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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, 2023

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	46-0524102
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
235 Walnut Street, Suite 6 **Framingham, MA**	**01702**
(Address of principal executive offices)	(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 □	Accelerated filer □
Non-accelerated filer ⊠	Smaller reporting company ⊠
	Emerging growth company □

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Securities Act. □

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. □

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued statements. □

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to Section 240.10D-1(b). □

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 $4,000,000. 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 February 14, 2024, 4,742,363 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.

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

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

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

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

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

The Company has recently devoted substantially all of its operational effort to the market adoption and commercial sales of AC5 Advanced Wound System, its first product. To date, the Company has principally raised capital through debt borrowings, the issuance of convertible debt, 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 current and potential products. However, there can be no assurance that the Company will be successful in securing additional capital when needed, on terms acceptable to the Company, if at all. Therefore, there exists substantial doubt about the Company's ability to continue as a going concern for one year past the issuance of the financial statements. The consolidated financial statements do not include any adjustments related to the recoverability of assets that might be necessary despite this uncertainty.

Business Overview

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

Core Technology

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

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

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

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

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

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

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

Operations

We have recently started to commercialization AC5 Advanced Wound System. We rely on both an internal commercial team and independent sales distributors to drive awareness and adoption of AC5 Advanced Wound System in several targeted channels with a particular focus on physician offices and government channels, such as Veterans Health Administration (VA) hospitals and military treatment facilities. We anticipate that material growth in the physician office setting will require product reimbursement. To that end, we applied to the Centers for Medicare and Medicaid Services (CMS) for a dedicated Healthcare Common Procedure Coding System (HCPCS) Level II reimbursement code specific to AC5 Advanced Wound System to better enable providers to bill third party payors for AC5 that is used in doctors' offices. The unique HCPCS code, A2020, was granted and made effective on April 1, 2023.

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

We will continue to seek partnerships with reputable, value-added independent sales distributors on a case-by-case basis to expand the overall reach and footprint of its total sales organization. Presently, our commercialization efforts and resources remain dedicated to the US market for advanced wound care.

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

Our long-term business plan includes the following goals:

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

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

- further develop our product clinical profile;
- enhance product packaging features;
- identify and address opportunities for supply chain efficiencies;
- assess our technology platform in order to identify and select product candidates for potential advancement into development;
- seek additional funding as required to support the previously described milestones necessary to support our operations;
- continue to expand and enhance our financial and operational reporting and controls;
- pursue commercial partnerships; and
- expand and enhance our intellectual property portfolio by filing new patent applications, obtaining allowances on currently filed patent applications, and/or adding to our trade secrets in self-assembly, manufacturing, analytical methods and formulation, as appropriate.

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

We have no commitments for 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.

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 February 14, 2024 we believe that our current cash on hand will meet our anticipated cash requirements into the second quarter of fiscal 2024. 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.

Research and Development

Preclinical and clinical testing is required in order to receive regulatory marketing authorizations for our products and to support those products upon and after commercialization, and we anticipate continuing such testing as appropriate.

Preclinical Testing

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

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

Before initiating or clinical trials and submitting marketing applications for a given product in most jurisdictions, we complete a biocompatibility assessment using a battery of standard in vitro and in vivo tests. Examples of such tests may include the following, as set forth in ISO 10993 issued by the International Organization for Standardization:

- in vitro cytotoxicity;
- in vitro blood compatibility;

- irritation/intracutaneous reactivity;
- sensitization (allergenic reaction);
- implantation (performed on devices that contact the body's interior);
- pyrogenicity (causing fever or inflammation); and
- systemic toxicity.

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

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

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

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

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

In an assessment versus 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' AC5 technology has also demonstrated hemostasis in liver and other organs in in vivo surgical models, including rapid hemostasis within 15 seconds. In a range of small and large animal models, our compositions have been shown to stop bleeding, seal leaking, allow for normal healing, and mitigate inflammation while being biocompatible.

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

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

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

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

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

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

Clinical Testing

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

In order to enroll patients in a clinical trial, we are required to obtain each patient's informed consent in a form and substance that complies with the 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.

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

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

Many factors could lead to delays or inefficiencies in conducting clinical trials, some of which are discussed under the heading "**RISK FACTORS**" in this prospectus. Further, we, the FDA or an institutional review board (IRB could suspend a clinical trial at any time for various reasons, including a belief that the risks to the subjects of the trial outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA clearance or approval to market the product in the US.

Regulatory

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

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

- product design, preclinical and clinical development and 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 US and AC5 Topical Hemostat in EU are classified as medical devices. Generally, a product is a medical device if it requires neither metabolic nor chemical activity to achieve the desired effect. AC5 self-assembly, which is the desired effect, is consistent with the medical device definition.

Medical devices in the US and EU are classified along a spectrum on the basis of the amount of risk to the patient associated with the medical device and the controls deemed necessary to reasonably ensure their safety and effectiveness. Class III status, which is the higher-level classification for devices compared to Classes II and I, involves additional procedures and regulatory scrutiny of the product candidate to obtain approvals. Class III devices are those that are deemed to pose the greatest risks, such as life-sustaining, life-supporting or implantable devices, or 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 US, and AC5 Topical Hemostat is a Class IIb medical device in EU.

In the US, the FDA recognizes these classes of medical devices:

- Class I, requiring general controls, including labeling, device listing, reporting and, for some products, adherence to good manufacturing practices through the FDA's quality system regulations and pre-market notification;
- Class II, requiring general controls and special controls, which may include performance standards and post-market surveillance; 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 or European Union Medical Device Regulation and is driven in part by the device's degree of contact with the patient, invasiveness, active nature, and indications for use. The medical device classes recognized in the EU are:

- Class IIa, which are considered low-medium risk devices and require certification by a Notified Body (defined below under the section entitled "*European Union Marketing Authorization (CE Mark) Process*");
- Class IIb, which are considered medium-high risk devices and require certification by a Notified Body; and
- Class III, which are considered high-risk devices and require certification by a Notified Body.

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

US Regulatory Marketing Authorization Process

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

AC5 Advanced Wound System, which is intended for external use, received marketing authorization through the 510(k) process. To obtain 510(k) clearance for a medical device, an applicant must submit a premarket notification to the FDA demonstrating that the device is "substantially equivalent" to a predicate device or devices, which is typically a legally marketed Class II device in the US. A device is substantially equivalent to a predicate device if it has the same intended use and (i) the same technological characteristics, or (ii) has different technological characteristics and the information submitted demonstrates that the device is as safe and effective as a legally marketed device and does not raise different questions of safety or effectiveness. In some cases, the submission must include data from human clinical studies. Marketing may commence when the FDA issues a clearance letter. Depending upon a product's underlying technology and intended use, as well as on FDA processes and procedures, seeking and obtaining a 510(k) can be a lengthy process.

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

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

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

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

European Union Marketing Authorization (CE Mark) Process

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

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

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

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

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

In 2017, the EU regulatory bodies implemented a Medical Device Regulation, which revises several aspects of the existing regulatory framework, such as clinical data requirements, and introduces new ones, such as Unique Device Identification. We, and the Notified Bodies who will oversee compliance to the new Medical Device Regulation, face uncertainties in the upcoming years as it is rolled out and enforced, creating risks in several areas, including the CE mark process, data transparency and application review timetables. The Medical Device Regulation became effective on May 26, 2021, although the European Commission has allowed an implementation period to facilitate transition from the Medical Device Directives. This transition period extends until the end of 2027 for high-risk devices and until the end of 2028 for medium and low risk devices.

Post-Approval Regulation

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

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

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

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

- Under the supervision of a health care professional, AC5 Advanced Wound System is a topical dressing used for the management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds.

- AC5 Topical Hemostat is intended for use locally as a dressing and to control mild to moderate bleeding, each during the management of injured skin and the micro-environment of an acute surgical wound.

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

For at least the near term future, in order to maximize operational efficiencies and to account for changing landscapes since the COVID-19 pandemic, during which both marketing authorizations were received, we have prioritized the launch of AC5 Advanced Wound System in the United States over that of AC5 Topical Hemostat in Europe, where we have not launched.

We expect the initial commercialization ramp to be gradual through 2024 and then moderately accelerate as we identify and encourage product use by key opinion leaders and early adopters in developing market channels.

We recently started to commercialize AC5 Advanced Wound System. We rely on both an internal commercial team and independent sales distributors to drive awareness and adoption of AC5 Advanced Wound System in several targeted channels with a particular focus on physician offices and government channels, such as Veterans Health Administration (VA) hospitals and military treatment facilities. These settings tend to have many patients whose needs we believe can be addressed by AC5 Advanced Wound System because it is a synthetic self-assembling wound care product that provides clinicians with multi-modal support and utility across all phases of wound healing. Numerous published case studies and accolades highlight the efficacy and safety of AC5 in the treatment of challenging chronic and acute surgical wounds, including limb salvage and healing after other modalities have failed.

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

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

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

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

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

The COVID-19 Pandemic Impact on Commercialization

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

- access to surgeons, potential strategic partners, and facilities outside of the United States has become curtailed;
- healthcare facilities often have rationed staff and resources, resulting in less 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;
- administrators who may be required to facilitate or approve new product intake are constrained by new and other pressing priorities; and
- the volume of elective surgical procedures has been constrained periodically;

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. The activities include development of our primary product candidates, as well as generation of appropriate analytical methods, scale-up, and other procedures for use by manufacturers and/or other members of our supply chain to produce or process our products at current and/or larger scale quantities for research, development, and commercialization.

Our products are regulated as medical devices, and as such, many of our activities have focused on optimizing traditional parameters to target specifications, biocompatibility, physical appearance, stability, and handling characteristics, among other metrics, to achieve the desired product. We and our partners intend to continue to monitor manufacturing processes and formulation methods closely, as success or failure in establishing and maintaining appropriate specifications may directly impact our ability to conduct additional preclinical and clinical trials and/or deliver commercial 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 to produce our current products rely on detailed, complex and difficult to manage synthetic organic chemistry processes. Although use of those methods requires that we engage manufacturers that possess the expertise, skill and know-how involved with those methods, the required equipment to use those methods is widely available. Our current products are synthesized from naturally occurring ingredients amino acids that, while not sourced from humans or other animals, do exist in their natural state in humans. That type of ingredient may be more likely to be categorized as “generally recognized as safe”, or “GRAS”, by the FDA.

Industry and Competition

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

Common features of our current and planned products, as described herein, are driven by the mechanism of action, which itself is derived from the underlying physicochemical properties or our AC5 self-assembling peptide technology and Arch’s product safety and performance specifications. Those features, which include, among others, that they possess barrier properties and can create an environment permissive to healing, can deliver a benefit in the treatment of external and internal wounds that are open, exposed, bleeding, leaking, and/or at risk for excessive inflammation or contamination.

Dermal Sciences

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

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

The incidence and prevalence of both acute surgical and chronic wounds is noteworthy. According to a 2020 report by Steiner et al for The Healthcare Cost and Utilization Project (www.ncbi.nlm.nih.gov/books/NBK442035), approximately 17 million hospital visits (inpatient and ambulatory) in 2014 resulted in almost 22 million invasive therapeutic surgeries. While more acute surgical wounds occur per year versus chronic wounds, the nature of chronic wounds provides addition greater challenges due to the prolonged duration of the healing period, the frequency of interventions needed to help the wound heal, and the often-underlying medical problem that placed the patient at risk for the wound in the first place, which is itself a hindrance to the healing process.

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

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

Venous leg ulcers, representing the most common chronic wounds, occur in approximately 2.2% of Americans over age 65 each year, according to Rice et al in 2014, which equates to roughly 1.2 million new wounds per year among just that population (www.doi.org/10.3111/13696998.2014.903258), while Qiu et al in 2021 provided an estimated prevalence of 2-4% (www.doi.org/10.3389/fmed.2021.614059). The Centers for Disease Control and Prevention estimates that approximately 56 million Americans are over age 65. Additional chronic wounds not accounted for above can include, among others, surgical wounds that become chronic wounds, typically in patients with co-morbidities.

The morbidity and mortality associated with wounds, and particularly chronic wounds, is problematic. A 2017 article by Järbrink et al noted that chronic wounds may not heal for several years or, in some cases, decades, during which time the patient may suffer from severe pain, emotional and physical distress, less mobility and greater social isolation, while the family may suffer from other stresses and challenges (www.doi.org/10.1186/s13643-016-0400-8). Woods et al in 2020 stated that only 2/3 of diabetic foot ulcers heal within 12 months (www.doi.org/10.1371/journal.pone.0232395). Some wounds just do not heal, remaining stagnant or progressing to limb loss or worse. Järbrink et al noted in 2017 that ulcers precede 85% of all amputations (www.doi.org/10.1186/s13643-016-0400-8).

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

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

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

According to a 2018 report by Nussbaum et al., data from calendar year 2014 estimated that Medicare alone spent between $28.1 to $96.8 billion for all wound care types, and that nearly 15% (8.2 million) of Medicare beneficiaries were diagnosed with at least one type of wound or wound-related infection (https://www.doi.org/10.1016/j.jval.2017.07.007). Furthermore, a 2017 report by Chan et al indicated that the mean one-year cost of care from the perspective of a health-care public payer was $44,200 for a diabetic foot ulcer, $15,400 for a pressure ulcer and $11,000 for a leg ulcer (https://www.doi.org/10.12968/jowc.2017.26.sup4.s4). Woods et al in 2020 estimated that the cost per admission among patients with diabetic foot ulcers was $8,145 if the wound was not infected and $11,290 if the wound was infected (www.doi.org/10.1371/journal.pone.0232395). Han et al noted in 2017 that lessening a hospital admission by just one day represents an enormous cost savings and is separately beneficial to the patient (https://www.doi.org/10.1007/s12325-017-0478-y).

A common wound care topic, which has been further highlighted during the COVID-19 pandemic, is how to provide high quality care in lower acuity settings. It is less expensive, more convenient, and potentially better for the patient if a wound care procedure, such as debridement, can be safely performed in a doctor’s office or wound clinic in lieu of a hospital operating room. For example, a report by Rogers et al in 2020 discussed changing sites of service to the lowest acuity setting in which care could be safely delivered (https://www.researchgate.net/publication/340950761). As such, we believe that wound care products should be designed to enable clinicians to “do more with less”, such as debride in a clinic or office a wound that otherwise may have required an operating room visit.

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

We believe that the aforementioned elevated wound incidence and prevalence, consequential morbidity and mortality, prolonged healing times and exorbitant cost of overall care underscores the potential opportunity for the overall market and for our products. We believe that the addressable market opportunity for advanced wound care products in the US alone can exceed $20 billion if improvements enable the best products to increase penetration at the expense of less effective wound care products and categories, 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., doctor’s offices) or higher acuity (e.g., operating rooms) settings;
- can be used in conjunction with aggressive surgical debridement;
- can be used on a wound whether or not it is bleeding;
- is agnostic to the presence of anti-thrombotic therapy (aka, blood thinners);
- can be used on a chronic, stalled wound that has been previously unresponsive to or failed treatment regimens;
- provides a protective barrier to mitigate contamination and modulating inflammation;
- donates moisture to the wound;
- can create wound microenvironment conducive to healing;
- aids in epithelial cell migration;
- creates an extracellular matrix-like structure to enable cell and tissue growth;
- is self-healing, in that it can dynamically self-repair around migrating cells;
- may reduce healing time and patient burden;
- is user-friendly, easy to prepare, and easy to apply;
- may be stored at ambient temperature; and
- may reduce treatment costs while improving outcomes in certain patients.

BioSurgery

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

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

- reliable;
- able to protect the wounds in tissues and organs where used;
- laparoscopic friendly;
- easily handled and applied;
- able to promote a clear field of vision and not obstruct view;

- sufficiently flowable;
- non-sticky (to tissue or equipment);
- permits normal healing;
- agnostic to the presence of antithrombotic medications ("blood thinners") to whether the patient has bleeding abnormalities;
- non-toxic; and
- not sourced from human or other animal blood or tissue components.

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

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

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

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

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

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

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

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

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

Participants in the hemostatic and sealant market include large medical device and biopharmaceutical companies, as well as various smaller companies. Commercially available hemostatic agents can cost between $50 and $500 per procedure, with the higher value-added products generally priced at the upper end of that range. We believe, however, that approaches to many surgical problems have evolved and will continue to do so, such that what may 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.

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

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

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

Other Governmental Regulations and Environmental Matters

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

Intellectual Property

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

As of February 2, 2024, we either own or license from others a number of US patents, US patent applications, foreign patents and foreign patent applications.

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

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

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

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

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

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

Employees

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

Recent Developments

On January 13, 2023, the Company filed a Certificate of Change to the Company's Articles of Incorporation, as amended, with the Secretary of State of the State of Nevada (the "Certificate of Change"), which effected, at 5:00 p.m. Eastern Time on January 17, 2023, a one-for-two-hundred (1:200) reverse stock split (the "Reverse Stock Split") of both the Company's issued and outstanding shares of Common Stock, and authorized shares of Common Stock.

As a result of the Reverse Stock Split, every two hundred (200) shares of Common Stock issued and outstanding was combined into one (1) share of Common Stock, with a proportionate 1:200 reduction in the Company's authorized Common Stock. The Reverse Stock Split affected all stockholders uniformly and did not alter any stockholder's percentage interest in the Company's equity, except to the extent that the Reverse Stock Split would have resulted in some stockholders owning a fractional share. No fractional shares were issued in connection with the Reverse Stock Split. Any fractional shares of Common Stock resulting from the Reverse Stock Split were rounded up to the nearest whole post-Reverse Stock Split share and no stockholders received cash in lieu of fractional shares.

The Reverse Stock Split did not change the par value of the Common Stock. All outstanding securities entitling their holders to purchase shares of Common Stock or acquire shares of Common Stock, including stock options, restricted stock units, and warrants, were adjusted as a result of the Reverse Stock Split, as required by the terms of those securities.

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

On January 18, 2023, the Company entered into Amendment No. 1 to the 2022 SPA (the "Amendment" and, together with the 2022 SPA, the "Amended 2022 SPA"), with certain Investors in connection with the second closing of the 2022 Convertible Note Offering for the issuance and sale by the Company to such Investors of an aggregate of (i) Unsecured Convertible Promissory Notes (each a "Second Note" and collectively, the "Second Notes") in the aggregate principal amount of $636,000, which includes an aggregate $106,000 original issue discount in respect of the Second Notes; (ii) warrants (the "Second Warrants") to purchase an aggregate of 127,968 shares (the "Second Warrant Shares") of Common Stock; and (iii) 9,598 shares of Common Stock (the "Second Inducement Shares"). The aggregate gross proceeds for the sale of the Second Notes, Second Warrants and Second Inducement Shares was approximately $530,000, before deducting any placement agent's fees and other estimated fees and offering expenses payable by the Company. The second closing of the sales of these securities under the Amended 2022 SPA occurred on January 18, 2023 (the "Second Closing Date"). As background, the Company originally entered into a Securities Purchase Agreement, dated July 6, 2022 (the "2022 SPA"), with certain institutional and accredited individual investors (collectively, the "Investors") for the issuance and sale by the Company to the Investors of convertible promissory notes (the "2022 Notes"), warrants (the "2022 Warrants") to purchase shares of common stock, par value $0.001 per share (the "Common Stock"), and shares of Common Stock (the "2022 Inducement Shares", and together with the 2022 Notes, and 2022 Warrants, the "2022 Convertible Note Offering"). The First Closing of the 2022 Convertible Note Offering occurred on July 6, 2022.

On February 14, 2023, the Company entered into an amendment to its outstanding 2022 Notes with the holders of such notes. Also on February 14, 2023, the Company entered into an amendment to its outstanding Second Notes with the holders of such notes. These actions amended the 2022 Notes and Second Notes to extend the Uplist Transaction deadline related to the Company's efforts to uplist to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American from February 15, 2023 to March 15, 2023.

As a result of the amendment to the 2022 Notes and Second Notes, and pursuant to the terms of the Company's outstanding Exchanged Notes, the Exchanged Notes were automatically amended to extend the date of completion of an Uplist Transaction from February 15, 2023 to March 15, 2023.

On March 10, 2023, the Company entered into exchange agreements (the "Exchange Agreements") with each holder (the "Warrantholders") of the Company's outstanding Series G Warrants to purchase shares of the Company's common stock, par value $0.001 per share (the "Common Stock") at an exercise price of $140.00 per share and the Company's outstanding Series H Warrants to purchase shares of Common Stock at an exercise price of $80.00 per share. Pursuant to the Exchange Agreements, the Warrantholders exchanged 34,013 Series G Warrants for 3,402 shares of Common Stock and 43,077 Series H Warrants for 8,617 shares of Common Stock.

On March 10, 2023, the Company entered into an amendment ("Amendment No. 2 to the First Notes") with the Requisite Holders of the Company's outstanding 2022 Notes, as amended on February 14, 2023, issued in connection with a private placement financing the Company completed on July 6, 2022 (the "First Closing"). On March 10, 2023, the Company also entered into an amendment ("Amendment No. 2 to the Second Notes" and, together with Amendment No. 2 to the First Notes, "Amendment No. 2 to the 2022 Notes") with the Requisite Holders of Company's Second Notes, as amended on February 14, 2023, issued in connection with a private placement financing the Company completed on January 18, 2023 (the "Second Closing" and, together with the First Closing, the "2022 Convertible Note Offering").

Under Amendment No. 2 to the 2022 Notes, the following amendments to the 2022 Notes will be effective at the moment in time immediately preceding the consummation of the offering (the "Effective Time") in connection with the uplist of the Common Stock to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (the "Uplist Transaction"). If a 2022 Note holder elects to participate in the Uplist Transaction (each, a "Participating Holder") for an amount equal to no less than 50% of the Participating Holder's original investment amount in the 2022 Private Placement Financing (the "Minimum Investment Amount"), such holder will be entitled to repayment of the principal amount of their 2022 Notes upon closing of the Uplist Transaction. In addition, the Company will issue to each Participating Holder a new convertible promissory note equal to the product of 2.4 and the sum of any prepayment premiums and total interest payable on such Participating Holder's 2022 Notes (the "2023 Notes"). The 2023 Notes will have a maturity date of July 6, 2024 and will be on substantially the same terms as the original 2022 Notes as applicable. For non-Participating Holders (each, a "Non-Participating Holder"), the maturity date of the 2022 Notes held by such Non-Participating Holder will be extended to July 6, 2024. Further, each Non-Participating Holder will waive their right to demand repayment of any portion of the outstanding balance of such holder's 2022 Notes upon an Uplist Transaction. Notwithstanding the foregoing, if the registration statement filed in connection with the Uplist Transaction is not declared effective by 11:59 P.M. (EST) on March 15, 2023 (the "Amendment No. 2 Termination Date"), Amendment No. 2 to the 2022 Notes will automatically terminate and shall be of no further force or effect without any further action by the Company or the Requisite Holders, provided, that the Amendment No. 2 Termination Date may be extended by the written approval of the Company and 2022 Notes holders which purchased at least 50% plus $1.00 of the 2022 Notes based on the initial principal amounts thereunder (the "Requisite Holders").

On March 10, 2023, the Company also entered into an amendment (the "Series 1 Note Amendment") with each of the holders of the Company's outstanding Series 1 Convertible Notes (as amended, the "Series 1 Notes"). Also on March 10, 2023, the Company entered into an amendment (the "Series 2 Note Amendment" and, together with the Series 1 Amendment, the "Series Note Amendments") with each of the holders of the Company's outstanding Series 2 Convertible Notes (as amended, the "Series 2 Notes" and, together with the Series 1 Notes, the "Series Convertible Notes"). Pursuant to the Series Note Amendments, the Company can elect to convert the principal and accrued interest under the Series Convertible Notes (the "Series Note Obligations") upon the earlier of the completion of an Uplist Transaction or maturity date of the Series 1 Notes and Series 2 Notes. In the event the Company exercises such option, the Series Note Obligations will be deemed to equal the product of 4.5 (which was previously 1.6 prior to the Series Note Amendments) and the outstanding Series Note Obligations. Notwithstanding the foregoing, if the registration statement filed in connection with the Uplist Transaction is not declared effective by 11:59 P.M. (EST) on March 15, 2023 or such later extended date as provided for therein (the "Series Note Amendments Termination Date"), the Series Note Amendments will automatically terminate without any further action by the Company or the holders of the Series Convertible Notes. The Series Note Amendments Termination Date will be automatically extended upon any extension of the Amendment No. 2 Termination Date.

On March 15, 2023, the Company entered into amendments to the 2022 Notes ("Amendment No. 3 to the First Notes") and Second Notes ("Amendment No. 3 to the Second Notes" and collectively, "Amendment No. 3 to the 2022 Notes" and, together with Amendment No. 2 to the 2022 Notes, the "Amendments to the 2022 Notes") with the Requisite Holders of the 2022 Notes and Second Notes. Under Amendment No. 3 to the 2022 Notes, the 2022 Notes and Second Notes were amended to extend the Amendment No. 2 Termination Date from March 15, 2023 to April 15, 2023, which had the effect of extending to Uplist Transaction deadline from March 15, 2023 to April 15, 2023.

As a result of the entry into the Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Exchanged Notes, the Exchanged Notes were automatically amended to (i) extend the Amendment No. 2 Termination Date from March 15, 2023 to April 15, 2023; (ii) modify the terms of the Uplist Transaction repayment provision; and (iii) provide for the issuance of the 2023 Notes, subject to completion of the Uplist Transaction. Also, on March 15, 2023, in connection with Amendment No. 3 to the 2022 Notes, and pursuant to the terms of the Company's outstanding Series Notes, the Series Notes were automatically amended to extend the date of completion of an Uplist Transaction from March 15, 2023 to April 15, 2023.

On April 15, 2023, the Company entered into an amendment ("Amendment No. 4 to the First Notes") with the holders of the Company's outstanding 2022 Notes, as amended on February 14, 2023, March 10, 2023 and March 15, 2023, issued in connection with the First Closing. On April 15, 2023, the Company also entered into an amendment ("Amendment No. 4 to the Second Notes" and, together with Amendment No. 4 to the First Notes, "Amendment No. 4 to the 2022 Notes") with the holders of the Company's outstanding Second Notes, as amended on February 14, 2023, March 10, 2023 and March 15, 2023 issued in connection with the Second Closing. Under Amendment No. 4 to the 2022 Notes, the 2022 Notes and Second Notes were amended to extend the date of the completion of an uplist to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (such transaction, an "Uplist Transaction") from April 15, 2023 to May 15, 2023.

As a result of the entry into Amendment No. 4 to the 2022 Notes, and pursuant to the terms of the Company's outstanding Exchanged Notes, the Exchanged Notes were automatically amended to extend the date of completion of an Uplist Transaction from April 15, 2023 to May 15, 2023. Also, on April 15, 2023, in connection with Amendment No. 4 to the 2022 Notes, and pursuant to the terms of the Company's outstanding Series Notes, the Series Notes were automatically amended to extend the date of the completion of an Uplist Transaction from April 15, 2023 to May 15, 2023.

On April 15, 2023, the Company entered into an amendment ("Amendment No. 1 to the A&R Registration Rights Agreement") to that certain Amended and Restated Registration Rights Agreement, dated as of January 18, 2023, by and among the Company and certain institutional and accredited individual investors (as amended, the "A&R Registration Rights Agreement"). Under Amendment No. 1 to the A&R Registration Rights Agreement, the A&R Registration Rights Agreement was amended to extend the filing deadline by which the Company is obligated to file with the Securities and Exchange Commission a registration statement under the Securities Act of 1933, as amended, registering certain securities issued in the Second Closing, from April 18, 2023 to June 17, 2023.

On May 15, 2023, the Company entered into Amendment No. 2 to the 2022 SPA related to the 2022 Convertible Note Offering (the "Amendment" and, together with the 2022 SPA, the "Amended 2022 SPA"), with certain Investors in connection with the third closing of the 2022 Convertible Note Offering for the issuance and sale by the Company to an Investor of an aggregate of (i) Unsecured Convertible Promissory Notes (each a "Third Note" and collectively, the "Third Notes") in the aggregate principal amount of $702,720, which includes an aggregate $214,720 original issue discount in respect of the Third Notes; (ii) warrants (the "Third Warrants") to purchase an aggregate of 141,396 shares (the "Third Warrant Shares") of Common Stock; and (iii) 10,608 shares of Common Stock (the "Third Inducement Shares"). The aggregate gross proceeds for the sale of the Third Notes, Third Warrants and Third Inducement Shares was approximately $488,000, before deducting the placement agent's fees and other estimated fees and offering expenses payable by the Company. The third closing of the sales of these securities under the Amended SPA occurred on May 15, 2023 (the "Third Closing Date").

On May 15, 2023, the Company entered into an amendment ("Amendment No. 5 to the First Notes") with the holders of the Company's outstanding 2022 Notes, as amended on February 14, 2023, March 10, 2023, March 15, 2023 and April 15, 2023, issued in connection with the First Closing to extend the date of the completion of the Uplist Transaction from May 15, 2023 to June 15, 2023. On May 15, 2023, the Company also entered into an amendment ("Amendment No. 5 to the Second Notes" and, together with Amendment No. 5 to the First Notes, "Amendment No. 5 to the 2022 Notes") with the holders of the Company's outstanding Second Notes, as amended on February 14, 2023, March 10, 2023, March 15, 2023 and April 15, 2023 issued in connection with the Second Closing to extend the date of the completion of the Uplist Transaction from May 15, 2023 to June 15, 2023.

As a result of the entry into Amendment No. 5 to the 2022 Notes, and pursuant to the terms of the Company's outstanding Exchanged Notes, the Exchanged Notes were automatically amended to extend the date of completion of an Uplist Transaction from May 15, 2023 to June 15, 2023. Also, on May 15, 2023, in connection with Amendment No. 5 to the 2022 Notes, and pursuant to the terms of the Company's outstanding Series Notes, the Series Notes were automatically amended to extend the date of the completion of an Uplist Transaction from May 15, 2023 to June 15, 2023.

Through May 15, 2023, the Company raised $538,000 in the form of shareholder advances from two different investors to support operations in advance of the Company's prospective Uplisting Transaction. On May 15, 2023, $488,000 of these shareholder advances, which was contributed by a single investor, were issued an Unsecured convertible note (the "Third Note") in connection with the Third Closing of the 2022 Convertible Note Offering. The remaining $50,000 that was raised by the Company in the form of shareholder advances was repaid per the agreed terms on July 7, 2023 for $60,000.

On May 18, 2023 and May 31, 2023, the Company raised $340,000 and $350,015 from a shareholder and a third-party investor, respectively, to support operations in advance of the Company's anticipated closing of the Bridge Offering (as defined below). On July 7, 2023, the amount prefunded by the current shareholder was included in the first closing of a common stock, pre-funded warrant and common warrants Bridge Offering. The amount prefunded by the third-party investor is expected to be included in a subsequent closing of the Bridge Offering.

On June 15, 2023, the Company entered into an amendment ("Amendment No. 6 to the First Notes") with the holders of the Company's outstanding 2022 Notes, as amended on February 14, 2023, March 10, 2023, March 15, 2023, April 15, 2023 and May 15, 2023, issued in connection with the First Closing to extend the date of the completion of the Uplist Transaction from June 15, 2023 to July 1, 2023. On June 15, 2023, the Company also entered into an amendment ("Amendment No. 6 to the Second Notes") with the holders of the Company's outstanding Second Notes, as amended on February 14, 2023, March 10, 2023, March 15, 2023, April 15, 2023 and May 15, 2023 issued in connection with the Second Closing to extend the date of the completion of the Uplist Transaction from June 15, 2023 to July 1, 2023. On June 15, 2023, the Company also entered into an amendment ("Amendment No. 1 to the Third Notes and, together with Amendment No. 6 to the First Notes and Amendment No. 6 to the Second Notes, the "First Series of Amendments to the 2022 Notes") with the holder of the Company's outstanding Third Notes issued in connection with the Third Closing to extend the date of the completion of the Uplist Transaction from June 15, 2023 to July 1, 2023.

As a result of the entry into First Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Exchanged Notes, the Exchanged Notes were automatically amended to extend the date of completion of an Uplist Transaction from June 15, 2023 to July 1, 2023. Also, on June 15, 2023, in connection with First Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Series Notes, the Series Notes were automatically amended to extend the date of the completion of the Uplist Transaction from June 15, 2023 to July 1, 2023.

On July 1, 2023, the Company entered into an amendment ("Amendment No. 7 to the First Notes") with the holders of the Company's outstanding 2022 Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, and June 15, 2023, issued in connection with the First Closing. On July 1, 2023, the Company also entered into an amendment ("Amendment No. 7 to the Second Notes") with the holders of the Company's outstanding Second Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, and June 15, 2023, issued in connection with the Second Closing. On July 1, 2023, the Company also entered into an amendment ("Amendment No. 2 to the Third Notes and, together with Amendment No. 7 to the First Notes and Amendment No. 7 to the Second Notes, the "Second Series of Amendments to the 2022 Notes") with the holders of the Company's outstanding Third Notes, as amended on June 15, 2023, issued in connection with the Third Closing. Under the Second Series of Amendments to the 2022 Notes, the 2022 Notes, Second Notes, and Third Notes were amended to extend the date of the completion of an uplist to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (such transaction, an "Uplist Transaction") from July 1, 2023 to July 31, 2023.

As a result of the entry into the Second Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Exchanged Notes, the Exchanged Notes were automatically amended to extend the date of completion of an Uplist Transaction from July 1, 2023 to July 31, 2023. Also, on July 1, 2023, in connection with the Second Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Series Notes, the Series Notes were automatically amended to extend the date of the completion of the Uplist Transaction from July 1, 2023 to July 31, 2023.

On July 7, 2023, the Company announced that it had entered into a Securities Purchase Agreement (the "Bridge SPA") with certain institutional and accredited individual investors (collectively, the "Investors") providing for the issuance and sale by the Company to the Investors of an aggregate of (i) 1,749,245 shares (the "Shares") of common stock, par value $0.001, of the Company (the "Common Stock") at a purchase price of $0.275 per share; (ii) 4,996,199 warrants (the "Pre-Funded Warrants") at a purchase price of $0.274 per Pre-Funded Warrant, to purchase an aggregate of 4,996,199 shares of Common Stock (the "Pre-Funded Warrant Shares"); and (iii) 13,490,888 warrants (the "Common Warrants") to purchase an aggregate 13,490,888 shares of Common Stock (the "Common Stock Warrants Shares"). The Shares, Pre-Funded Warrants, and Common Warrants were issued as part of a private placement offering authorized by the Company's Board of Directors (the "Bridge Offering").

Pursuant to the lock-up agreement provided for by the Bridge SPA, the Investors agreed that they would either (A) purchase securities, for cash, in an offering conducted in conjunction with an uplist of the Common Stock to any of, and in compliance with the rules of, the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (the "Uplist Transaction") with an aggregate purchase price equal to at least 4.3 multiplied by the aggregate purchase price paid by the Investor for the Shares, Pre-Funded Warrants and Common Warrants under the Bridge SPA or (B) be subject to a lock-up provision not to sell or otherwise transfer any of the Shares, Pre-Funded Warrant Shares or Common Warrant Shares acquired by them in the Bridge Offering until the one-year anniversary of the Closing Date. The aggregate gross proceeds for the sale of the Shares, Pre-Funded Warrants, and Common Warrants will be approximately $1.85 million, before deducting the placement agent's fees and other estimated fees and offering expenses payable by the Company. The closing of the sales of these securities under the Bridge SPA occurred on July 7, 2023 (the "Closing Date").

The Bridge SPA also provides additional provisions including: i) certain adjustments that would require the Company to issue additional securities to the Investors if the effective offering price to the public of Common Stock in connection with the next underwritten public offering is less than $4.00 per share; ii) a requirement to register the Shares, Pre-Funded Warrant Shares, and Common Stock Warrant Shares on a subsequent registration statement or statements; and, iii) certain restrictions on the Company's ability to conduct subsequent sales of its equity securities and certain business activities.

On July 7, 2023, the Company also entered into an amendment ("Amendment No. 8 to the First Notes") with the holders of the Company's outstanding 2022 Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, and July 1, 2023, issued in connection with the First Closing. On July 1, 2023, the Company also entered into an amendment ("Amendment No. 8 to the Second Notes") with the holders of the Company's outstanding Second Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, and July 1, 2023, issued in connection with the Second Closing. On July 1, 2023, the Company also entered into an amendment ("Amendment No. 3 to the Third Notes", and, together with Amendment No. 8 to the First Notes and Amendment No. 8 to the Second Notes, the "Third Series of Amendments to the 2022 Notes") with the holders of the Company's outstanding Third Notes, as amended on June 15, 2023, and as subsequently amended on July 1, 2023, issued in connection with the Third Closing.

Under the Third Series of Amendments to the 2022 Notes, the following amendments to the 2022 Notes, Second Notes, and Third Notes will be simultaneously effective upon the closing of an offering conducted in conjunction with an uplist of the Common Stock to any of, and in compliance with the rules of, the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (the "Uplist Transaction"). The Specified Percentage (as defined below) of the then outstanding principal amount of the 2022 Notes, Second Notes, and Third Notes shall automatically convert (the "Automatic Conversion") into shares of Common Stock, with the conversion price for purposes of such Automatic Conversion being equal to the lower of (i) the per unit price at which any units (each unit being comprised of one share or share equivalent and accompanying warrants, if any) are sold in the Uplist Transaction or (ii) the price at which warrants issued in the Uplist Transaction are exercisable (but in no event increased above the conversion price in effect immediately prior to the pricing of the Uplist Transaction).

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

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

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

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

On July 7, 2023 the Company paid $60,000 to a shareholder that had previously advanced the Company $50,000 to support operations. The payment satisfied all remaining obligations in connection with the $538,000 of shareholder advances received by the Company through May 15, 2023. The additional $488,000 was issued as a Third Note.

Additional information related to all such matters can be found in the Form 8-K filed by the Company with Securities and Exchange Commission on July 13, 2023.

During July 2023, the Company entered into a finance agreement with First Insurance Funding to fund a portion of its insurance policies. For the year ended September 30, 2023, the amount financed is approximately $395,000 and incurs interest rates ranging from 7.49% to 9.90%. The Company is required to make monthly payments of approximately $35,000 through April 2024.

On July 12, 2023, the Company secured countersigned notices of conversion from all remaining holders of the Series 1 Convertible Notes and provided instructions to its transfer agent to issue a total of 59,912 shares of Common Stock in full satisfaction of all previously outstanding Series 1 Convertible Notes. Pursuant to the Series 1 Convertible Notes, the Company can elect to convert the principal and accrued interest under the Series Convertible Notes obligation (the "Series Note Obligations") upon the earlier of the effective time of the Uplisting Transaction, or the maturity date. In the case of an In-Kind Note Repayment, the outstanding Note Obligations will be calculated by increasing by thirty-five percent the aggregate sum of the unpaid Principal Amount held by each Holder and the accrued interest at a rate of ten percent per annum, subject to, with respect to any portion of the Principal Amount that is converted or prepaid before the twelve month anniversary of the Issuance Date, a minimum interest payment equal to ten percent of the amount that is converted or prepaid. As consideration for agreeing to subordinate to the 2022 Notes, the premium applicable in connection with an In-Kind Note Repayment at maturity was increased from thirty-five percent to sixty percent. On March 10, 2023, the Company entered into Amendment 2 of the Series 1 Convertible notes and pursuant this amendment, the Company can elect to convert the principal and accrued interest under the Series Convertible Notes (the "Series Note Obligations") upon the earlier of the effective time of the Uplisting Transaction, or the maturity date. In the event the Company exercises such option, the Series Note Obligations will be deemed to equal the product of 4.5 (which was previously 1.6 prior to the Series Note Amendments) and the outstanding Series Note Obligations.

On July 18, 2023, the Board of the Directors of the Company (our "Board) executed a unanimous written consent that, among other things, approved, subject to the approval of a majority of the stockholders of the Company, the following: 1) amend the Amended and Restated Articles of Incorporation (the "Articles") to a) increase the number of authorized shares of common stock, par value $0.001 (the "Common Stock") from 12 million to 350 million, b) create 5,000,000 shares of "blank check" preferred stock, and c) approve a reverse split at a ratio of between 1.5-for-1 and 20-for-1 without any proportionate decrease in the number of authorized shares; 2) amend the Bylaws of the Company to a) allow action by written consent of stockholders representing more than 50% of the total number of shares of Common Stock currently issued and outstanding, and b) establish that holders of thirty-three and one-third (33.3333%) of the total number of shares of Common Stock currently issued and outstanding shall constitute a quorum at any meeting of stockholders for the transaction of business, except as otherwise provided by the NRS or by the Articles; and, 3) approve the 2023 Omnibus Equity Incentive Plan with an initial reservation of 455,169 shares, options or other such grants.

Additional information related to such matters can be found in the Form 8-K filed by the Company with Securities and Exchange Commission on July 24, 2023.

On July 31, 2023, the Company entered into an amendment ("Amendment No. 9 to the First Notes") with the holders of the Company's outstanding 2022 Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023 and July 7, 2023 issued in connection with the First Closing. On July 31, 2023, the Company also entered into an amendment ("Amendment No. 9 to the Second Notes") with the holders of the Company's outstanding Second Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, and July 7, 2023 issued in connection with the Second Closing. On July 31, 2023, the Company also entered into an amendment ("Amendment No. 4 to the Third Notes and, together with Amendment No. 9 to the First Notes and Amendment No. 9 to the Second Notes, the "Fourth Series of Amendments to the 2022 Notes") with the holders of the Company's outstanding Third Notes, as amended on June 15, 2023, and as subsequently amended on July 1, 2023 and July 7, 2023 issued in connection with the Third Closing. Under the Fourth Series of Amendments to the 2022 Notes, the 2022 Notes, Second Notes, and Third Notes were amended to extend the date of the completion of an uplist to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (such transaction, an "Uplist Transaction") from July 31, 2023 to August 31, 2023.

As a result of the entry into the Fourth Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Exchanged Notes, the Exchanged Notes were automatically amended to extend the date of completion of an Uplist Transaction from July 31, 2023 to August 31, 2023. Also, on July 31, 2023, in connection with the Fourth Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Series Notes, the Series Notes were automatically amended to extend the date of the completion of the Uplist Transaction from July 31, 2023 to August 31, 2023.

On August 13, 2023, our Board adopted and approved the Amended and Restated 2023 Equity Incentive Plan (the "A&R Plan"), subject to stockholder approval, which amended and restated the Company's 2023 Equity Incentive Plan originally approved by the Board on July 18, 2023 (the "Plan"). The Plan was amended and restated to (i) shorten the Plan's duration from 10 years to 6 years, (ii) decrease the annual Evergreen Shares (as defined in the A&R Plan) percentage from six percent (6%) to five percent (5%), (iii) limit the Plan's incremental 15% increases to shares issued in connection with the "Bridge Financing", the "Uplist Transaction" and/or, to the extent provided by the A&R Plan, a "Qualifying Offering" (as such terms are defined in the A&R Plan), and (iv) require that seventy-five percent (75%) of the Evergreen Shares be granted as stock options, stock appreciation rights and/or performance-based awards, among other things. Additional information related to such matters can be found in the Form 8-K filed by the Company with Securities and Exchange Commission on August 23, 2023.

On August 22, 2023, the Company received a written consent in lieu of a meeting of stockholders representing a majority of the voting power of the outstanding shares of voting stock of the Company (the "Majority Stockholders") approving the A&R Plan and thereafter, the Company filed a preliminary Information Statement on Schedule 14C (the "Information Statement") with the Securities and Exchange Commission (the "SEC") with respect to the transactions contemplated hereby.

On August 30, 2023, the Company entered into an amendment ("Amendment No. 10 to the First Notes") with the holders of the Company's outstanding 2022 Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 7, 2023, and July 31, 2023 issued in connection with the First Closing. On August 30, 2023, the Company also entered into an amendment ("Amendment No. 10 to the Second Notes") with the holders of the Company's outstanding Second Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 7, 2023, and July 31, 2023 issued in connection with the Second Closing. On August 30, 2023, the Company also entered into an amendment ("Amendment No. 5 to the Third Notes" and, together with Amendment No. 10 to the First Notes and Amendment No. 10 to the Second Notes, the "Fifth Series of Amendments to the 2022 Notes") with the holders of the Company's outstanding Third Notes, as amended on June 15, 2023, and as subsequently amended on July 1, 2023, July 7, 2023, and July 31, 2023 issued in connection with the Third Closing. Under the Fifth Series of Amendments to the 2022 Notes, the 2022 Notes, Second Notes, and Third Notes were amended to extend the date of the completion of an uplist to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (such transaction, an "Uplist Transaction") from August 31, 2023, to September 30, 2023.

As a result of the entry into the Fifth Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Exchanged Notes, the Exchanged Notes were automatically amended to extend the date of completion of an Uplist Transaction from August 31, 2023, to September 30, 2023. Also, on August 30, 2023, in connection with the Fifth Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Series Notes, the Series Notes were automatically amended to extend the date of the completion of the Uplist Transaction from August 31, 2023 to September 30, 2023.

On August 30, 2023, the Company also entered into an amendment ("Amendment No. 1 to the Second A&R Registration Rights Agreement") to that certain Second Amended and Restated Registration Rights Agreement, dated as of May 15, 2023, with effect as of June 17, 2023, by and among the Company and certain institutional and accredited individual investors (the "Second A&R Registration Rights Agreement"). Under Amendment No. 1 to the Second A&R Registration Rights Agreement, the Second A&R Registration Rights Agreement was amended to extend the filing deadline by which the Company is obligated to file with the Securities and Exchange Commission (the "SEC") a registration statement under the Securities Act of 1933, as amended, registering certain securities issued in the Second Closing and Third Closing to the date that is 45 days following the Uplist Transaction.

On August 30, 2023, the Company also entered into an amendment ("Amendment No. 1 to the Bridge SPA"), with certain institutional and accredited individual investors that participated in the first closing of the Bridge Offering to extend the date by which additional closings under the SPA are permitted from 30 days after the Initial Closing Date to 90 days after the Initial Closing Date.

On August 30, 2023, the Company also entered into an amendment ("Amendment No. 1 to the Registration Rights Agreement") to that certain Registration Rights Agreement, dated as of July 7, 2023, by and among the Company and certain institutional and accredited individual investors (the "Registration Rights Agreement"). Under Amendment No. 1 to the Registration Rights Agreement, the Registration Rights Agreement was amended to extend the filing deadline by which the Company is obligated to file with the SEC a registration statement under the Securities Act of 1933, as amended, registering certain securities issued in the Bridge Offering, to the earlier of (i) the date that is 30 days following the Uplist Transaction and (ii) October 31, 2023.

Additional information related to all such matters can be found in the Form 8-K filed by the Company with the Securities and Exchange Commission on September 6, 2023.

On August 31, 2023, the Company consummated a second closing of the Bridge Offering pursuant to the terms and conditions of the SPA with certain institutional and accredited individual investors (collectively, the "Investors") providing for the issuance and sale by the Company to the Investors of an aggregate of (i) 1,527,150 shares of Common Stock (the "Shares") at a purchase price of $0.275 per share; (ii) 1,058,743 pre-funded warrants (the "Pre-Funded Warrants") to purchase an aggregate of 1,058,743 shares of Common Stock, at a purchase price of $0.274 per Pre Funded Warrant (the "Pre-Funded Warrant Shares"); and (iii) 5,171,786 warrants (the "Common Warrants" and together with the Pre-Funded Warrants, the "Warrants") to purchase an aggregate of 5,171,786 shares of Common Stock (the "Common Warrant Shares" and together with the Pre-Funded Warrant Shares, the "Warrant Shares"). The Shares, Pre-Funded Warrants, and Common Warrants were issued as part of the second closing of the Bridge Offering. Additional information related to such matters can be found in the Form 8-K filed by the Company with Securities and Exchange Commission on September 7, 2023.

On September 1, 2023, the Company filed a definitive Information Statement with the SEC and commenced mailing the definitive Information Statement to the Company's stockholders notifying them of the action taken by written consent on August 22, 2023 to approve the A&R Plan. Under the applicable SEC regulations, the A&R Plan became effective 20 days from the date of the mailing of the definitive Information Statement to the Company's stockholders.

On September 21, 2023, the Company amended its Articles of Incorporation by filing a Certificate of Amendment (the "Certificate of Amendment") with the Secretary of State of Nevada to increase the total number of authorized shares of common stock, par value $0.001 per share, from 12,000,000 to 350,000,000, and to authorize 5,000,000 shares of "blank check" preferred stock, par value $0.001 per share. The Certificate of Amendment was authorized by the Board of Directors on July 18, 2023, and the amendments to the Company's Articles of Incorporation were approved by the Company's stockholders on August 22, 2023.

On September 30, 2023 the Company entered into an amendment ("Amendment No. 11 to the First Notes") with the holders of the Company's outstanding 2022 Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, and August 30, 2023 issued in connection with the First Closing. On September 30, 2023, the Company also entered into an amendment ("Amendment No. 11 to the Second Notes") with the holders of the Company's outstanding Second Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, and August 30, 2023 issued in connection with the Second Closing. On September 30, 2023, the Company also entered into an amendment ("Amendment No. 6 to the Third Notes" and, together with Amendment No. 11 to the First Notes and Amendment No. 11 to the Second Notes, the "Sixth Series of Amendments to the 2022 Notes") with the holders of the Company's outstanding Third Notes, as amended on June 15, 2023, and as subsequently amended on July 1, 2023, July 7, 2023, July 31, 2023, and August 30, 2023 issued in connection with the Third Closing. Under the Sixth Series of Amendments to the 2022 Notes, the 2022 Notes, Second Notes, and Third Notes were amended to extend the date of the completion of an uplist to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (such transaction, an "Uplist Transaction") from September 30, 2023 to October 31, 2023.

As a result of the entry into the Sixth Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Exchanged Notes, the Exchanged Notes were automatically amended to extend the date of completion of an Uplist Transaction from September 30, 2023, to October 31, 2023. Also, on September 30, 2023, in connection with the Sixth Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Series Notes, the Series Notes were automatically amended to extend the date of the completion of the Uplist Transaction from September 30, 2023 to October 31, 2023.

Additional information related to such matters can be found in the Form 8-K filed by the Company with the Securities and Exchange Commission on October 4, 2023.

On October 30, 2023, the Company received a shareholder advance of $100,000 to support the operations of the Company.

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

On November 8, 2023, the Company entered into an amendment ("Amendment No. 12 to the First Notes") with the holders of the Company's outstanding 2022 Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023 and September 30, 2023 issued in connection with the First Closing. On November 8, 2023, the Company also entered into an amendment ("Amendment No. 12 to the Second Notes") with the holders of the Company's outstanding Second Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023 and September 30, 2023 issued in connection with the Second Closing. On November 8, 2023, the Company also entered into an amendment ("Amendment No. 7 to the Third Notes" and, together with Amendment No. 12 to the First Notes and Amendment No. 12 to the Second Notes, the "Seventh Series of Amendments to the 2022 Notes") with the holders of the Company's outstanding Third Notes, as amended on June 15, 2023, and as subsequently amended on July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023 and September 30, 2023 issued in connection with the Third Closing. Under the Seventh Series of Amendments to the 2022 Notes, the 2022 Notes, Second Notes, and Third Notes were amended to extend the date of the completion of an Uplist Transaction from October 31, 2023, to November 15, 2023.

In addition to the foregoing, the following amendments to the 2022 Notes, Second Notes, and Third Notes will be simultaneously effective upon the closing of the Uplist Transaction. Fifty percent (50%) of the then outstanding principal amount of the 2022 Notes, Second Notes and Third Notes shall automatically convert (the "Automatic Conversion") into shares of Common Stock, with the conversion price for purposes of such Automatic Conversion of $4.00. Upon the Automatic Conversion and to the extent that the beneficial ownership of a holder of 2022 Notes, Second Notes, and Third Notes (a "Holder" and, all holders of 2022 Notes together, the "Holders") would increase over the applicable Ownership Limitation, the Holder will receive pre-funded warrants in lieu of shares of Common Stock otherwise issuable to the Holder in connection with the Automatic Conversion, which may be exercised on a cashless basis, shall be exercisable immediately upon issuance and shall contain a customary beneficial ownership limitation provision.

In addition, upon the Automatic Conversion, the Holder shall receive a warrant (the "Uplist Conversion Warrant", and the shares issuable upon exercise thereof, the "Uplist Conversion Warrant Shares") to purchase a number of shares of Common Stock equal to 6.3812 times the dollar amount under the 2022 Notes, Second Notes, Third Notes that was converted in the Automatic Conversion. The Uplist Conversion Warrant shall have an exercise price per share of $4.00 and shall otherwise be identical to the PIPE Common Warrant.

As a result of the entry into the Seventh Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Exchanged Notes, the Exchanged Notes were automatically amended to extend the date of completion of an Uplist Transaction from October 31, 2023, to November 15, 2023. Also, on November 8, 2023, in connection with the Seventh Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Series Notes, the Series Notes were automatically amended to extend the date of the completion of the Uplist Transaction from October 31, 2023 to November 15, 2023.

On November 8, 2023, the Company also entered into an amendment ("Amendment No. 2 to the Second A&R Registration Rights Agreement") to that certain Second Amended and Restated Registration Rights Agreement, dated as of May 15, 2023, as amended on June 17, 2023, by and among the Company and certain institutional and accredited individual investors (as amended, the "Second A&R Registration Rights Agreement"). Under Amendment No. 2 to the Second A&R Registration Rights Agreement, the Second A&R Registration Rights Agreement was amended to (I) extend the filing deadline by which the Company is obligated to file with the SEC a registration statement under the Securities Act of 1933, as amended, registering certain securities issued in the 2022 Convertible Note Offering to the earlier of (i) the date that is 30 days following the Uplist Transaction and (ii) November 30, 2023, and (II) to provide for the inclusion of the Registerable Securities (as defined therein) in the Uplist S-1 (as defined therein).

On November 8, 2023, the Company also entered into an amendment to the Bridge SPA ("Amendment No. 2 to the Bridge SPA"), with certain institutional and accredited individual investors that participated in the Bridge Offering. Under Amendment No. 2 to the Bridge SPA, upon the closing of the next underwritten public offering of Common Stock (the "Qualifying Offering"), which the Company agreed is the Uplist Transaction, if the effective offering price to the public per share of Common Stock (the "Qualifying Offering Price") is lower than $4.00 per share, then the Company shall issue additional Bridge Pre-Funded Warrants (the "True-Up Pre-Funded Warrants"), or shares of Common Stock (the "True-Up Shares") in lieu thereof to the extent necessary to cause the Company to meet the listing requirements of the Company's proposed trading market in the Uplist Transaction, in an amount reflecting a reduction in the purchase price paid for the Bridge Shares and Bridge Pre-Funded Warrants that equals the proportion by which the Qualifying Offering Price is less than $4.00.

On November 8, 2023, the Company also entered into an amendment ("Amendment No. 2 to the Bridge Registration Rights Agreement") to that certain Registration Rights Agreement, dated as of July 7, 2023, as amended on August 30, 2023, by and among the Company and certain institutional and accredited individual investors (as amended the "Bridge Registration Rights Agreement"). Under Amendment No. 2 to the Bridge Registration Rights Agreement, the Bridge Registration Rights Agreement was amended to (I) extend the filing deadline by which the Company is obligated to file with the SEC a registration statement under the Securities Act of 1933, as amended, registering certain securities issued in the Bridge Offering, to the earlier of (i) the date that is 30 days following the Uplist Transaction and (ii) November 30, 2023, and (II) to provide for the inclusion of the Registerable Securities (as defined therein) in the Uplist S-1 (as defined therein).

Additional information related to all such matters can be found in the Form 8-K filed by the Company with the Securities and Exchange Commission on November 15, 2023.

On November 13, 2023, the Company received a shareholder advance of $100,000 to support the operations of the Company.

On November 21, 2023, and effective as of November 15, 2023, the Company entered into an amendment ("Amendment No. 13 to the First Notes") with the holders of the Company's outstanding 2022 Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023, September 30, 2023, and October 31, 2023 issued in connection with the First Closing. On November 21, 2023, and effective as of November 15, 2023, the Company also entered into an amendment ("Amendment No. 13 to the Second Notes") with the holders of the Company's outstanding Second Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023, September 30, 2023 and October 31, 2023 issued in connection with the Second Closing. On November 21, 2023, and effective as of November 15, 2023, the Company also entered into an amendment ("Amendment No. 8 to the Third Notes" and, together with Amendment No. 13 to the First Notes and Amendment No. 13 to the Second Notes, the "Eighth Series of Amendments to the 2022 Notes") with the holder of the Company's outstanding Third Notes, as amended on June 15, 2023, and as subsequently amended on July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023, September 30, 2023 and October 31, 2023 issued in connection with the Third Closing. Under the Eighth Series of Amendments to the 2022 Notes, the 2022 Notes, Second Notes, and Third Notes were amended to extend the date of the completion of an uplist to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange, or NYSE American (such transaction, an "Uplist Transaction") from November 15, 2023, to January 6, 2024.

As a result of the entry into the Eighth Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Exchanged Notes, the Exchanged Notes were automatically amended to extend the date of completion of an Uplist Transaction from November 15, 2023, to January 6, 2024. Also, on November 21, 2023, in connection with the Eighth Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Series Notes, the Series Notes were automatically amended to extend the date of the completion of the Uplist Transaction from November 15, 2023 to January 6, 2024.

On November 21, 2023, the Company also entered into an amendment ("Amendment No. 3 to the Second A&R Registration Rights Agreement") to that certain Second Amended and Restated Registration Rights Agreement, dated as of May 15, 2023, as amended on June 17, 2023, and as subsequently amended on November 8, 2023 by and among the Company and certain institutional and accredited individual investors (as amended, the "Second A&R Registration Rights Agreement"). Under Amendment No. 3 to the Second A&R Registration Rights Agreement, the Second A&R Registration Rights Agreement was amended to extend the filing deadline by which the Company is obligated to file with the Securities and Exchange Commission (the "SEC") a registration statement under the Securities Act of 1933, as amended, registering certain securities issued in the 2022 Convertible Note Offering to the earlier of (i) the date that is 30 days following the Uplist Transaction and (ii) January 31, 2024.

On November 22, 2023, the Company entered into an amendment ("Amendment No. 3 to the Bridge Registration Rights Agreement") to that certain Registration Rights Agreement, dated as of July 7, 2023, as amended on August 30, 2023, and as subsequently amended on November 8, 2023, by and among the Company and certain institutional and accredited individual investors (as amended the "Bridge Registration Rights Agreement") in connection with a private placement offering of pre-funded warrants to purchase shares of common stock, par value $0.001, of the Company ("Common Stock"), common warrants to purchase shares of Common Stock, and shares of Common Stock (the "Bridge Offering"). Under Amendment No. 3 to the Bridge Registration Rights Agreement, the Bridge Registration Rights Agreement was amended to extend the filing deadline by which the Company is obligated to file with the SEC a registration statement under the Securities Act of 1933, as amended, registering certain securities issued in the Bridge Offering, to the earlier of (i) the date that is 30 days following the Uplist Transaction and (ii) January 31, 2024.

Additional information related to all such matters can be found in the Form 8-K filed by the Company with the Securities and Exchange Commission on November 22, 2023.

On November 29, 2023, the Company received a shareholder advance of $250,000 to support the operations of the Company.

On November 30, 2023, the Company provided instructions to its transfer agent to issue a total of 52,917 shares of Common Stock in full satisfaction of all previously outstanding Series 2 Convertible Notes. Pursuant to the Series 2 Convertible Notes, the Company can elect to convert the principal and accrued interest under the Series Convertible Notes obligation (the "Series Note Obligations") upon the earlier of the effective time of the Uplisting Transaction, or the maturity date. In the case of an In-Kind Note Repayment, the outstanding Note Obligations will be calculated by increasing by thirty-five percent the aggregate sum of the unpaid Principal Amount held by each Holder and the accrued interest at a rate of ten percent per annum, subject to, with respect to any portion of the Principal Amount that is converted or prepaid before the twelve month anniversary of the Issuance Date, a minimum interest payment equal to ten percent of the amount that is converted or prepaid. As consideration for agreeing to subordinate to the 2022 Notes, the premium applicable in connection with an In-Kind Note Repayment at maturity was increased from thirty-five percent to sixty percent. On March 10, 2023, the Company entered into Amendment 2 of the Series 2 Convertible Notes and pursuant this amendment, the Company can elect to convert the principal and accrued interest under the Series Convertible Notes (the "Series Note Obligations") upon the earlier of the effective time of the Uplisting Transaction, or the maturity date. In the event the Company exercises such option, the Series Note Obligations will be deemed to equal the product of 4.5 (which was previously 1.6 prior to the Series Note Amendments) and the outstanding Series Note Obligations.

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

From December 13, 2023 to December 14, 2023, two purchaser parties (the "Advancing Purchasers") to the previously disclosed Securities Purchase Agreement (the "SPA") dated November 8, 2023, among Arch Therapeutics, Inc. (the "Company") and the purchasers party thereto (including the Advancing Purchasers), advanced the Company an aggregate of $500,000 (the "Advances"), which Advances are being treated as partial prepayment of the purchase price for the Advancing Purchasers under the SPA. If the transactions contemplated by the SPA are not consummated by February 29, 2023, the Company will be obligated to repay the Advances to the Advancing Purchasers within three business days thereafter.

On January 5, 2024, the Company entered into an amendment ("Amendment No. 14 to the First Notes") with the holders of the Company's outstanding 2022 Notes, as amended on February 14, 2023, March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023, September 30, 2023, October 31, 2023, and November 15, 2023 issued in connection with the First Closing. On January 5, 2024, the Company also entered into an amendment ("Amendment No. 14 to the Second Notes") with the holders of the Company's outstanding Second Notes, as amended on February 14, 2023, March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023, September 30, 2023, October 31, 2023, and November 15, 2023 issued in connection with the Second Closing. On January 5, 2024, the Company also entered into an amendment ("Amendment No. 9 to the Third Notes" and, together with Amendment No. 14 to the First Notes and Amendment No. 14 to the Second Notes, the "Amendments to the 2022 Notes") with the holders of the Company's outstanding Third Notes, as amended on June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023, September 30, 2023, October 31, 2023, and November 15, 2023 issued in connection with the Third Closing. Under the Amendments to the 2022 Notes, the Second Notes and the Third Notes were amended to extend the date of the completion of an uplist to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange, or NYSE American (such transaction, an "Uplist Transaction") and to extend the respective maturity date of each of the 2022 Notes from January 6, 2024, to March 15, 2024.

As a result of the entry into the Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Exchanged Notes, the Exchanged Notes were automatically amended to extend the date of completion of an Uplist Transaction from January 6, 2024, to March 15, 2024.

On January 9, 2024, the Audit Committee of the Board of Directors (the "Audit Committee") of Arch Therapeutics, Inc. (the "Company") dismissed Baker Tilly US, LLP ("Baker Tilly") as the Company's independent registered public accounting firm, effectively immediately. Also on January 9, 2024, the Audit Committee approved the appointment of Weinberg & Company, P.A. ("Weinberg") as the Company's new independent registered public accounting firm, effective immediately. Additional information related to all such matters can be found in the Form 8-K filed by the Company with Securities and Exchange Commission on January 12, 2024.

ITEM 1A. RISK FACTORS

Investment in our securities involves a high degree of risk. You should carefully consider the risks that are summarized below and discussed in greater detail in the following pages 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 2024.
- We have incurred significant losses since inception, we expect to continue to incur losses for the foreseeable future, and we may not generate sufficient revenue to achieve or maintain profitability.
- 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, including our obligation to repay the outstanding balance under the 2022 Notes upon such holder's demand for repayment upon the completion of an Uplist Transaction, are secured by security interests in substantially all of our assets and our failure to comply with the terms and covenants of the 2022 Notes could result in our loss of substantially all of our assets.
- The holders of our 2022 Notes, Second Notes, Third Notes and Fourth Notes have certain additional rights upon an event of default under such notes which could harm our business, financial condition, and results of operations and could require us to reduce or cease our operations.
- If we issue additional shares in the future, including issuances of shares upon exercise of our outstanding warrants or conversion of our outstanding convertible notes, our existing stockholders will be significantly diluted, and our stock price may be negatively affected.
- If we do not successfully commercialize our products, we will continue to incur losses and will never be profitable.
- Our business may be materially adversely affected by the coronavirus (COVID-19) pandemic. Should the pandemic or its aftereffects continue, our business operations could and will likely be delayed or interrupted.
- Our flagship product is novel without any history of use in the clinical fields in which it is marketed requiring education and training regarding its application to gain and maintain market acceptance by patients, physicians, healthcare payors or others in the medical community.
- Applications for regulatory marketing authorization for commercialization of our additional products or elements of our supply chain may not be accepted, or if accepted, may be voluntarily withdrawn, or eventually rejected, and the future success of our business is significantly dependent on the success of our being able to obtain regulatory marketing authorization for our development stage candidates.

- Our additional product candidates are inherently risky because they are based on novel technologies and thus create significant challenges with respect to product development and optimization, engineering, manufacturing, scale-up, quality systems, pre-clinical in vitro and in vivo testing, government regulation and approval, third-party reimbursement and market acceptance.

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

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

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

- Any clinical trials that are planned or are conducted on our flagship product or additional product candidates may not start or may fail. Clinical trials are lengthy, complex and extremely expensive processes with uncertain expenditures and results and frequent failures.

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

- The flagship product for which we obtained required regulatory marketing authorization is subject to post-approval regulation, and we may be subject to penalties if we fail to comply with such post-approval requirements.

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

- We face competition from companies that have greater resources than we do, and we may not be able to effectively compete against these companies.

- If others claim we and/or the parties from whom we license some of our intellectual property are infringing on their intellectual property rights, we may be subject to costly and time-consuming litigation.

- There is not now, and there may not ever be, an active market for our Common Stock, which trades in the over-the-counter market in low volumes and at volatile prices. Although we have applied to list our Common Stock on the Nasdaq Capital Market there is no assurance that our application will be approved.

- 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. For the year ended September 30, 2023, the Company recorded a net loss of $6,982,836 and used cash in operations of $3,374,216. These factors raise substantial doubt about the Company’s ability to continue as a going concern within one year of the date that the financial statements are issued. In addition, the Company’s independent registered public accounting firm, in their report on the Company’s September 30, 2023 audited financial statements, raised substantial doubt about the Company’s ability to continue as a going concern. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

As of February 14, 2024, we believe that our current cash will only meet anticipated cash requirements into the second quarter of fiscal 2024 and we will need to raise additional capital before then.

During the fiscal 2023 and 2022, we obtained additional cash to continue operations and fund our planned future operations, which include research and development of our product candidates, steps related to seeking regulatory marketing authorization for our initial product candidates and planning for their commercialization in the US and the EU. Even with the additional funds received from these financings, there exists substantial doubt about our ability to continue as a going concern.

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

As noted above under the risk factor entitled "*There is substantial doubt about our ability to continue as a going concern*," we have only recently commenced commercial sales of our first product, AC5Advanced Wound System and we have incurred substantial net losses as a result. Consequently, we have incurred losses in each year since our inception and we expect that losses will continue to be incurred in the foreseeable future in the operation of our business. To date, we have financed our operations primarily through equity and debt investments by founders, other investors and third parties, and we expect to continue to rely on these sources of funding, to the extent available in the foreseeable future. Losses from operations have resulted principally from costs incurred in research and development programs and from general and administrative expenses, including significant costs associated with establishing and maintaining intellectual property rights, significant legal and accounting costs incurred in connection with both the closing of the Merger and complying with public company reporting and control obligations, and personnel expenses. We have devoted much of our operational effort to date to the research and development of our core technology, including selecting our initial product composition, conducting safety and other related tests, conducting a human trial for safety and performance, developing methods for manufacturing scale-up, reproducibility and validation, and developing and protecting the intellectual property rights underlying our technology platform.

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

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

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 February 14, 2024, we believe that our current cash on hand will meet our anticipated cash requirements into the second quarter of fiscal 2024. 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 fiscal years 2023 and 2022, we obtained additional cash from debt and equity financings to continue operations and fund our planned future operations, which include research and development of our product candidates, steps related to seeking regulatory marketing authorization for our initial product candidates and planning for their commercialization in the US and Europe. Even with the additional funds received from these financings, there exists substantial doubt about our ability to continue as a going concern. In addition, our plans may change and/or we may use our capital resources more rapidly than we currently anticipate. We presently expect that our expenses will increase in connection with our ongoing activities to support our business operations, inclusive of regulatory submissions, marketing authorization, and commercialization of our product candidates and products, and, therefore, we will require additional funding.

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

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

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

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

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

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

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

The Bridge SPA contains certain restrictions on the Company's ability to conduct subsequent sales of its equity securities and certain business activities. In particular, until July 7, 2024, the Company will be prohibited from effecting or entering into agreements to effect any issuance by the Company or its subsidiary of Common Stock or Common Stock equivalents (or a combination of units thereof) involving a Variable Rate Transaction (as defined below) including, but not limited to, an equity line of credit or "At-the-Market" financing facility. The Uplist PIPE has the effect of extending that prohibition to November 8, 2024 with a similar provision.

The 2022 Notes SPA contains certain restrictions on our ability to conduct subsequent sales of our equity securities and certain business activities. In particular until the 2022 Notes are paid in full and/or converted in full and the 2022 Warrants are exercised in full, we are prohibited from (i) changing the nature of business, (ii) selling, divesting, acquiring, or changing the structure of any material assets other than in the ordinary course of business; or (iii) negotiating or entering into certain variable rate debt transactions; in each instance without each applicable 2022 Note holder's prior written consent, which shall not be unreasonably withheld.

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

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

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

In addition, the 2022 Notes contain customary events of default, which include, among other things, (i) our failure to pay when due any principal or interest payment under the 2022 Notes; (ii) our insolvency; (iii) delisting of our Common Stock; (iv) our breach of any material covenant or other material term or condition under the 2022 Notes; and (v) our breach of any representations or warranties under the 2022 Notes which cannot be cured within five (5) days. Further, events of default under the 2022 Notes also include (i) the unavailability of Rule 144 at certain times; (ii) our failure to deliver the shares of Common Stock to the 2022 Note holder upon exercise by such holder of its conversion rights under the 2022 Notes; (iii) our loss of the "bid" price for our Common Stock and/or a market and such loss is not cured during the specified cure periods; and (iv) our failure to complete an Uplist Transaction by March 15, 2024.

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

Under the 2022 Notes, the holders have certain rights upon an event of default. Such rights include that, upon an event of default, the 2022 Notes will become immediately due and payable and we will be obligated to pay to each such note holder an amount equal to (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 $73.12 (which will automatically change to $4.00 as of the closing of the Uplist PIPE through the operation of the Most Favored Nation Provision) at the time of payment.

In addition, the 2022 Notes are subject to prepayment penalties, subject to adjustment as a result of certain time-based prepayment premiums set forth in such notes; 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 March 15, 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 rate of the lesser of (i) eighteen percent (18%) per annum or (ii) the Default Interest Rate.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We are dependent on third parties in our supply chain, including manufacturers, service providers, and other vendors, and the processes that they employ to make major and minor components of our products, and this dependence exposes us to risks associated with regulatory requirements, delivery schedules, manufacturing capability, quality control, quality assurance and costs. We make periodic changes within our supply chain, for example, as our business needs evolve; and/or if a third-party does not perform as agreed or desired; and/or if we decide to add an additional manufacturer, service provider, or vendor where we were previously single sourced; and/or if processes are altered to meet evolving scale requirements. For instance, the Company harmonized its 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 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 world increase, and the probability of successfully commercializing a product would decrease. Any or all of those circumstances would materially adversely affect our business.

We are subject to extensive and dynamic medical device regulations outside of the 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 flagship product and additional product candidates may not start or may fail.

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

- FDA or other regulatory authorities, or other relevant decision-making bodies do not grant permission to proceed or place a trial on clinical hold due to safety concerns or other reasons;
- sufficient suitable subjects do not enroll, enroll more slowly than anticipated or remain in our trials;
- we fail to produce necessary amounts of the product or product candidate;
- subjects experience an unacceptable rate of efficacy of the product or product candidate;
- subjects experience an unacceptable rate or severity of adverse side effects, demonstrating a lack of safety of the product or product candidate;
- any portion of the trial or related studies produces negative or inconclusive results or other adverse events;
- reports from preclinical or clinical testing on similar technologies and products raise safety and/or efficacy concerns;
- third-party clinical investigators lose their licenses or permits necessary to perform our clinical trials, do not perform their clinical trials on the anticipated schedule or consistent with the clinical trial protocol, GCP or regulatory requirements, or other third parties do not perform data collection and analysis in a timely or accurate manner;
- inspections of clinical trial sites by the FDA or an 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;
- prohibit us from using some or all of the resulting data in support of our marketing applications with the FDA or other applicable agencies;
- manufacturing facilities of our third-party manufacturers are ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of cGMP or other applicable requirements;

- third-party contractors become debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements;

- the FDA or other regulatory authorities impose requirements on the design, structure, or other features of the clinical trials for our product candidates that we and/or our third-party contractors are unable to satisfy;

- one or more IRB refuses to approve, suspends or terminates a trial at an investigational site, precludes enrollment of additional subjects, or withdraws its approval of the trial;

- the FDA or other regulatory authorities seek the advice of an advisory committee of physician and patient representatives that may view the risks of our product candidates as outweighing the benefits;

- the FDA or other regulatory authorities require us to expand the size and scope of the clinical trials, which we may not be able to do; or

- the FDA or other regulatory authorities impose prohibitive post-marketing restrictions on any of our product candidates that attain marketing authorization.

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

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

To obtain marketing approvals in the 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 market any product. There can be no assurance as to the success of any such marketing strategy that we develop or that we will be able to build a successful sales and marketing organization. If we cannot effectively market those products we seek to market directly, such products' prospects will be harmed.

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

AC5 Advanced Wound System and any other product for which we are able to obtain marketing approval or other required certifications, and for which we are able to obtain approval of the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA, comparable foreign regulatory authorities, or their designees, including through periodic inspections. These requirements include, without limitation, submissions of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents. The global regulatory environment is increasingly stringent and unpredictable, and requirements continue to differ among countries. We expect this global regulatory environment will continue to evolve, potentially impacting the cost, time, or our ability to receive or maintain clearances or approvals.

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

We are also subject to periodic inspections for compliance with applicable quality system regulations (e.g., 21 CFR 820, EU MDR) which govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, and servicing of finished medical devices intended for human use. In addition, the FDA and other regulatory bodies, both in and outside the U.S. (including the Federal Trade Commission, the Office of the Inspector General of the Department of Health and Human Services, the U.S. Department of Justice, and various state Attorneys General), monitor the promotion and advertising of our products. Any adverse regulatory action, depending on its magnitude, may limit our ability to effectively market and sell our products, limit our ability to obtain future pre-market approvals or result in a substantial modification to our business practices and operations. Maintaining compliance with any such regulations that may be applicable to us or our product candidates in the future would require significant time, attention, and expense. Even if marketing approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or other conditions of approval or may contain requirements for costly and time-consuming post-marketing approval testing and surveillance to monitor the safety or efficacy of the product.

Discovery after approval of previously unknown problems with any approved product candidate or related manufacturing processes, or failure to comply with regulatory requirements or agreements with regulatory agencies or their designees, may result in consequences to us such as:

- restrictions on the marketing or distribution of a product, including refusals to permit the import or export of the product;
- the requirement to include warning labels on the products;
- withdrawal or recall of the products from the market;
- refusal by the FDA or other regulatory agencies to approve pending applications or supplements to approved applications that we may submit;
- suspension of any ongoing clinical trials;
- fines, restitution or disgorgement of profits or revenue;
- supply chain disruptions due to dependency on key suppliers;
- reputational damage affecting customer trust and market share;
- litigation costs and financial judgments from adverse effects or non-compliance;
- impacts from changes in regulatory standards or approval processes;
- suspension or withdrawal of marketing approvals or certifications; or
- civil or criminal penalties.

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

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

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

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

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

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

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

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

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

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

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

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

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

If required regulatory authorizations are obtained to market any of our product candidates, then we may consider entering into additional collaboration arrangements with medical technology, pharmaceutical or biotechnology companies and/or seek to establish strategic relationships with marketing partners for the development, sale, marketing and/or distribution of our products within or outside of the 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 February 2, 2024, we either own or license from others a number of US patents, US patent applications, foreign patents and foreign patent applications.

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

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

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

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

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

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

Our research, development and commercialization activities, as well as any product candidates or products resulting from those activities, may infringe or be accused of infringing a patent or other intellectual property under which we do not hold a license or other rights. Third parties may own or control those patents or other rights in the 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 and Investor Warrants

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

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

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

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

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

Under the 2022 Notes, we are obligated to complete an Uplist Transaction by February 29, 2024 to the Nasdaq Capital Market or an Alternate Exchange. We do not currently meet the initial listing standards of such national securities exchanges. In the event we are unable to uplist our Common Stock, we anticipate that our Common Stock will continue to be quoted on the OTCQB or another over-the-counter quotation system. In those venues, our stockholders may find it difficult to obtain accurate quotations as to the market value of their shares of our Common Stock and may find few buyers to purchase their stock and few market makers to support its price. There is no assurance that our Common Stock will ever be listed on a national securities exchange, that we will be able to comply with or continue to meet such applicable listing standards.

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

There is no established public trading market for our Investor Warrants. Although we plan to apply to have the Investor Warrants listed on the Nasdaq Capital Market or Alternate Exchange under the symbol "ARTHW," there is no assurance our application will be approved, or even if it is approved, that a public trading market will develop or if one develops that it will be maintained. Without a public market, the liquidity of the Investor Warrants will remain limited.

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

On August 22, 2023, the stockholders approved a reverse stock split between 1-for-1.5 to 1-for-20, and the Company intends to effect the Reverse Split at a ratio of 1-for-8 prior to the pricing of this offering, and without correspondingly decreasing the number of authorized shares of Common Stock. Even if our planned Reverse Split increases the market price of our Common Stock sufficiently so that we comply with the minimum market price requirement, no assurance can be given that we will be able to comply with the other standards that we are required to meet in order to be approved for listing on the Nasdaq Capital Market or an Alternate Exchange or maintain a listing of our Common Stock on such exchange. Our failure to meet these requirements prior to listing will result in the offering not occurring and our failure to meet these requirements following listing may result in our Common Stock being delisted from the Nasdaq Capital Market or an Alternate Exchange.

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

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

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

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

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

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

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

Sales of substantial amounts of our Common Stock in the public market or the perception that such sales could occur, could adversely affect the trading price of our Common Stock, and may make it more difficult for you to sell your Common Stock at a time and price that you deem appropriate. We are unable to predict the effect that such sales may have on the prevailing price of our Common Stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

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

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

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

As of February 14, 2024, there were issued and outstanding (or expected to be issued and outstanding, as specified below): (i) options granted to employees, directors and consultants under our 2013 Stock Incentive Plan (the "**2013 Plan**") to purchase up to an aggregate of 100,300 shares of Common Stock at exercise prices ranging from $4.00 to $130.00 per share and with a weighted average exercise price of $37.34 per share; (ii) 26,284,002 shares of Common Stock issuable upon the exercise of outstanding warrants, having a weighted average exercise price of $1.71 per share (which includes 18,798,526 Common Warrants that will automatically be cancelled and exchanged for 56,395,578 Exchange Investor Warrants at the closing of this offering); (iii) Series 2 Convertible Notes convertible into 52,917 shares of Common Stock at a conversion price of $50.00 per share; (iv) 1,567,127 shares of Common Stock issuable upon regular (non-Automatic) conversion of the 2022 Notes at the conversion price of $4.00 per share (taking into account the operation of the Most Favored Nation Provision as a result of the Uplist PIPE); (v) 1,716,780 shares of Common Stock to be issuable upon exercise at $0.001 per share of the PIPE Pre-Funded Warrants; (vi) 1,716,780 shares of Common Stock to be issuable upon exercise at $4.00 per share of the PIPE Investor Warrants; (vii) 85,839 shares of Common Stock to be issuable upon exercise at $5.15625 per share of the PIPE Placement Agent Warrants; and (viii) 455,168 shares of Common Stock reserved for future issuance under the 2023 Plan.

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

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

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 either have a public float of less than $250 million as of the last business day of our second fiscal quarter or annual revenues of less than $100 million during our most recently completed fiscal year and a public float of less than $700 million. Smaller reporting companies are able to provide simplified executive compensation disclosures in their filings; are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting; and have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports and in a registration statement under the Exchange Act on Form 10. Decreased disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects.

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 February 14, 2024, we believe that our current cash on hand will meet our anticipated cash requirements into the second quarter of fiscal 2024. 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 February 14, 2024, 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 2.4% 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 1C. CYBERSECURITY

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, 2022 at our current location. During October 2021, we extended the lease through March 31, 2022 at our current location. Effective April 1, 2022 we have converted our current lease to a monthly rental.

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 February 14, 2024, there were approximately 130 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**") is a biotechnology company developing and marketing a products based on our innovative AC5® self-assembling technology platform. Arch arose from the June 26, 2013 merger (the "**Merger**") of three entities previously known as Arch Biosurgery, Inc., Almah, Inc., and Arch Acquisition Corporation, respectively.

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

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

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

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

The Company has recently devoted a substantial part of its operational effort to the market adoption and commercial sales of AC5® Advanced Wound System, its first product. To date, the Company has principally raised capital through debt borrowings, the issuance of convertible debt, 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 current and potential products. However, there can be no assurance that the Company will be successful in securing additional capital when needed, on terms acceptable to the Company, if at all. Therefore, there exists substantial doubt about the Company's ability to continue as a going concern for one year past the issuance of the financial statements. The consolidated financial statements do not include any adjustments related to the recoverability of assets that might be necessary despite this uncertainty.

Liquidity

We devote a significant amount of our efforts on fundraising, planning and conducting clinical trials, activities in connection with obtaining regulatory approval, and product research. We have principally raised capital through borrowings, the issuance of convertible debt, and units consisting of Common Stock and warrants to fund our operations. For the year ended September 30, 2023, we had a net loss of $6,982,836 versus a net loss of $5,275,854 in the prior year. The losses for each of the years ended September 30, 2023 and 2022 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, and general corporate legal expense. For the fiscal year ended September 30, 2023 the loss from operations was partially offset by extinguishment of the derivative liabilities and, for the fiscal year ended September 30, 2022, an expiration of the Series F derivative liability. Cash used in operating activities decreased $1,081,859 during the year ended September 30, 2023 to $3,374,216, compared to $4,456,075 for the year ended September 30, 2022. Cash at September 30, 2023 decreased by $524,220 to $222,720 compared to $746,940 as of September 30, 2022.

Business Overview

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

Core Technology

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

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

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

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

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

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

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

Operations

We have recently started to commercialization AC5 Advanced Wound System. We rely on both an internal commercial team and independent sales distributors to drive awareness and adoption of AC5 Advanced Wound System in several targeted channels with a particular focus on physician offices and government channels, such as Veterans Health Administration (VA) hospitals and military treatment facilities. We anticipate that material growth in the physician office setting will require product reimbursement. To that end, we applied to the Centers for Medicare and Medicaid Services (CMS) for a dedicated Healthcare Common Procedure Coding System (HCPCS) Level II reimbursement code specific to AC5 Advanced Wound System to better enable providers to bill third party payors for AC5 that is used in doctors' offices. The unique HCPCS code, A2020, was granted and made effective on April 1, 2023.

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

We will continue to seek partnerships with reputable, value-added independent sales distributors on a case-by-case basis to expand the overall reach and footprint of its total sales organization. Presently, our commercialization efforts and resources remain dedicated to the US market for advanced wound care.

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

Our long-term business plan includes the following goals:

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

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

- further develop our product clinical profile;
- enhance product packaging features;
- identify and address opportunities for supply chain efficiencies;
- assess our technology platform in order to identify and select product candidates for potential advancement into development;
- seek additional funding as required to support the previously described milestones necessary to support our operations;
- continue to expand and enhance our financial and operational reporting and controls;
- pursue commercial partnerships; and
- expand and enhance our intellectual property portfolio by filing new patent applications, obtaining allowances on currently filed patent applications, and/or adding to our trade secrets in self-assembly, manufacturing, analytical methods and formulation, as appropriate.

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

We have no commitments for 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.

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 believe that, as of February 14, 2024, our current cash on hand will meet our anticipated cash requirements into the second quarter of fiscal 2024.

Research and Development

Preclinical and clinical testing is required in order to receive regulatory marketing authorizations for our products and to support those products upon and after commercialization, and we anticipate continuing such testing as appropriate.

Preclinical Testing

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

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

Before initiating or clinical trials and submitting marketing applications for a given product in most jurisdictions, we complete a biocompatibility assessment using a battery of standard in vitro and in vivo tests. Examples of such tests may include the following, as set forth in ISO 10993 issued by the International Organization for Standardization:

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

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

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

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

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

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

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

In an assessment versus 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' AC5 technology has also demonstrated hemostasis in liver and other organs in in vivo surgical models, including rapid hemostasis within 15 seconds. In a range of small and large animal models, our compositions have been shown to stop bleeding, seal leaking, allow for normal healing, and mitigate inflammation while being biocompatible.

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

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

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

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

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

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

Clinical Testing

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

In order to enroll patients in a clinical trial, we are required to obtain each patient's informed consent in a form and substance that complies with the 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.

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

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

Many factors could lead to delays or inefficiencies in conducting clinical trials, some of which are discussed under the heading "**RISK FACTORS**" in this prospectus. Further, we, the FDA or an institutional review board (*IRB*) could suspend a clinical trial at any time for various reasons, including a belief that the risks to the subjects of the trial outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA clearance or approval to market the product in the US.

Regulatory

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

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

- product design, preclinical and clinical development and 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 US and AC5 Topical Hemostat in EU are classified as medical devices. Generally, a product is a medical device if it requires neither metabolic nor chemical activity to achieve the desired effect. AC5 self-assembly, which is the desired effect, is consistent with the medical device definition.

Medical devices in the US and EU are classified along a spectrum on the basis of the amount of risk to the patient associated with the medical device and the controls deemed necessary to reasonably ensure their safety and effectiveness. Class III status, which is the higher-level classification for devices compared to Classes II and I, involves additional procedures and regulatory scrutiny of the product candidate to obtain approvals. Class III devices are those that are deemed to pose the greatest risks, such as life-sustaining, life-supporting or implantable devices, or 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 US, and AC5 Topical Hemostat is a Class IIb medical device in EU.

In the US, the FDA recognizes these classes of medical devices:

- Class I, requiring general controls, including labeling, device listing, reporting and, for some products, adherence to good manufacturing practices through the FDA's quality system regulations and pre-market notification;
- Class II, requiring general controls and special controls, which may include performance standards and post-market surveillance; 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 or European Union Medical Device Regulation and is driven in part by the device's degree of contact with the patient, invasiveness, active nature, and indications for use. The medical device classes recognized in the EU are:

- Class IIa, which are considered low-medium risk devices and require certification by a Notified Body (defined below under the section entitled "*European Union Marketing Authorization (CE Mark) Process*");
- Class IIb, which are considered medium-high risk devices and require certification by a Notified Body; and
- Class III, which are considered high-risk devices and require certification by a Notified Body.

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

US Regulatory Marketing Authorization Process

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

AC5 Advanced Wound System, which is intended for external use, received marketing authorization through the 510(k) process. To obtain 510(k) clearance for a medical device, an applicant must submit a premarket notification to the FDA demonstrating that the device is "substantially equivalent" to a predicate device or devices, which is typically a legally marketed Class II device in the US. A device is substantially equivalent to a predicate device if it has the same intended use and (i) the same technological characteristics, or (ii) has different technological characteristics and the information submitted demonstrates that the device is as safe and effective as a legally marketed device and does not raise different questions of safety or effectiveness. In some cases, the submission must include data from human clinical studies. Marketing may commence when the FDA issues a clearance letter. Depending upon a product's underlying technology and intended use, as well as on FDA processes and procedures, seeking and obtaining a 510(k) can be a lengthy process.

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

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

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

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

European Union Marketing Authorization (CE Mark) Process

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

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

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

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

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

In 2017, the EU regulatory bodies implemented a Medical Device Regulation, which revises several aspects of the existing regulatory framework, such as clinical data requirements, and introduces new ones, such as Unique Device Identification. We, and the Notified Bodies who will oversee compliance to the new Medical Device Regulation, face uncertainties in the upcoming years as it is rolled out and enforced, creating risks in several areas, including the CE mark process, data transparency and application review timetables. The Medical Device Regulation became effective on May 26, 2021, although the European Commission has allowed an implementation period to facilitate transition from the Medical Device Directives. This transition period extends until the end of 2027 for high-risk devices and until the end of 2028 for medium and low risk devices.

Post-Approval Regulation

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

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

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

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

- Under the supervision of a health care professional, AC5 Advanced Wound System is a topical dressing used for the management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds.

- AC5 Topical Hemostat is intended for use locally as a dressing and to control mild to moderate bleeding, each during the management of injured skin and the micro-environment of an acute surgical wound.

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

For at least the near term future, in order to maximize operational efficiencies and to account for changing landscapes since the COVID-19 pandemic, during which both marketing authorizations were received, we have prioritized the launch of AC5 Advanced Wound System in the United States over that of AC5 Topical Hemostat in Europe, where we have not launched.

We expect the initial commercialization ramp to be gradual through 2024 and then moderately accelerate as we identify and encourage product use by key opinion leaders and early adopters in developing market channels.

We recently started to commercialize AC5 Advanced Wound System. We rely on both an internal commercial team and independent sales distributors to drive awareness and adoption of AC5 Advanced Wound System in several targeted channels with a particular focus on physician offices and government channels, such as Veterans Health Administration (VA) hospitals and military treatment facilities. These settings tend to have many patients whose needs we believe can be addressed by AC5 Advanced Wound System because it is a synthetic self-assembling wound care product that provides clinicians with multi-modal support and utility across all phases of wound healing. Numerous published case studies and accolades highlight the efficacy and safety of AC5 in the treatment of challenging chronic and acute surgical wounds, including limb salvage and healing after other modalities have failed.

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

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

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

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

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

The COVID-19 Pandemic Impact on Commercialization

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

- access to surgeons, potential strategic partners, and facilities outside of the United States has become curtailed;
- healthcare facilities often have rationed staff and resources, resulting in less 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;
- administrators who may be required to facilitate or approve new product intake are constrained by new and other pressing priorities; and
- the volume of elective surgical procedures has been constrained periodically;

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. The activities include development of our primary product candidates, as well as generation of appropriate analytical methods, scale-up, and other procedures for use by manufacturers and/or other members of our supply chain to produce or process our products at current and/or larger scale quantities for research, development, and commercialization.

Our products are regulated as medical devices, and as such, many of our activities have focused on optimizing traditional parameters to target specifications, biocompatibility, physical appearance, stability, and handling characteristics, among other metrics, to achieve the desired product. We and our partners intend to continue to monitor manufacturing processes and formulation methods closely, as success or failure in establishing and maintaining appropriate specifications may directly impact our ability to conduct additional preclinical and clinical trials and/or deliver commercial 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 to produce our current products rely on detailed, complex and difficult to manage synthetic organic chemistry processes. Although use of those methods requires that we engage manufacturers that possess the expertise, skill and know-how involved with those methods, the required equipment to use those methods is widely available. Our current products are synthesized from naturally occurring ingredients amino acids that, while not sourced from humans or other animals, do exist in their natural state in humans. That type of ingredient may be more likely to be categorized as “generally recognized as safe”, or “GRAS”, by the FDA.

Industry and Competition

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

Common features of our current and planned products, as described herein, are driven by the mechanism of action, which itself is derived from the underlying physicochemical properties or our AC5 self-assembling peptide technology and Arch’s product safety and performance specifications. Those features, which include, among others, that they possess barrier properties and can create an environment permissive to healing, can deliver a benefit in the treatment of external and internal wounds that are open, exposed, bleeding, leaking, and/or at risk for excessive inflammation or contamination.

Dermal Sciences

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

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

The incidence and prevalence of both acute surgical and chronic wounds is noteworthy. According to a 2020 report by Steiner et al for The Healthcare Cost and Utilization Project (www.ncbi.nlm.nih.gov/books/NBK442035), approximately 17 million hospital visits (inpatient and ambulatory) in 2014 resulted in almost 22 million invasive therapeutic surgeries. While more acute surgical wounds occur per year versus chronic wounds, the nature of chronic wounds provides addition greater challenges due to the prolonged duration of the healing period, the frequency of interventions needed to help the wound heal, and the often-underlying medical problem that placed the patient at risk for the wound in the first place, which is itself a hindrance to the healing process.

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

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

Venous leg ulcers, representing the most common chronic wounds, occur in approximately 2.2% of Americans over age 65 each year, according to Rice et al in 2014, which equates to roughly 1.2 million new wounds per year among just that population (www.doi.org/10.3111/13696998.2014.903258), while Qiu et al in 2021 provided an estimated prevalence of 2-4% (www.doi.org/10.3389/fmed.2021.614059). The Centers for Disease Control and Prevention estimates that approximately 56 million Americans are over age 65. Additional chronic wounds not accounted for above can include, among others, surgical wounds that become chronic wounds, typically in patients with co-morbidities.

The morbidity and mortality associated with wounds, and particularly chronic wounds, is problematic. A 2017 article by Järbrink et al noted that chronic wounds may not heal for several years or, in some cases, decades, during which time the patient may suffer from severe pain, emotional and physical distress, less mobility and greater social isolation, while the family may suffer from other stresses and challenges (www.doi.org/10.1186/s13643-016-0400-8). Woods et al in 2020 stated that only 2/3 of diabetic foot ulcers heal within 12 months (www.doi.org/10.1371/journal.pone.0232395). Some wounds just do not heal, remaining stagnant or progressing to limb loss or worse. Järbrink et al noted in 2017 that ulcers precede 85% of all amputations (www.doi.org/10.1186/s13643-016-0400-8).

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

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

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

According to a 2018 report by Nussbaum et al., data from calendar year 2014 estimated that Medicare alone spent between $28.1 to $96.8 billion for all wound care types, and that nearly 15% (8.2 million) of Medicare beneficiaries were diagnosed with at least one type of wound or wound-related infection (https://www.doi.org/10.1016/j.jval.2017.07.007). Furthermore, a 2017 report by Chan et al indicated that the mean one-year cost of care from the perspective of a health-care public payer was $44,200 for a diabetic foot ulcer, $15,400 for a pressure ulcer and $11,000 for a leg ulcer (https://www.doi.org/10.12968/jowc.2017.26.sup4.s4). Woods et al in 2020 estimated that the cost per admission among patients with diabetic foot ulcers was $8,145 if the wound was not infected and $11,290 if the wound was infected (www.doi.org/10.1371/journal.pone.0232395). Han et al noted in 2017 that lessening a hospital admission by just one day represents an enormous cost savings and is separately beneficial to the patient (https://www.doi.org/10.1007/s12325-017-0478-y).

A common wound care topic, which has been further highlighted during the COVID-19 pandemic, is how to provide high quality care in lower acuity settings. It is less expensive, more convenient, and potentially better for the patient if a wound care procedure, such as debridement, can be safely performed in a doctor’s office or wound clinic in lieu of a hospital operating room. For example, a report by Rogers et al in 2020 discussed changing sites of service to the lowest acuity setting in which care could be safely delivered (https://www.researchgate.net/publication/340950761). As such, we believe that wound care products should be designed to enable clinicians to “do more with less”, such as debride in a clinic or office a wound that otherwise may have required an operating room visit.

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

We believe that the aforementioned elevated wound incidence and prevalence, consequential morbidity and mortality, prolonged healing times and exorbitant cost of overall care underscores the potential opportunity for the overall market and for our products. We believe that the addressable market opportunity for advanced wound care products in the US alone can exceed $20 billion if improvements enable the best products to increase penetration at the expense of less effective wound care products and categories, 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., doctor’s offices) or higher acuity (e.g., operating rooms) settings;
- can be used in conjunction with aggressive surgical debridement;
- can be used on a wound whether or not it is bleeding;
- is agnostic to the presence of anti-thrombotic therapy (aka, blood thinners);
- can be used on a chronic, stalled wound that has been previously unresponsive to or failed treatment regimens;
- provides a protective barrier to mitigate contamination and modulating inflammation;
- donates moisture to the wound;
- can create wound microenvironment conducive to healing;
- aids in epithelial cell migration;
- creates an extracellular matrix-like structure to enable cell and tissue growth;
- is self-healing, in that it can dynamically self-repair around migrating cells;
- may reduce healing time and patient burden;
- is user-friendly, easy to prepare, and easy to apply;
- may be stored at ambient temperature; and
- may reduce treatment costs while improving outcomes in certain patients.

BioSurgery

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

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

- reliable;
- able to protect the wounds in tissues and organs where used;
- laparoscopic friendly;
- easily handled and applied;
- able to promote a clear field of vision and not obstruct view;

- sufficiently flowable;
- non-sticky (to tissue or equipment);
- permits normal healing;
- agnostic to the presence of antithrombotic medications ("blood thinners") to whether the patient has bleeding abnormalities;
- non-toxic; and
- not sourced from human or other animal blood or tissue components.

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

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

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

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

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

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

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

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

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

Participants in the hemostatic and sealant market include large medical device and biopharmaceutical companies, as well as various smaller companies. Commercially available hemostatic agents can cost between $50 and $500 per procedure, with the higher value-added products generally priced at the upper end of that range. We believe, however, that approaches to many surgical problems have evolved and will continue to do so, such that what may 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.

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

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

- The favorable handling characteristics of AC5 Devices result, in part, from their non-sticky and non-glue-like nature. However, if a surgeon or healthcare provider requires a product to adhere tissues together, or provide similar glue-like action, then AC5 Devices in their current form would not achieve that effect.

- While we project that our products will be sufficiently economical to manufacture at scale, they may not be able to compete from a price perspective with inexpensive products.

- We have generated less data in humans compared to many successful products in the Dermal Sciences or BioSurgery categories.

- While we believe that the flowable nature of our products before they assemble into a dense nanofiber network can provide a meaningful advantage, some surgeons may prefer a solid product in certain applications.

- Reimbursement for some competing products and product categories may be more established, making it surgeon less likely to use a newer product with limited history of successful reimbursement.

Other Governmental Regulations and Environmental Matters

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

Intellectual Property

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

As of February 2, 2024, we either own or license from others a number of US patents, US patent applications, foreign patents and foreign patent applications.

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

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

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

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

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

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

Employees

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

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 January 13, 2023, the Company filed a Certificate of Change to the Company's Articles of Incorporation, as amended, with the Secretary of State of the State of Nevada (the "Certificate of Change"), which effected, at 5:00 p.m. Eastern Time on January 17, 2023, a one-for-two-hundred (1:200) reverse stock split (the "Reverse Stock Split") of both the Company's issued and outstanding shares of Common Stock, and authorized shares of Common Stock.

As a result of the Reverse Stock Split, every two hundred (200) shares of Common Stock issued and outstanding was combined into one (1) share of Common Stock, with a proportionate 1:200 reduction in the Company's authorized Common Stock. The Reverse Stock Split affected all stockholders uniformly and did not alter any stockholder's percentage interest in the Company's equity, except to the extent that the Reverse Stock Split would have resulted in some stockholders owning a fractional share. No fractional shares were issued in connection with the Reverse Stock Split. Any fractional shares of Common Stock resulting from the Reverse Stock Split were rounded up to the nearest whole post-Reverse Stock Split share and no stockholders received cash in lieu of fractional shares.

The Reverse Stock Split did not change the par value of the Common Stock. All outstanding securities entitling their holders to purchase shares of Common Stock or acquire shares of Common Stock, including stock options, restricted stock units, and warrants, were adjusted as a result of the Reverse Stock Split, as required by the terms of those securities.

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

On January 18, 2023, the Company entered into Amendment No. 1 to the 2022 SPA (the "Amendment" and, together with the SPA, the "Amended 2022 SPA"), with certain Investors in connection with the second closing of the 2022 Convertible Note Offering for the issuance and sale by the Company to such Investors of an aggregate of (i) Unsecured Convertible Promissory Notes (each a "Second Note" and collectively, the "Second Notes") in the aggregate principal amount of $636,000, which includes an aggregate $106,000 original issue discount in respect of the Second Notes; (ii) warrants (the "Second Warrants") to purchase an aggregate of 127,968 shares (the "Second Warrant Shares") of Common Stock; and (iii) 9,598 shares of Common Stock (the "Second Inducement Shares"). The aggregate gross proceeds for the sale of the Second Notes, Second Warrants and Second Inducement Shares was approximately $530,000, before deducting any placement agent's fees and other estimated fees and offering expenses payable by the Company. The second closing of the sales of these securities under the Amended 2022 SPA occurred on January 18, 2023 (the "Second Closing Date"). As background, the Company originally entered into a Securities Purchase Agreement, dated July 6, 2022 (the "2022 SPA"), with certain institutional and accredited individual investors (collectively, the "Investors") for the issuance and sale by the Company to the Investors of convertible promissory notes (the "2022 Notes"), warrants (the "2022 Warrants") to purchase shares of common stock, par value $0.001 per share (the "Common Stock"), and shares of Common Stock (the "2022 Inducement Shares", and together with the 2022 Notes, and 2022 Warrants, the "2022 Convertible Note Offering"). The First Closing of the 2022 Convertible Note Offering occurred on July 6, 2022.

On February 14, 2023, the Company entered into an amendment to its outstanding 2022 Notes issued on July 6, 2022 with the holders of such notes. Also on February 14, 2023, the Company entered into an amendment to its outstanding Second Notes issued on January 18, 2023 with the holders of such notes. These actions amended the 2022 Notes and Second Notes to extend the Uplist Transaction deadline related to the Company's efforts to uplist to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American from February 15, 2023 to March 15, 2023.

As a result of the amendment to the 2022 Notes and Second Notes, and pursuant to the terms of the Company's outstanding Exchanged Notes, the Exchanged Notes were automatically amended to extend the date of completion of an Uplist Transaction from February 15, 2023 to March 15, 2023.

On March 10, 2023, the Company entered into exchange agreements (the "Exchange Agreements") with each holder (the "Warrantholders") of the Company's outstanding Series G Warrants to purchase shares of the Company's common stock, par value $0.001 per share (the "Common Stock") at an exercise price of $140.00 per share and the Company's outstanding Series H Warrants to purchase shares of Common Stock at an exercise price of $80.00 per share. Pursuant to the Exchange Agreements, the Warrantholders exchanged 34,013 Series G Warrants for 3,402 shares of Common Stock and 43,077 Series H Warrants for 8,617 shares of Common Stock.

On March 10, 2023, the Company entered into an amendment ("Amendment No. 2 to the First Notes") with the Requisite Holders of the Company's outstanding 2022 Notes, as amended on February 14, 2023, issued in connection with a private placement financing the Company completed on July 6, 2022 (the "First Closing"). On March 10, 2023, the Company also entered into an amendment ("Amendment No. 2 to the Second Notes" and, together with Amendment No. 2 to the First Notes, "Amendment No. 2 to the 2022 Notes") with the Requisite Holders of Company's Second Notes, as amended on February 14, 2023, issued in connection with a private placement financing the Company completed on January 18, 2023 (the "Second Closing" and, together with the First Closing, the "2022 Convertible Note Offering").

Under Amendment No. 2 to the 2022 Notes, the following amendments to the 2022 Notes will be effective at the moment in time immediately preceding the consummation of the offering (the "Effective Time") in connection with the uplist of the Common Stock to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (the "Uplist Transaction"). If a 2022 Note holder elects to participate in the Uplist Transaction (each, a "Participating Holder") for an amount equal to no less than 50% of the Participating Holder's original investment amount in the 2022 Private Placement Financing (the "Minimum Investment Amount"), such holder will be entitled to repayment of the principal amount of their 2022 Notes upon closing of the Uplist Transaction. In addition, the Company will issue to each Participating Holder a new convertible promissory note equal to the product of 2.4 and the sum of any prepayment premiums and total interest payable on such Participating Holder's 2022 Notes (the "2023 Notes"). The 2023 Notes will have a maturity date of July 6, 2024 and will be on substantially the same terms as the original 2022 Notes as applicable. For non-Participating Holders (each, a "Non-Participating Holder"), the maturity date of the 2022 Notes held by such Non-Participating Holder will be extended to July 6, 2024. Further, each Non-Participating Holder will waive their right to demand repayment of any portion of the outstanding balance of such holder's 2022 Notes upon an Uplist Transaction. Notwithstanding the foregoing, if the registration statement filed in connection with the Uplist Transaction is not declared effective by 11:59 P.M. (EST) on March 15, 2023 (the "Amendment No. 2 Termination Date"), Amendment No. 2 to the 2022 Notes will automatically terminate and shall be of no further force or effect without any further action by the Company or the Requisite Holders, provided, that the Amendment No. 2 Termination Date may be extended by the written approval of the Company and 2022 Notes holders which purchased at least 50% plus $1.00 of the 2022 Notes based on the initial principal amounts thereunder (the "Requisite Holders").

On March 10, 2023, the Company also entered into an amendment (the "Series 1 Note Amendment") with each of the holders of the Company's outstanding Series 1 Convertible Notes (as amended, the "Series 1 Notes"). Also on March 10, 2023, the Company entered into an amendment (the "Series 2 Note Amendment" and, together with the Series 1 Amendment, the "Series Note Amendments") with each of the holders of the Company's outstanding Series 2 Convertible Notes (as amended, the "Series 2 Notes" and, together with the Series 1 Notes, the "Series Convertible Notes"). Pursuant to the Series Note Amendments, the Company can elect to convert the principal and accrued interest under the Series Convertible Notes (the "Series Note Obligations") upon the earlier of the completion of an Uplist Transaction or maturity date of the Series 1 Notes and Series 2 Notes. In the event the Company exercises such option, the Series Note Obligations will be deemed to equal the product of 4.5 (which was previously 1.6 prior to the Series Note Amendments) and the outstanding Series Note Obligations. Notwithstanding the foregoing, if the registration statement filed in connection with the Uplist Transaction is not declared effective by 11:59 P.M. (EST) on March 15, 2023 or such later extended date as provided for therein (the "Series Note Amendments Termination Date"), the Series Note Amendments will automatically terminate without any further action by the Company or the holders of the Series Convertible Notes. The Series Note Amendments Termination Date will be automatically extended upon any extension of the Amendment No. 2 Termination Date.

On March 15, 2023, the Company entered into amendments to the 2022 Notes ("Amendment No. 3 to the First Notes") and Second Notes ("Amendment No. 3 to the Second Notes" and collectively, "Amendment No. 3 to the 2022 Notes" and, together with Amendment No. 2 to the 2022 Notes, the "Amendments to the 2022 Notes") with the Requisite Holders of the 2022 Notes and Second Notes. Under Amendment No. 3 to the 2022 Notes, the 2022 Notes and Second Notes were amended to extend the Amendment No. 2 Termination Date from March 15, 2023 to April 15, 2023, which had the effect of extending to Uplist Transaction deadline from March 15, 2023 to April 15, 2023.

As a result of the entry into the Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Exchanged Notes, the Exchanged Notes were automatically amended to (i) extend the Amendment No. 2 Termination Date from March 15, 2023 to April 15, 2023; (ii) modify the terms of the Uplist Transaction repayment provision; and (iii) provide for the issuance of the 2023 Notes, subject to completion of the Uplist Transaction. Also, on March 15, 2023, in connection with Amendment No. 3 to the 2022 Notes, and pursuant to the terms of the Company's outstanding Series Notes, the Series Notes were automatically amended to extend the date of completion of an Uplist Transaction from March 15, 2023 to April 15, 2023.

On April 15, 2023, the Company entered into an amendment ("Amendment No. 4 to the First Notes") with the holders of the Company's outstanding 2022 Notes, as amended on February 14, 2023, March 10, 2023 and March 15, 2023, issued in connection with the First Closing. On April 15, 2023, the Company also entered into an amendment ("Amendment No. 4 to the Second Notes" and, together with Amendment No. 4 to the First Notes, "Amendment No. 4 to the 2022 Notes") with the holders of the Company's outstanding Second Notes, as amended on February 14, 2023, March 10, 2023 and March 15, 2023 issued in connection with the Second Closing. Under Amendment No. 4 to the 2022 Notes, the 2022 Notes and Second Notes were amended to extend the date of the completion of an uplist to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (such transaction, an "Uplist Transaction") from April 15, 2023 to May 15, 2023.

As a result of the entry into Amendment No. 4 to the 2022 Notes, and pursuant to the terms of the Company's outstanding Exchanged Notes, the Exchanged Notes were automatically amended to extend the date of completion of an Uplist Transaction from April 15, 2023 to May 15, 2023. Also, on April 15, 2023, in connection with Amendment No. 4 to the 2022 Notes, and pursuant to the terms of the Company's outstanding Series Notes, the Series Notes were automatically amended to extend the date of the completion of an Uplist Transaction from April 15, 2023 to May 15, 2023.

On April 15, 2023, the Company entered into an amendment ("Amendment No. 1 to the A&R Registration Rights Agreement") to that certain Amended and Restated Registration Rights Agreement, dated as of January 18, 2023, by and among the Company and certain institutional and accredited individual investors (as amended, the "A&R Registration Rights Agreement"). Under Amendment No. 1 to the A&R Registration Rights Agreement, the A&R Registration Rights Agreement was amended to extend the filing deadline by which the Company is obligated to file with the Securities and Exchange Commission a registration statement under the Securities Act of 1933, as amended, registering certain securities issued in the Second Closing, from April 18, 2023 to June 17, 2023.

On May 15, 2023, the Company entered into Amendment No. 2 to the 2022 SPA related to the 2022 Convertible Note Offering (the "Amendment" and, together with the 2022 SPA, the "Amended 2022 SPA"), with certain Investors in connection with the third closing of the 2022 Convertible Note Offering for the issuance and sale by the Company to an Investor of an aggregate of (i) Unsecured Convertible Promissory Notes (each a "Third Note" and collectively, the "Third Notes") in the aggregate principal amount of $702,720, which includes an aggregate $214,720 original issue discount in respect of the Third Notes; (ii) warrants (the "Third Warrants") to purchase an aggregate of 141,396 shares (the "Third Warrant Shares") of Common Stock; and (iii) 10,608 shares of Common Stock (the "Third Inducement Shares"). The aggregate gross proceeds for the sale of the Third Notes, Third Warrants and Third Inducement Shares was approximately $488,000, before deducting the placement agent's fees and other estimated fees and offering expenses payable by the Company. The third closing of the sales of these securities under the Amended SPA occurred on May 15, 2023 (the "Third Closing Date").

On May 15, 2023, the Company entered into an amendment ("Amendment No. 5 to the First Notes") with the holders of the Company's outstanding 2022 Notes, as amended on February 14, 2023, March 10, 2023, March 15, 2023 and April 15, 2023, issued in connection with the First Closing to extend the date of the completion of the Uplist Transaction from May 15, 2023 to June 15, 2023. On May 15, 2023, the Company also entered into an amendment ("Amendment No. 5 to the Second Notes" and, together with Amendment No. 5 to the First Notes, "Amendment No. 5 to the 2022 Notes") with the holders of the Company's outstanding Second Notes, as amended on February 14, 2023, March 10, 2023, March 15, 2023 and April 15, 2023 issued in connection with the Second Closing to extend the date of the completion of the Uplist Transaction from May 15, 2023 to June 15, 2023.

As a result of the entry into Amendment No. 5 to the 2022 Notes, and pursuant to the terms of the Company's outstanding Exchanged Notes, the Exchanged Notes were automatically amended to extend the date of completion of an Uplist Transaction from May 15, 2023 to June 15, 2023. Also, on May 15, 2023, in connection with Amendment No. 5 to the 2022 Notes, and pursuant to the terms of the Company's outstanding Series Notes, the Series Notes were automatically amended to extend the date of the completion of an Uplist Transaction from May 15, 2023 to June 15, 2023.

Through May 15, 2023, the Company raised $538,000 in the form of shareholder advances from two different investors to support operations in advance of the Company's prospective Uplisting Transaction. On May 15, 2023, $488,000 of these shareholder advances, which was contributed by a single investor, were issued an Unsecured convertible note (the "Third Note") in connection with the Third Closing of the 2022 Convertible Note Offering. The remaining $50,000 that was raised by the Company in the form of shareholder advances was repaid per the agreed terms on July 7, 2023 for $60,000.

On May 18, 2023 and May 31, 2023, the Company raised $340,000 and $350,015 from a shareholder and a third-party investor, respectively, to support operations in advance of the Company's anticipated closing of the Bridge Offering (as defined below). On July 7, 2023, the amount prefunded by the current shareholder was included in the first closing of a common stock, pre-funded warrant and common warrants Bridge Offering. The amount prefunded by the third-party investor is expected to be included in a subsequent closing of the Bridge Offering.

On June 15, 2023, the Company entered into an amendment ("Amendment No. 6 to the First Notes") with the holders of the Company's outstanding 2022 Notes, as amended on February 14, 2023, March 10, 2023, March 15, 2023, April 15, 2023 and May 15, 2023, issued in connection with the First Closing to extend the date of the completion of the Uplist Transaction from June 15, 2023 to July 1, 2023. On June 15, 2023, the Company also entered into an amendment ("Amendment No. 6 to the Second Notes") with the holders of the Company's outstanding Second Notes, as amended on February 14, 2023, March 10, 2023, March 15, 2023, April 15, 2023 and May 15, 2023 issued in connection with the Second Closing to extend the date of the completion of the Uplist Transaction from June 15, 2023 to July 1, 2023. On June 15, 2023, the Company also entered into an amendment ("Amendment No. 1 to the Third Notes and, together with Amendment No. 6 to the First Notes and Amendment No. 6 to the Second Notes, the "First Series of Amendments to the 2022 Notes") with the holder of the Company's outstanding Third Notes issued in connection with the Third Closing to extend the date of the completion of the Uplist Transaction from June 15, 2023 to July 1, 2023.

As a result of the entry into First Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Exchanged Notes, the Exchanged Notes were automatically amended to extend the date of completion of an Uplist Transaction from June 15, 2023 to July 1, 2023. Also, on June 15, 2023, in connection with First Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Series Notes, the Series Notes were automatically amended to extend the date of the completion of the Uplist Transaction from June 15, 2023 to July 1, 2023.

On July 1, 2023, the Company entered into an amendment ("Amendment No. 7 to the First Notes") with the holders of the Company's outstanding 2022 Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, and June 15, 2023, issued in connection with the First Closing. On July 1, 2023, the Company also entered into an amendment ("Amendment No. 7 to the Second Notes") with the holders of the Company's outstanding Second Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, and June 15, 2023, issued in connection with the Second Closing. On July 1, 2023, the Company also entered into an amendment ("Amendment No. 2 to the Third Notes and, together with Amendment No. 7 to the First Notes and Amendment No. 7 to the Second Notes, the "Second Series of Amendments to the 2022 Notes") with the holders of the Company's outstanding Third Notes, as amended on June 15, 2023, issued in connection with the Third Closing. Under the Second Series of Amendments to the 2022 Notes, the 2022 Notes, Second Notes, and Third Notes were amended to extend the date of the completion of an uplist to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (such transaction, an "Uplist Transaction") from July 1, 2023 to July 31, 2023.

As a result of the entry into the Second Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Exchanged Notes, the Exchanged Notes were automatically amended to extend the date of completion of an Uplist Transaction from July 1, 2023 to July 31, 2023. Also, on July 1, 2023, in connection with the Second Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Series Notes, the Series Notes were automatically amended to extend the date of the completion of the Uplist Transaction from July 1, 2023 to July 31, 2023.

On July 7, 2023, the Company announced that it had entered into a Securities Purchase Agreement (the "Bridge SPA") with certain institutional and accredited individual investors (collectively, the "Investors") providing for the issuance and sale by the Company to the Investors of an aggregate of (i) 1,749,245 shares (the "Shares") of common stock, par value $0.001, of the Company (the "Common Stock") at a purchase price of $0.275 per share; (ii) 4,996,199 warrants (the "Pre-Funded Warrants") at a purchase price of $0.274 per Pre-Funded Warrant, to purchase an aggregate of 4,996,199 shares of Common Stock (the "Pre-Funded Warrant Shares"); and (iii) 13,490,888 warrants (the "Common Warrants") to purchase an aggregate 13,490,888 shares of Common Stock (the "Common Stock Warrants Shares"). The Shares, Pre-Funded Warrants, and Common Warrants were issued as part of a private placement offering authorized by the Company's Board of Directors (the "Bridge Offering").

Pursuant to the lock-up agreement provided for by the Bridge SPA, the Investors agreed that they would either (A) purchase securities, for cash, in an offering conducted in conjunction with an uplist of the Common Stock to any of, and in compliance with the rules of, the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (the "Uplist Transaction") with an aggregate purchase price equal to at least 4.3 multiplied by the aggregate purchase price paid by the Investor for the Shares, Pre-Funded Warrants and Common Warrants under the Bridge SPA or (B) be subject to a lock-up provision not to sell or otherwise transfer any of the Shares, Pre-Funded Warrant Shares or Common Warrant Shares acquired by them in the Bridge Offering until the one-year anniversary of the Closing Date. The aggregate gross proceeds for the sale of the Shares, Pre-Funded Warrants, and Common Warrants will be approximately $1.85 million, before deducting the placement agent's fees and other estimated fees and offering expenses payable by the Company. The closing of the sales of these securities under the Bridge SPA occurred on July 7, 2023 (the "Closing Date").

The Bridge SPA also provides additional provisions including: i) certain adjustments that would require the Company to issue additional securities to the Investors if the effective offering price to the public of Common Stock in connection with the next underwritten public offering is less than $4.00 per share; ii) a requirement to register the Shares, Pre-Funded Warrant Shares, and Common Stock Warrant Shares on a subsequent registration statement or statements; and, iii) certain restrictions on the Company's ability to conduct subsequent sales of its equity securities and certain business activities.

On July 7, 2023, the Company also entered into an amendment ("Amendment No. 8 to the First Notes") with the holders of the Company's outstanding 2022 Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, and July 1, 2023, issued in connection with the First Closing. On July 1, 2023, the Company also entered into an amendment ("Amendment No. 8 to the Second Notes" with the holders of the Company's outstanding Second Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, and July 1, 2023, issued in connection with the Second Closing. On July 1, 2023, the Company also entered into an amendment ("Amendment No. 3 to the Third Notes", and, together with Amendment No. 8 to the First Notes and Amendment No. 8 to the Second Notes, the "Third Series of Amendments to the 2022 Notes") with the holders of the Company's outstanding Third Notes, as amended on June 15, 2023, and as subsequently amended on July 1, 2023, issued in connection with the Third Closing.

Under the Third Series of Amendments to the 2022 Notes, the following amendments to the 2022 Notes, Second Notes, and Third Notes will be simultaneously effective upon the closing of an offering conducted in conjunction with an uplist of the Common Stock to any of, and in compliance with the rules of, the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (the "Uplist Transaction"). The Specified Percentage (as defined below) of the then outstanding principal amount of the 2022 Notes, Second Notes, and Third Notes shall automatically convert (the "Automatic Conversion") into shares of Common Stock, with the conversion price for purposes of such Automatic Conversion being equal to the lower of (i) the per unit price at which any units (each unit being comprised of one share or share equivalent and accompanying warrants, if any) are sold in the Uplist Transaction or (ii) the price at which warrants issued in the Uplist Transaction are exercisable (but in no event increased above the conversion price in effect immediately prior to the pricing of the Uplist Transaction).

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

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

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

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

On July 7, 2023 the Company paid $60,000 to a shareholder that had previously advanced the Company $50,000 to support operations. The payment satisfied all remaining obligations in connection with the $538,000 of shareholder advances received by the Company through May 15, 2023. The additional $488,000 was issued as a Third Note.

Additional information related to all such matters can be found in the Form 8-K filed by the Company with Securities and Exchange Commission on July 13, 2023.

During July 2023, the Company entered into a finance agreement with First Insurance Funding to fund a portion of its insurance policies. For the year ended September 30, 2023, the amount financed is approximately $395,000 and incurs interest rates ranging from 7.49% to 9.90%. The Company is required to make monthly payments of approximately $35,000 through April 2024.

On July 12, 2023, the Company secured countersigned notices of conversion from all remaining holders of the Series 1 Convertible Notes, and provided instructions to its transfer agent to issue a total of 59,912 shares of Common Stock in full satisfaction of all previously outstanding Series 1 Convertible Notes. Pursuant to the Series 1 Convertible Notes, the Company can elect to convert the principal and accrued interest under the Series Convertible Notes obligation (the "Series Note Obligations") upon the earlier of the effective time of the Uplisting Transaction, or the maturity date. In the case of an In-Kind Note Repayment, the outstanding Note Obligations will be calculated by increasing by thirty-five percent the aggregate sum of the unpaid Principal Amount held by each Holder and the accrued interest at a rate of ten percent per annum, subject to, with respect to any portion of the Principal Amount that is converted or prepaid before the twelve month anniversary of the Issuance Date, a minimum interest payment equal to ten percent of the amount that is converted or prepaid. As consideration for agreeing to subordinate to the 2022 Notes, the premium applicable in connection with an In-Kind Note Repayment at maturity was increased from thirty-five percent to sixty percent. On March 10, 2023, the Company entered into Amendment 2 of the Series 1 Convertible notes and pursuant this amendment, the Company can elect to convert the principal and accrued interest under the Series Convertible Notes (the "Series Note Obligations") upon the earlier of the effective time of the Uplisting Transaction, or the maturity date. In the event the Company exercises such option, the Series Note Obligations will be deemed to equal the product of 4.5 (which was previously 1.6 prior to the Series Note Amendments) and the outstanding Series Note Obligations.

On July 18, 2023, the Board executed a unanimous written consent that, among other things, approved, subject to the approval of a majority of the stockholders of the Company, the following: 1) amend the Amended and Restated Articles of Incorporation (the "Articles") to a) increase the number of authorized shares of common stock, par value $0.001 (the "Common Stock") from 12 million to 350 million, b) create 5,000,000 shares of "blank check" preferred stock, and c) approve a reverse split at a ratio of between 1.5-for-1 and 20-for-1 without any proportionate decrease in the number of authorized shares; 2) amend the Bylaws of the Company to a) allow action by written consent of stockholders representing more than 50% of the total number of shares of Common Stock currently issued and outstanding, and b) establish that holders of thirty-three and one-third (33.3333%) of the total number of shares of Common Stock currently issued and outstanding shall constitute a quorum at any meeting of stockholders for the transaction of business, except as otherwise provided by the NRS or by the Articles; and, 3) approve the 2023 Omnibus Equity Incentive Plan with an initial reservation of 455,169 shares, options or other such grants.

Additional information related to such matters can be found in the Form 8-K filed by the Company with Securities and Exchange Commission on July 24, 2023.

On July 31, 2023, the Company entered into an amendment ("Amendment No. 9 to the First Notes") with the holders of the Company's outstanding 2022 Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023 and July 7, 2023 issued in connection with the First Closing. On July 31, 2023, the Company also entered into an amendment ("Amendment No. 9 to the Second Notes") with the holders of the Company's outstanding Second Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, and July 7, 2023 issued in connection with the Second Closing. On July 31, 2023, the Company also entered into an amendment ("Amendment No. 4 to the Third Notes and, together with Amendment No. 9 to the First Notes and Amendment No. 9 to the Second Notes, the "Fourth Series of Amendments to the 2022 Notes") with the holders of the Company's outstanding Third Notes, as amended on June 15, 2023, and as subsequently amended on July 1, 2023 and July 7, 2023 issued in connection with the Third Closing. Under the Fourth Series of Amendments to the 2022 Notes, the 2022 Notes, Second Notes, and Third Notes were amended to extend the date of the completion of an uplist to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (such transaction, an "Uplist Transaction") from July 31, 2023 to August 31, 2023.

As a result of the entry into the Fourth Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Exchanged Notes, the Exchanged Notes were automatically amended to extend the date of completion of an Uplist Transaction from July 31, 2023 to August 31, 2023. Also, on July 31, 2023, in connection with the Fourth Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Series Notes, the Series Notes were automatically amended to extend the date of the completion of the Uplist Transaction from July 31, 2023 to August 31, 2023.

On August 13, 2023, our Board adopted and approved the Amended and Restated 2023 Equity Incentive Plan (the "A&R Plan"), subject to stockholder approval, which amended and restated the Company's 2023 Equity Incentive Plan originally approved by the Board on July 18, 2023 (the "Plan"). The Plan was amended and restated to (i) shorten the Plan's duration from 10 years to 6 years, (ii) decrease the annual Evergreen Shares (as defined in the A&R Plan) percentage from six percent (6%) to five percent (5%), (iii) limit the Plan's incremental 15% increases to shares issued in connection with the "Bridge Financing", the "Uplist Transaction" and/or, to the extent provided by the A&R Plan, a "Qualifying Offering" (as such terms are defined in the A&R Plan), and (iv) require that seventy-five percent (75%) of the Evergreen Shares be granted as stock options, stock appreciation rights and/or performance-based awards, among other things. Additional information related to such matters can be found in the Form 8-K filed by the Company with Securities and Exchange Commission on August 23, 2023.

On August 22, 2023, the Company received a written consent in lieu of a meeting of stockholders representing a majority of the voting power of the outstanding shares of voting stock of the Company (the "Majority Stockholders") approving the A&R Plan and thereafter, the Company filed a preliminary Information Statement on Schedule 14C (the "Information Statement") with the Securities and Exchange Commission (the "SEC") with respect to the transactions contemplated hereby.

On August 30, 2023,the Company entered into an amendment ("Amendment No. 10 to the First Notes") with the holders of the Company's outstanding 2022 Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 7, 2023, and July 31, 2023 issued in connection with the First Closing. On August 30, 2023, the Company also entered into an amendment ("Amendment No. 10 to the Second Notes") with the holders of the Company's outstanding Second Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 7, 2023, and July 31, 2023 issued in connection with the Second Closing. On August 30, 2023, the Company also entered into an amendment ("Amendment No. 5 to the Third Notes" and, together with Amendment No. 10 to the First Notes and Amendment No. 10 to the Second Notes, the "Fifth Series of Amendments to the 2022 Notes") with the holders of the Company's outstanding Third Notes, as amended on June 15, 2023, and as subsequently amended on July 1, 2023, July 7, 2023, and July 31, 2023 issued in connection with the Third Closing. Under the Fifth Series of Amendments to the 2022 Notes, the 2022 Notes, Second Notes, and Third Notes were amended to extend the date of the completion of an uplist to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (such transaction, an "Uplist Transaction") from August 31, 2023, to September 30, 2023.

As a result of the entry into the Fifth Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Exchanged Notes, the Exchanged Notes were automatically amended to extend the date of completion of an Uplist Transaction from August 31, 2023, to September 30, 2023. Also, on August 30, 2023, in connection with the Fifth Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Series Notes, the Series Notes were automatically amended to extend the date of the completion of the Uplist Transaction from August 31, 2023 to September 30, 2023.

On August 30, 2023, the Company also entered into an amendment ("Amendment No. 1 to the Second A&R Registration Rights Agreement") to that certain Second Amended and Restated Registration Rights Agreement, dated as of May 15, 2023, with effect as of June 17, 2023, by and among the Company and certain institutional and accredited individual investors (the "Second A&R Registration Rights Agreement"). Under Amendment No. 1 to the Second A&R Registration Rights Agreement, the Second A&R Registration Rights Agreement was amended to extend the filing deadline by which the Company is obligated to file with the Securities and Exchange Commission (the "SEC") a registration statement under the Securities Act of 1933, as amended, registering certain securities issued in the Second Closing and Third Closing to the date that is 45 days following the Uplist Transaction.

On August 30, 2023, the Company also entered into an amendment ("Amendment No. 1 to the Bridge SPA"), with certain institutional and accredited individual investors that participated in the first closing of the Bridge Offering to extend the date by which additional closings under the SPA are permitted from 30 days after the Initial Closing Date to 90 days after the Initial Closing Date.

On August 30, 2023, the Company also entered into an amendment ("Amendment No. 1 to the Registration Rights Agreement") to that certain Registration Rights Agreement, dated as of July 7, 2023, by and among the Company and certain institutional and accredited individual investors (the "Registration Rights Agreement"). Under Amendment No. 1 to the Registration Rights Agreement, the Registration Rights Agreement was amended to extend the filing deadline by which the Company is obligated to file with the SEC a registration statement under the Securities Act of 1933, as amended, registering certain securities issued in the Bridge Offering, to the earlier of (i) the date that is 30 days following the Uplist Transaction and (ii) October 31, 2023.

Additional information related to all such matters can be found in the Form 8-K filed by the Company with the Securities and Exchange Commission on September 6, 2023.

On August 31, 2023, the Company consummated a second closing of the Bridge Offering pursuant to the terms and conditions of the SPA with certain institutional and accredited individual investors (collectively, the "Investors") providing for the issuance and sale by the Company to the Investors of an aggregate of (i) 1,527,150 shares of Common Stock (the "Shares") at a purchase price of $0.275 per share; (ii) 1,058,743 pre-funded warrants (the "Pre-Funded Warrants") to purchase an aggregate of 1,058,743 shares of Common Stock, at a purchase price of $0.274 per Pre Funded Warrant (the "Pre-Funded Warrant Shares"); and (iii) 5,171,786 warrants (the "Common Warrants" and together with the Pre-Funded Warrants, the "Warrants") to purchase an aggregate of 5,171,786 shares of Common Stock (the "Common Warrant Shares" and together with the Pre-Funded Warrant Shares, the "Warrant Shares"). The Shares, Pre-Funded Warrants, and Common Warrants were issued as part of the second closing of the Bridge Offering. Additional information related to such matters can be found in the Form 8-K filed by the Company with Securities and Exchange Commission on September 7, 2023.

On September 1, 2023, the Company filed a definitive Information Statement with the SEC and commenced mailing the definitive Information Statement to the Company's stockholders notifying them of the action taken by written consent on August 22, 2023 to approve the A&R Plan. Under the applicable SEC regulations, the A&R Plan became effective 20 days from the date of the mailing of the definitive Information Statement to the Company's stockholders.

On September 21, 2023, the Company amended its Articles of Incorporation by filing a Certificate of Amendment (the "Certificate of Amendment") with the Secretary of State of Nevada to increase the total number of authorized shares of common stock, par value $0.001 per share, from 12,000,000 to 350,000,000, and to authorize 5,000,000 shares of "blank check" preferred stock, par value $0.001 per share. The Certificate of Amendment was authorized by our Board on July 18, 2023, and the amendments to the Company's Articles of Incorporation were approved by the Company's stockholders on August 22, 2023.

On September 30, 2023, the Company entered into an amendment ("Amendment No. 11 to the First Notes") with the holders of the Company's outstanding 2022 Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, and August 30, 2023 issued in connection with the First Closing. On September 30, 2023, the Company also entered into an amendment ("Amendment No. 11 to the Second Notes") with the holders of the Company's outstanding Second Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, and August 30, 2023 issued in connection with the Second Closing. On September 30, 2023, the Company also entered into an amendment ("Amendment No. 6 to the Third Notes" and, together with Amendment No. 11 to the First Notes and Amendment No. 11 to the Second Notes, the "Sixth Series of Amendments to the 2022 Notes") with the holders of the Company's outstanding Third Notes, as amended on June 15, 2023, and as subsequently amended on July 1, 2023, July 7, 2023, July 31, 2023, and August 30, 2023 issued in connection with the Third Closing. Under the Sixth Series of Amendments to the 2022 Notes, the 2022 Notes, second Notes, and Third notes were amended to extend the date of the completion of an uplist to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American (such transaction, an "Uplist Transaction") from September 30, 2023 to October 31, 2023.

As a result of the entry into the Sixth Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Exchanged Notes, the Exchanged Notes were automatically amended to extend the date of completion of an Uplist Transaction from September 30, 2023, to October 31, 2023. Also, on September 30, 2023, in connection with the Sixth Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Series Notes, the Series Notes were automatically amended to extend the date of the completion of the Uplist Transaction from September 30, 2023 to October 31, 2023.

Additional information related to such matters can be found in the Form 8-K filed by the Company with the Securities and Exchange Commission on October 4, 2023.

On October 30, 2023, the Company received a shareholder advance of $100,000 to support the operations of the Company.

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

On November 8, 2023, the Company entered into an amendment ("Amendment No. 12 to the First Notes") with the holders of the Company's outstanding 2022 Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023 and September 30, 2023 issued in connection with the First Closing. On November 8, 2023, the Company also entered into an amendment ("Amendment No. 12 to the Second Notes") with the holders of the Company's outstanding Second Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023 and September 30, 2023 issued in connection with the Second Closing. On November 8, 2023, the Company also entered into an amendment ("Amendment No. 7 to the Third Notes" and, together with Amendment No. 12 to the First Notes and Amendment No. 12 to the Second Notes, the "Seventh Series of Amendments to the 2022 Notes") with the holders of the Company's outstanding Third Notes, as amended on June 15, 2023, and as subsequently amended on July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023 and September 30, 2023 issued in connection with the Third Closing. Under the Seventh Series of Amendments to the 2022 Notes, the 2022 Notes, Second Notes, and Third Notes were amended to extend the date of the completion of an Uplist Transaction from October 31, 2023, to November 15, 2023.

In addition to the foregoing, the following amendments to the 2022 Notes, Second Notes, and Third Notes will be simultaneously effective upon the closing of the Uplist Transaction. Fifty percent (50%) of the then outstanding principal amount of the 2022 Notes, Second Notes and Third Notes shall automatically convert (the "Automatic Conversion") into shares of Common Stock, with the conversion price for purposes of such Automatic Conversion of $4.00. Upon the Automatic Conversion and to the extent that the beneficial ownership of a holder of 2022 Notes, Second Notes, and Third Notes (a "Holder" and, all holders of 2022 Notes together, the "Holders") would increase over the applicable Ownership Limitation, the Holder will receive pre-funded warrants in lieu of shares of Common Stock otherwise issuable to the Holder in connection with the Automatic Conversion, which may be exercised on a cashless basis, shall be exercisable immediately upon issuance and shall contain a customary beneficial ownership limitation provision.

In addition, upon the Automatic Conversion, the Holder shall receive a warrant (the "Uplist Conversion Warrant", and the shares issuable upon exercise thereof, the "Uplist Conversion Warrant Shares") to purchase a number of shares of Common Stock equal to 6.3812 times the dollar amount under the 2022 Notes, Second Notes, Third Notes that was converted in the Automatic Conversion. The Uplist Conversion Warrant shall have an exercise price per share of $4.00 and shall otherwise be identical to the PIPE Common Warrant.

As a result of the entry into the Seventh Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Exchanged Notes, the Exchanged Notes were automatically amended to extend the date of completion of an Uplist Transaction from October 31, 2023, to November 15, 2023. Also, on November 8, 2023, in connection with the Seventh Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Series Notes, the Series Notes were automatically amended to extend the date of the completion of the Uplist Transaction from October 31, 2023 to November 15, 2023.

On November 8, 2023, the Company also entered into an amendment ("Amendment No. 2 to the Second A&R Registration Rights Agreement") to that certain Second Amended and Restated Registration Rights Agreement, dated as of May 15, 2023, as amended on June 17, 2023, by and among the Company and certain institutional and accredited individual investors (as amended, the "Second A&R Registration Rights Agreement"). Under Amendment No. 2 to the Second A&R Registration Rights Agreement, the Second A&R Registration Rights Agreement was amended to (I) extend the filing deadline by which the Company is obligated to file with the SEC a registration statement under the Securities Act of 1933, as amended, registering certain securities issued in the 2022 Convertible Note Offering to the earlier of (i) the date that is 30 days following the Uplist Transaction and (ii) November 30, 2023, and (II) to provide for the inclusion of the Registerable Securities (as defined therein) in the Uplist S-1 (as defined therein).

On November 8, 2023, the Company also entered into an amendment to the Bridge SPA ("Amendment No. 2 to the Bridge SPA"), with certain institutional and accredited individual investors that participated in the Bridge Offering. Under Amendment No. 2 to the Bridge SPA, upon the closing of the next underwritten public offering of Common Stock (the "Qualifying Offering"), which the Company agreed is the Uplist Transaction, if the effective offering price to the public per share of Common Stock (the "Qualifying Offering Price") is lower than $4.00 per share, then the Company shall issue additional Bridge Pre-Funded Warrants (the "True-Up Pre-Funded Warrants"), or shares of Common Stock (the "True-Up Shares") in lieu thereof to the extent necessary to cause the Company to meet the listing requirements of the Company's proposed trading market in the Uplist Transaction, in an amount reflecting a reduction in the purchase price paid for the Bridge Shares and Bridge Pre-Funded Warrants that equals the proportion by which the Qualifying Offering Price is less than $4.00.

On November 8, 2023, the Company also entered into an amendment ("Amendment No. 2 to the Bridge Registration Rights Agreement") to that certain Registration Rights Agreement, dated as of July 7, 2023, as amended on August 30, 2023, by and among the Company and certain institutional and accredited individual investors (as amended the "Bridge Registration Rights Agreement"). Under Amendment No. 2 to the Bridge Registration Rights Agreement, the Bridge Registration Rights Agreement was amended to (I) extend the filing deadline by which the Company is obligated to file with the SEC a registration statement under the Securities Act of 1933, as amended, registering certain securities issued in the Bridge Offering, to the earlier of (i) the date that is 30 days following the Uplist Transaction and (ii) November 30, 2023, and (II) to provide for the inclusion of the Registerable Securities (as defined therein) in the Uplist S-1 (as defined therein).

Additional information related to all such matters can be found in the Form 8-K filed by the Company with the Securities and Exchange Commission on November 15, 2023.

On November 13, 2023, the Company received a shareholder advance of $100,000 to support the operations of the Company.

On November 21, 2023, and effective as of November 15, 2023, the Company entered into an amendment ("Amendment No. 13 to the First Notes") with the holders of the Company's outstanding 2022 Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023, September 30, 2023, and October 31, 2023 issued in connection with the First Closing. On November 21, 2023, and effective as of November 15, 2023, the Company also entered into an amendment ("Amendment No. 13 to the Second Notes") with the holders of the Company's outstanding Second Notes, as amended on February 14, 2023, and as subsequently amended on March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023, September 30, 2023 and October 31, 2023 issued in connection with the Second Closing. On November 21, 2023, and effective as of November 15, 2023, the Company also entered into an amendment ("Amendment No. 8 to the Third Notes" and, together with Amendment No. 13 to the First Notes and Amendment No. 13 to the Second Notes, the "Eighth Series of Amendments to the 2022 Notes") with the holder of the Company's outstanding Third Notes, as amended on June 15, 2023, and as subsequently amended on July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023, September 30, 2023 and October 31, 2023 issued in connection with the Third Closing. Under the Eight Series of Amendments to the 2022 Notes, the 2022 Notes, Second Notes, and Third Notes were amended to extend the date of the completion of an uplist to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange, or NYSE American (such transaction, an "Uplist Transaction") from November 15, 2023, to January 6, 2024.

As a result of the entry into the Eighth Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Exchanged Notes, the Exchanged Notes were automatically amended to extend the date of completion of an Uplist Transaction from November 15, 2023, to January 6, 2024. Also, on November 21, 2023, in connection with the Eighth Series of Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Series Notes, the Series Notes were automatically amended to extend the date of the completion of the Uplist Transaction from November 15, 2023 to January 6, 2024.

On November 21, 2023, the Company also entered into an amendment ("Amendment No. 3 to the Second A&R Registration Rights Agreement") to that certain Second Amended and Restated Registration Rights Agreement, dated as of May 15, 2023, as amended on June 17, 2023, and as subsequently amended on November 8, 2023 by and among the Company and certain institutional and accredited individual investors (as amended, the "Second A&R Registration Rights Agreement"). Under Amendment No. 3 to the Second A&R Registration Rights Agreement, the Second A&R Registration Rights Agreement was amended to extend the filing deadline by which the Company is obligated to file with the Securities and Exchange Commission (the "SEC") a registration statement under the Securities Act of 1933, as amended, registering certain securities issued in the 2022 Convertible Note Offering to the earlier of (i) the date that is 30 days following the Uplist Transaction and (ii) January 31, 2024.

On November 22, 2023, the Company entered into an amendment ("Amendment No. 3 to the Bridge Registration Rights Agreement") to that certain Registration Rights Agreement, dated as of July 7, 2023, as amended on August 30, 2023, and as subsequently amended on November 8, 2023, by and among the Company and certain institutional and accredited individual investors (as amended the "Bridge Registration Rights Agreement") in connection with a private placement offering of pre-funded warrants to purchase shares of common stock, par value $0.001, of the Company ("Common Stock"), common warrants to purchase shares of Common Stock, and shares of Common Stock (the "Bridge Offering"). Under Amendment No. 3 to the Bridge Registration Rights Agreement, the Bridge Registration Rights Agreement was amended to extend the filing deadline by which the Company is obligated to file with the SEC a registration statement under the Securities Act of 1933, as amended, registering certain securities issued in the Bridge Offering, to the earlier of (i) the date that is 30 days following the Uplist Transaction and (ii) January 31, 2024.

Additional information related to all such matters can be found in the Form 8-K filed by the Company with the Securities and Exchange Commission on November 22, 2023.

On November 29, 2023, the Company received a shareholder advance of $250,000 to support the operations of the Company.

On November 30, 2023, the Company provided instructions to its transfer agent to issue a total of 52,917 shares of Common Stock in full satisfaction of all previously outstanding Series 2 Convertible Notes. Pursuant to the Series 2 Convertible Notes, the Company can elect to convert the principal and accrued interest under the Series Convertible Notes obligation (the "Series Note Obligations") upon the earlier of the effective time of the Uplisting Transaction, or the maturity date. In the case of an In-Kind Note Repayment, the outstanding Note Obligations will be calculated by increasing by thirty-five percent the aggregate sum of the unpaid Principal Amount held by each Holder and the accrued interest at a rate of ten percent per annum, subject to, with respect to any portion of the Principal Amount that is converted or prepaid before the twelve month anniversary of the Issuance Date, a minimum interest payment equal to ten percent of the amount that is converted or prepaid. As consideration for agreeing to subordinate to the 2022 Notes, the premium applicable in connection with an In-Kind Note Repayment at maturity was increased from thirty-five percent to sixty percent. On March 10, 2023, the Company entered into Amendment 2 of the Series 2 Convertible Notes and pursuant this amendment, the Company can elect to convert the principal and accrued interest under the Series Convertible Notes (the "Series Note Obligations") upon the earlier of the effective time of the Uplisting Transaction, or the maturity date. In the event the Company exercises such option, the Series Note Obligations will be deemed to equal the product of 4.5 (which was previously 1.6 prior to the Series Note Amendments) and the outstanding Series Note Obligations.

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

From December 13, 2023 to December 14, 2023, two purchaser parties (the "Advancing Purchasers") to the previously disclosed Securities Purchase Agreement (the "SPA") dated November 8, 2023, among Arch Therapeutics, Inc. (the "Company") and the purchasers party thereto (including the Advancing Purchasers), advanced the Company an aggregate of $500,000 (the "Advances"), which Advances are being treated as partial prepayment of the purchase price for the Advancing Purchasers under the SPA. If the transactions contemplated by the SPA are not consummated by February 29, 2023, the Company will be obligated to repay the Advances to the Advancing Purchasers within three business days thereafter.

On January 5, 2024, the Company entered into an amendment ("Amendment No. 14 to the First Notes") with the holders of the Company's outstanding 2022 Notes, as amended on February 14, 2023, March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023, September 30, 2023, October 31, 2023, and November 15, 2023 issued in connection with the First Closing. On January 5, 2024, the Company also entered into an amendment ("Amendment No. 14 to the Second Notes") with the holders of the Company's outstanding Second Notes, as amended on February 14, 2023, March 10, 2023, March 15, 2023, April 15, 2023, May 15, 2023, June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023, September 30, 2023, October 31, 2023, and November 15, 2023 issued in connection with the Second Closing. On January 5, 2024, the Company also entered into an amendment ("Amendment No. 9 to the Third Notes" and, together with Amendment No. 14 to the First Notes and Amendment No. 14 to the Second Notes, the "Amendments to the 2022 Notes") with the holders of the Company's outstanding Third Notes, as amended on June 15, 2023, July 1, 2023, July 7, 2023, July 31, 2023, August 30, 2023, September 30, 2023, October 31, 2023, and November 15, 2023 issued in connection with the Third Closing. Under the Amendments to the 2022 Notes, the Second Notes and the Third Notes were amended to extend the date of the completion of an uplist to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange, or NYSE American (such transaction, an "Uplist Transaction") and to extend the respective maturity date of each of the 2022 Notes from January 6, 2024, to March 15, 2024.

As a result of the entry into the Amendments to the 2022 Notes, and pursuant to the terms of the Company's outstanding Exchanged Notes, the Exchanged Notes were automatically amended to extend the date of completion of an Uplist Transaction from January 6, 2024, to March 15, 2024.

On January 9, 2024, the Audit Committee of the Board of Directors (the "Audit Committee") of Arch Therapeutics, Inc. (the "Company") dismissed Baker Tilly US, LLP ("Baker Tilly") as the Company's independent registered public accounting firm, effectively immediately. Also on January 9, 2024, the Audit Committee approved the appointment of Weinberg & Company, P.A. ("Weinberg") as the Company's new independent registered public accounting firm, effective immediately. Additional information related to all such matters can be found in the Form 8-K filed by the Company with Securities and Exchange Commission on January 12, 2024.

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, 2023 Compared to Year Ended September 30, 2022

	September 30, 2023 ($)	September 30, 2022 ($)	Increase (Decrease) ($)
Revenue	75,724	15,652	60,072
Operating Expenses			
Cost of revenues	78,163	51,489	26,674
Selling, general and administrative	4,371,164	4,519,636	148,472
Research and development	670,880	1,153,333	(482,453)
Loss from Operations	(5,120,207)	(5,708,806)	(604,251)
Other (expense) income	(1,938,353)	432,952	(2,255,305)
Net loss	(6,982,836)	(5,275,854)	(1,590,982)

Revenue

Revenue for the year ended September 30, 2023 was $75,724, an increase of $60,072 compared to $15,652 for the year ended September 30, 2022. Revenue for the year ended September 30, 2023 was the of result multiple transactions into a single hospital as well as transactions into multiple Veterans Administration Hospitals *(the* "*VA*") consisting of twenty (20) total units through our distribution partner, Lovell Government Services *("LGS*"). Revenue for the year ended September 30, 2022 was the result of four transactions into multiple VA Hospitals consisting of ten (10) total units through our distribution partner, *LG*S.

Cost of revenues

Cost of revenues during the year ended September 30, 2023 was $78,163, an increase of $26,674 compared to $51,489 for the year ended September 30, 2022. Cost of revenue includes product costs, third party warehousing, overhead allocation, royalty, and shipping costs.

Selling, General and Administrative Expense

General and administrative expense during the year ended September 30, 2023 was $4,371,164 a decrease of $148,453 compared to $4,519,636 for the year ended September 30, 2022. The decrease in selling, general and administrative expense for the year ended September 30, 2023 is primarily attributable to an increase in legal and consulting costs, which were more than offset by a decrease in compensation costs and patent costs.

Research and Development Expense

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

O*ther (Expense) Income*

Other expense during the year ended September 30, 2023 was $1,938,353, an increase of $2,371,305 compared to total other income of $432,952 for the year ended September 30, 2022. The increase in other (expense) income is attributable to interest expense partially offset by gain for the extinguishment of derivative liabilities.

Liquidity and Capital Resources

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, 2023, we had total current assets of $1,950,090 (including cash of $222,720) and a working capital deficit of $7,515,831. Our working capital as of September 30, 2023 and September 30, 2022 is summarized as follows:

	September 30, 2023	September 30, 2022
Total Current Assets	$ 1,950,090	$ 2,598,195
Total Current Liabilities	9,465,921	3,320,494
Working Capital	$ (7,515,831)	$ (722,299)

Total current assets as of September 30, 2023 were $1,950,090, a decrease of $648,105 compared to $2,598,195 as of September 30, 2022. 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 2nd and 3rd closings of our 2022 Note Financing and our bridge equity financing. Our total current assets as of September 2022 and 2022 were comprised primarily of cash, inventory and prepaid expense.

Total current liabilities as of September 30, 2023 were $9,465,921, an increase of $6,145,427 compared to $3,320,494 as of September 30, 2022. The increase is primarily due to an increase in accounts payable, current portion of the Series 2 Convertible Notes, current portion of the unsecured convertible notes, the current portion of the 2022 notes and accrued interest.

Cash Flow

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

Cash Used in Operating Activities

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

Cash Used in Investing Activities

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

Cash Provided by Financing Activities

Cash provided by financing activities decreased $81,859, to $2,854,517 for the fiscal year ended September 30, 2023, compared to $2,936,376 for the fiscal year ended September 30, 2022. For the year ended September 30, 2023, the cash provided by financing activities increased as a result from net proceeds of $2,209,839 raised from bridge equity financing and proceeds of $995,000 received from the issuance of unsecured convertible notes partially offset by repayment of financed insurance premium of $352,198. For the year ended September 30, 2022, the cash provided by financing activities resulted from net proceeds of $3,042,633 raised from the issuance of senior secured convertible notes, warrants and inducement shares partially offset by repayment of financed insurance premium.

Cash Requirements

We anticipate that our operating expenses, interest expense and other expenses will increase significantly as we continue to implement our business plan and pursue our operational goals. As of February 14, 2024, we believe that our current cash on hand will meet our anticipated cash requirements into the second quarter of fiscal 2024. 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 and the 2022 SPA (see Note 6) 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

For the year ended September 30, 2023, the Company recorded a net loss of $6,982,836 and used cash in operations of $3,374,216. These factors raise substantial doubt about the Company's ability to continue as a going concern within one year of the date that the financial statements are issued. In addition, the Company's independent registered public accounting firm, in their report on the Company's September 30, 2023 audited financial statements, raised substantial doubt about the Company's ability to continue as a going concern. The financial statements included in this 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

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 and September 2023, pursuant to Exchange Act Rule 13a-15(b). Our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were not effective as of September 30, 2022. Since that time, management performed a comprehensive review regarding the effectiveness of the design of our disclosure controls and procedures (as defined by Exchange Act Rules 13a-15(e) or 15d-15(e)), which included additional oversight and training internally, as well as the retention of an external consultant to advise and review all matters of technical accounting and compliance with GAAP as a means to improve the effectiveness of disclosure controls and procedures, and resulted in the establishment of new policies and procedures to correct the prior deficiencies. As of September 30, 2023, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were effective.

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*"). Based on such evaluation, management concluded that the Company's internal control over financial reporting was effective as of September 30, 2023.

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, 2023, there were several changes in our internal control over financial reporting that management believes has materially improved our internal controls over financial reporting. Changes installed during the fiscal year ended September 30, 2023 included, but not necessarily limited to, i) a review of all internal policies related to internal control and disclosure, ii) enhanced controls related to the cash management and permissions, iii) establishment of additional policies to ensure sufficient controls and disclosure, iv) incremental oversight and communication to monitor compliance with such policies, v) implementation of additional training and cross-training for critical accounting functions to improve the effectiveness of internal control over financial reporting, and vi) the retention of an external consultant to advise on such matters and other technical accounting issues. In additional to the foregoing, 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:

Name	Position	Age	Director/Officer Since
Dr. Terrence W. Norchi	President, Chief Executive Officer and Chairman of the Board of Directors	59	April 2013
Punit Dhillon	Director	43	July 2018
Laurence Hicks	Director	58	September 2021
Dr. Guy L. Fish	Director	63	December 2021
Michael S. Abrams	Chief Financial Officer	53	May 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.

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, 2023 were timely, with the exception of three reports for management and a board member which were filed shortly after the completion of the financing in August 2023, but after the deadline. Two members from the management team and one board member participated in the August financing.

ITEM 11. EXECUTIVE COMPENSATION

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

Summary Compensation Table

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

(1) Represents the aggregate grant date fair values of awards granted during the fiscal year ended September 30, 2023 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, 2023 refer to Note 2 "Stock-Based Compensation" in our consolidated financial statements included in this filing.

(2) Daniel Yrigoyen resigned effective December 5, 2023.

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.

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

Outstanding Equity Awards At Fiscal Year-End

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

	Option Awards				Stock Awards	
Name	**Number of Securities Underlying Unexercised Options (#) Exercisable**	**Number of Securities Underlying Unexercised Options (#) Unexercisable**	**Option Exercise Price ($)**	**Option Expiration Date**	**Number of Shares or Units of Stock That Have Not Vested (#)**	**Market Value of Shares or Units of Stock That Have Not Vested ($)**
Dr. Terrence W. Norchi	2,500	—(1)	70	3/23/2024		
	2,000	—(2)	38	1/21/2025		
	1,775	—(3)	56	8/17/2025		
	6,250	—(4)	78	5/2/2026		
	3,250	—(5)	130	2/2/2027		
	1,800	—(6)	85	7/18/2028		
	5,000	—(7)	45.84	12/19/2029		
	5,000	—(8)	20.56	9/26/2031		
	3,334	1,666(9)	20.26	9/26/2031		
	1,737	4,513(10)	8.02	11/9/2023		
Michael S. Abrams	2,084	416(11)	26.58	5/2/2031		
	1,167	583(12)	20.56	9/26/2031		
	1,250	3,250(13)	8.02	11/9/2032		
Daniel M. Yrigoyen	542	208(14)	18	7/29/2031		
	667	333(15)	20.26	09/26/2031		
	334	416(16)	12.10	05/23/2032		
	695	1,805(17)	8.02	11/09/2032		

(1) Represents an option to purchase 2,500 shares of Common Stock with a grant date of March 23, 2014. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, 25% of the shares shall vest 12 months following the date of grant and 1/24th of the remaining shares shall vest on each of the monthly anniversaries of the grant date, commencing April 23, 2015.

(2) Represents an option to purchase 2,000 shares of Common Stock with a grant date of January 22, 2015. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, 25% of the shares shall vest 12 months following the date of grant and 1/24th of the remaining shares shall vest on each of the monthly anniversaries of the grant date, commencing February 22, 2016.

(3) Represents an option to purchase 1,775 shares of Common Stock with a grant date of August 18, 2015. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, and 1/36th of the remaining shares shall vest on each of the monthly anniversaries of the grant date, commencing September 18, 2015.

(4) Represents an option to purchase 6,250 shares of Common Stock granted on May 3, 2016. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vesting immediately, the remaining unvested Shares subject to the Option shall vest on each of the next thirty-six (36) monthly anniversaries of the date of grant.

(5) Represents an option to purchase 3,250 shares of Common Stock granted on February 3, 2017. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vesting immediately, the remaining unvested Shares subject to the Option shall vest on each of the next thirty-six (36) monthly anniversaries of the date of grant.

(6) Represents an option to purchase 1,800 shares of Common Stock with a grant date of July 19, 2018. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, and 1/36th of the remaining shares shall vest on each of the monthly anniversaries of the grant date, commencing August 19, 2018.

(7) Represents an option to purchase 625 shares of Common Stock with a grant date of December 20, 2019. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, and 1/36th of the remaining shares shall vest on each of the monthly anniversaries of the grant date, commencing January 20, 2019.

(8) Represents an option to purchase 5,000 shares of Common Stock with a grant date of September 27, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with 33% of the shares vested immediately on the date of grant and the remaining shares to vest in 24 equal installments commencing on the first anniversary on the date of grant.

(9) Represents an option to purchase 5,000 shares of Common Stock with a grant date of September 27, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.

(10) Represents an option to purchase 6,250 shares of Common Stock with a grant date of November 10, 2022. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.

(11) Represents an option to purchase 2,500 shares of Common Stock with a grant date of May 3, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with 30% of the shares vested immediately on the date of grant and the remaining shares to vest in 24 equal installments commencing on the first anniversary on the date of grant.

(12) Represents an option to purchase 1,750 shares of Common Stock with a grant date of September 27, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.

(13) Represents an option to purchase 4,500 shares of Common Stock with a grant date of November 10, 2022. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.

(14) Represents an option to purchase 750 shares of Common Stock with a grant date of July 30,2021. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant and the remaining shares to vest in 24 equal installments commencing on the first anniversary on the date of grant.

(15) Represents an option to purchase 1,000 shares of Common Stock with a grant date of September 27, 2021. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.

(16) Represents an option to purchase 750 shares of Common Stock with a grant date of 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.

(17) Represents an option to purchase 2,500 shares of Common Stock with a grant date of November 10, 2022. The vesting period of the shares underlying the option commenced on the date of grant, with shares to vest in 36 equal installments commencing on the first anniversary on the date of grant.

Compensation of Directors

On March 23, 2014, our Board 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, 2023:

Director Compensation Table

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

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

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

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

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 and the holders of a majority of our standing common stock approved and adopted the Arch Therapeutics, Inc. 2013 Stock Incentive Plan (the "2013 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, 2023, the Plan has reserved 185,572 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) 15,000 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. On June 18, 2023, the 2013 stock Incentive Plan expired.

On July 18, 2023, our Board adopted and approved the 2023 Equity Incentive Plan (the "2023 Plan") and reserved 455,169 shares of the Company's common stock, par value $0.001 for issuance thereunder to employees, officers, directors and consultants of the Company. The Plan has a term of 6 years and is intended to replace the Company's 2013 Stock Incentive Plan, which expired on June 18, 2023. The Plan permits the Company to grant a variety of forms of awards, including stock options, stock appreciation rights, restricted stock, restricted stock units, and dividend equivalent rights, to allow the Company to adapt its incentive compensation program to meet its needs. In addition, the number of shares of Common Stock available for issuance under the Plan will automatically increase on October 1st of each fiscal year of the Company commencing with October 1, 2023, and on each October 1 thereafter until the 10th anniversary of the date of the Plan's initial adoption by the Board, in an amount equal to six percent (6%) of the total number of shares of Common Stock outstanding on September 30th of the preceding fiscal year. Furthermore, effective at the close of business on the date of the closing (the "Uplist Date") of the public offering in connection with which the Common Stock becomes tradeable on a national exchange and on the first day of each fiscal quarter of the Company thereafter until the earlier of (i) the five-year anniversary of the Uplist Date and (ii) August 30, 2028, the number of shares of Common Stock available for issuance under the Plan shall automatically increase by an amount equal to fifteen percent (15%) of the incremental number of shares of Common Stock, if any, issued by the Company (i) with respect to the Uplist Date, since the date on which the stockholders ratified the Plan, and (ii) with respect to each fiscal quarter thereafter, during the previous fiscal quarter (excluding in each case shares of Common Stock issued pursuant to awards under the Plan).

The following table provides information as of September 30, 2023 with respect to our equity compensation plan:

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				
2013 Stock Incentive Plan	100,300	$	38.00	—
2023 Stock Incentive Plan	—		—	455,169
Equity compensation plans not approved by security holders	—		—	—
Total	100,300	$	38.00	455,169

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information regarding the beneficial ownership of our Common Stock by (i) each person who, to our knowledge, beneficially owns more than 5% of our Common Stock; (ii) each of our directors and named executive officers; and (iii) all of our directors and executive officers as a group. Unless otherwise indicated in the footnotes to the following table, the address of each person named in the table is: c/o Arch Therapeutics, Inc., 235 Walnut St., Suite #6, Framingham, Massachusetts 01702. The information set forth in the table below is based on 4,689,446 shares of our Common Stock outstanding on February 1, 2024. Shares of our Common Stock subject to options, warrants, or other rights currently exercisable or exercisable within 60 days of February 1, 2024 are deemed to be beneficially owned and outstanding for computing the share ownership and percentage of the person holding such options, warrants or other rights, but are not deemed outstanding for computing the percentage of any other person.

The following table is presented after taking into account the applicable ownership limitation to which certain holders of our 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 2022 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.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned (1)
5%+ Stockholders:		
Oasis Capital, LLC (2)	300,000	6.4%
Bigger Capital Fund, LP & District 2 Capital Fund LP (3)	300,000	6.4%
Walley Opportunities Master Fund 1 Ltd (4)	300,000	6.4%
Cavalry Fund 1 LP (5)	300,000	6.4%
Brandt & Mona Wilson	300,000	6.4%
Ana and Michael A. Parker (7)	300,000	6.4%
Andrew Stahl (8)	300,000	6.4%
Sixth Borough Capital Fund, LP (9)	300,000	6.4%
Named Executive Officers and Directors:		
Terrence Norchi (10)	114,584	2.4%
Punit Dhillon (11)	6,042	*%
Laurence Hicks (12)	22,076	*%
Michael Abrams (13)	24,216	1%
Daniel Yrigoyen (14)	3,403	*%
Guy Fish (15)	2,187	*%
Named Officers and Directors as a Group	172,508	3.6%

Shares of our Common Stock subject to options, warrants, or other rights currently exercisable or convertible or exercisable or convertible within 60 days of February 1, 2024, are deemed to be beneficially owned and outstanding for computing the share ownership and percentage of the person holding such options, warrants or other rights, but are not deemed outstanding for computing the percentage of any other person.

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

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

Related Party Transactions

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

On 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 approximately $80,000.

On August 10, 2023 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 approximately $7,500.

Review, Approval or Ratification of Transactions with Related Persons

Due to the small size of our Company, at this time we have determined to rely on our full Board 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, 2023 and 2022 and all other fees paid by us for services rendered by our principal accountants:

	2023	2022
Audit Fees	$ 30,000	$ 152,500
Audit-Related Fees	—	98,000
Tax Fees	—	—
All Other Fees	—	—
Total	$ 30,000	$ 250,500

Audit Fees. The fees identified under this caption were for professional services rendered by Weinberg & Company, P.A., our current principal accountant, during the fiscal year ended September 30, 2023 for the audit of our annual consolidated financial statements, and by Baker Tilly US, LLP, our prior principal accountant, during the fiscal year ended September 30, 2022 for the audit of our annual consolidated financial statements. The fees identified under this caption for the fiscal year ended September 30, 2022 also include fees for professional services rendered by Baker Tilly 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, 2023 and 2022 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, 2023 and 2022 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 2023 and 2022 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:

(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.	File No.	Filing Date
2.1	Agreement and Plan of Merger dated May 10, 2013, by and among Almah, Inc., Arch Acquisition Corporation, and Arch Therapeutics, Inc.		8-K	2.1	333-178883	5/13/2013
2.2	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.		10-Q	10.11	000-54986	8/14/2013
3.1	Restated Articles of Incorporation of Arch Therapeutics, Inc.		10-Q	3.1	000-54986	07/23/2020
3.2	Amended and Restated Bylaws, as adopted on August 15, 2022		8-K/A	3.1	000-54986	08/17/2022
3.3	Certificate of Amendment of Articles of Incorporation, as amended, of Arch Therapeutics, Inc., effective September 21, 2023		8-K	3.1	000-54986	09/27/2023
4.1	Description of Securities		10-K	4.1	000-54986	12/11/2020
4.2	Form of Bridge Pre-Funded Warrant		10-Q	4.1	000-54986	08/11/2023
4.3	Form of Bridge Common Warrant		10-Q	4.2	000-54986	08/11/2023
4.4	Form of Bridge Placement Agent Warrant		8-K	4.3	000-54986	09/07/2023
4.5	Form of PIPE Pre-Funded Warrant		S-1/A	4.7	333-268008	11/09/2023
4.6	Form of PIPE Investor Warrant		S-1/A	4.8	333-268008	11/09/2023
4.7	Form of PIPE Placement Agent Warrant		S-1/A	4.9	333-268008	11/09/2023
4.8	Form of True-Up Pre-Funded Warrant		S-1/A	4.10	333-268008	11/09/2023
4.9	Form of 2022 Note Conversion Pre-Funded Warrant		S-1/A	4.11	333-268008	11/09/2023
4.10	Form of Uplist Conversion Warrant		S-1/A	4.12	333-268008	11/09/2023
4.11	Form of Exchange Investor Warrant		S-1/A	4.13	333-268008	11/09/2023

10.1#	Termination Agreement and Release dated June 25, 2013, between ABS and Terrence W. Norchi	8-K	10.7	333-178883	6/26/2013
10.2#	Executive Employment Agreement dated June 26, 2013 between Arch Therapeutics, Inc. and Terrence W. Norchi	8-K	10.8	333-178883	6/26/2013
10.3#	First Amendment to Executive Employment Agreement, dated March 23, 2014, by and between Arch Therapeutics, Inc. and Terrence W. Norchi Stock	8-K	10.1	000-54986	3/27/2014
10.4#	Executive Employment Agreement dated June 26, 2013 between Arch Therapeutics, Inc. and Alan T. Barber	8-K	10.9	333-178883	6/26/2013
10.5#	Executive Employment Agreement, effective July 8, 2013, by and between Arch Therapeutics, Inc. and William M. Cotter	8-K	10.1	000-54986	7/8/2013
10.6#	First Amendment to Executive Employment Agreement, dated March 23, 2014, by and between Arch Therapeutics, Inc. and William M. Cotter	8-K	10.2	000-54986	3/27/2014
10.7#	Separation Agreement dated June 15, 2015 by and between Arch Therapeutics, Inc. and William M. Cotter	10-Q	10.3	000-54986	8/7/2015
10.8#	Executive Employment Agreement, effective July 7, 2014, by and between Arch Therapeutics, Inc. and Richard E. Davis	8-K	10.1	000-54986	7/7/2014
10.9#	First Amendment to Executive Employment Agreement, dated July 27, 2015, by and between Arch Therapeutics, Inc. and Richard E. Davis	8-K	10.1	000-54986	7/31/2015
10.10#	Consulting Agreement dated October 15, 2015 by and between Arch Therapeutics, Inc. and Dr. Arthur Rosenthal	S-1/A	10.40	333-206873	10/16/2015
10.11#	Arch Therapeutics, Inc. 2013 Stock Incentive Plan	8-K	10.1	333-178883	6/24/2013
10.12#	Form of Stock Option Award Agreement under Arch Therapeutics, Inc. 2013 Stock Incentive Plan	10-Q	10.13	000-54986	8/14/2013

10.13#	Form of Restricted Stock Unit Award Agreement under Arch Therapeutics, Inc. 2013 Stock Incentive Plan	10-Q	10.14	000-54986	8/14/2013
10.14#	Form of Restricted Stock Bonus Award Agreement under Arch Therapeutics, Inc. 2013 Stock Incentive Plan	10-Q	10.15	000-54986	8/14/2013
10.15#	Form of Restricted Stock Award Agreement	8-K	10.2	000-54986	5/6/2016
10.16	Binding Letter of Intent by and between Almah, Inc. and Arch Therapeutics, Inc. dated April 19, 2013	8-K	10.1	333-178883	4/25/2013
10.17	Promissory Note by and between Almah, Inc. and Arch Therapeutics, Inc. dated April 19, 2013	8-K	10.2	333-178883	4/25/2013
10.18	Financing Agreement by and between Almah, Inc. and Coldstream Summit Ltd. Dated April 19, 2013	8-K	10.3	333-178883	4/25/2013
10.19	Form of Securities Purchase Agreement	8-K	10.4	333-178883	4/25/2013
10.20	Form of Warrant	8-K	10.5	333-178883	4/25/2013
10.21	Amended and Restated Exclusive Patent License Agreement dated May 23, 2011 between ABS and the Massachusetts Institute of Technology, as amended by the First Amendment to Amended and Restated Exclusive Patent License Agreement dated May 15, 2012 between ABS and the Massachusetts Institute of Technology, and further amended by the Second Amendment to Amended and Restated Exclusive Patent License Agreement dated February 1, 2013 between ABS and the Massachusetts Institute of Technology, as further amended by the Third Amendment to Amended and Restated Exclusive Patent License Agreement dated April 30, 2013 between ABS and the Massachusetts Institute of Technology, and as further amended by the Letter Agreement dated June 10, 2013 between ABS and the Massachusetts Institute of Technology	8-K	10.6	333-178883	6/26/2013
10.22	Life Sciences Accelerator Funding Agreement dated September 30, 2013 between Arch Therapeutics, Inc. and the Massachusetts Life Sciences Center	8-K	10.1	000-54986	10/4/2013
10.23	Form of Warrant to Purchase Shares of Common Stock dated September 30, 2013 issued by Arch Therapeutics, Inc. to the Massachusetts Life Sciences Center ((included as Exhibit B in Exhibit 10.22)	8-K	10.2	000-54986	10/4/2013
10.24	Form of MLSC Subordination Agreement	8-K	10.1	000-54986	9/9/2013
10.25	Amendment Agreement to Arch Therapeutics, Inc. Accelerator Funding Agreement dated September 28, 2016 by and between Arch Therapeutics, Inc. and Massachusetts Life Sciences Center	8-K	10.1	000-54986	9/29/2016
10.26	Securities Purchase Agreement dated January 30, 2014, by and among Arch Therapeutics, Inc. and the investors listed on the Schedule of Buyers attached thereto	8-K	10.1	000-54986	1/31/2014
10.27	Form of Series A Warrant to Purchase Common Stock	8-K	4.1	000-54986	1/31/2014

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

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

10.68	First Amendment to Employment Agreement, effective August 9, 2021, by and between Arch Therapeutics, Inc. and Dan M. Yrigoyen	8-K	10.2	000-54986	8/11/2021
10.69	Form of Securities Purchase Agreement, dated July 6, 2022, by and among the Company and the signatories thereto	8-K	10.1	000-54986	7/8/2022
10.70	Form of First Notes	8-K	10.2	000-54986	7/8/2022
10.70.1	Form of First Notes Amendment	8-K	10.1	000-54986	02/16/2023
10.70.2	Form of Amendment No. 2 to First Notes, dated March 10, 2023	8-K	10.2	000-54986	03/17/2023
10.70.3	Form of Amendment No. 3 to First Notes, dated March 15, 2023	8-K	10.4	000-54986	03/17/2023
10.70.4	Form of Amendment No. 4 to First Notes, dated April 15, 2023	8-K	10.1	000-54986	04/20/2023
10.70.5	Form of Amendment No. 5 to First Notes	10-Q	10.5	000-54986	05/23/2023
10.70.6	Form of Amendment No. 6 to First Notes, dated June 15, 2023	8-K	10.1	000-54986	06/22/2023
10.70.7	Form of Amendment No. 7 to First Notes, dated July 1, 2023	8-K	10.1	000-54986	07/07/2023
10.70.8	Form of Amendment No. 8 to First Notes	10-Q	10.17	000-54986	08/11/2023
10.70.9	Form of Amendment No. 9 to First Notes, dated July 31, 2023	8-K	10.1	000-54986	08/04/2023
10.70.10	Form of Amendment No. 10 to First Notes, dated August 30, 2023	8-K	10.1	000-54986	09/06/2023
10.70.11	Form of Amendment No. 11 to First Notes, dated September 30, 2023	8-K	10.1	000-54986	10/04/2023
10.70.12	Form of Amendment No. 12 to First Notes	S-1/A	10.37.12	333-268008	11/09/2023
10.71	Form of First Warrant	8-K	10.3	000-54986	7/8/2022
10.72	Form of Registration Rights Agreement, dated July 6, 2022, by and among the Company and the signatories thereto	8-K	10.4	000-54986	7/8/2022
10.73	Form of Security Agreement, dated July 6, 2022, by and among the Company and the signatories thereto	8-K	10.5	000-54986	7/8/2022

10.74	Form of Second Note	8-K	10.2	000-54986	01/20/2023
10.74.1	Form of Second Note Amendment	8-K	10.2	000-54986	02/16/2023
10.74.2	Form of Amendment No. 2 to Second Notes, dated March 10, 2023	8-K	10.3	000-54986	03/17/2023
10.74.3	Form of Amendment No. 3 to Second Notes, dated March 15, 2023	8-K	10.5	000-54986	03/17/2023
10.74.4	Form of Amendment No. 4 to Second Notes, dated April 15, 2023	8-K	10.2	000-54986	04/20/2023
10.74.5	Form of Amendment No. 5 to Second Notes	10-Q	10.6	000-54986	05/23/2023
10.74.6	Form of Amendment No. 6 to Second Notes, dated June 15, 2023	8-K	10.2	000-54986	06/22/2023
10.74.7	Form of Amendment No. 7 to Second Notes, dated July 1, 2023	8-K	10.2	000-54986	07/07/2023
10.74.8	Form of Amendment No. 8 to Second Notes	10-Q	10.18	000-54986	08/11/2023
10.74.9	Form of Amendment No. 9 to Second Notes, dated July 31, 2023	8-K	10.2	000-54986	08/04/2023
10.74.10	Form of Amendment No. 10 to Second Notes, dated August 30, 2023	8-K	10.2	000-54986	09/06/2023
10.74.11	Form of Amendment No. 11 to Second Notes, dated September 30, 2023	8-K	10.2	000-54986	10/04/2023
10.74.12	Form of Amendment No. 12 to Second Notes	S-1/A	10.41.12	333-268008	11/09/2023
10.75	Form of Second Warrant	8-K	10.3	000-54986	01/20/2023
10.76	Form of Amended and Restated Registration Rights Agreement, dated January 18, 2023, by and among the Company and the signatories thereto	8-K	10.4	000-54986	01/20/2023
10.76.1	Form of Amendment No. 1 to the A&R Registration Rights Agreement	8-K	10.3	000-54986	04/20/2023
10.77	Form of Amendment No. 1 to Securities Purchase Agreement, dated January 18, 2023, by and among the Company and the signatories thereto	8-K	10.1	000-54986	01/20/2023
10.78	Form of Amendment No. 2 to Securities Purchase Agreement, dated May 15, 2023, by and among the Company and the signatories thereto	10-Q	10.1	000-54986	05/23/2023

10.79	Form of Exchange Agreement, dated March 10, 2023	8-K	10.1	000-54986	03/17/2023
10.80	Form of Third Note	10-Q	10.2	000-54986	05/23/2023
10.80.1	Form of Amendment No. 1 to Third Notes, dated June 15, 2023	8-K	10.3	000-54986	06/22/2023
10.80.2	Form of Amendment No. 2 to Third Notes, dated July 1, 2023	8-K	10.3	000-54986	07/07/2023
10.80.3	Form of Amendment No. 3 to Third Notes	10-Q	10.19	000-54986	08/11/2023
10.80.4	Form of Amendment No. 4 to Third Notes, dated July 31, 2023	8-K	10.3	000-54986	08/04/2023
10.80.5	Form of Amendment No. 5 to Third Notes, dated August 30, 2023	8-K	10.3	000-54986	09/06/2023
10.80.6	Form of Amendment No. 6 to Third Notes, dated September 30, 2023	8-K	10.3	000-54986	10/04/2023
10.80.7	Form of Amendment No. 7 to Third Notes	S-1/A	10.47.7	333-268008	11/09/2023
10.81	Form of Third Warrant	10-Q	10.3	000-54986	05/23/2023
10.82	Form of Second A&R Registration Rights Agreement	10-Q	10.4	000-54986	05/23/2023
10.82.1	Form of Amendment No. 1 to Second A&R Registration Rights Agreement	8-K	10.4	000-54986	09/06/2023
10.82.2	Form of Amendment No. 2 to Second A&R Registration Rights Agreement	S-1/A	10.49.2	333-268008	11/09/2023
10.83	Arch Therapeutics, Inc. Amended and Restated 2023 Omnibus Equity Incentive Plan	8-K	10.1	000-54986	08/23/2023
10.84	Form of Omnibus Amendment to Notes and Warrants	10-Q	10.20	000-54986	08/11/2023
10.85	Form of Securities Purchase Agreement, dated July 7, 2023, by and among the Company and the signatories thereto	10-Q	10.24	000-54986	08/11/2023
10.85.1	Form of Amendment No. 1 to Securities Purchase Agreement	8-K	10.5	000-54986	09/06/2023
10.85.2	Form of Amendment No. 2 to Securities Purchase Agreement	S-1/A	10.52.2	333-268008	11/09/2023
10.86	Form of Registration Rights Agreement, dated July 7, 2023, by and among the Company and the signatories thereto	10-Q	10.25	000-54986	08/11/2023

10.86.1	Form of Amendment No. 1 to Registration Rights Agreement		S-1/A	10.53.1	333-268008	11/09/2023
10.86.2	Form of Amendment No. 2 to Registration Rights Agreement		S-1/A	10.53.2	333-268008	11/09/2023
10.87	Form of PIPE Securities Purchase Agreement		S-1/A	10.54	333-268008	11/09/2023
10.88	Form of PIPE Registration Rights Agreement		S-1/A	10.55	333-268008	11/09/2023
10.89	PIPE Placement Agency Agreement		S-1/A	10.56	333-268008	11/09/2023
10.90	Form of Bridge Lock-Up Agreement		S-1/A	10.57	333-268008	11/09/2023
10.91	Form of Amendment No. 13 to the First Notes, dated November 21, 2023		8-K	10.1	000-54986	11/22/2023
10.92	Form of Amendment No. 13 to the Second Notes, dated November 21, 2023		8-K	10.2	000-54986	11/22/2023
10.93	Form of Amendment No. 8 to the Third Notes, dated November 21, 2023		8-K	10.3	000-54986	11/22/2023
10.94	Form of Amendment No. 3 to Second A&R Registration Rights Agreement		8-K	10.4	000-54986	11/22/2023
10.95	Form of Amendment No. 3 to the Bridge Registration Rights Agreement		8-K	10.5	000-54986	11/22/2023
10.96	Form of Amendment No. 14 to the First Notes, dated January 5, 2024		8-K	10.1	000-54986	01/11/2024
10.97	Form of Amendment No. 14 to the Second Notes, dated January 5, 2024		8-K	10.2	000-54986	01/11/2024
10.98	Form of Amendment No. 9 to the Third Notes, dated January 5, 2024		8-K	10.3	000-54986	01/11/2024
21.1	List of Subsidiaries		8-K	21.1	333-178883	6/26/2013
24.1	Power of Attorney (included on the signature page hereto)	X				
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities and Exchange Act of 1934	X				
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities and Exchange Act of 1934	X				

32.1	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	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: February 14, 2024

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.

SIGNATURE	TITLE	DATE
/s/ Terrence W. Norchi, MD Terrence W. Norchi, MD	President, Chief Executive Officer and Director (*Principal Executive Officer*)	February 14, 2024
/s/ Michael S. Abrams Michael S. Abrams	Chief Financial Officer (Principal *Financial and Accounting Officer*)	February 14, 2024
/s/ Punit Dhillon Punit Dhillon	Director	February 14, 2024
/s/ Laurence Hicks Laurence Hicks	Director	February 14, 2024
/s/ Guy Fish Guy Fish	Director	February 14, 2024

ARCH THERAPEUTICS, INC. AND SUBSIDIARY

CONSOLIDATED FINANCIAL STATEMENTS

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

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

Going Concern

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

Basis for Opinion

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

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

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

Critical Audit Matter

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

Convertible note transactions

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

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

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

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

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

/s/Weinberg & Company, P.A.
Los Angeles, California
February 14, 2024

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

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

Basis for Opinion

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

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

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

/s/ Baker Tilly US, LLP

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

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

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

	September 30, 2023	September 30, 2022
ASSETS		
Current assets:		
Cash	$ 222,720	$ 746,940
Inventory	1,364,504	1,414,848
Prepaid expenses and other current assets	362,866	436,407
Total current assets	1,950,090	2,598,195
Long-term assets:		
Property and equipment, net	4,599	2,044
Other assets	3,500	3,500
Total long-term assets	8,099	5,544
Total assets	$ 1,958,189	$ 2,603,739
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 2,304,207	$ 1,328,000
Accrued expenses and other liabilities	467,496	318,505
Insurance premium financing	243,285	247,933
Convertible notes payable, senior secured, current portion, net of discount	3,519,103	—
Convertible notes payable, unsecured, current portion, net of discount	1,658,702	—
Convertible notes payable, Series 2, unsecured, current portion	450,000	550,000
Accrued interest, current portion	823,128	127,781
Derivative liability, current portion	—	748,275
Total current liabilities	9,465,921	3,320,494
Long-term liabilities:		
Convertible notes payable, senior secured, net of discount	—	1,662,492
Convertible notes payable, unsecured, long-term	—	699,781
Convertible notes payable, Series 2, unsecured, long-term	—	450,000
Accrued interest, long-term	—	204,575
Derivative liability, long-term	—	459,200
Total long-term liabilities	—	3,476,048
Total liabilities	9,465,921	6,796,542
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized, none issued and outstanding as of September 30, 2023 and 2022	—	—
Common stock, $0.001 par value, 350,000,000 and 4,000,000 shares authorized as of September 30, 2023 and 2022, 4,689,446 and 1,252,734 shares issued and outstanding as of September 30, 2023 and 2022	4,689	1,252
Additional paid-in capital	54,543,188	50,878,718
Accumulated deficit	(62,055,609)	(55,072,773)
Total stockholders' deficit	(7,507,732)	(4,192,803)
Total liabilities and stockholders' deficit	$ 1,958,189	$ 2,603,739

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

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

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

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

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

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

Fiscal Year Ended September 30, 2022	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
Balance at September 30, 2021	—	$ —	1,186,901	$ 1,186	$ 48,770,059	$ (49,796,919)	$ (1,025,674)
Net loss	—	—	—	—	—	(5,275,854)	(5,275,854)
Issuance of common stock and warrants, net of financing costs	—	—	63,833	64	1,609,077	—	1,609,141
Vesting of restricted stock issued	—	—	2,000	2	(2)	—	—
Stock-based compensation expense	—	—	—	—	499,584	—	499,584
Balance at September 30, 2022	—	$ —	1,252,734	$ 1,252	$ 50,878,718	$ (55,072,773)	$ (4,192,803)

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

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

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

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

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

1. DESCRIPTION OF BUSINESS

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

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

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

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

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

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

Going Concern

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

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

Basis of Presentation

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

On January 6, 2023, the directors of the Company authorized a reverse share split of the issued and outstanding Common Shares in a ratio of 1:200, effective January 17, 2023 (the "Reverse Share Split"). All information included in these consolidated financial statements has been adjusted, on a restrospective basis, to reflect the Reverse Share Split, unless otherwise stated. All outstanding securities entitling their holders to purchase shares of Common Stock or acquire shares of Common Stock, including stock options, restricted stock units, and warrants, were adjusted as a result of the Reverse Stock Split, as required by the terms of those securities.

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

Use of Estimates

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

Revenue recognition

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

The Company's source of revenue is product sales. Contracts with customers contain a single performance obligation and the Company recognizes revenue upon shipment from the Company's third-party warehouse which is when control of the product is transferred to the customers. In circumstances where the transaction price is not able to be determined at the time of shipment, the Company does not recognize revenue or any receivable amount until such time that the final transaction price is established and shipped to customer.

Cost of Revenues

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

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. The Company had no cash equivalents as of September 30, 2023 and 2022.

Inventories

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

Concentration of Credit Risk

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

Property and Equipment

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

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment when circumstances indicate the carrying value of an asset may not be recoverable in accordance with FASB ASC Topic 360, *Property, Plant and Equipment*. For assets that are to be held and used, impairment is recognized when the estimated undiscounted cash flows associated with the asset or group of assets is less than their carrying value. If impairment exists, an adjustment is made to write the asset down to its fair value, and a loss is recorded as the difference between the carrying value and fair value. Fair values are determined based on quoted market values, discounted cash flows or internal and external appraisals, as applicable. For the years ended September 30, 2023 and 2022 there has not been any impairment of long-lived assets.

Leases

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

The Company leases its office facility on a month to month basis with a monthly lease of approximately $3,500. The terms of the lease provide break options allowing both landlord and tenant to terminate on provision of not less than one month's prior written notice.

Derivative Liabilities

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

Complex Financial Instruments

The Company does not use derivative instruments to hedge exposures to cash flow, market, or foreign currency risks. The Company evaluates its financial instruments, including warrants, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. The Company values its derivatives using the Black-Scholes option-pricing model or other acceptable valuation models, including Monte-Carlo simulations. Derivative instruments are valued at inception, upon events such as an exercise of the underlying financial instrument, and at subsequent reporting periods. The classification of derivative instruments, including whether such instruments should be recorded as liabilities, is re-assessed at the end of each reporting period. The Company reviews the terms of debt instruments, equity instruments, and other financing arrangements to determine whether there are embedded derivative features, including embedded conversion options that are required to be bifurcated and accounted for separately as a derivative financial instrument. Additionally, in connection with the issuance of financing instruments, the Company may issue freestanding options and warrants, including options or warrants to non-employees in exchange for consulting or other services performed.

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

Income Taxes

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

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

Research and Development

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

Stock-Based Compensation

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

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

Loss per Common Share

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

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

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

Fair Value Measurements

The Company measures both financial and nonfinancial assets and liabilities in accordance with FASB ASC Topic 820, *Fair Value Measurements and Disclosures*, including those that are recognized or disclosed in the consolidated financial statements at fair value on a recurring basis. The standard created a fair value hierarchy which prioritizes the inputs to valuation techniques used to measure fair value into three broad levels as follows:

Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities;

Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and

Level 3 inputs are unobservable inputs that reflect the Company's own views about the assumptions market participants would use in pricing the asset or liability.

At September 30, 2023 and 2022, the carrying amounts of cash, accounts payables and accrued expense and other liabilities approximate fair value because of their short-term nature. The carrying amounts for the Company's convertible notes (see Notes 6,7, and 8) approximate fair value because borrowing rates and terms are similar to comparable market participants.

Financial Statement Reclassification

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

Recent Accounting Pronouncements

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt — Modifications and Extinguishments (Subtopic 470-50), Compensation — Stock Compensation (Topic 718), and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options ("ASU 2021-04"). ASU 2021-04 provides guidance as to how an issuer should account for a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option (i.e., a warrant) that remains classified after modification or exchange as an exchange of the original instrument for a new instrument. An issuer should measure the effect of a modification or exchange as the difference between the fair value of the modified or exchanged warrant and the fair value of that warrant immediately before modification or exchange and then apply a recognition model that comprises four categories of transactions and the corresponding accounting treatment for each category (equity issuance, debt origination, debt modification, and modifications unrelated to equity issuance and debt origination or modification). ASU 2021-04 is effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply the guidance provided in ASU 2021-04 prospectively to modifications or exchanges occurring on or after the effective date. The Company adopted ASU 2021-04 effective October 1, 2022. The adoption of ASU 2021-04 did not have any impact on the Company's consolidated financial statement presentation or disclosures.

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

3. INVENTORIES

Inventories consist of the following:

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

4. INSURANCE PREMIUM FINANCING

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

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

5. DERIVATIVE LIABILITIES

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

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

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

Fair Value Measurements Using Significant Unobservable Inputs - Year Ended September 30, 2023
(Level 3)

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

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

	Series F	Series G	Series H
Beginning balance at September 30, 2021	$ 1,000,000	$ 748,275	$ 459,200
Expiration of derivative liability	(1,000,000)	—	—
Ending balance at September 30, 2022	$ —	$ 748,275	$ 459,200

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

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

6. CONVERTIBLE NOTES PAYABLE, SENIOR SECURED

	September 30, 2023	September 30, 2022
Senior Secured Convertible Promissory Notes (the "2022 Notes", includes $96,000 of related party notes)	$ 4,230,000	$ 4,230,000
Unamortized debt discount	(710,897)	(2,567,508)
Net Balance	3,519,103	1,662,492
Current Balance	(3,519,103)	-
Non-Current Balance	-	1,662,492

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

The 2022 Notes are secured by tangible and intangible assets of the Company, bears interest at a rate of 10% per annum payable at maturity or upon conversion, originally matured January 6, 2024 (which was subsequently extended to March 15, 2024), and are convertible into shares of the Company's common stock at a conversion price of $9.14 per share. The 2022 Notes contain customary events of default. Further, events of default under the 2022 Notes also include (i) the unavailability of Rule 144 on or after January 6, 2023; (ii) our failure to deliver the shares of common stock to the 2022 Note holder upon exercise by such holder of its conversion rights under the 2022 Note; (iii) our loss of the "bid" price for its common stock and/or a market and such loss is not cured during the specified cure periods; and (iv) our failure to complete an uplisting of our Common Stock to any of the Nasdaq Global Market, Nasdaq Capital Market, New York Stock Exchange or NYSE American by March 15, 2024 (the "Uplist Transaction"). During the year ended September 2023, for no additional consideration, the 2022 Notes were amended several times in order to allow the Company to issue additional notes payable, extend the completion date for the Uplist Transaction, and amend certain provisions with regards to mandatory conversion of the notes upon the Uplist Transaction.

In connection with the issuance of the 2022 Notes, the Company granted the 2022 Notes noteholders 425,562 warrants to purchase shares of common stock. The warrants are fully vested, exercisable at $9.94 per share and expire in 5 years. The Company estimated the relative fair value of the warrants to be $1,470,000 using the Black Scholes option pricing model. The Company also issued note holders 63,842 shares of the Company's common stock with a relative fair value of $315,000. The Company also issued 31,510 warrants to purchase shares of common stock to the placement agent that assisted in the 2022 Notes offering. The placement agent warrants are fully vested, exercisable at $10.06 per share and will expire in 5 years. The Company estimated the relative fair value of the placement agent warrants to be $219,894 using the Black Scholes option pricing model. The Company incurred direct legal and professional fees of $555,414 as part of this offering.

The Company recorded 2022 Notes with total principal of $4,230,000. In addition, total debt discount of $2,870,000 was recorded to account for the 2022 Notes OID of $705,000, the relative fair value of the warrants of $1,470,000, the relative fair value of common stock issued of $315,000, and direct legal and professional fees incurred in the 2022 Notes offering of $555,414. The debt discount is being amortized over the term of the notes using the effective interest rate method. During the year ended September 30, 2022, the Company amortized debt discount of $302,000.

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

7. CONVERTIBLE NOTES PAYABLE, UNSECURED

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

Exchanged Notes (July 2022)

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

Second Closing Notes (January 2023)

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

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

Third Closing Notes (March, April and May 2023)

In March, April and May 2023, pursuant to the SPA, as amended, investors agreed to purchase Unsecured Convertible Promissory Notes (the "Third Closing Notes") in the aggregate of $703,000 in exchange for cash proceeds of $488,000, net of original issue discount (OID) of $215,000. The notes are unsecured, bear interest at a rate of 10% per annum, originally matured January 6, 2024 (which was subsequently extended to March 15, 2024), and are convertible into shares of the Company's common stock with a conversion price of $9.14 per share.

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

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

Debt discount on unsecured convertible promissory notes

As a result of the issuance of the Second Closing and the Third Closing Notes, the Company recorded debt discount in the aggregate of $834,000 to account for the Second Closing and the Third Closing Notes OID of $321,000, the relative fair value of the warrants issued of $433,000, the relative fair value of common stock issued of $44,000, and direct legal and professional fees incurred of $36,000. The debt discount is being amortized over the term of the notes using the effective interest rate method.

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

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

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

8. CONVERTIBLE NOTES PAYABLE, SERIES 1 AND 2

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

Series 1 Convertible Notes

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

The Series 1 Convertible Notes provide, among other things:

(i) interest at a rate of 10% per annum;
(ii) term of approximately three years;
(iii) allow for the Company's ability to prepay the Series Convertible Notes, in whole or in part, at any time;
(iv) allow the automatic conversion of the Series 1 Convertible Notes upon a change of control into shares of the Company's common stock, at a conversion price of $54.00 per share;
(v) allow the holders to convert the principal of the Series 1 Convertible Notes, along with accrued interest, in whole or in part, into shares of common stock at the conversion price of $54.00 per share;
(vi) allow for the Company's ability to convert all note obligations outstanding upon a qualified equity financing into shares of common stock at the corresponding price per share of the qualified equity financing;
(vii) the Company's ability to convert the principal of the Series 1 Convertible Notes, along with accrued interest, in whole or in part, into shares of Common Stock at the respective Conversion Price in the event the volume weighted average price ("VWAP") of the Common Stock equals or exceeds $64.00 per share for at least fifteen consecutive Trading Days;
(viii) the Company's ability to convert all outstanding Note Obligations into shares of Common Stock at the respective Conversion Price (an "In Kind Note Repayment") in lieu of repaying the Note Obligations outstanding on the Maturity Date, subject to a conversion multiplier of 4.5, as amended.

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

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

Series 2 Convertible Notes

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

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

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

9. INCOME TAXES

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

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

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

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

As of September 30, 2023 and 2022, the Company had federal net operating loss carryforwards totaling approximately $48,200,000 and $42,700,000, respectively, which may be available to offset future taxable income. The pre-2018 federal net operating loss carryforwards total approximately $21,750,000, and begin to expire in 2026. Due to the CARES Act, federal net operating losses generated in tax years beginning after December 31, 2017 can be carried forward indefinitely. As of September 30, 2023 and 2022, the Company has federal net operating loss carryforwards with an indefinite life of $26,444,000 and $20,945,000. As of September 30, 2023 and 2022, the Company had federal research and experimentation credit carryforwards of $679,000 and $626,000, respectively, which may be available to offset future income tax liabilities and which would begin to expire in 2028.

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

As the Company has not yet achieved profitable operations, management believes the tax benefits as of September 30, 2023 and 2022 did not satisfy the realization criteria set forth in FASB ASC Topic 740, *Income Taxes*, and therefore has recorded a valuation allowance for the entire deferred tax asset. The valuation allowance increased in 2023 by approximately $1,976,000 and increased in 2022 by approximately $483,000. The Company's effective income tax rate differed from the federal statutory rate due to state taxes and the Company's full valuation allowance, the latter of which reduced the Company's effective federal income tax rate to zero.

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

As of September 30, 2023, the Company is open to examination in the U.S. federal and certain state jurisdictions for tax years ended September 30, 2023, 2022, 2021 and 2020. In addition, any loss years remain open to the extent that losses are available for carryover to future years. Therefore, the tax years ended 2010 through 2021 remain open for examination by the IRS.

The Coronavirus Aid, Relief and Economic Security (CARES) Act was enacted on March 27, 2020. The CARES Act affected items such as carryback periods for net operating losses, modifications to the net interest deduction limitations and changes to tax depreciation methods. The company has taken the CARES Act into consideration for the tax year ended September 30, 2023 and continues to evaluate the impact of the CARES act on the business.

10. STOCKHOLDERS DEFICIT

Common Stock

During the year ended September 30, 2023, the Company issued 3,436,712 shares of Common Stock, par value $0.001, as follows: (i) 250 shares issued in connection with the vesting of a restricted stock grant; (ii) 3,344,321 shares issued in connection with certain financing activities involving the sale of Common Stock and warrants to certain accredited investors in exchange for the net cash proceeds of $2,209,839 (the "Bridge Offering"); (iii) 20,210 inducement shares issued in connection with the closing of the Second Notes and Third Notes; (iv) 12,019 shares issued in connection with the exchange of Series G and Series H warrants for Common Stock; and (v) 59,912 shares issued in connection with the conversion of the Company's outstanding Series 1 Notes into Common stock.

Common Stock Options

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

	Option Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at September 30, 2021	124,495	$ 58.00	1.86	$ 140,151
Awarded	6,625	$ 6.00		
Forfeited/Cancelled	(32,494)	$ 70.00		
Outstanding at September 30, 2022	98,626	$ 52.00	1.46	$ 16,900
Awarded	24,500	$ 8.00		-
Forfeited/Cancelled	(21,001)	$ 68.00	-	-
Outstanding at September 30, 2023	102,125	$ 38.00	3.9	$ —
Vested at September 30, 2023	82,940	$ 44.00	4.89	$ —
Vested and expected to vest at September 30, 2023	102,125	$ 38.00	3.9	$ —

During the year ended September 30, 2022, the Company granted 2,375 options to employees and directors and 4,250 options to consultants to purchase shares of common stock under the 2013 Plan. The stock options issued to employees and directors vest over a period of 36 months, and options issued to consultants vest over a period of 12 months. The weighted average exercise price for all options was $10.02. Options issued to employees and consultants expire in 5 years. Options issued to management and directors expire after 10 years. Total fair value of the stock options issued was $47,609 using the Black-Scholes Option Pricing Model. The following assumptions were used to calculate the fair value - expected volatility, 86.8% - 98.5%, risk-free interest rate, 1.5% - 3.5%, expected dividend yield, 0%, expected term, 3.6 - 5.8 years.

During the year ended September 30, 2023, the Company granted 20,875 options to employees and directors and 3,625 options to consultants to purchase shares of common stock under the 2013 Plan. The stock options issued to employees vest over a period 36 months, and options issued to consultants and directors vest over a period of 12 months. The exercise price for all options granted was $8.02. Options issued to employees and consultants expire in 5 years. Options issued to management and directors expire after 10 years. Total fair value of the stock options issued $156,275 using the Black-Scholes Option Pricing Model. The following assumptions were used to calculate the fair value - expected volatility, 102.8% - 103. 4 %, risk-free interest rate, 3.8% - 4.0%, expected dividend yield, 0%, expected term, 4.1 – 5.8 years.

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

As of September 30, 2023, there is approximately $162,000 of unrecognized compensation expense related to unvested stock-based compensation arrangements granted under the 2013 Plan. That cost is expected to be recognized over a weighted average period of 1.80 years. As of September 30, 2023, 0 shares are available for future grants under the 2013 Plan as the plan is now expired.

Common Stock Warrants

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

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

Restricted Stock

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

On September 27, 2021, the Company awarded 1,500 shares of Restricted Stock to a consultant. The shares subject to this grant were awarded under the 2013 Plan and vested in three separate tranches on January 12, 2022, July 12, 2022 and January 12, 2023.

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

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

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

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

For the years ended September 30, 2023 and 2022 compensation expense recorded for the restricted stock awards was approximately $3,000 and $40,000, respectively. As of September 30, 2023, there is no unrecognized compensation expense related to unvested stock-based compensation arrangements granted under the 2013 Plan.

11. COMMITMENTS AND CONTINGENCIES

In the ordinary course of business, the Company enters into various agreements containing standard indemnification provisions. The Company's indemnification obligations under such provisions are typically in effect from the date of execution of the applicable agreement through the end of the applicable statute of limitations. The aggregate maximum potential future liability of the Company under such indemnification provisions is uncertain. As of September 30, 2023 and 2022, no amounts have been accrued related to such indemnification provisions.

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

MIT Licensing Agreement

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

In exchange for the licenses granted in the agreement, the Company has paid MIT license maintenance fees and patent prosecution costs. The Company paid license maintenance fees of $50,000 to MIT in the fiscal years ended September 30, 2023 and 2022. For the years ended September 30, 2023 and 2022, the annual MIT license maintenance fees of $50,000 are included in accrued expenses and other liabilities on the Consolidated Balance Sheets. The license maintenance fees and patent prosecution costs cover the contract year beginning January 1 through December 31. Annual license maintenance obligations extend through the life of the patents. In addition, MIT is entitled to royalties on applicable future product sales, if any. The annual payments may be applied towards royalties payable to MIT for that year for product sales.

The Company is obligated to indemnify MIT and related parties from losses arising from claims relating to the exercise of any rights granted to the Company under the license, with certain exceptions. The maximum potential amount of future payments the Company could be required to make under this provision is unlimited. The Company considers there to be a low performance risk as of September 30, 2023.

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

12. SUBSEQUENT EVENTS

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

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

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

In November 2023, the Company amended the Second A&R Registration Rights Agreement to that certain Second Amended and Restated Registration Rights Agreement, dated as of May 15, 2023 to (I) extend the filing deadline by which the Company is obligated to file with the SEC a registration statement under the Securities Act of 1933, as amended, registering certain securities issued in the 2022 Convertible Note Offering to the earlier of (i) the date that is 30 days following the Uplist Transaction and (ii) January 31, 2024 (such date was subsequently extended to March 15, 2024), and (II) to provide for the inclusion of the Registerable Securities (as defined therein) in the Uplist S-1 (as defined therein).

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

Exhibit 31.1

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.

February 14, 2024

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

Exhibit 31.2

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.

February 14, 2024

/s/ Michael S. Abrams
Michael S. Abrams
Chief Financial Officer and Treasurer (Principal Financial Officer)

Exhibit 32.1

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.

February 14, 2024

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.