the Company and the Placement Agent, the Company agreed to pay the Placement Agent cash fees equal to (i) 7.5% of the gross proceeds received by the Company from certain investors in the 2021 Financing, and (ii) 6.0% of the gross proceeds received by the Company from certain investors that had pre-existing relationships with the Company. In addition, the Placement Agent received a one-time non-accountable expense fee of \$10,000, up to \$50,000 for fees and expenses of legal counsel and other out-of-pocket expenses and \$10,000 for clearing expenses. Pursuant to the 2021 Engagement Agreement, the Company also agreed to issue to the Placement Agent, or its designees, warrants to purchase up to 7.5% of the aggregate number of Shares sold to the 2021 Investors, or warrants to purchase up to 3,234,375 shares (the "*2021 Placement Agent Warrants*") of the Company's Common Stock. The 2021 Placement Agent 2 Warrants have substantially the same terms as the Series K Warrants, except that the exercise price of the 2021 Placement Agent Warrants is \$0.20 per share. The 2021 Engagement Agreement contained indemnity and other customary provisions for transactions of this nature.

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

The number of shares of the Company's Common Stock into which each of the Series K Warrants is exercisable and the exercise price therefore are subject to adjustment, as set forth in the Series K Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise). During the fiscal year ended September 30, 2022, no Series K Warrants or 2021 Placement Agent Warrants had been exercised. As of September 30, 2022, up to 32,343,754 and 3,234,375 shares may be acquired upon the exercise of the Series K Warrants and Placement Agent Warrants, respectively.

#### Common Stock

On February 17, 2021 the Closing Date of the 2021 Financing, the Company issued 43,125,004 shares of Common Stock.

## Equity Value of Warrants

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

## **10. 2022 CONVERTIBLE NOTE OFFERING**

On July 7, 2022, the Company announced that it had entered into a Securities Purchase Agreement (the "2022 SPA") with certain institutional and accredited individual investors (collectively, the "2022 Investors") providing for the issuance and sale by the Company to the 2022 Investors of (i) Senior Secured Convertible Promissory Notes (each a "2022 Note" and collectively, the "2022 Notes") in the aggregate principal amount of \$4.23 million, which includes an aggregate \$0.705 million original issue discount in respect of the 2022 Notes; (ii) Warrants (the "2022 Warrants"), to purchase an aggregate of 85,110,664 shares (the "2022 Warrant Shares") of Common Stock; and (iii) 12,766,600 shares of Common Stock (the "2022 Inducement Shares") equal to 15% of the principal amount of the 2022 Notes divided by the closing price of the Common Stock immediately prior to the Closing Date (as defined below). The 2022 Notes, 2022 Warrants and 2022 Inducement Shares were issued as part of a convertible note offering authorized by the Company's board of directors (the "2022 Note Offering"). The aggregate gross proceeds for the sale of the 2022 Notes, 2022 Warrants and 2022 Inducement Shares was approximately \$3.5 million, before deducting debt issuance costs of \$775,000 consisting of fair value of the placement agent's warrants of approximately \$220,000 and other estimated fees and offering expenses payable by the Company of approximately \$555,000. The closing of the sales of these securities under the 2022 SPA occurred on July 6, 2022 (the "2022 Closing Date").

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

The 2022 Notes are convertible into shares of Common Stock at the option of each holder of the 2022 Notes from the date of issuance at \$0.0457 (the "Conversion Price") through the later of (i) January 6, 2024 (the "Maturity Date") and (ii) the date of payment of the Default Amount (as defined in the 2022 Note); *provided, however*, certain 2022 Notes include a provision preventing such conversion if, as a result, the holder, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder's, would be deemed to beneficially own more than 4.99% of the Common Stock (as applicable, the "Ownership Limitation") immediately after giving effect to the Conversion; and *provided further*, the holder, upon notice to us, may increase or decrease the Ownership Limitation; *provided that* (i) the Ownership Limitation may only be increased to a maximum of 9.99% of the Common Stock; and (ii) any increase in the Ownership Limitation will not become effective until the 61st day after delivery of such waiver notice. The Conversion Price is subject to adjustment as set forth in the 2022 Notes.

The 2022 Notes contain customary events of default, which include, among other things, (i) our failure to pay when due any principal or interest payment under the 2022 Notes; (ii) our insolvency; (iii) delisting of our Common Stock; (iv) our breach of any material covenant or other material term or condition under the 2022 Notes; and (v) our breach of any representations or warranties under the 2022 Notes which cannot be cured within five (5) days. Further, events of default under the 2022 Notes also include (i) the unavailability of Rule 144 on or after January 6, 2023; (ii) our failure to deliver the shares of Common Stock to the 2022 Note holder upon exercise by such holder of its conversion rights under the 2022 Note; (iii) our loss of the "bid" price for its Common Stock and/or a market and such loss is not cured during the specified cure periods; and (iv) our failure to complete an uplisting of our Common Stock to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American by February 15, 2023 (an "Uplist Transaction").

The 2022 Warrants (i) have an exercise price of \$0.0497 per share; (ii) have a term of exercise equal to 5 years after their issuance date; (iii) became exercisable immediately after their issuance; and (iv) have a provision preventing the exercisability of such 2022 Warrant if, as a result of the exercise of the 2022 Warrant, the holder, together with its affiliates and any other persons whose beneficial ownership of our Common Stock would be aggregated with the holder's, would be deemed to beneficially own more than the Ownership Limitation. The holder, upon notice to us, may increase or decrease the Ownership Limitation; *provided that* (i) the Ownership Limitation may only be increased to a maximum of 9.99% of our Common Stock; and (ii) any increase in the Ownership Limitation will not become effective until the 61st day after delivery of such waiver notice. The number of shares of Common Stock into which each of the 2022 Warrants is exercisable and the exercise price therefor are subject to adjustment as set forth in the 2022 Warrants, including standard antidilution provisions, and adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise). In the event of a Fundamental Transaction (as defined in the 2022 Warrants) holders of the 2022 Warrants would be entitled to receive alternate consideration in connection with such Fundamental Transaction, but only to the extent that holders of our Common Stock were entitled to receive the same. Moreover, as long as the 2022 Notes and 2022 Warrants remaining outstanding, upon the issuance of any security in connection with any potential future financing activity on terms more favorable than the existing terms, the Company has an obligation to notify the holders of the 2022 Notes and 2022 Warrants of such more favorable terms and to use best efforts to effect such terms in the 2022 Notes and 2022 Warrants. Finally, because of the Company's net loss position, the shares underlying the 2022 Notes on an as converted basis are excluded from the calculation of basic and fully diluted earnings per share. Similarly, because of the Company's net loss position, there was no impact on the calculation of basic and fully diluted earnings per share related to the classification of the 2022 Warrants as participating securities.

The Company retained a placement agent in connection with the private placement of \$2.4 million of the 2022 Notes to the institutional investors. The Company paid the 2022 Placement Agent 10% of the gross proceeds in the 2022 Placement Agent from certain institutional investors, or \$240,000 and we also reimbursed the 2022 Placement Agent approximately \$58,000 for non-accountable banking fees, legal fees and other expenses. In addition, we issued 2022 Placement Agent Warrants to purchase an aggregate of 6,301,969 shares of Common Stock. An additional \$1.1 million was raised in connection with the placement of the private placement notes, which included certain accredited investors some of which were Board members and executive officers of the Company. Board member, Laurence Hicks, and executive officers, Terrence W. Norchi and Michael S. Abrams, invested in the 2022 Senior Secured Convertible Notes. The investment made in the 2022 Senior Secured Convertible Notes made by the Board member and executive officers totaled \$80,000.

In addition, as a part of the 2022 Convertible Notes Offering, certain holders (the "Series Holders") of the Company's 10% Series 2 Convertible Notes (the "Series Notes") agreed to exchange their Series 2 Notes for promissory notes of the Company on substantially similar terms to those of the 2022 Notes (the "Subordinated Notes"). The Subordinated Notes are convertible into 15,312,493 shares of Common Stock at a conversion price of \$0.0457. The holders of the Subordinated Notes did not receive warrants or inducement shares. In connection with the issuance of the Subordinated Notes, the Series Holders entered into a subordination agreement on July 6, 2022 (the "Closing Date") to subordinate their rights in respect of the Subordinated Notes to the rights of the Investors in respect of the 2022 Notes. As of July 7, 2022, approximately \$600,000 of the Series 2 Notes and accrued interest of approximately \$100,000 were included in the exchange.

Further, in connection with the 2022 Note Financing, we are required to complete an Uplist Transaction by February 15, 2023 under the terms of the 2022 Notes. If we are unable to complete an Uplist Transaction, then the 2022 Notes will become immediately due and payable and we will be obligated to pay to each 2022 Note holder an

amount equal to 125%, multiplied by the sum of the outstanding principal amount of the 2022 Notes plus any accrued and unpaid interest on the unpaid principal amount of the 2022 Notes to the date of payment, plus any default interest and any other amounts owed to the holder, payable in cash or shares of Common Stock.

During the fiscal year ended September 30, 2022, the Company recorded interest expense on the 2022 Notes of approximately \$421,000 consisting of accrued interest of approximately \$119,000 and accretion of original issue discount debt discount and issuance costs of approximately \$302,000.

#### Allocation of Proceeds

The Company accounted for the Senior Secured Convertible Notes, the 2022 Warrants, and the 2022 Inducement Shares relating to the aforementioned July 2022 Senior Secured Convertible Promissory Notes in accordance with ASC 470-20-25-2 “Debt” which states that the allocation of the proceeds from the financing shall be based on the relative fair values of the securities issued at the time of the issuance. The 2022 Inducement Shares and the 2022 Warrants, which are indexed to the Company’s stock, are classified within stockholders’ equity (deficit) in the accompanying consolidated financial statements. The allocated value of the 2022 Inducement Shares and the 2022 Warrants are \$314,523 and \$1,470,133, respectively. The allocated value of the Senior Secured Convertible Notes are \$1,740,344 were allocated as long-term liabilities in the accompanying consolidated financial statements. The fair value of the 2022 Placement Agent Warrants of \$219,894 are being accounted for as debt issuance costs and are classified within stockholders’ equity (deficit) in the accompanying consolidated financial statements. As of September 30, 2022, the net carrying amount of the Senior Secured Convertible Notes was \$2,362,273 with unamortized debt discount and issuance costs of \$2,567,507.

The 2022 Warrants and the 2022 Placement Agent Warrants were valued as of July 6, 2022 using the Black Scholes Model with the following assumptions:

	2022 Investor Warrants	2022 Placement Agent Warrants
Closing price per share of Common Stock	\$ 0.0499	\$ 0.0499
Exercise price per share	\$ 0.0497	\$ 0.0503
Expected volatility	88.44%	88.44%
Risk-free interest rate	2.96%	2.96%
Dividend yield	—	—
Remaining expected term of underlying securities (years)	5.0	5.0

## 11. SERIES 1 AND SERIES 2 CONVERTIBLE NOTES

On June 4, 2020 and November 6, 2020, the Company issued unsecured 10% Series 1 Convertible Notes (“*Series 1 Notes*”) and Series 2 Convertible Notes (“*Series 2 Notes*”), and collectively with the Series 1 Notes, the “*Convertible Notes*”) in the aggregate principal amount of \$550,000 and \$1,050,000, respectively. The maturity dates of the Series 1 Notes and Series 2 Notes are June 30, 2023 and November 30, 2023, respectively. The Convertible Notes provide, among other things, for (i) a term of approximately three years; (ii) the Company’s ability to prepay the Convertible Notes, in whole or in part, at any time; (iii) the automatic conversion of the Convertible Notes upon a Change of Control (all capitalized terms not otherwise defined to have the meaning ascribed to such terms of the Convertible Notes) into shares of the Company’s Common Stock, at a per share price of \$0.27 and \$0.25 (the “*Conversion Price*”) for the Series 1 Notes and Series 2 Notes, respectively; (iv) the ability of the holders of the Convertible Note (a “*Holder*”) to convert the principal of the Convertible Notes, along with accrued interest, in whole or in part, into shares of Common Stock at the respective Conversion Price; (v) the Company’s ability to convert all Note Obligations outstanding upon a Qualified Equity Financing into shares of Common Stock at the respective Conversion Price; (vi) the Company’s ability to convert the principal of the Convertible Notes, along with accrued interest, in whole or in part, into shares of Common Stock at the respective Conversion Price in the event the volume weighted average price (“*VWAP*”) of the Common Stock equals or exceeds \$0.32 per share for at least fifteen consecutive Trading Days; (vii) the Company’s ability to convert all outstanding Note Obligations into shares of Common Stock at the respective Conversion Price (an “*In-Kind Note Repayment*”) in lieu of repaying the Note Obligations outstanding on the Maturity Date, provided, however, that in the case of an In-Kind Note Repayment, the outstanding Note Obligations will be calculated by increasing by thirty-five percent the aggregate sum of the unpaid Principal Amount held by each Holder and the accrued interest at a rate of ten percent per annum, subject to, with respect to any portion of the Principal Amount that is converted or prepaid before the twelve month anniversary of the Issuance Date, a minimum interest payment equal to ten percent of the amount that is converted or prepaid. As consideration for agreeing to subordinate, the premium applicable in connection with an In-Kind Note Repayment at maturity was increased from thirty-five percent to sixty percent.

Beginning June 22, 2015 and through June 30, 2015, the Company entered into a series of substantially similar subscription agreements with 20 accredited investors providing for the issuance and sale by the Company to the 2015 Investors, in a private placement, of an aggregate of 14,390,754 Units at a purchase price of \$0.22 per Unit. Each Unit consisted of a share of Common Stock and a Series D Warrant to purchase a share of Common Stock at an exercise price of \$0.25 per share at any time prior to the fifth anniversary of the issuance date of the Series D Warrant and the shares issuable upon exercise of the Series D Warrants.

On June 3, 2020, the Company entered into an agreement (the “*Agreement*”) with the holders of a majority (the “*Majority Holders*”) of the outstanding warrants classified as “*Series D Warrants*”, resulting in approximately \$850,000 of proceeds as a result of the full exercise of all Series D Warrants. Under the terms of the Agreement, in exchange for fully exercising their remaining Series D Warrants for 4,727,273 shares of Common Stock on June 4, 2020, the Majority Holders were issued warrants to purchase 3,545,454 shares of Common Stock at an exercise price of \$0.25 over a 1-year term (“*Series J Warrants*”). On November 6, 2020, as consideration for an investment in the Convertible Notes, the Company entered into an amendment to the Series J Warrants with a holder of a Series J Warrant exercisable for up to 3,375,000 shares of Common Stock, to extend the term of the Series J Warrant from one year to thirty months.

On June 22, 2020, the Company entered into a Series J Warrant Issuance Agreement (the “*Keyes Sulat Agreement*”) with the Keyes Sulat Revocable Trust (the “*Trust*”), also a holder of outstanding Series D Warrants, resulting in approximately \$82,000 of proceeds as a result of the full exercise of the Trust’s Series D Warrants. Under the terms of the Keyes Sulat Agreement, in exchange for fully exercising the Trust’s remaining Series D Warrants for 454,546 shares of Common Stock on June 22, 2020, the Trust was issued Series J Warrants to purchase 340,910 shares of Common Stock at an exercise price of \$0.25 over a one-year term. James R. Sulat, a former member of the Board, is a co-trustee of the Trust, of which members of Mr. Sulat’s immediate family are beneficiaries. Mr. Sulat disclosed his interest in the Trust to the Board prior to its approval of the transaction and abstained from voting on the transaction.

As described in Note 10, above, as a part of the 2022 Convertible Notes Offering, certain holders of the Series Notes agreed to exchange Notes with principal amounts of \$600,000 and accrued interest of approximately \$100,000 for promissory notes of the Company on substantially similar terms to those of the 2022 Notes (the “*Exchanged Notes*”). As of July 6, 2022, \$699,780 of principal and accrued interest of the Series 2 notes was exchanged for the Senior Secured Convertible Notes. In connection with the issuance of the Exchanged Notes, the Series Holders entered into a subordination agreement on the *Closing Date* to subordinate their rights to the rights of the Investors in respect of the 2022 Notes.

During the fiscal years ended September 30, 2022 and 2021, the Company recorded interest expense on the Series 1 and Series 2 Convertible Notes of approximately \$146,000 and \$150,000, respectively.

## 12. INCOME TAXES

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

	2022	2021
Net operating loss carryforwards	\$ 11,485,524	\$ 10,022,020
Capitalized expenditures	1,535,736	1,703,849
Research and development credit carryforwards	946,243	946,158
Stock based compensation	1,427,946	2,352,432
Property and Equipment	2,616	2,740
Accrued expenses	162,191	57,812
Inventory allowance	70,805	62,946
Gross deferred tax assets	15,631,061	15,147,957
Deferred tax asset valuation allowance	(15,631,061)	(15,147,957)
Net deferred tax assets	\$ -	\$ -

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

	2022	2021
Expected income tax (benefit) at federal statutory rate	21.00%	21.00%
<u>Increase/(Decrease) due to:</u>		
State income taxes – net of federal benefit	3.65%	5.80%
<u>Permanent Differences:</u>		
Key man life insurance	---	(0.01)%
Stock Based Compensation	(18.10)%	---
R&D, taken as a credit	(0.23)%	(0.29)%
Adjustment to fair value of derivative	3.98%	0.37%
PPP Loan Forgiveness	---	0.60%
Other	(1.14)%	(1.41)%
Change in Valuation Allowance	(9.16)%	(26.06)%
Total Income Tax Provision / (Benefit)	---	---

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

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

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

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

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

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

### **13. PAYROLL PROTECTION PROGRAM LOAN**

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

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

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

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

### **14. STOCK-BASED COMPENSATION**

#### 2013 Stock Incentive Plan

On June 18, 2013, the Company established the 2013 Stock Incentive Plan (the "*2013 Plan*"). Under the 2013 Plan, during the fiscal year ended September 30, 2021, a maximum number of 31,114,256 shares of the Company's authorized and available common stock could be issued in the form of options, stock appreciation rights, sales or bonuses of restricted stock, restricted stock units or dividend equivalent rights, and an award may consist of one such security or benefit, or two or more of them in any combination or alternative. The 2013 Plan provides that on the first business day of each fiscal year commencing with fiscal year 2014, the number of shares of our common stock reserved for issuance under the 2013 Plan for all awards except for incentive stock option awards will be subject to increase by an amount equal to the lesser of (A) 3,000,000 Shares, (B) four (4) percent of the number of shares outstanding on the last day of the immediately preceding fiscal year of the Company, or (C) such lesser number of shares as determined by the Company's Board of Directors (the "*Board*"). The exercise price of each option shall be the fair value as determined in good faith by the Board at the time each option is granted. On October 1, 2021, the aggregate number of authorized shares under the Plan was further increased by 3,000,000 shares to a total of 34,114,256 shares.

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

Share-based awards

During the year ended September 30, 2022, the Company granted 475,000 options to employees and directors and 850,000 options to consultants to purchase shares of common stock under the 2013 Plan.

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

Common Stock Options

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

	<b>Option Shares Outstanding</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term (years)</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at September 30, 2021	24,899,014	\$ 0.29	1.83	\$ 140,151
Awarded	1,325,000	\$ 0.03		
Forfeited/Cancelled	(6,498,818)	\$ 0.35		
Outstanding at September 30, 2022	19,725,196	\$ 0.26	1.46	\$ 16,900
Vested at September 30, 2022	16,504,312	\$ 0.29	1.52	\$ —
Vested and expected to vest at September 30, 2022	19,725,196	\$ 0.26	1.46	\$ 16,900

As of September 30, 2022, 8,273,158 shares are available for future grants under the 2013 Plan. Share-based compensation expense recorded in the Company's Consolidated Statements of Operations for the year ended September 30, 2022 and 2021 resulting from stock options awarded to the Company's employees, directors and consultants was approximately \$459,000 and \$391,000, respectively. Of this amount during the years ended September 30, 2022 and 2021, \$148,000 and \$124,000, respectively, were recorded as research and development expenses, and \$311,000 and \$267,000, respectively were recorded as general and administrative expenses in the Company's Consolidated Statements of Operations.

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

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

Restricted Stock

On October 14, 2020, the Company awarded 50,000 shares of Restricted Stock to a consultant. The shares subject to this grant were awarded under the 2013 Plan and vested 90 days from the date of the award.

On January 27, 2021, the Company awarded 500,000 shares of Restricted Stock to a consultant. The shares subject to this grant were awarded under the 2013 Plan and vested immediately.

On July 30, 2021, the Company awarded 150,000 shares of Restricted Stock to an employee. The shares subject to this grant were awarded under the 2013 Plan and 50,000 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 300,000 shares of Restricted Stock to a consultant. The shares subject to this grant were awarded under the 2013 Plan and 1/12 of the shares will vest on each of the next twelve monthly anniversaries.



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

	2022	2021
Non Vested at September 30, 2021 and 2020	450,000	
Awarded	—	1,000,000
Vested	(400,000)	(550,000)
Forfeited	—	—
Non Vested at September 30, 2022 and 2021	50,000	450,000

The weighted average restricted stock award date fair value information for the years ended September 30, 2022 and 2021 follows:

	2022	2021
Non Vested at September 30, 2021 and 2020	\$ 0.10	\$ —
Awarded		0.13
Vested	(0.10)	(0.16)
Forfeited		—
Non Vested at September 30, 2022 and 2021	\$ 0.09	\$ 0.10

For the years ended September 30, 2022 and 2021 compensation expense recorded for the restricted stock awards was approximately \$40,000 and \$105,000, respectively. As of September 30, 2022, there is approximately \$3,000 of unrecognized compensation expense related to unvested stock-based compensation arrangements granted under the 2013 Plan.

## 15. COMMITMENTS AND CONTINGENCIES

In the ordinary course of business, the Company enters into various agreements containing standard indemnification provisions. The Company's indemnification obligations under such provisions are typically in effect from the date of execution of the applicable agreement through the end of the applicable statute of limitations. The aggregate maximum potential future liability of the Company under such indemnification provisions is uncertain. As of September 30, 2022 and 2021, no amounts have been accrued related to such indemnification provisions.

From time to time, the Company may be exposed to litigation in connection with its operations. The Company's policy is to assess the likelihood of any adverse judgments or outcomes related to legal matters, as well as ranges of probable losses.

#### *MIT Licensing Agreement*

In December 2007, the Company entered into a license agreement with MIT pursuant to which the Company acquired an exclusive world-wide license to develop and commercialize technology related to self-assembling peptide compositions, and methods of making and using such compositions in medical and non-medical applications, including claims that cover the Company's proposed products and methods of use thereof. The license also provides non-exclusive rights to additional intellectual property in the fields that cover the Company's proposed products and methods of use thereof, in order to provide freedom to operate. The license provides the Company a right to sublicense the exclusively licensed intellectual property. The Company has not sublicensed the exclusively licensed intellectual property to any party for any field.

In exchange for the licenses granted in the agreement, the Company has paid MIT license maintenance fees and patent prosecution costs. The Company paid license maintenance fees of \$50,000 to MIT in the fiscal years ended September 30, 2022 and 2021. For the years ended September 30, 2022 and 2021, the annual MIT license maintenance fees of \$50,000 are included in accrued expenses and other liabilities on the Consolidated Balance Sheets. The license maintenance fees and patent prosecution costs cover the contract year beginning January 1 through December 31. Annual license maintenance obligations extend through the life of the patents. In addition, MIT is entitled to royalties on applicable future product sales, if any. The annual payments may be applied towards royalties payable to MIT for that year for product sales.

The Company is obligated to indemnify MIT and related parties from losses arising from claims relating to the exercise of any rights granted to the Company under the license, with certain exceptions. The maximum potential amount of future payments the Company could be required to make under this provision is unlimited. The Company considers there to be a low performance risk as of September 30, 2022.

The agreement expires upon the expiration or abandonment of all patents that are issued and licensed to the Company by MIT under such agreement. The Company expects that patents will be issued from presently pending U.S. and foreign patent applications. Any such patent will have a term of 20 years from the filing date of the underlying application. MIT may terminate the agreement immediately, if the Company ceases to carry on its business, if any nonpayment by the Company is not cured or the Company commits a material breach that is not cured. The Company may terminate the agreement for any reason upon six months' notice to MIT.

#### *Leases*

The Company's corporate offices are located in Framingham, MA. During July 2017, we entered into a three-year operating lease commencing October 1, 2017 and ending on September 30, 2020 at our current location, pursuant to which we are obliged to pay annual rent of \$38,400 during the first year, \$39,600 during the second year and \$42,000 during the third year. During August 2020, we extended the lease through September 30, 2021 at our current location pursuant to which we are obligated to pay annual rent of \$42,000. During October 2021 we extended the lease for six months through March 31, 2022 at our current location pursuant to which we are obligated to pay \$21,000. As of April 1, 2022 we have converted our current lease to a monthly rental and are obligated to pay \$3,500 per month. As of September 30, 2022 and 2021, there was no ROU asset or liability. We believe our present offices are suitable for our current and planned near-term operations.

## **16. RISKS AND UNCERTAINTIES - COVID-19 AND GEOPOLITICAL CONFLICTS**

The Company sources its materials and services for its products and product candidates from facilities in areas impacted or which may be impacted by the outbreak of the COVID-19 or geopolitical conflicts. The Company's ability to obtain future inventory may be impacted, therefore potentially affecting the Company's future revenue stream. In addition, the Company has historically and principally funded its operations through debt borrowings, the issuance of convertible debt, and the issuance of units consisting of Common Stock and warrants which may also be impacted by economic conditions beyond the Company's control as well as uncertainties resulting from geopolitical conflicts, including the recent war in Ukraine. The extent to which the COVID-19 and recent events in Ukraine will impact the global economy and the Company is uncertain and cannot be reasonably measured.

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in Registration Statements (Nos. 333-234811, 333-253588, 333-267004, and 333-268008) on Forms S-1 and (Nos. 333-193516, 333-201229, 333-207314, 333-214429, 333-220918, 333-228886, 333- 235715, 333-252133, and 333-261918) on Forms S-8 of our report dated December 28, 2022, relating to the consolidated financial statements of Arch Therapeutics, Inc. and Subsidiary (the Company), appearing in this Annual Report on Form 10-K as of and for the years ended September 30, 2022 and 2021. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ Baker Tilly US, LLP  
Tewksbury, Massachusetts

December 28, 2022

# CERTIFICATIONS

I, Terrence W. Norchi, certify that:

1. I have reviewed this Annual Report on Form 10-K of Arch Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  1. (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  2. (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

December 28, 2022

/s/ Terrence W. Norchi, MD  
 Terrence W. Norchi, MD  
*President and Chief Executive Officer (Principal Executive Officer)*

# CERTIFICATIONS

I, Michael S. Abrams, certify that:

1. I have reviewed this Annual Report on Form 10-K of Arch Therapeutics, Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  1. (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  2. (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

December 28, 2022

/s/ Michael S. Abrams

Michael S. Abrams

*Chief Financial Officer and Treasurer (Principal Financial Officer)*

CERTIFICATION  
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Each of the undersigned hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in his capacity as the specified officer of Arch Therapeutics, Inc. (the “Company”) and to the best of his knowledge, that:

- (1) the Annual Report on Form 10-K of the Company for the period ended September 30, 2020 (the “Report”) fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: December 28, 2022      By: /s/ Terrence W. Norchi, MD  
Terrence W. Norchi, MD  
*President and Chief Executive Officer*  
*(Principal Executive Officer)*

By: /s/ Michael S. Abrams  
Michael S. Abrams  
*Chief Financial Officer*  
*(Principal Financial and Accounting Officer)*

This certification accompanies this Annual Report on Form 10-K pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

A signed original of this certification required by Section 906 of the Sarbanes-Oxley Act of 2002, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.