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, 2020
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 ☐
Non-accelerated filer ☒
Accelerated filer ☐
Smaller reporting company ☒
Emerging growth company ☐

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

EXPLANATORY NOTE

The registrant met the "smaller reporting company", and non-accelerated filer requirements as of the end of its 2020 fiscal year pursuant to Rule 12b-2 of the Securities Exchange Act of 1934, as amended, based upon the aggregate worldwide market value of the voting and non-voting common equity held by the registrant's non-affiliates as of March 31, 2020.

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 $37,000,000. For purposes of this calculation, it has been assumed that shares of common stock held by each director, each officer and each person who owns 10% or more of the registrant's outstanding common stock are held by affiliates.

As of December 10, 2020, 193,044,766 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

TABLE OF CONTENTS

This Annual Report on Form 10-K 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 commercialize and generate revenues or profits from our anticipated products; Arch's ability to achieve the desired 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 on Form 10-K unless otherwise indicated, the "Company", "we", "us", "our", and "Arch" refer to Arch Therapeutics, Inc. and its consolidated subsidiary, Arch Biosurgery, Inc.

AC5, AC5-G, AC5-V, AC5-P, Crystal Clear Surgery, NanoDrape and NanoBioBarrier and associated logos are trademarks and/or registered trademarks of Arch Therapeutics, Inc. and subsidiary. All other trademarks, trade names and service marks included in this Annual Report on Form 10-K are the property of their respective owners.

PART I

ITEM 1. BUSINESS

The following discussion should be read in conjunction with our consolidated financial statements and the related notes and other financial information included in this Annual Report on Form 10-K.

Corporate Overview

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

For financial reporting purposes, the Merger represented a "reverse merger." ABS was deemed to be the accounting acquirer in the transaction and the predecessor of Arch. Consequently, the accumulated deficit and the historical operations that are reflected in the Company's consolidated financial statements prior to the Merger are those of ABS. All share information has been restated to reflect the effects of the Merger. The Company's financial information has been consolidated with that of ABS after consummation of the Merger on June 26, 2013, and the historical financial statements of the Company before the Merger have been replaced with the historical financial statements of ABS before the Merger in this report.

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

As of September 30, 2020, the Company has generated no operating revenues and has devoted substantially all of its efforts toward product research and development and

conducting the clinical and regulatory programs required to commercialize its products. To date, the Company has principally raised capital through debt borrowings, the issuance of convertible debt, and the issuance of units consisting of common stock and warrants.

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

Current Business

We are a biotechnology company marketing or developing a number of products based on our innovative AC5® self-assembling technology platform. We believe these products can be important advances in the field of stasis and barrier applications, which includes stopping bleeding ("hemostasis"), controlling leaking ("sealant") and managing wounds created during surgery, trauma or interventional care or from disease. We have generated no revenues to date and have devoted substantially all of our operational effort to the research, development and regulatory programs necessary to turn our core technology into commercial products. Our goal is to make care faster and safer for patients with products for use in external wounds, which we refer to as Dermal Sciences applications, and products for use inside the body, which we refer to as Biosurgery applications.

To date, the Company has principally raised capital through debt borrowings, the issuance of convertible debt and the issuance of units consisting of its common stock, par value $0.001 per share ("Common Stock"), and warrants. The Company expects to incur substantial expenses for the foreseeable future relating to the research, development, clinical trials, and commercialization of its current and potential products. As of December 10, 2020, we believe that our current cash on hand will meet our anticipated cash requirements into the second quarter of fiscal 2021. The Company will be required to raise additional capital, obtain alternative means of financial support, or both, in order to continue to fund operations. There can be no assurance that the Company will be successful in securing additional resources when needed on terms acceptable to the Company, if at all. Therefore, there exists substantial doubt about the Company's ability to continue as a going concern.

Core Technology

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

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

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

Based on the intended application, we believe that the underlying AC5 SAP technology can impart important features and benefits to our products that may include, for instance, stopping bleeding (hemostasis), mitigating contamination, modulating inflammation, donating moisture, and enabling an appropriate wound microenvironment conducive to healing. 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, and does not possess sticky or glue-like handling characteristics. We believe these properties enhance its utility in several settings and contribute to its user-friendly profile.

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

Operations

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

Our present operating model relies on our small core team of key personnel, including employees, consultants, and advisors, who collaborate with third party service providers and facilities to conduct scale research, development, clinical, regulatory, manufacturing, commercialization legal, and other activities. Our internal team collectively has a broad range of expertise and experience working with and managing third party vendors. This general approach enables us to use the services of third party entities, which are expert in various aspects of our operations, while preserving capital and efficiencies by avoiding certain internal scale-up costs and resource duplication.

Our long-term business plan includes the following goals:

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

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

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

In addition to capital required for operating expenses, depending upon additional input from EU and US regulatory authorities, as well as the potential for additional regulatory filings and approvals during the next 2 years, additional capital may be required. 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 filing. We anticipate that our operating and other expenses will continue to increase as we continue to implement our business plan and pursue and achieve these goals. After giving effect to the funds received in past equity and debt financings and assuming our use of that funding at the rate we presently anticipate, as of December 10, 2020 we believe that our current cash on hand will meet our anticipated cash requirements into the second quarter of fiscal 2021. 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.

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, revenue to fund our business from operations, and we will need to obtain 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 would be available when needed on acceptable terms, 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.

Research and Development

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

Preclinical Testing

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

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

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

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

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

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

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

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

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

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

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

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

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

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/or other collaborators.

In order to complete a clinical trial, we are required to enroll a sufficient number of patients to conduct the trial after obtaining each patient's informed consent in a form and substance that complies with FDA and/or other regulatory authority requirements as well as state and federal privacy and human subject protection regulations. Many factors could lead to delays or inefficiencies in conducting clinical trials, some of which are discussed under the heading "RISK FACTORS" in this Annual Report on Form 10-K. Further, we, the FDA or an institutional review board ("IRB") could suspend a clinical trial at any time for various reasons, including a belief that the risks to the subjects of the trial outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA clearance or approval to market the product in the U.S.

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

On December 16, 2015, we announced that we had received clearance from a regulatory authority in Western Europe to initiate our first human study to assess the safety and performance in humans of our then product candidate that is presently known as AC5 Advanced Wound System in the United States and AC5 Topical Hemostat in Europe. The single-center, randomized, single-blind prospective clinical study (NCT 02704104) was conducted in Galway, Ireland. The description below will refer to the product by its European name, AC5 Topical Hemostat.

On August 15, 2016, we announced that AC5 Topical Hemostat met its primary and secondary endpoints, and on October 31, 2016, we further announced that additional analysis indicated that it demonstrated similar effects in a subgroup of patients who were taking a prescribed antiplatelet medication, commonly known as a blood thinner, such as aspirin.

The clinical study enrolled 46 patients, including 10 who were taking antiplatelet therapy. Each patient had bleeding wounds created as a result of the excision of at least two skin lesions under local anesthetic in the same setting. On a randomized basis, one lesion received AC5 Topical Hemostat and the other(s) received a control treatment consisting of standard therapy (saline). Each subject was followed-up for safety assessment both on Day 7 and again on Day 30, which marked the end of the subject's participation in the clinical study.

The objectives of the study were to evaluate the safety and performance of AC5 Topical Hemostat in patients scheduled to undergo excision of skin lesions on their trunk or upper limbs. The primary endpoint was safety throughout the surgical procedure and until the end of a 30-day follow-up period post procedure. Safety of the clinical investigation device was determined by monitoring for treatment related adverse events. The primary objective was met, as the safety outcomes of both the AC5 Topical Hemostat treatment group and the control group were similar. No serious adverse events were reported.

A secondary endpoint was performance as assessed by TTH. The median TTH of wounds in the AC5 treatment group was 41% faster than for those in the control group. This result was statistically significant ($p< 0.001$, Wilcoxon signed rank test). An additional secondary endpoint of healing of treated wounds was assessed as measured by the ASEPSIS wound score at Days 7 and 30. There was no evidence, at either follow-up day, of an adverse effect of AC5 Topical Hemostat treatment on the wound ASEPSIS score. The ASEPSIS score did not appear to be compromised, as the majority of patients had an ASEPSIS score of 0 in both wounds at Days 7 and 30. All AC5-treated wounds healed satisfactorily as per wound healing scoring criteria.

The clinical study indicated that AC5 Topical Hemostat shortened TTH versus a control whether or not patients were taking antiplatelet therapy, suggesting that AC5 Topical Hemostat performance is not affected by antiplatelet therapy. The reduced median TTH of the AC5 Topical Hemostat treated wounds versus the control wounds was statistically significant for both the overall group of 46 patients ($p<0.001$) and for the subgroup of 10 patients on antiplatelet therapy ($p=0.005$). Further, the median TTH for wounds treated with AC5 Topical Hemostat was less than 30 seconds for both the overall study group and for the subset of patients taking antiplatelet therapy.

Separately, on September 5, 2018 we announced topline data for a human irritation/sensitization patch test study that we conducted to address a request by the Food and Drug Administration ("FDA" or "the Agency") for a product that eventually received marketing authorization and is known as AC5 Advanced Wound System. The study, designed as a single-center, prospective, clinical investigation in approximately 50 healthy subjects, comprised an induction phase separated from a challenge phase by a rest period.

During the induction phase, a patch containing our product was applied to each subject's back three times weekly over 21 days for a total of 9 applications. With each re-application, the skin beneath the patch was evaluated, and any findings were scored per protocol. After a 14-day rest period, subjects entered the challenge phase, received one additional application, and after a two-day rest period, were evaluated over 48 hours.

The results indicated that AC5 Advanced Wound System is neither an irritant nor a sensitizer. Additionally, no immunogenic response and no serious or other adverse events attributable to the device were reported in any of the enrolled subjects.

At the 2020 Symposium on Advanced Wound Care (SAWC) Fall, which took place from November 4-6, 2020 and was hosted online due to the Covid-19 pandemic, several observational clinical case reports were presented. In a patient's 10-year-old pressure ulcer, also known as a decubitus ulcer, concomitant use of debridement (surgical excision of dead, contaminated, or damaged tissue) and AC5 Advanced Wound System every other week over a six week period allowed for a more aggressive procedure with bleeding control in a low acuity clinic setting and without the need for thrombin or sutures. The nanofiber network formed by AC5 Advanced Wound System appeared to cohesively seal the wound bed surface after debridement removed biofilm and senescent host cells. The resulting scaffold allowed for the adhesion, migration, and proliferation of healthy host cells and favorable wound healing outcomes. The patient's wound approached 50% reduction in volume, despite having previously been refractory and stalled over the course of a decade. The patient reported that a significant reduction in drainage and bleeding resulted in easier at-home wound care with fewer in-between clinic visits.

In a patient's 25-year-old chronic refractory burn wound, AC5 Advanced Wound System was applied weekly for four weeks with concomitant debridement. AC5 Advanced Wound System enabled aggressive debridement, facilitated removal of infected granulation tissue, formed a clear conforming seal on the wound and remained affixed to the surface of the irregular wound bed in the presence of copious bleeding. On a second debridement performed a week later, the wound bed surface was much less friable and produced less bleeding. After two interventions, the wound bed quality improved and exhibited a healthier tissue appearance, less exudate, less accumulation of slough on the wound surface, and new evidence of granulation buds. The patient noted cessation of intermittent bleeding episodes, thus alleviating the burden of at-home wound care. The use of AC5 Advanced Wound System was associated with accelerated healing of the stalled refractory burn wound and a marked improvement in the patient's quality-of-life.

In a patient who underwent an emergency vascular bypass operation for a limb-threatening posterior tibial ischemia, the surgical site dehisced (opened up), became infected, and resisted healing. This complex surgical wound was treated with six weeks of standard care without improvement, followed by subsequent treatment with a collagenase ointment for two weeks and a skin graft, which failed. The non-healing wound was then treated with excisional debridement and concomitant application of AC5 Advanced Wound System weekly for three weeks. Due to co-existing peripheral arterial disease, the patient was not a candidate for compression dressings. The combination of debridement and AC5 Advanced Wound System was associated with quickly restarting the previously stalled healing process, thus allowing the patient to resume at-home wound care. The development of a healthy and stable granular wound bed and wound closure was achieved without the need for additional skin grafts. The results indicate that the use of this dressing may obviate the need for continued costly treatments and procedures, thus reducing the total cost of lower extremity wound care, while improving patients' quality of life.

Regulatory

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

Our research, development and clinical programs, as well as our manufacturing and marketing operations that may be performed by us or third party service providers on our behalf, are subject to extensive regulation in the United States and other countries. Notably, for example, AC5 Advanced Wound System is subject to regulation as a medical device under the U.S. Food Drug and Cosmetic Act (the "FDCA") as implemented and enforced by the FDA and equivalent regulations that are enforced by foreign agencies in

any other countries in which we pursue commercialization. The FDA and its foreign counterparts generally govern the following activities that we do or will perform or that will be performed on our behalf, as well as potentially additional activities, to ensure that products we may manufacture, promote and distribute domestically or export internationally are safe and effective for their intended uses:

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

Medical Device Classification in the United States and Europe

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

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

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

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

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

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

- Class IIa, which are considered low-medium risk devices and require certification by a notified body;

- Class IIb, which are considered medium-high risk devices and require certification by a notified body; and
- Class III, which are considered high-risk devices and require certification by a notified body.

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

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, also known as a 510(k), which must be submitted to the FDA for clearance, or a PMA application, which the FDA must approve prior to marketing in the United States. The FDA ultimately determines the appropriate regulatory path. For purposes herein, references to regulatory approval and marketing authorization may be used interchangeably.

We believe that the products we are currently pursuing for internal use will require a PMA approval prior to commercialization. However, we are in the process of commercializing an initial product for external use that has been cleared through the 510(k) process. To obtain 510(k) marketing clearance for a medical device, an applicant must submit a premarket notification to the FDA demonstrating that the device is "substantially equivalent" to a predicate device or devices, which is typically a legally marketed Class II device in the United States. A device is substantially equivalent to a predicate device if it has the same intended use and (i) the same technological characteristics, or (ii) has different technological characteristics and the information submitted demonstrates that the device is as safe and effective as a legally marketed device and does not raise different questions of safety or effectiveness. In some cases, the submission must include data from human clinical studies. Marketing may commence when the FDA issues a clearance letter finding substantial equivalence. Depending upon a product's underlying technology and intended use, as well as on FDA processes and procedures, seeking and obtaining a 510(k) can be a lengthy process.

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

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

Further, if post-approval modifications are made, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling or

design, then new PMAs or PMA supplements would be required. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is typically limited to information needed to support the changes from the device covered by the original PMA and accordingly may not require as extensive clinical and other data.

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

European Union Marketing Authorization (CE Mark) Process

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

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

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

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

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

In 2017, the European Union regulatory bodies finalized a new Medical Device Regulation ("MDR"). The MDR changes several aspects of the existing regulatory framework, such as clinical data requirements, and introduces new ones, such as Unique Device Identification ("UDI"). We, and the Notified Bodies who will oversee compliance to the new MDR, face uncertainties in the upcoming years as the MDR is rolled out and enforced, creating risks in several areas, including the CE mark process, data transparency and application review timetables. The MDR was to be implemented on May 25, 2020, however, the implementation date has been postponed to May 26, 2021 due to the effects of Covid-19.

Post-Approval Regulation

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

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

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

Regulation by Other Foreign Agencies

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

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

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

In line with plans to better harmonize our United States and European product supply chains by using an additional supplier and additional manufacturing processes in the production of AC5 Topical Gel, Arch filed documentation with the FDA seeking such clearance in the United States for these additions, each of which had been incorporated into the technical documentation for the European CE mark filing. On March 23, 2020, we announced that the 510(k) premarket notification for AC5 Topical Gel had been reviewed and cleared by the FDA, allowing for the product to be marketed in the United States with the aforementioned additions. AC5 Topical Gel was subsequently renamed to AC5 Advanced Wound System in the United States.

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

On November 28, 2018 we announced that we had submitted the required documents for AC5 Topical Hemostat to its notified body seeking a CE mark. On August 5, 2019, we announced that during the review period, we had received and responded to customary written and verbal questions related to the technical file, and that BSI had recently indicated that the responses provided and assessed during the review period were acceptable so far. In that announcement, we further expressed our belief that the delay by the regulatory authority in completing the CE mark technical file review appeared to be due to a backlog of work for EU notified bodies related to both Brexit and the implementation of the new EU Medical Devices Regulation.

On April 13, 2020, the Company announced thatreceipt of the CE (Conformité Européenne) mark for AC5 Topical Hemostat, allowing for commercialization in Europe as a dressing and to control bleeding in external skin wounds in both out-patient and in-patient settings.

Commercialization Strategy

Our commercialization efforts are currently focused on our Dermal Sciences products, AC5 Advanced Wound System in the United States and AC5 Topical Hemostat in Europe. The indication for use, or purpose, for each product follows:

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

We announced receipt of the CE mark for AC5 Topical Hemostat on April 13, 2020. We announced receipt of 510(k) premarket notification clearances for AC5 Advanced Wound System on December 17, 2018, providing marketing authorization, and on March 23, 2020, clearing use of an additional supplier and additional manufacturing processes.

The Covid-19 pandemic environment has introduced new challenges related to product launch, marketing and sales, as clinicians and facilities are increasingly focused on managing resources, the disease, or its potential spread. We believe that these challenges may present an opportunity for our new technology to address certain poorly met needs. We have observed that:

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

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 discussions with surgeons, economic stakeholders and other decision-making personnel often include whether AC5 Advanced Wound System may enable them to accomplish more for their patients while deploying overall fewer resources and achieving desired outcomes.

We expect our Dermal Sciences product commercialization to be gradual, initially, and moderately accelerate into new market channels. In addition to identifying and encouraging product use by key opinion leaders and early adopters, we will prioritize our focus on private and government facilities. Hospitals in the Veterans Health Administration (“VA Hospitals”), for example, tend to have many patients whose needs we believe we can help address. We prioritized the launch of AC5 Advanced Wound System in the United States over that of AC5 Topical Hemostat in Europe to maximize operational efficiencies in light of the Covid-19 pandemic.

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

While our core team oversees initial inventory distribution from the warehouse to the customer, our sales and marketing plans include entering into collaboration agreements with contract sales partners and/or strategic partners to commercialize our products in both domestic and international markets

We are committed to continuous improvement processes. We will collect feedback and data when feasible and appropriate to help us better serve patients and doctors; to develop our 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 will be collected by informal feedback, observational case reports and/or clinical trials. We anticipate seeking reimbursement via codes based upon Current Procedural Terminology (CPT), hospital Diagnosis-related Groups (DRG) and Ambulatory Payment Classifications (APC).

We envision adding additional resources to our team to help commercialize the Dermal Sciences products. Our Biosurgery products for internal use will require additional preclinical and clinical testing before we seek marketing authorization to commercialize them.

Manufacturing

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

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

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

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

Industry and Competition

Arch is developing technology for Dermal Sciences and Biosurgery applications, including wound care, surgical procedures on and in the body, and endoscopic gastrointestinal procedures, and others. Our initial clinical trial for safety and performance assessed use in an external application. Additional human studies are intended to follow. We seek to provide a product set with broad utility in external and internal applications. Features of the technology highlight its potential utility in a range of settings, including traditional open procedures and the often more challenging minimally invasive surgeries.

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

Dermal Sciences

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

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

According to a 2018 report produced by iData Research, in the United States, advanced wound dressings account for approximately $2 billion in annual revenues. The true cost to care for wounds, including chronic wounds, such as venous leg ulcers, diabetic foot ulcers, and pressure ulcers, remains unknown. However, a 2018 report by Nussbaum et al., data from calendar year 2014 estimates that total Medicare spending for all wound types ranges from $28.1 to $96.8 billion and that 14.5% (8.2 million) of Medicare beneficiaries were diagnosed with at least one type of wound or wound-related infection. Many surgeons believe that chronic wounds are essentially chronic infections that must be aggressively debrided in order to heal. Furthermore, a 2017 report by Chan et al., indicates that the mean one year cost of care from a health-care public payer perspective was $44,200 for a diabetic foot ulcer, $15,400 for a pressure ulcer and $11,000 for a leg ulcer. The Agency for Healthcare Research & Quality estimates that 2.5 million Americans develop pressure ulcers annually.

We believe that these disease and economic burdens highlight potential needs and opportunities for our products.

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 dressing provide some utility and possess some novel features, surgeons often describe an inability to differentiate them from one another. Additionally, many advanced products are both expensive and require other interventions to the wound plus a passage of time for the wound bed to adequately be prepared before they can be used, adding additional burden to their use.

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

Biosurgery

We are developing Biosurgery products for internal use, including for hemostasis and sealant applications, gastrointestinal endoscopic mucosal resections and endoscopic submucosal dissections, and others.

According to a 2012 report produced by MedMarket Diligence, LLC, approximately 114 million surgical and procedure-based wounds occur annually worldwide, including 36 million from surgery in the United States. Available data indicates that there may be increased pressure to perform more complex surgeries at reduced costs, including conducting operations in less expensive outpatient settings. Although accurate current statistics are difficult to obtain, a National Health Statistics Report from 2006 and updated in 2009 indicates that outpatient surgery volume was increasing by approximately 5% annually, and a 2009 report covering surgical procedures in the United States suggests that inpatient surgery volume was declining 1% per year. We believe that a motivating factor of this trend may be the increased costs associated with hospital inpatient procedures performed in operating rooms, which, according to MedMarket Diligence, have been estimated to cost between $2,000 and $10,000 per hour. 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 minimally invasive surgery ("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 commonly recognized types of MIS, although there are many additional types. Advantages of MIS tends 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 converting the surgery to a traditional open procedure.

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

We believe that our technology will be useful in addressing the constant demand for better performance and safety in MIS, traditional surgery, NOTES, and other procedures. Additional general long term trends that may support a demand for products include:

- increasing surgical procedure volume growth, including ambulatory same day procedures;
- efforts to reduce operating room use and time; and
- increased use of anticoagulants, which predispose patients to bleeding.

In the course of 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 a number of 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 carefully 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.

Commercially available products in the hemostasis field with which we expect our products to compete if they obtain required regulatory approvals can cost between $50 and $500 per procedure, with the higher value added products generally priced at the upper end of that range.

Participants in the hemostatic and sealant market currently include large companies, such as Johnson & Johnson and its affiliated companies, Becton Dickinson and its C. R. Bard unit, Baxter International Inc., as well as various smaller companies. Certain companies in other sectors, such as pharmaceuticals, wound care, and orthopedics, among others, are also interested in these markets.

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 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, driven by an increasing elderly population and incidence of gastrointestinal malignancies. While comprehensive data is not readily available, a report by Persistence Market Research projects global revenues in EMR of approximately $2.5 billion in 2025, with ESD representing additional opportunity. Persistence Market Research further projects share of EMR procedures to be approximately 42% for colon cancer, 30% for stomach cancer, and 20% for esophageal cancer. The opportunity is noteworthy in North America, Europe, and also Asia, where a higher prevalence of certain gastrointestinal malignancies and lower screening rates leads to later discovery and removal of tumors than desired

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 desire for an 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, including Boston Scientific, have products that provide either a lift or are hemostatic, but not both. AC5-G was featured in a video presentation during the Emerging Technology Session of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) 2020 Annual Meeting, which took place from August 11-13, 2020.

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

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

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

Other Governmental Regulations and Environmental Matters

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

Intellectual Property

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

As of December 2, 2020, we either own or license from others a number of U.S. patents, U.S. patent applications, foreign patents and foreign patent applications.

Six patent portfolios assigned to Arch Biosurgery, Inc. include a total of 40 patents and pending applications in a total of nine jurisdictions, including twelve patents and pending applications in the US. These portfolios cover self-assembling peptides, formulations and methods of use thereof and self-assembling peptidomimetics and methods of use thereof, including seven 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; and US 10,682,386) that expire between 2026 and 2034 (absent patent term extension), as well as fifteen patents that have been either allowed, issued or granted in foreign jurisdictions.

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

The two portfolios exclusively licensed from MIT include a total of 22 patents and pending applications drawn to self-assembling peptides, formulations and methods of use thereof and self-assembling peptidomimetics and methods of use thereof in a total of nine jurisdictions. The portfolios include five issued US patents (US 9,511,113; US 9,084,837; US 10,137,166; US 9,327,010; and US 9,364,513) that expire between 2026 and 2027 (absent patent term extension), as well as fourteen 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 four issued US patents (US 7,449,180; US 7,846,891; US 7,713,923; and US 8,901,084) that expire between 2021 and 2024 (absent patent term extension), as well as five 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 its subsidiary.

Employees

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

ITEM 1A. RISK FACTORS

Investment in our Common Stock involves a high degree of risk. You should carefully consider the risks that are summarized below and discussed in greater detail in the following pages before making an investment decision. If any of the following risks and uncertainties actually occur, our business, financial condition, and results of operations could be negatively impacted and you could lose all or part of your investment.

Risk Factor Summary

- There is substantial doubt about our ability to continue as a going concern. We have not generated any revenue from operations since inception, and we believe that our current cash on hand will meet our anticipated cash requirements only into the second quarter of fiscal 2021.
- We have incurred significant losses since inception, we expect to continue to incur losses for the foreseeable future, and we may never generate revenue or achieve or maintain profitability.
- Given our lack of revenue, we may need to raise additional capital, which may not be available to us on acceptable terms, or at all.

- 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.
- Applications for regulatory marketing authorization for commercialization of our products or elements of our supply chain may not be accepted, or if accepted, may be voluntarily withdrawn or eventually rejected, and the future success of our business is significantly dependent on the success of our being able to obtain regulatory marketing authorization for our development stage candidates.
- Our principal product candidates are inherently risky because they are based on novel technologies and thus create significant challenges with respect to product development and optimization, engineering, manufacturing, scale-up, quality systems, pre-clinical in vitro and in vivo testing, government regulation and approval, third-party reimbursement and market acceptance.
- Any changes in our supply chain, including to the third party contract manufacturers, service providers, or other vendors, or in the processes that they employ, could adversely affect us.
- If the FDA or similar foreign agencies or intermediaries impose requirements or an alternative product classification more onerous than we anticipate, our business could be adversely affected.
- We are subject to extensive and dynamic medical device regulations outside of the United States, which may impede or hinder the approval, marketing authorization or sale of our products and, in some cases, may ultimately result in an inability to obtain approval of certain products or may result in the recall or seizure of previously approved or authorized products.
- Any clinical trials that are planned or are conducted on our product candidates may not start or may fail. Clinical trials are lengthy, complex and extremely expensive processes with uncertain expenditures and results and frequent failures.
- We cannot market and sell any product candidate in the United States or in any other country or region if we fail to obtain the necessary marketing authorization, clearances or certifications from applicable government agencies.
- Any product for which we obtain required regulatory marketing authorization could be subject to post-approval regulation, and we may be subject to penalties if we fail to comply with such post-approval requirements.
- Use of third parties to manufacture our product candidates may increase the risk that preclinical development, clinical development and potential commercialization of our product candidates could be delayed, prevented or impaired.
- We face competition from companies that have greater resources than we do, and we may not be able to effectively compete against these companies.

- If others claim we and/or the parties from who we license some of our intellectual property are infringing on their intellectual property rights, we may be subject to costly and time-consuming litigation.
- There is not now, and there may not ever be, an active market for our Common Stock, which trades in the over-the-counter market in low volumes and at volatile prices.
- The market price of our Common Stock is and is expected to continue to be in the near term, less than $5.00 per share and is therefore a “penny stock.” Brokers and dealers effecting transactions in “penny stock” must disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities.

Risks Related to our Business

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

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

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

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

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

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

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

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

In addition, and as noted elsewhere, we believe that our current cash on hand will meet our anticipated cash requirements into the second quarter of fiscal 2021. Accordingly, while the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the coronavirus could materially and adversely affect our business and the value of our common stock.

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

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

Our initial product candidates are currently being used by clinicians and to date we have not generated any revenue and we have incurred substantial net losses as a result. As of December 10, 2020, we believe that our current cash will meet anticipated requirements into the second quarter of fiscal 2021 and we will need to raise additional capital before then.

During the first quarter of Fiscal 2020, the third quarter of fiscal 2020 and the first quarter of fiscal 2021, we obtained additional cash to continue operations and fund our planned future operations, which include research and development of our product candidates, steps related to seeking regulatory marketing authorization for our initial product candidates, and planning for their commercialization in the U.S. and Europe. Even with the additional funds received from the 2019 SPA and the October 2019 SPA the Series 1 convertible promissory notes and the Series 2 convertible promissory notes 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 generate 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 not generated any product revenue to-date. 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 entirely 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:

- develop our principal product candidates, and the underlying technology, including advancing applications and conducting biocompatibility and other preclinical 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 succeed in developing and eventually commercializing 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 operating revenues or 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 operating revenues or 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 prices of our Common Stock could cause our stockholders to lose all or a part of their investment in the Company.

We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts and could cause our business to fail.

Based on our current operating expenses and working capital requirements, as of December 10, 2020, we believe that our current cash on hand will meet our anticipated cash requirements into the second quarter of fiscal 2021. Notwithstanding that, depending upon additional input from EU and US regulatory authorities, we may need to raise additional capital before then. For example, on December 18, 2017, we voluntarily withdrew a 510(k) notification for AC5 Topical Gel after receiving questions from the FDA for which an adequately comprehensive response could not be provided within the FDA's congressionally-mandated 90-day review period. While on October 1, 2018, we announced that we both completed the necessary steps required to refile our 510(k) submission for AC5 Topical Gel and filed a 510(k) submission during the third calendar quarter of 2018, the resubmission process required us to expend a minimum of $100,000 that we had not anticipated spending and delayed the clearance of our 510(k) submission.

During the first quarter of Fiscal 2020, the third quarter of Fiscal 2020 and the first quarter of Fiscal 2021, we obtained additional cash to continue operations and fund our planned future operations, including the continuation of our ongoing research and development efforts, the licensing or acquisition of new assets, and researching and developing any potential patents, the related compounds and any further intellectual property that we may acquire. In addition, our plans may change and/or we may use our capital resources more rapidly than we currently anticipate. We presently expect that our expenses will increase in connection with our ongoing activities to support our business operations, inclusive of regulatory submissions, marketing authorization, and commercialization of our product candidates and products, and, therefore, we will require additional funding.

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

- the scope, progress and results of our research and development collaborations;
- the extent of potential direct or indirect grant funding for our research and development activities;
- the scope, progress, results, costs, timing and outcomes of any regulatory process and clinical trials conducted for any of our product candidates;
- the timing of entering into, and the terms of, any collaboration agreements with third parties relating to any of our product candidates;
- the timing of and the costs involved in obtaining regulatory marketing authorization for our product candidates;
- the costs of operating, expanding and enhancing our operations to support our clinical activities and, if our product candidates are approved, commercialization activities;
- the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities;

- the costs associated with maintaining and expanding our product pipeline;

- the costs associated with expanding our geographic focus;
- operating revenues, if any, received from sales of our product candidates, if any are approved by the FDA or other applicable regulatory agencies;
- the cost associated with being a public company, including obligations to regulatory agencies, and increased investor relations and corporate communications expenses; and
- the costs of additional general and administrative personnel, including accounting and finance, legal and human resources employees.

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

In addition, we are bound by certain contractual terms and obligations that may limit or otherwise impact our ability to raise additional funding in the near-term including, but not limited to, provisions in the Securities Purchase Agreements that we entered into on February 20, 2017 (the "2017 SPA") and June 28, 2018 (the "2018 SPA") in connection with the registered direct financings that closed on February 24, 2017 (the "2017 Financing") and July 2, 2018 (the "2018 Financing"), respectively, in each case as described in greater detail in the risk factor entitled "***The terms of the 2017 Financing and 2018 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 2017 Financing and 2018 Financing could impose additional challenges on our ability to raise funding in the future.

In particular, both the 2017 SPA and 2018 SPA contain provisions that provide that until such time as the three lead investors in the 2017 Financing and 2018 Financing, respectively, collectively own less than 20% of the Series F Warrants or Series G Warrants as applicable, purchased by them pursuant to the 2017 SPA or 2018 SPA, as applicable, the Company is prohibited from effecting or entering into an agreement to effect any issuance by the Company or its subsidiary of Common Stock or securities convertible, exercisable or exchangeable for Common Stock (or a combination of units thereof) involving a Variable Rate Transaction including, but not limited to, an equity line of credit or "At-the-Market" financing facility.

As of December 10, 2020, none of the lead investors for either the 2017 Financing or 2018 Financing have exercised or transferred any of their Series F Warrants and Series G Warrants. As defined in the 2017 SPA and 2018 SPA, Variable Rate Transaction means a transaction in which the Company (a) issues or sells any debt or equity securities that are convertible into, exchangeable or exercisable for, or include the right to receive additional shares of Common Stock either (A) at a conversion price, exercise price or exchange rate or other price that is based upon and/or varies with the trading prices of or quotations for the shares of Common Stock at any time after the initial issuance of such debt or equity securities, or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such debt or equity security or upon the occurrence of specified or contingent events directly or indirectly related to the business of the Company or the market for the Common Stock (excluding adjustments under customary anti-dilution provisions) or (b) enters into, or effects a transaction under, any agreement, including, but not limited to, an equity line of credit, whereby the Company may issue securities at a future determined price. These provisions could make our securities less attractive to investors and could limit our ability to obtain adequate financing on a timely basis or on acceptable terms in the future, which could have significant harmful effects on our financial condition and business and could include substantial limitations on our ability to continue to conduct operations.

Our short 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. 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, or conduct sales and marketing activities necessary for successful product commercialization.

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

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

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

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

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

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

Our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and the related regulations regarding our required assessment of our internal controls over financial

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

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

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

Risks Related to Our Business, Financial Position and Capital Requirements - Legal, political and economic uncertainty surrounding the exit of the United Kingdom from the European Union is a source of instability and uncertainty.

Legal, political and economic uncertainty surrounding the exit of the United Kingdom from the European Union is a source of instability and uncertainty.

The uncertainty concerning the U.K's legal, political and economic relationship with the E.U. after the Transition Period may be a source of instability in the international markets, create significant currency fluctuations, and/or otherwise adversely affect trading agreements or similar cross-border co-operation arrangements (whether economic, tax, fiscal, legal, regulatory or otherwise).

These developments, or the perception that any of them could occur, have had, and may continue to have, a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and limit the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the U.K. financial and banking markets, as well as on the regulatory process in Europe. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility.

If the U.K. and the E.U. are unable to negotiate acceptable trading and customs terms or if other E.U. Member States pursue withdrawal, barrier-free access between the U.K. and other E.U. Member States or among the European Economic Area ("E.E.A.") overall could be diminished or eliminated. The long-term effects of Brexit will depend on any agreements (or lack thereof) between the U.K. and the E.U. and, in particular, any arrangements for the U.K. to retain access to E.U. markets after the Transition Period. Such a withdrawal from the E.U. is unprecedented, and it is unclear how the U.K. access to the European single market for goods, capital, services and labor within the E.U., or single market, and the wider commercial, legal and regulatory environment, will impact our U.K. operations.

We may also face new regulatory costs and challenges that could have an adverse effect on our operations and development programs. For example, the U.K. could lose the benefits of global trade agreements negotiated by the E.U. on behalf of its members, which may result in increased trade barriers that could make our doing business in the E.U. and the E.E.A. more difficult. There may continue to be economic uncertainty surrounding the consequences of Brexit, which could adversely affect our financial condition, results of operations, cash flows and market price of our common stock.

Risks Related to the Development and Commercialization of our Product Candidates

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

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

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

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

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

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

The Chemistry, Manufacturing and Control ("CMC") process 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 principal product candidates 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 the 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, 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 the AC5 Topical Advanced Wound System that is commercially available in the United States. The Company filed documentation with the FDA related to these supply chain changes and announced on March 23, 2020 that the FDA provided the required clearance to market with the supply chain and manufacturing process changes. We cannot yet provide assurance that the changes or resulting product will prove acceptable to us.

The manufacturing, production, and sterilization methods that we intend to be utilized are detailed and complex and are a difficult process to manage.

We intend to utilize third-party manufacturers to manufacture and sterilize our products. We believe that our proposed manufacturing methods make our choice of manufacturer and sterilizer critical, as they must possess sufficient expertise in synthetic organic chemistry and device manufacturing. If such manufacturers are unable to properly manufacture to product specifications or sterilize our products adequately, that could severely limit our ability to market our products.

Compliance with governmental regulations regarding the treatment of animals used in research could increase our operating costs, which would adversely affect the commercialization of our technology.

The Animal Welfare Act ("AWA") is the federal law that covers the treatment of certain animals used in research. Currently, the AWA imposes a wide variety of specific regulations that govern the humane handling, care, treatment and transportation of certain animals by producers and users of research animals, most notably relating to personnel, facilities, sanitation, cage size, and feeding, watering and shipping conditions. Third parties with whom we contract are subject to registration, inspections and reporting requirements under the AWA. Furthermore, some states have their own regulations, including general anti-cruelty legislation, which establish certain standards in handling animals. Comparable rules, regulations, and or obligations exist in many foreign jurisdictions. If our contractors or we fail to comply with regulations concerning the treatment of animals used in research, we may be subject to fines and penalties and adverse publicity, and our operations could be adversely affected.

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

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

We are subject to extensive and dynamic medical device regulations outside of the United States, which may impede or hinder the approval

or sale of our products and, in some cases, may ultimately result in an inability to obtain approval of certain products or may result in the recall or seizure of products that were previously approved.

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

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

In addition, exported devices are subject to the regulatory requirements of each country to which the device is exported. Most foreign countries possess medical devices regulations and require that they be applied to medical devices before they can be commercialized. There can be no assurance that we will receive the required approvals for our products on a timely basis or that any approval will not be subsequently withdrawn or conditioned upon extensive post-market study requirements.

Our global regulatory environment is becoming increasingly stringent and unpredictable, which could increase the time, cost and complexity of obtaining marketing authorization for our products, as well as the clinical and regulatory costs of supporting those approvals. Several countries that did not have regulatory requirements for medical devices have established such requirements in recent years and other countries have expanded existing regulations. Certain regulators are exhibiting less flexibility by requiring, for example, the collection of local preclinical and/or clinical data prior to approval. While harmonization of global regulations has been pursued, requirements continue to differ significantly among countries. We expect the global regulatory environment to continue to evolve, which could impact our ability to obtain future approvals for our products and increase the cost and time to obtain such approvals. By way of example, the European Union regulatory bodies recently finalized a new Medical Device Regulation ("MDR"). The MDR changes several aspects of the existing regulatory framework, such as clinical data requirements, and introduces new ones, such as Unique Device Identification ("UDI"). We, and the Notified Bodies who will oversee compliance to the new MDR, face uncertainties in the upcoming years as the MDR is rolled out and enforced, creating risks in several areas, including the CE mark process, data transparency and application review timetables. The MDR was to be implemented on May 25, 2020, however, the implementation date has been postponed till May 26, 2021 due to the effects of Covid-19.

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

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

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

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

- FDA or other regulatory authorities, or other relevant decision-making bodies do not grant permission to proceed or place a trial on clinical hold due to safety concerns or other reasons;
- sufficient suitable subjects do not enroll, enroll more slowly than anticipated or remain in our trials;
- we fail to produce necessary amounts of the product or product candidate;
- subjects experience an unacceptable rate of efficacy of the product or product candidate;
- subjects experience an unacceptable rate or severity of adverse side effects, demonstrating a lack of safety of the product or product candidate;
- any portion of the trial or related studies produces negative or inconclusive results or other adverse events;
- reports from preclinical or clinical testing on similar technologies and products raise safety and/or efficacy concerns;
- third-party clinical investigators lose their licenses or permits necessary to perform our clinical trials, do not perform their clinical trials on the anticipated schedule or consistent with the clinical trial protocol, GCP or regulatory requirements, or other third parties do not perform data collection and analysis in a timely or accurate manner;
- inspections of clinical trial sites by the FDA or an institutional review board ("IRB") or other applicable regulatory authorities find violations that require us to undertake corrective action, suspend or terminate one or more testing sites, or prohibit us from using some or all of the resulting data in support of our marketing applications with the FDA or other applicable agencies;
- manufacturing facilities of our third-party manufacturers are ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of current good manufacturing practices ("cGMP") or other applicable requirements;
- third-party contractors become debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements;
- the FDA or other regulatory authorities impose requirements on the design, structure or other features of the clinical trials for our product candidates that we and/or our third-party contractors are unable to satisfy;
- one or more IRB refuses to approve, suspends or terminates a trial at an investigational site, precludes enrollment of additional subjects, or withdraws its approval of the trial;
- the FDA or other regulatory authorities seek the advice of an advisory committee of physician and patient representatives that may view the risks of our product candidates as outweighing the benefits;
- the FDA or other regulatory authorities require us to expand the size and scope of the clinical trials, which we may not be able to do; or
- the FDA or other regulatory authorities impose prohibitive post-marketing restrictions on any of our product candidates that attain marketing authorization.

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

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

We cannot sell our product candidates in any country until regulatory agencies grant marketing approval, clearance or other required certification. 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 any other product candidate we may pursue, which we may never be able to do, it would likely be a process that takes many years to achieve.

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

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

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

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

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

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

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

Any product for which we obtain required regulatory marketing authorization could be subject to post-approval regulation, and we may be subject to penalties if we fail to comply with such post-approval requirements.

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

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

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

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

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

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

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

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

We have limited personnel with experience in medical device development and manufacturing, do not own or operate manufacturing facilities, and generally lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We currently intend to 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 product candidates.

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

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

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

We compete with other pharmaceutical and medical device companies, including companies that may develop products that make our product 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 candidates and establish programs to educate and train surgeons as to the distinctive characteristics of our product candidates, we will not be able to generate revenues on our product candidates.

Acceptance in the marketplace of 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.

We face uncertainty related to pricing, reimbursement and healthcare reform, which could reduce our potential revenues.

If our product candidates are approved for commercialization, any sales will depend in part on the availability of direct or indirect coverage and reimbursement from third-party payers such as government insurance programs, including Medicare and Medicaid, private health insurers, health maintenance organizations and other healthcare related organizations. If our product candidates obtain marketing approval, pricing and reimbursement may be uncertain. Both the federal and state governments in the U.S. and foreign governments continue to propose and pass new legislation affecting coverage and reimbursement policies, which are designed to contain or reduce the cost of healthcare. Further, federal, state and foreign healthcare proposals and reforms could limit the prices that can be charged for the product candidates that we may develop, which may limit our commercial opportunity. Adoption of our product candidates by the medical community may be limited if doctors and hospitals do not receive adequate partial or full reimbursement for use of our products or procedures in which our products are used, if any are commercialized. In some foreign jurisdictions, marketing approval or allowance could be dependent upon pre-marketing price negotiations. As a result, any denial of private or government payer coverage or inadequate reimbursement for procedures performed using our products, before or upon commercialization, could harm our business and reduce our prospects for generating revenue.

In addition, the U.S. Congress periodically adopts and changes legislation regarding health insurance. As a result, substantial changes to the system for paying for healthcare in the U.S. may include some combination of modifications to the existing system of private payers and government programs, such as Medicare, Medicaid and State Children's Health Insurance Program, as well as other changes. Restructuring the coverage of medical care in the U.S. could impact reimbursement for medical devices such as our product

candidates. If reimbursement for our products, if any, is substantially less than we expect, or rebate obligations associated with them are substantially increased, our business could be materially and adversely impacted.

The use of our 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 clinical trial liability coverage. We will need to obtain additional product liability insurance coverage if and when we begin commercialization of any of our product candidates. If claims against us exceed any applicable insurance coverage we may obtain, then our business could be adversely impacted. Regardless of whether we would be ultimately successful in any product liability litigation, such litigation could consume substantial amounts of our financial and managerial resources, which could significantly harm our business.

Risks Related to our Intellectual Property

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

Our success will depend in large part on our ability to obtain and maintain protection in the U.S. and other countries for the intellectual property rights covering or incorporated into our technology and products. The ability to obtain patents covering technology in the field of medical devices generally is highly uncertain and involves complex legal, technical, scientific and factual questions. We may not be able to obtain and maintain patent protection relating to our technology or products. Many of our owned or licensed patent applications are pending. Even if issued, patents issued or licensed to us may be challenged, narrowed, invalidated, held to be unenforceable or circumvented, or determined not to cover our product candidates or our competitors' products, which could limit our ability to stop competitors from marketing identical or similar products. Because our patent portfolio includes certain patents and applications that are in-licensed on a non-exclusive basis, other parties may be able to develop, manufacture, market and sell products with similar features covered by the same patent rights and technologies, which in turn could significantly undercut the value of any of our product candidates and adversely affect our business. Our licensed MIT European patent No. 1879606 was opposed; however, this patent was maintained in amended form following an administrative hearing. Both parties have appealed this decision. A decision is not expected before the end of 2020. If the Opponents prevail in the appeal, European Patent No. 1879606 will be fully or partially invalidated, resulting in potential loss of rights. European patent No. 2581097 was opposed. The Opposition Division revoked the patent. This decision was appealed. If the Opponent prevails in the appeal, European Patent No. 2581097 could be fully or partially invalidated, resulting in potential loss of rights. Further, we cannot be certain that we were the first to make the inventions claimed in the patents we own or license, or that protection of the inventions set forth in those patents was the first to be filed in the U.S. Third parties that have filed patents or patent applications covering similar technologies or processes may challenge our claim of sole right to use the intellectual property covered by the patents we own or exclusively license. Moreover, changes in applicable intellectual property laws or interpretations thereof in the U.S. and other countries may diminish the value of our intellectual property rights or narrow the scope of our patent protection. Any failure to obtain or maintain adequate protection for our intellectual property would materially harm our business, product development programs and prospects. In addition, our proprietary information, trade secrets and know-how are important components of our intellectual property rights. We seek to protect our proprietary information, trade secrets, know-how and confidential information, in part, with confidentiality agreements with our employees, corporate partners, outside scientific collaborators, sponsored researchers, consultants and other advisors. We also have invention or patent assignment agreements with our employees and certain consultants and advisors. If our employees or consultants breach those agreements, we may not have adequate remedies for any of those breaches. In addition, our proprietary information, trade secrets and know-how may otherwise become known to or be independently developed by others. Enforcing a claim that a party illegally obtained and/or for which a party is using our proprietary information, trade secrets and/or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek to defend, enforce and/or determine the scope of our intellectual property rights, and failure to obtain or maintain protection thereof could adversely affect our competitive business position and results of operations.

Many of our owned patent applications are pending, and our patent portfolio includes certain patents and applications that are in-licensed on a non-exclusive basis

As of December 2, 2020, we either own or license from others a number of U.S. patents, U.S. patent applications, foreign patents and foreign patent applications.

Six patent portfolios assigned to Arch Biosurgery, Inc. include a total of 40 patents and pending applications in a total of nine jurisdictions, including twelve patents and pending applications in the US. These portfolios cover self-assembling peptides, formulations and methods of use thereof and self-assembling peptidomimetics and methods of use thereof, including seven 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; and US 10,682,386) that expire between 2026 and 2034 (absent patent term extension) as well as fifteen patents that have been either allowed, issued or granted in foreign jurisdictions.

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

The two portfolios exclusively licensed from MIT include a total of 22 patents and pending applications drawn to self-assembling peptides, formulations and methods of use thereof and self-assembling peptidomimetics and methods of use thereof in a total of nine jurisdictions. The portfolios include five issued US patents (US 9,511,113; US 9,084,837; US 10,137,166; US 9,327,010; and US 9,364,513) that expire between 2026 and 2027 (absent patent term extension), as well as fourteen patents that have been either allowed, issued or granted in foreign jurisdictions.

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

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

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

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

could be prevented from commercializing one or more product candidates, or be forced to cease some aspects of our business operations, if, as a result of actual or threatened infringement claims, we are unable to enter into licenses on acceptable terms or at all or otherwise settle such claims. Further, if any such claims were successful against us, we could be forced to pay substantial damages. Any of those results could significantly harm our business, prospects and operations.

Risks Related to Ownership of our Common Stock

There is not now, and there may not ever be, an active market for our Common Stock, which trades in the over-the-counter market in low volumes and at volatile prices.

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

We do not now meet the initial listing standards of the Nasdaq Stock Market or any other national securities exchange. We presently 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.

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

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.

If we issue additional shares in the future, including issuances of shares upon exercise of the Series J Warrants, Series I Warrants, Placement Agent Warrants, Series H Warrants, Series G Warrants, Series F Warrants, Series E Warrants and our Series 1 and Series 2 Convertible Notes, our existing stockholders will be diluted.

As of July 1, 2020, our articles of incorporation authorize the issuance of up to 800,000,000 shares of Common Stock. In June 2020, we issued certain of holders of our Series D Warrants Series J Warrants to acquire up to 3,886,364 shares of our Common Stock at an initial exercise price of $0.25 per share as consideration for those holders exercising their Series D Warrants in full to acquire 5,181,819 shares of our Common Stock at $0.18 per share. As of December 10, 2020, up to 3,886,364 shares may be acquired upon the exercise of the Series J Warrants.

In connection with the October 2019 Financing that closed on October 18, 2019, we issued an aggregate of 14,285,714 shares of our Common Stock, which equaled approximately 8% of the 173,577,233 shares of our Common Stock that were issued and outstanding immediately prior to the commencement of the October 2019 Financing. Upon the closing of the October 2019 Financing, we also issued Series I Warrants to acquire up to an additional 14,285,714 shares of our Common Stock at an initial exercise price of $0.22 per share and additional warrants to acquire up to an additional 1,071,429 shares of our Common Stock at an initial exercise price of $0.21875 per share to designees of H.C. Wainwright & Co., LLC, the placement agent that the Company engaged in connection with the October 2019 Financing (the "Placement Agent Warrants"). As of December 10, 2020, up to 14,285,714 shares may be acquired upon the exercise of the Series I Warrants and up to 1,071,429 shares may be acquired upon the exercise of the Placement Agent Warrants.

In connection with the financing that closed on May 14, 2019 (the "2019 Financing"), we issued an aggregate of 8,615,384 shares of our Common Stock, which equaled approximately 5% of the 164,961,849 shares of our Common Stock that were issued and outstanding immediately prior to the commencement of the 2019 Financing. Upon the closing of the 2019 Financing, we also issued Series H Warrants to acquire up to an additional 8,615,384 shares of our Common Stock at an initial exercise price of $0.40 per share. As of December 10, 2020, up to 8,615,384 shares may be acquired upon the exercise of the Series H Warrants.

In connection with the 2018 Financing that closed on July 2, 2018, we issued an aggregate of 9,070,000 shares of our Common Stock, which equaled approximately 6% of the 154,052,013 shares of our Common Stock that were issued and outstanding immediately prior to the commencement of the 2018 Financing. Upon the closing of the 2018 Financing, we also issued Series G Warrants to acquire up to an additional 6,802,500 shares of our Common Stock at an initial exercise price of $0.70 per share. As of December 10, 2020, up to 6,802,500 shares may be acquired upon the exercise of the Series G Warrants.

In connection with the 2017 Financing that closed on February 24, 2017, we issued an aggregate of 10,166,664 shares of our Common Stock, which equaled approximately 7% of the 136,745,712 shares of our Common Stock that were issued and outstanding immediately prior to the commencement of the 2017 Financing. Upon the closing of the 2017 Financing, we also issued Series F Warrants to acquire up to an additional 5,591,664 shares of our Common Stock at an initial exercise price of $0.75 per share. As of December 10, 2020, up to 5,591,664 shares may be acquired upon the exercise of the Series F Warrants.

In connection with the 2016 Private Placement Financing that closed on May 26, 2016, we issued an aggregate of 9,418,334 shares of our Common Stock, which equaled approximately 8% of the 118,592,070 shares of our Common Stock that were issued and outstanding immediately prior to the commencement of the 2016 Private Placement Financing. Upon the closing of the 2016 Private Placement Financing, we also issued Series E Warrants to acquire up to an additional 7,063,748 shares of our Common Stock at an initial exercise price of $0.4380 per share. As of December 10, 2020, up to 4,214,582 shares may be acquired upon the exercise of the Series E Warrants.

In addition to the aforementioned warrants, in June 2020 and November 2020, we issued $550,000 and $1,050,000 in aggregate principal amount of our Series 1 Unsecured Convertible Promissory Notes and Series 2 Unsecured Convertible Promissory Notes, respectively (collectively, the "Convertible Notes"). The Convertible Notes (i) have a three year term; (ii) accrue interest on the unpaid principal balance at a rate equal to ten percent (10.0%), and (iii) can be converted into shares of our Common Stock at a conversion price of $0.27 per share and $0.25 per share, respectively. At maturity, at our sole option, we may convert the principal and accrued interest under the Convertible Notes (the "Note Obligations") into shares of our Common Stock at the applicable conversion price in lieu of repaying the Convertible Notes; provided, however, in the event we exercise this option, the Note Obligations will be deemed to equal the product of 1.35 and the outstanding Note Obligations.

Additionally, as of December 10, 2020, 6,868,356 shares of Common Stock were reserved for future issuance under the 2013 Plan, of which 19,129,998 shares are subject to

outstanding option awards granted under the 2013 Plan at exercise prices ranging from $0.17 to $0.65 per share and with a weighted average exercise price of $0.36 per share and the numbers issuable under the 2013 Plan will increase by up to 3 million shares on the first business day of each following fiscal year as set forth in the 2013 Plan. Finally, in addition to the Series J Warrants, Series I Warrants, Placement Agent Warrants, Series H Warrants granted in connection with the 2019 Financing, the Series G Warrants granted in connection with the 2018 Financing, the Series F Warrants granted in connection with the 2017 Financing, the Series E Warrants granted in connection with the 2016 Private Placement Financing and the shares of Common Stock potentially issuable under the Convertible Notes there are currently outstanding warrants to acquire up to 145,985 shares of our Common Stock which are related to the Massachusetts Life Sciences Center ("MSLC") note. Any future grants of options, warrants or other securities exercisable or convertible into our Common Stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our Common Stock.

In addition to capital raising activities, other possible business and financial uses for our authorized Common Stock include, without limitation, future stock splits, acquiring other companies, businesses or products in exchange for shares of Common Stock, issuing shares of our Common Stock to partners in connection with strategic alliances, attracting and retaining employees by the issuance of additional securities under our various equity compensation plans, compensating consultants by issuing shares or options to purchase shares of our Common Stock, or other transactions and corporate purposes that our Board of Directors deems are in the Company's best interest. By way of example, on (i) August 9, 2016, we issued 225,000 shares of restricted stock and options to purchase up to an additional 375,000 shares of Common Stock at an exercise price of price of $0.72 per share in connection with our entrance into a consulting agreement with Acorn Management Partners, LLC ("Acorn") in consideration of the services to be provided under and in accordance with the terms of such consulting agreement; and (ii) August 6, 2015, we issued an aggregate of 600,000 shares of restricted stock in connection with our entrance into separate consulting agreements with two investor relations firms, Excelsior Global Advisors LLC and Acorn, in each case in consideration of the services to be provided under and in accordance with the terms of each consulting agreement. Additionally, shares of Common Stock could be used for anti-takeover purposes or to delay or prevent changes in control or management of the Company. We cannot provide assurances that any issuances of Common Stock will be consummated on favorable terms or at all, that they will enhance stockholder value, or that they will not adversely affect our business or the trading price of our Common Stock. The issuance of any such shares will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our Common Stock. If we issue any such additional shares, such issuance will reduce the proportionate ownership and voting power of all current shareholders. Further, such issuance may result in a change of control of our corporation.

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

As noted above under the risk factor entitled, "***We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts and could cause our business to fail***," as of December 10, 2020 we believe that our current cash on hand will meet our anticipated cash requirements into the second quarter of fiscal 2021. To raise capital, we may sell Common Stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. Any such sales of our Common Stock by us or resale of our Common Stock by our existing stockholders could cause the market price of our Common Stock to decline.

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

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

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

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

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

Certain of our directors and executive officers own a significant percentage of our outstanding capital stock. As of December 10, 2020, Dr. Terrence W. Norchi, our Chairman of the Board, President and Chief Executive Officer, James R. Sulat, a director and Punit Dhillon, a director beneficially own (as determined under Section 13(d) of the Exchange Act and the rules and regulations thereunder) approximately 11% of our shares of Common Stock. Accordingly, these members of our Board of Directors and management team have substantial voting power to approve matters requiring stockholder approval, including without limitation the election of directors, and have significant influence over our affairs. This concentration of ownership could have the effect of delaying or preventing a change in control of our Company, even if such a change in control would be beneficial to our stockholders.

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

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

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

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

We are a public reporting company in the U.S., and, accordingly, are subject to the information and reporting requirements of the Exchange Act and other federal securities laws, including the obligations imposed by the Sarbanes-Oxley Act. The costs associated with preparing and filing annual, quarterly and current reports, proxy statements and other information with the SEC in the ordinary course, as well as preparing and filing audited financial statements, has caused, and could continue to cause, our operational expenses to remain at higher levels or continue to increase.

Shares of our Common Stock that have not been registered under federal securities laws are subject to resale restrictions imposed by Rule 144. In addition, any shares of

our Common Stock that are held by affiliates, including any that are registered, will be subject to the resale restrictions of Rule 144.

Rule 144 imposes requirements on us and our stockholders that must be met in order to effect a sale thereunder. As a result, it will be more difficult for us to raise funding to support our operations through the sale of debt or equity securities unless we agree to register such securities under the Securities Act, which could cause us to expend significant additional time and cash resources and which we presently have no intention to pursue. Further, it may be more difficult for us to compensate our employees and consultants with our securities instead of cash. We were a shell company prior to the closing of the Merger, and such status could also limit our use of our securities to pay for any acquisitions we may seek to pursue in the future (although none are currently planned) and could cause the value of our securities to decline. In addition, any shares held by affiliates, including shares received in any registered offering, will be subject to certain additional requirements in order to effect a sale of such shares under Rule 144.

We do not intend to pay cash dividends on our capital 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.

We are at risk of securities class action litigation that could result in substantial costs and divert management's attention and resources.

In the past, securities class action litigation has been brought against companies following periods of volatility of its securities in the marketplace, particularly following a company's initial public offering. Due to the volatility of our stock price, we could be the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

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

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

As of December 10, 2020, there were approximately 100 holders of record of our common stock.

Dividends

We have never declared or paid any cash dividends or distributions on our capital stock. We currently intend to retain our future earnings, if any, to support operations and to finance expansion and therefore we do not anticipate paying any cash dividends on our Common Stock in the foreseeable future.

Recent sales of unregistered securities and use of proceeds

On June 22, 2020, the Company entered into a Series J Warrant Issuance Agreement with the Keyes Sulat Revocable Trust (the "**Trust**") pursuant to which the Company agreed to issue the Trust a Series J Warrant to purchase up to 340,910 shares of common stock at an exercise price of $0.25 over a 1 year term (the "**Trust Series J Warrant**") upon the Trust's exercise of its Series D Warrant to purchase the 454,546 shares of common stock issuable thereunder at $0.18 per share. Later that day, the Trust exercised its Series D Warrant in full and the Company issued the Trust Series J Warrant upon receipt of the aggregate $81,818 exercise price. James R. Sulat, a member of the Board, is a co-trustee of the Trust, of which members of Mr. Sulat's immediate family are beneficiaries. Mr. Sulat disclosed his interest in the Trust to the Board prior to its approval of the transaction and abstained from voting on the transaction.

The Company did not engage an underwriter, and the issuance of the Trust Series J Warrant and the shares of Common Stock issuable thereunder has not been registered under the Securities Act in reliance upon an exemption from registration under Section 4(a)(2) of the Securities Act. Such securities may not be offered or sold in the United States absent registration under or exemption from the Securities Act and any applicable state securities laws. The Company determined that the issuance of such securities qualified for an exemption under Section 4(a)(2) of the Securities Act based on the following facts: (A) the Trust represented that (i) it is an accredited investor as defined in Rule 501

promulgated under the Securities Act; (ii) the Trust acquired the Securities for investment only and not with a view towards, or for resale in connection with, the public sale or distribution thereof in violation of applicable securities laws; (iii) the Trust has sufficient investment experience to evaluate the risks of the investment; and (B)(1) the Company used no advertising or general solicitation in connection with the issuance and sale of the securities to the Trust and (2) the securities will be issued as restricted securities.

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 Form 10-K 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 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 commercialize and generate revenues or profits from our anticipated products; Arch's ability to achieve the desired regulatory approvals 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 under the caption "**Risk Factors**" in this Form 10-K and in the documents Arch has filed, or will file with the SEC. We undertake no duty to update any of these forward-looking statements after the date of filing of this Form 10-K to conform such forward-looking statements to actual results or revised expectations, except as otherwise required by law.

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

Corporate Overview

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

For financial reporting purposes, the Merger represented a "reverse merger." ABS was deemed to be the accounting acquirer in the transaction and the predecessor of Arch. Consequently, the accumulated deficit and the historical operations that are reflected in the Company's consolidated financial statements prior to the Merger are those of ABS. All share information has been restated to reflect the effects of the Merger. The Company's financial information has been consolidated with that of ABS after consummation of the Merger on June 26, 2013, and the historical financial statements of the Company before the Merger have been replaced with the historical financial statements of ABS before the Merger in this report.

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

Liquidity

We have generated no operating revenues to date. 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. For the year ended September 30, 2020, we had a net loss of $4,691,377 versus a net loss of $4,547,582 in the prior year. The losses for each of the years ended September 30, 2020 and 2019 can be attributable to research and development expenses, including regulatory approval and product research, general and administrative costs, primarily relating to legal costs associated with intellectual property and patent application costs, general corporate legal expenses all of which were partially offset by adjustments to the derivative liabilities. Cash used in operating activities decreased $223,547 during the year ended September 30, 2020 to $5,044,755, compared to $5,268,302 for the year ended September 30, 2019. Cash at September 30, 2020 decreased by $1,221,020 to $959,309 compared to $2,180,329 as of September 30, 2019.

Business Overview

We are a biotechnology company marketing or developing a number of products based on our innovative AC5® self-assembling technology platform. We believe these products can be important advances in the field of stasis and barrier applications, which includes stopping bleeding ("hemostasis"), controlling leaking ("sealant") and managing wounds created during surgery, trauma or interventional care or from disease. We have generated no revenues to date and have devoted substantially all of our operational effort to the research, development and regulatory programs necessary to turn our core technology into commercial products. Our goal is to make care faster and safer for patients with products for use in external wounds, which we refer to as Dermal Sciences applications, and products for use inside the body, which we refer to as Biosurgery applications.

Core Technology

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

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

- Peptide strands line up with neighboring peptide strands, interacting via hydrogen bonds (non-covalent bonds) to form a ribbon-like structure called a beta sheet.

- This process continues such that hundreds of strands organize with charged and polar side chains oriented on one face and non-polar side chains oriented on the opposite face of the beta sheets.
- Interactions of the resulting structure with water molecules and ions results in formation nanofibrils, which extend in length and can join together to form larger nanofibers.
- This network of AC5 peptide nanofibers forms the physical-mechanical barrier that is responsible for sealant, hemostatic and other properties, regardless of the presence of antithrombotic agents, and which subsequently becomes the scaffold that supports the repair and regeneration of damaged tissue.

Based on the intended application, we believe that the underlying AC5 SAP technology can impart important features and benefits to our products that may include, for instance, stopping bleeding (hemostasis), mitigating contamination, modulating inflammation, donating moisture, and enabling an appropriate wound microenvironment conducive to healing. 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, and does not possess sticky or glue-like handling characteristics. We believe these properties enhance its utility in several settings and contribute to its user-friendly profile.

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

Operations

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

Our long-term business plan includes the following goals:

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

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

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

In addition to capital required for operating expenses, depending upon additional input from EU and US regulatory authorities, as well as the potential for additional regulatory filings and approvals during the next 2 years, additional capital may be required.

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 filing. We anticipate that our operating and other expenses will continue to increase as we continue to implement our business plan and pursue and achieve these goals. After giving effect to the funds received in past equity and debt financings and assuming our use of that funding at the rate we presently anticipate, as of December 10, 2020 we believe that our current cash on hand will meet our anticipated cash requirements into the second quarter of fiscal 2021. We could spend our financial resources much faster than we expect, in which case we would need to raise additional capital as our current funds may not be sufficient to operate our business for the entire duration of that period.

Preclinical Testing

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

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

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

Clinical Testing

We have engaged and continue to engage third parties in the United States and abroad to advise on and/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/or other collaborators.

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

Commercialization

Our commercialization efforts are currently focused on our Dermal Sciences products, AC5 Advanced Wound System in the United States and AC5 Topical Hemostat in Europe. The indication for use, or purpose, for each product follows:

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

In practice, we envision that both products will be used in comparable wounds, including, in particular, acute or chronic wounds that require surgical intervention. Examples include, surgical excision of dead, contaminated, or damaged tissue, otherwise known as debridement, in chronic wounds; complicated wounds created during an acute surgical procedure; failed acute surgical wounds; wounds requiring wound bed preparation in advance of other procedures; wounds in need of an advanced dressing that incorporates an initial protective barrier function followed by a scaffolding or lattice function that enables healing.

We announced receipt of 510(k) premarket notification clearances for AC5 Advanced Wound System on December 17, 2018, providing marketing authorization, and on March 23, 2020, clearing use of an additional supplier and additional manufacturing processes. We announced receipt of the CE mark for AC5 Topical Hemostat on April 13, 2020.

The Covid-19 pandemic environment has introduced new challenges related to product launch, marketing and sales, as clinicians and facilities are increasingly focused on managing resources, the disease, or its potential spread. We believe that these challenges may present an opportunity for our new technology to address certain poorly met needs.

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

We expect our Dermal Sciences product commercialization to be gradual, initially, and moderately accelerate into new market channels. In addition to identifying and encouraging product use by key opinion leaders and early adopters, we will prioritize our focus on private and government facilities. Hospitals in the Veterans Health Administration (“VA Hospitals”), for example, tend to have many patients whose needs we believe we can help address. We prioritized the launch of AC5 Advanced Wound System in the United States over that of AC5 Topical Hemostat in Europe to maximize operational efficiencies in light of the Covid-19 pandemic.

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

Manufacturing

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

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

Merger with ABS and Related Activities

As noted earlier in this document, on June 26, 2013, the Company completed the Merger with ABS, pursuant to which ABS became a wholly owned subsidiary of the Company. In contemplation of the Merger, effective May 24, 2013, the Company increased its authorized common stock, par value $0.001 per share (“Common Stock”), from 75,000,000 shares to 300,000,000 shares and effected a forward stock split, by way of a stock dividend, of its issued and outstanding shares of Common Stock at a ratio of 11 shares to each one issued and outstanding share. Also, in contemplation of the Merger, effective June 5, 2013, the Company changed its name from Almah, Inc. to Arch Therapeutics, Inc. and changed the ticker symbol under which its Common Stock trades on the OTC Bulletin Board from “AACH” to “ARTH”.

Recent Developments

On October 17, 2019, the Company announced the pricing of registered direct offering of 14,285,714 units, each unit consisting of a share of the Company’s common stock, and a Series I Warrant (“Series I Warrant”) to purchase a share of our common stock for the combined purchase price of $0.175 per unit. The Series I Warrants have an exercise price of $0.22 per share and are exercisable for a period of five years. The offering closed on October 18, 2019. The gross proceeds to the Company from the 2019 Financing were approximately $2.5 million before deducting financing costs of approximately $333,000. Pursuant to the Engagement Agreement, the Company also agreed to issue to the Placement Agent, or its designees, warrants to purchase up to 1,071,429 shares (the “Placement Agent Warrants”). The Placement Agent Warrants have substantially

the same terms as the Series I Warrants, except that the exercise price of the Placement Agent Warrants is $0.21875 per share and the term of the Placement Agent Warrants is five years.

On March 23, 2020, we announced thatthe FDA provided clearance to market AC5® Topical Gel that is manufactured using an additional supplier and manufacturing processes. AC5® Topical Gel is intended for use in the management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds.

On April 13, 2020 we announced receipt of the CE (Conformité Européenne) mark for a first-in-class wound care product, AC5™ Topical Hemostat, allowing for commercialization in Europe as a dressing and to control bleeding in external skin wounds in both out- and in-patient settings.

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

The PPP Loan has a two-year term and bears interest at a rate of 1.00% per annum. Monthly principal and interest payments are deferred until the earliest of ten months after the end of our covered period or the date the SBA makes a decision on our loan forgiveness application. Unless the PPP Loan is forgiven, the Company will be required to make monthly payments of principal and interest of approximately $20,000 to the Lender.

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

Under the terms of the CARES Act, PPP loan recipients can apply for and be granted forgiveness for all or a portion of loan granted under the PPP. Such forgiveness will be determined, subject to limitations, based on the use of loan proceeds for payment of payroll costs and any payments of mortgage interest, rent, and utilities. However, no assurance is provided that forgiveness for any portion of the PPP Loan will be obtained. During November 2020, the Company applied for forgiveness of the PPP loan.

On June 4, 2020, the Company issued unsecured 10% Series 1 Convertible Notes in the aggregate principal amount of $550,000. The Series 1 Convertible Notes provide, among other things, for (i) a term of approximately three (3) years; (ii) the Company's ability to prepay the Series 1 Convertible Notes, in whole or in part, at any time; (iii) the automatic conversion of the Series 1 Convertible Notes upon a Change of Control (all capitalized terms not otherwise defined to have the meaning ascribed to such terms in the Convertible Notes) into shares of the Company's common stock, par value $0.001 per share ("**Common Stock**"), at a per share price of $0.27 (the "Conversion Price"); (iv) the ability of a holder of a Series 1 Convertible Note (a "**Holder**") to convert the Convertible Note and accrued interest, in whole or in part, into shares of Common Stock at the Conversion Price; (v) the Company's ability to convert all Note Obligations outstanding upon a Qualified Equity Financing into shares of Common Stock at the Conversion Price; (vi) the Company's ability to convert Convertible Notes and accrued interest, in whole or in part, into shares of Common Stock at the Conversion Price in the event the volume weighted average price ("VWAP") of the Common Stock equals or exceeds $0.32 per share for at least fifteen (15) consecutive Trading Days; (vii) the Company's ability to convert all outstanding Note Obligations into shares of Common Stock at the Conversion Price (an "**In-Kind Note Repayment**") in lieu of repaying the Note Obligations outstanding on the Maturity Date, June 30, 2023; provided, however, that in the case of an In-Kind Note Repayment, the outstanding Note Obligations will be calculated by increasing by thirty-five percent (35%) the aggregate sum of the unpaid Principal Amount held by each Holder and the accrued interest at a rate of ten percent (10%) per annum, subject to, with respect to any portion of the Principal Amount that is converted or prepaid before the twelve month anniversary of the Issuance Date, a minimum interest payment equal to ten percent (10%) of the amount that is converted or prepaid.

On June 3, 2020, the Company entered into an agreement (the "**Agreement**") with the holders of a majority (the "**Majority Holders**") of the outstanding Series D Warrants (the "**Warrant**") resulting in approximately $850,000 of proceeds as a result of the full exercise of their Warrants. The Agreement provides for the reduction of the Series D Warrant exercise price from $0.25 to $0.18 per share, and the elimination of a provision that prevents the Series D Warrants from being exercised if the holder's beneficial ownership would exceed 4.9% as a result. Under the terms of the Agreement, in exchange for fully exercising their remaining Warrants for 4,727,273 shares of common stock on June 4, 2020, the Majority Holders were issued Series J Warrants to purchase 3,545,454 shares of common stock at an exercise price of $0.25 over a 1 year term.

On June 22, 2020, the Company entered into a Series J Warrant Issuance Agreement (the "Keyes Sulat Agreement") with the Keyes Sulat Revocable Trust (the **Trust**"), also a holder of outstanding Series D Warrants, resulting in approximately $82,000 of proceeds as a result of the full exercise of the Trust's Warrants. Under the terms of the Keyes Sulat Agreement, in exchange for fully exercising the Trust's remaining Warrants for 454,546 shares of common stock on June 22, 2020, the Trust was issued Series J Warrants to purchase 340,910 shares of common stock at an exercise price of $0.25 over a 1 year term. James R. Sulat, a member of the Board, is a co-trustee of the Trust, of which members of Mr. Sulat's immediate family are beneficiaries. Mr. Sulat disclosed his interest in the Trust to the Board prior to its approval of the transaction and abstained from voting on the transaction. On June 30, 2020, the remaining 3,792,570 Series D Warrants expired.

On July 1, 2020, a special meeting of the Company was held. At the meeting, the stockholders approved an increase to the number of authorized shares of our common stock, par value $0.001 per share ("**Common Stock**"), from 300,000,000 to 800,000,000 shares. The results of the stockholders' vote were 103,553,044 votes for, 33,707,332 votes against and 3,678,519 abstained.

On November 6, 2020, the Company issued unsecured 10% Series 2 Convertible Notes in the aggregate principal amount of $1,050,000. The Series 2 Convertible Notes provide, among other things, for (i) a term of approximately three (3) years; (ii) the Company's ability to prepay the Series 2 Convertible Notes, in whole or in part, at any time; (iii) the automatic conversion of the Convertible Notes upon a Change of Control (all capitalized terms not otherwise defined to have the meaning ascribed to such terms in the Series 2 Convertible Notes) into shares of the Company's common stock, par value $0.001 per share (Common Stock), at a per share price of $0.25 (the "**Conversion Price**"); (iv) the ability of a holder of a Convertible Note (a "**Holder**") to convert the Convertible Note and accrued interest, in whole or in part, into shares of Common Stock at the Conversion Price; (v) the Company's ability to convert all Note Obligations outstanding upon a Qualified Equity Financing into shares of Common Stock at the Conversion Price; (vi) the Company's ability to convert Convertible Notes and accrued interest, in whole or in part, into shares of Common Stock at the Conversion Price in the event the volume weighted average price ("VWAP") of the Common Stock equals or exceeds $0.32 per share for at least fifteen (15) consecutive Trading Days; (vii) the Company's ability to convert all outstanding Note Obligations into shares of Common Stock at the Conversion Price (an "**In-Kind Note Repayment**") in lieu of repaying the Note Obligations outstanding on the Maturity Date, November 30, 2023; provided, however, that in the case of an In-Kind Note Repayment, the outstanding Note Obligations will be calculated by increasing by thirty-five percent (35%) the aggregate sum of the unpaid Principal Amount held by each Holder and the accrued interest at a rate of ten percent (10%) per annum, subject to, with respect to any portion of the Principal Amount that is converted or prepaid before the twelve month anniversary of the Issuance Date, a minimum interest payment equal to ten percent (10%) of the amount that is converted or prepaid.

In addition, on November 6, 2020, as consideration for an investment in the Convertible Notes, the Company entered into an Amendment to the Series J Warrant to Purchase Common Stock, with a holder of a Series J Warrant exercisable for up to 3,375,000 shares of Common Stock, to extend the term of the Series J Warrant from one (1) year to thirty (30) months.

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, 2020 Compared to Year Ended September 30, 2019

	September 30, 2020	September 30, 2019	Increase (Decrease)
Revenue	$ -	$ -	$ -
Operating Expenses			
General and Administrative	3,759,554	3,974,919	(215,365)
Research and Development	1,611,094	2,396,838	(785,744)
Loss from Operations	(5,370,648)	(6,371,757)	(1,001,109)
Other Income	679,271	1,824,175	(1,144,904)
Net Loss	$ (4,691,377)	$ (4,547,582)	$ 143,795

Revenue

We did not generate any revenue in either of the years ended September 30, 2020 or 2019.

General and Administrative Expense

General and administrative expenses during the fiscal year ended September 30, 2020 were $3,759,554 a decrease of $215,365 compared to $3,974,919 for the fiscal year ended September 30, 2019. The decrease in general and administrative expense is primarily attributable to a decrease in stock-based compensation, defense of patent and patent prosecution costs and consulting costs partially offset by the increases in payroll costs and corporate legal fees. General and administrative expenses are generally expected to increase during fiscal 2021 as a result of the establishment and execution of commercialization efforts, additional staffing, increased stock-based compensation as well as increased costs associated with the Company's continued fundraising efforts.

Research and Development Expense

Research and development expense during the fiscal year ended September 30, 2020 was $1,611,094, a decrease of $785,744 compared to $2,396,838 for the fiscal year ended September 30, 2019. The decrease in research and development expense is primarily attributable to a decrease in product and development costs, preparation of regulatory filings and compensation costs. Research and development expenses are expected to increase during fiscal 2021 as a result of our plans for additional product development, clinical and regulatory programs.

O*ther Income/(Expense)*

Other income during the year ended September 30, 2020 was $679,271, a decrease of $1,144,904 compared to total other income of $1,824,175 for the year ended September 30, 2019. The net decrease in other income was the result of the change in the fair value of derivative liabilities.

Liquidity and Capital Resources

Working Capital

At September 30, 2020, we had total current assets of $2,142,975 (including cash of $959,309) and working capital of $1,496,734. Our working capital as of September 30, 2020 and September 30, 2019 is summarized as follows:

	September 30, 2020	September 30, 2019
Total Current Assets	$ 2,142,975	$ 2,889,681
Total Current Liabilities	646,241	713,811
Working Capital	$ 1,496,734	$ 2,175,870

Total current assets as of September 30, 2020 were $2,142,975, a decrease of $746,706 compared to $2,889,681 as of September 30, 2019. The decrease in current assets is primarily attributable to general and administrative expenses and research and development expenses incurred in connection with activities to develop our primary product candidate partially offset by $2,167,162 received from the issuance of common stock and warrants, $176,300 received from the PPP Loan, $550,000 received from the issuance of convertible notes and $932,728 from the exercise of Series D Warrants. Our total current assets as of September 30, 2020 and September 30, 2019 were comprised primarily of cash, inventory and prepaid expenses and other current assets.

Total current liabilities as of September 30, 2020 were $646,241, a decrease of $67,570 compared to $713,811 as of September 30, 2019. The decrease is primarily due to a decrease in accounts payable partially offset by the current portion of the PPP Loan and an increase in accrued expenses and other liabilities. Our total current liabilities as of September 30, 2020 were comprised of accounts payable, accrued expenses and other liabilities and the current portion of the PPP loan. Our total current liabilities as of September 30, 2019 were comprised of accounts payable and accrued expenses and other liabilities.

Cash Flow

	September 30, 2020	September 30, 2019
Cash Used in Operating Activities	$ (5,044,755)	$ (5,268,302)
Cash Used in Investing Activities	(2,455)	-
Cash Provided by Financing Activities	3,826,190	2,781,221
Net decrease in cash	$ (1,221,020)	$ (2,487,081)

Cash Used in Operating Activities

Cash used in operating activities decreased $223,547 to $5,044,755 during the fiscal year ended September 30, 2020 compared to $5,268,302 for the fiscal year ended September 30, 2019. The decrease in cash used in operating activities is primarily attributable to a reduction in consulting costs, payroll and product and development costs partially offset by inventory costs.

Cash Used in Investing Activities

Cash used in investing activities increased $2,455 to $2,455 during the fiscal year ended September 30, 2020, compared to $0 during the fiscal year ended September 30, 2019.

For the fiscal year ended September 30, 2020, cash used in investing activities is attributed to computer hardware purchases.

Cash Provided by Financing Activities

Cash provided by financing activities increased $1,044,969, to $3,826,190 during the fiscal year ended September 30, 2020, compared to $2,781,221 during the fiscal year ended September 30, 2019. For the year ended September 30, 2020, the cash provided by financing activities resulted from $2,167,162 from the issuance of common stock and warrants in the October 2019 Financing, $176,300 received from the PPP loan, $550,000 received from the issuance of a convertible note and $932,728 from the exercise of Series D Warrants. For the year ended September 30, 2019, the cash provided by financing activities resulted from $2,748,821 from the issuance of common stock and warrants in the 2019 Financing and $32,400 from the exercise of stock option to purchase 87,567 shares of our Common Stock.

Cash Requirements

We anticipate that our operating and other expenses will increase significantly as we continue to implement our business plan and pursue our operational goals. As of December 10, 2020, we believe that our current cash on hand will meet our anticipated cash requirements into the second quarter of fiscal 2021. Notwithstanding this, depending upon additional input from EU and US regulatory authorities, we do not expect to generate sufficient revenues from operations before we need to raise additional capital. Further, our estimates regarding our use of cash could change if we encounter unanticipated difficulties or other issues arise, including without limitation those set forth under the heading " **RISK FACTORS** " in this filing, in which case our current funds may not be sufficient to operate our business for the period we expect.

To date we have generated no operating revenues. We expect to generate revenue in the near future. 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 principal product candidate, seeking regulatory approval of that or any other product candidate we may choose to develop, commercializing any product candidate 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 2017 SPA and 2018 SPA 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 2017 SPA and 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 2017 Financing and the 2018 Financing collectively own less than 20% of the Series F Warrants and Series G Warrants purchased by them pursuant to the 2017 SPA and 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. In addition, as described in greater detail under the Risk Factor entitled "***The terms of the 2017 Financing, 2018 Financing and October 2019 Financing could impose additional challenges on our ability to raise funding in the future***," included in this Annual Report on Form 10-K, the 2017 SPA and the 2018 SPA imposes certain restrictions on our ability to issue equity or debt securities

Going Concern

From inception, we have not earned operating revenues from sales of products or services and have recurring losses from operations. While the Company anticipates that it will have enough cash on hand into the second quarter of fiscal 2021, the continuation of our business as a going concern is dependent upon raising additional capital and eventually attaining and maintaining profitable operations. As of September 30, 2020, there is substantial doubt about the Company's ability to continue as a going concern. The financial statements included in this Annual Report on Form 10-K do not include any adjustments that might be necessary should operations discontinue.

Critical Accounting Policies

Pursuant to certain disclosure guidance issued by the SEC, the SEC defines "critical accounting policies" as those that require the application of management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Our critical accounting policies that we anticipate will require the application of our most difficult, subjective or complex judgments are as follows:

Basis of Presentation

The audited consolidated financial statements presented with this Form 10-K 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.

The Company has devoted substantially all of its efforts to developing technologies, raising capital, establishing customer and vendor relationships, and recruiting new employees.

Use of Estimates

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

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 ASC 360*Property, Plant and Equipment*. For assets that are to be held and used, impairment is recognized when the estimated undiscounted cash flows associated with the asset or group of assets is less than their carrying value. If impairment exists, an adjustment is made to write the asset down to its fair value, and a loss is recorded as the difference between the carrying value

and fair value. Fair values are determined based on quoted market values, discounted cash flows or internal and external appraisals, as applicable. Assets to be disposed of are carried at the lower of carrying value or estimated net realizable value.

Research and Development

We expense internal and external research and development costs, including costs of funded research and development arrangements, in the period incurred.

Accounting for Stock-Based Compensation

The Company accounts for employee and nonemployee stock-based compensation in accordance with the guidance of Financial Accounting Standards Board ("FASB") ASC Topic 718, *Compensation-Stock Compensation* ("FASB ASC Topic 718"), which requires all share-based payments to be recognized in the consolidated financial statements based on their fair values. In accordance with FASB ASC Topic 718, we have elected to use the Black-Scholes option-pricing model to determine the fair value of options granted and we recognize 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. Prior to January 1, 2018, the Company did not have a sufficient history of market prices of the Common Stock, and as such volatility was estimated in accordance with ASC 718-10-S99 *Compensation-Stock Compensation* ("ASC 718-10-S99"). Prior to January 1, 2018, the Company's expected volatility was derived from the historical daily change in the market price of its common stock since it exited shell company status, as well as the historical daily change in the market price for the peer groups as determined by the Company. Effective January 1, 2018, the Company is using its historical market prices to calculate the volatility of its common stock. The life term 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. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Stock-based compensation expense, when recognized in the financial statements, is based on awards that are ultimately expected to vest.

Fair Value Measurements

We measure 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 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 our own views about the assumptions market participants would use in pricing the asset or liability.

Income Taxes

In accordance with FASB ASC 740,*Income Taxes*, we recognize 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.

We provide reserves for potential payments of tax to various tax authorities related to uncertain tax positions when management determines that it is probable that a loss will be incurred related to these matters and the amount of the loss is reasonably determinable.

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*. 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, goods-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.

Recent Accounting Guidance

Accounting Standards Update (ASU) 2018-07, *Compensation—Stock Compensation (Topic 718) Improvements to Nonemployee Share-Based Payment Accounting* was issued by the Financial Accounting Standards Board (FASB) in June 2018. The purpose of this amendment is to address aspects of the accounting for nonemployee share-based payment transactions. The amendments in this Update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted. The Company adopted ASU 2018-07 during our first quarter of fiscal year 2020, and the impact was considered immaterial on our consolidated financial statements.

ASU 2016-02, *Leases (Topic 842)* was issued by the FASB in February 2016. The purpose of this amendment is to recognize most operating leases by recording a right-to-use asset and corresponding lease liability. The amendments in this Update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2018. The Company adopted ASU 2016-02 during our first quarter of fiscal year 2020, and the impact has been recorded within the consolidated financial statements using the modified retrospective method.

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 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, 2020, pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures are effective as of September 30, 2020 in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms.

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, 2020.

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, 2020, there have been no changes in our internal control over financial reporting that have materially affected or are reasonably likely to materially affect our internal controls over financial reporting. From time to time, we make changes to our internal control over financial reporting that are intended to enhance its effectiveness and which do not have a material effect on our overall internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

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	55	April 2013
James R. Sulat	Director	70	August 2015
Punit Dhillon	Director	40	July 2018
Richard E. Davis	Chief Financial Officer	62	July 2014

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-U.S. pharmaceutical equities at Sanford C. Bernstein in New York City. Dr. Norchi earned an M.B.A. from the Massachusetts Institute of Technology, Sloan School of Management in 1996. Dr. Norchi earned an M.D. degree in 1990 from Northeast Ohio Medical University and completed his internal medicine residency in 1994 at Baystate Medical Center, Tufts University School of Medicine, where he was selected to serve as the Chief Medical Resident. Dr. Norchi brings to our Board 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 Overseers of the Boston Museum of Science.

James R. Sulat. Mr. Sulat joined our Board of Directors in August 2015. Mr. Sulat has served as a member of the Supervisory Board for Valneva SE, a European biotech company focusing on vaccines, since 2005. In addition, Mr. Sulat has served as a member of the Board of Directors for AMAG Pharmaceuticals, Inc., a pharmaceutical company focused on the development and commercialization of specialty pharmaceutical products, since 2014. Previously, Mr. Sulat served as the Chief Executive Officer and Chief Financial Officer for Maxygen, Inc., from 2009 to 2013. Mr. Sulat also served as a member of the Board of Directors for Maxygen, Inc., from 2003 to 2013. Prior to that, Mr. Sulat served as the Chief Executive Officer, Chief Financial Officer and a member of the Board of Directors for Memory Pharmaceuticals Corp., from 2005 to 2008. Mr. Sulat previously served in senior executive roles for R.R. Donnelley & Sons, Co., Chiron Corporation, Stanford Health Services, Inc., and Esprit de Corp, Inc. Mr. Sulat also previously served as a member of the Board of Directors for Momenta Pharmaceuticals, Inc., Tolero Pharmaceuticals, Inc., Diadexus, Inc., Codexis, Inc., Ariat International, Inc., General Surgical Innovations, Inc., and Vans, Inc. Mr. Sulat received a B.S. in Administrative Sciences from Yale University, and an M.B.A. and an M.S. in Health Services Administration from Stanford University.

Punit Dhillon. Mr. Dhillon joined our Board of Directors in July 2018. Mr. Dhillon brings over 15 years of global industry experience to Arch's Board with a wealth of knowledge and experience operationally in medical devices, advancing programs from scientific research through clinical development, regulatory approval, and into healthcare systems globally. Mr. Dhillon's business and management experience includes corporate finance, integration, intellectual property licensing, strategy implementation, mergers and acquisitions and collaborations with academic and other institutions. Strategic partnerships established by Mr. Dhillon include early and late stage deals with Merck and Pfizer. Mr. Dhillon co-founded and previously served as Chief Executive Officer and a member of the board of directors of OncoSec, a biotechnology company pioneering new technologies to stimulate the body's immune system to target and attack cancer. Prior to that, Mr. Dhillon served as Vice President of Finance and Operations at Inovio Pharmaceuticals, Inc. (formerly Inovio Biomedical Corporation), a DNA vaccine development company, from September 2003 until March 2011. Mr. Dhillon is also a director of Emerald Health Sciences, Inc. and Audit Committee Chair of Emerald Health Therapeutics, Inc. (TSXV: EMH) and Emerald Bioscience, Inc. (OTCQB: NMUS). Mr. Dhillon was recognized as one of the "Top 100 CEOs" by PharmaVoice in 2013, as "Most Admired CEO" by The San Diego Business Journal in 2016, and as a finalist for Ernst & Young's Annual "Entrepreneur of the Year." Mr. Dhillon has a Bachelor of Arts with honors in Political Science and a minor in Business Administration from Simon Fraser University.

Richard E. Davis. Mr. Davis brings a proven and successful record of more than 25 years of progressive and diversified business, financial and operational leadership within both publicly traded and privately held, domestic and multinational companies. From July 2001 through July 2014, he has been an advisor to small and mid-size companies assisting them in their strategizing, accounting, financial reporting, and investor and banking needs. From February 2001 until June 2011, he was President, Chief Operating Officer and Chief Financial Officer at NMT Medical, Inc., a NASDAQ-traded medical device company. Mr. Davis also served on its Board of Directors. In this role he developed and executed strategic and operational plans that resulted in revenue growth of 35 percent, 13 consecutive quarters of profitability, increased stock price and analyst coverage from five major investment firms; directed the stabilization of a French subsidiary and led successful efforts in raising $6 million from institutional investors to fund ongoing FDA-approved clinical trials. Prior to that, he was Vice President and Chief Financial Officer at Q-Peak, Inc., where he oversaw all financial and administrative functions. Earlier, he worked in a variety of senior level positions at the Coleman Company, The TJX Companies, Inc. and Wang Laboratories. He holds a Master of Business Administration degree with a Finance concentration from Babson College and a Bachelor of Business Administration degree from the University of Massachusetts Amherst.

Term of Office of Directors

Our directors are elected at each annual meeting of stockholders and serve until the next annual meeting of stockholders or until their successor has been duly elected and qualified, or until the earlier of their death, resignation or removal.

Family Relationships

On July 20, 2018, the Company announced that the Board appointed Punit Dhillon (“Mr. Dhillon”), the co-founder and former President and CEO of OncoSec Medical Incorporated (“OncoSec”), a biotechnology company pioneering new technologies to stimulate the body’s immune system to target and attack cancer, as a director of the Company effective on July 19, 2018. Mr. Dhillon is the nephew of Dr. Avtar Dhillon (“Dr. Dhillon”), who was previously chairman of the board of directors of the Company, was previously a member of the board of directors of OncoSec, and is currently a Chairman of the board of directors of Emerald Health Sciences, Inc. Dr. Dhillon is also currently serving as an advisor to the Company.

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

Our Board of Directors has not established a separate standing audit committee within the meaning of Section 3(a)(58)(A) of the Exchange Act. Instead, the entire Board of Directors presently acts as the audit committee within the meaning of that section and will continue to do so upon the appointment of any new directors until such time as a separate standing audit committee has been established. Our Board of Directors has determined that each member is an “audit committee financial expert” as defined by applicable SEC rules.

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.

ITEM 11. EXECUTIVE COMPENSATION

The following table summarizes all compensation recorded by us in each of the fiscal years ended September 30, 2020 and September 30, 2019 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	2020	438,111	81,090	-	178,300	-	697,501
President and Chief Executive Officer	2019	429,250	-	-	-	-	429,250
Richard E. Davis	2020	335,513	51,750	-	124,810	-	512,073
Chief Financial Officer	2019	328,333	-	-	-	-	328,333

(1) Represents the aggregate grant date fair values of awards granted during the fiscal year ended September 30, 2020 under ASC Topic 718, which is calculated as of the grant date using a Black-Scholes option-pricing model. Accordingly, the dollar amounts listed do not necessarily reflect the dollar amount of compensation that may be realized by our executive officers. For information on the valuation assumptions with respect to option grants made during the fiscal year ended September 30, 2020 refer to Note 14 "Stock-Based Compensation" in our consolidated financial statements included in this filing.

Employment Agreements with Named Executive Officers

Terrence W. Norchi

On June 25, 2013, we entered into an executive employment agreement with Dr. Terrence W. Norchi, our President and Chief Executive Officer and a member of our Board of Directors, which became effective as of June 26, 2013. Dr. Norchi's employment agreement continues until terminated by Dr. Norchi, or us and provided for an initial annual base salary of $275,000, and eligibility to receive an annual cash bonus in an amount up to 30% of Dr. Norchi's then-current annual base salary. In addition, Dr. Norchi's employment agreement provides that his annual base salary will be reviewed from time to time in accordance with the established procedures of the Company for adjusting salaries for similarly situated employees. Annual bonuses are awarded at the sole discretion of our Board of Directors. If Dr. Norchi's employment is terminated by us (unless such termination is "For Cause" (as defined in his employment agreement)), or by Dr. Norchi for "Good Reason" (as defined in his employment agreement), then Dr. Norchi, upon signing a release in favor of the Company, will be entitled to severance in an amount equal to 12 months of Dr. Norchi's then-current annual base salary, payable in the form of salary continuation, plus, if Dr. Norchi elects and subject to certain other conditions, payment of Dr. Norchi's premiums to continue his group health coverage under COBRA until the earlier of (i) 12 months following the date of such termination; or (ii) the date Dr. Norchi becomes covered under another employer's health plan. In addition, Dr. Norchi's employment agreement provides that, in the event of a change of control of the Company, termination by Dr. Norchi for Good Reason, termination by the Company for any reason other than For Cause, or termination as a result of Dr. Norchi's death, all unvested shares under outstanding equity grants to Dr. Norchi, if any, shall automatically accelerate and become fully vested. On March 13, 2014, Mr. 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.

Richard E. Davis

On July 7, 2014, we entered into an executive employment agreement with Mr. Davis, our Chief Financial Officer and Treasurer. The agreement continues until terminated by us or by Mr. Davis. Pursuant to the terms of the agreement, Mr. Davis is entitled to an initial annual base salary of $200,000 and is eligible to receive an annual cash bonus in an amount of up to 25% of Mr. Davis' then-current annual base salary. Annual bonuses are awarded at the sole discretion of our Board of Directors. In addition, Mr. Davis' 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. Davis' employment is terminated by us at any time after August 7, 2014 (unless such termination is "For Cause" (as defined in his employment agreement)), or by Mr. Davis for "Good Reason" (as defined in his employment agreement), then Mr. Davis, upon signing a release in favor of the Company, would be entitled to severance in an amount equal to six months of Mr. Davis' then-current annual base salary, payable in the form of salary continuation, plus, if Mr. Davis elects and subject to certain other conditions, payment of Mr. Davis' 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. Davis becomes covered under another employer's health plan. In addition, Mr. Davis' 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. Davis, if any, shall automatically accelerate and become fully vested. On July 27, 2015, Mr. Davis's employment agreement was amended to increase his annual base salary by $50,000 to $250,000, retroactively effective as of July 1, 2015. In connection with the Board of Directors' annual review of Mr. Davis' base salary, Mr. Davis' annual base salary was increased to $325,000 effective July 1, 2017. In connection with the Board of Directors' annual review of Mr. Davis' base salary, Mr. Davis' annual base salary was increased to $345,000 effective August 1, 2019.

The 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; and (b) "Good Reason" is, without the executive's written consent, (1) a reduction in the executive's annual base salary comparable to reductions generally applicable to similarly situated executives of the Company if such reduction occurs during the first 365 days of employment and is greater than 15%, (2) a relocation of the executive to a facility or location that is more than 50 miles from his primary place of employment and results in an increase in one-way driving distance by more than 50 miles (provided that any such relocation shall not constitute Good Reason if the executive is permitted to perform his duties remotely from or near his home for two weeks per month), or (3) a material and adverse change in the executive's authority, duties, or responsibilities with the Company or reporting relationship within 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, 2020:

	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	500,000	-(1)	0.35	03/22/2024		
	400,000	-(2)	0.19	01/21/2025		
	355,000	-(3)	0.28	08/17/2025		
	1,250,000	-(4)	0.39	05/02/2026		
	650,000	-(5)	0.65	02/02/2027		
	285,000	75,000(6)	0.425	07/18/2028		
	437,500	562,500(7)	0.2292	12/20/2029		
Richard E. Davis	500,000	-(8)	0.22	07/06/2024		
	500,000	-(9)	0.19	01/21/2025		
	175,000	-(10)	0.28	08/17/2025		
	150,000	-(11)	0.39	05/02/2026		
	500,000	-(12)	0.65	02/02/2027		
	217,708	57,292(13)	0.425	07/18/2028		
	306,250	393,750(14)	0.2292	12/20/2029		

(1) Represents an option to purchase 500,000 shares of Common Stock with a grant date of March 23, 2014. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, 25% of the shares shall vest 12 months following the date of grant and 1/24th 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 400,000 shares of Common Stock with a grant date of January 22, 2015. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, 25% of the shares shall vest 12 months following the date of grant and 1/24th 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 355,000 shares of Common Stock with a grant date of August 1, 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 1,250,000 shares of Common Stock granted on May 3, 2016. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vesting immediately, the remaining unvested Shares subject to the Option shall vest on each of the next thirty-six (36) monthly anniversaries of the date of grant.

(5) Represents an option to purchase 650,000 shares of Common Stock granted on February 3, 2017. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vesting immediately, the remaining unvested Shares subject to the Option shall vest on each of the next thirty-six (36) monthly anniversaries of the date of grant.

(6) Represents an option to purchase 360,000 shares of Common Stock with a grant date of July 19, 2018. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, and 1/36th 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 1,000,000 shares of Common Stock with a grant date of December 20, 2019. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, and 1/36th 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 500,000 shares of Common Stock with a grant date of July 7, 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 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 500,000 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, 2015.

(10) Represents an option to purchase 175,000 shares of Common Stock with a grant date of August 18, 2015. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, and 1/36th of the remaining shares shall vest on each of the monthly anniversaries of the grant date, commencing September 18, 2015.

(11) Represents an option to purchase 150,000 shares of Common Stock granted on May 3, 2016. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vesting immediately, the remaining unvested Shares subject to the Option shall vest on each of the next thirty-six (36) monthly anniversaries of the date of grant.

(12) Represents an option to purchase 500,000 shares of Common Stock granted on February 3, 2017. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vesting immediately, the remaining unvested Shares subject to the Option shall vest on each of the next thirty-six (36) monthly anniversaries of the date of grant.

(13) Represents an option to purchase 275,000 shares of Common Stock granted on July 19, 2018. 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.

(14) Represents an option to purchase 700,000 shares of Common Stock granted on December 20, 2019. 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.

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. Prior to the adoption of the revised director compensation policy, the person serving as the Chairman of our Board of Directors received an aggregate annual cash fee of $110,000 for that chairperson role, and all other non-employee directors received an annual cash fee of $35,000.

The following table summarizes all compensation paid to our non-employee directors during the fiscal year ended September 30, 2020:

Director Compensation Table

	Fees Earned or Paid In Cash ($)	Stock Awards ($)	Option Awards ($)	All other Compensation ($)	Total ($)
James R. Sulat (1)	25,000	-	68,760	-	93,760
Punit Dhillon (2)	50,000	-	68,760	-	118,760

(1) Mr. Sulat was appointed as a member of the Board on August 19, 2015. The aggregate number of shares of Common Stock underlying option awards outstanding as of September 30, 2020 held by Mr. Sulat was 940,000.

(2) 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, 2020 held by Mr. Dhillon was 500,000.

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

Securities Authorized for Issuance under Equity Compensation Plans

On June 18, 2013, our Board of Directors and the holders of a majority of our standing common stock approved and adopted the Arch Therapeutics, Inc. 2013 Stock Incentive Plan (the "Plan"). The Plan permits us to grant a variety of forms of awards, including stock options, stock appreciation rights, restricted stock, restricted stock units, and dividend equivalent rights, to allow us to adapt our incentive compensation program to meet our needs. As of September 30, 2020, the Plan has reserved 28,114,256 shares of our common stock for issuance thereunder in awards granted to employees, directors and/or consultants. The Plan provides that on the first business day of each fiscal year commencing with fiscal year 2013, the number of shares of our common stock reserved for issuance under the Plan for all awards except for incentive stock option awards will be subject to increase by an amount equal to the lesser of (i) 3,000,000 shares, (ii) 4% of the number of shares outstanding on the last day of our immediately preceding fiscal year, or (iii) such lesser number of shares as determined by the administrator of the Plan, which is currently our Board of Directors. As a result of that provision, as of October 1, 2020, the number of shares reserved for issuance under the Plan increased by 3,000,000 to 31,114,256. The following table provides information as of September 30, 2020 with respect to our equity compensation plans:

Equity Compensation Plan Information

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	18,248,346	$ 0.36	4,750,008
Equity compensation plans not approved by security holders	—	—	—
Total	18,248,346	$ 0.36	4,750,008

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 193,044,766 shares of our Common Stock outstanding on December 10, 2020. Shares of our Common Stock subject to options, warrants, or other rights currently exercisable or exercisable within 60 days of December 10, 2020 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 ownership limitations to which certain holders of our Series E Warrants, and Series 2 Unsecured Convertible Promissory Notes, and all the holders of our Series F Warrants, Series G Warrants, Series H Warrants, Series I Warrants and, Placement Agent Warrants, and Series J Warrants are subject to (the "Ownership Limitation). 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 the Ownership Limitation, 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:		
Twelve Pins Partners (2)	10,000,000	5.18%
Ana B. Parker (3)	18,744,291	9.71%
Directors and Executive Officers		
Terrence Norchi (4)	17,549,909	8.91%
James R. Sulat (5)	3,286,053	1.69%
Punit Dhillon (6)	500,000	0.26%
Richard E. Davis (7)	3,308,208	1.69%
Current Directors and Named Executive Officers as a Group (4 persons)	24,644,171	12.24%

Shares of our Common Stock subject to options, warrants, or other rights currently exercisable or convertible or exercisable or convertible within 60 days of December 10, 2020, are deemed to be beneficially owned and outstanding for computing the share ownership and percentage of the person holding such options, warrants or other rights, but are not deemed outstanding for computing the percentage of any other person.

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

(2) Dr. Norchi is the sole member of Twelve Pins Partners, LLC and has sole voting and investment control with respect to the shares it holds. Dr. Norchi disclaims beneficial ownership of these securities except to the extent of his pecuniary interest therein.

(3) Represents (i) 7,863,400 shares of Common Stock owned individually by Ana Parker; (ii) 1,380,891 shares of Common Stock owned individually by Michael A. Parker, Ana Parker's spouse; and (iii) 5,000,000 shares of Common Stock owned through Tungsten III LLC, of which Michael Parker is the sole manager. Excludes 4,500,000 shares of Common Stock that may be acquired upon the exercise of Series D Warrants (which expire on September 30, 2020), any of the 1,583,334 shares of Common Stock that may be acquired upon the exercise of Series E Warrants (which expire May 26, 2021), any of the 600,000 shares of Common Stock that may be acquired upon the exercise of Series G Warrants (which expire July 7, 2023), any of the 1,230,769 shares of Common Stock that may be acquired upon the exercise of Series H Warrants (which expire May 14, 2024) or any of the 3,428,571 shares of Common Stock that may be acquired upon the exercise of Series I Warrants (which expire October 18, 2024), since such warrants cannot be exercised until such time as the holder would not beneficially own, after such exercise, more than 4.9% of the outstanding shares of Common Stock; *provided, however*, that the holder may waive such ownership limitation, in which case such waiver will become effective sixty-one (61) days after the holder's delivery of such waiver notice. As of December 10, 2020, Ms. Parker has not waived such limitation.

(4) Represents (a) 10,000,000 shares of our Common Stock held by Twelve Pins Partners, LLC, with respect to which Dr. Norchi holds sole voting and investment control; (b) 1,419,076 shares issued to Dr. Norchi upon the closing of the Merger in exchange for the cancellation of shares of Common Stock and convertible notes of ABS owned by him immediately prior to the closing of the Merger; (c) 1,130,000 shares of restricted stock granted to Dr. Norchi on May 3, 2016; (d) 650,000 shares of restricted stock granted to Dr. Norchi on February 3, 2017;(e) 360,000 shares of restricted stock granted to Dr. Norchi on July 19, 2018; and (f) 3,990,833 shares subject to options exercisable within 60 days after December 10, 2020. Dr. Norchi disclaims beneficial ownership of the securities held by Twelve Pins Partners, LLC except to the extent of his pecuniary interest therein.

(5) Represents (a) 370,000 shares of our Common Stock directly held by Mr. Sulat; (b) 922,267 shares of our Common Stock held by the Keyes Sulat Revocable Trust; (c) 41,666 shares of our Common Stock held by the Brenna Keyes Sulat Irrevocable Trust; (d) 41,666 shares of our Common Stock held by the Nathaniel Keyes Sulat Irrevocable Trust; (e) a Series D Warrant exercisable for 454,546 shares of our Common Stock, a Series E Warrant exercisable for 83,333 shares of our Common Stock and a Series F Warrant exercisable for 45,833 shares of our Common stock, in each case held by Keyes Sulat Revocable Trust; (f) a Series F Warrant exercisable for 22,916 shares of our Common stock held by the Brenna Keyes Sulat Irrevocable Trust; (g) a Series F Warrant exercisable for 22,916 shares of our Common stock held by the Nathaniel Keyes Sulat Irrevocable Trust; and (h) 1,607,044 shares subject to options exercisable within 60 days after December 10, 2020. Mr. Sulat disclaims beneficial ownership of the securities held by Keyes Sulat Revocable Trust, Brenna Keyes Sulat Irrevocable Trust and Nathaniel Keyes Sulat Irrevocable Trust except, in each case, to the extent of his pecuniary interest therein.

(6) Represents 500,000 shares of our Common Stock subject to options exercisable within 60 days after December 10, 2020.

(7) Represents (a) 103,000 of our restricted Common Stock granted to Mr. Davis on May 3, 2016; (b) 500,000 shares our restricted Common Stock granted to Mr. Davis on February 3, 2017; (c) 275,000 shares our restricted Common Stock granted to Mr. Davis on July 19, 2018; and (d) 2,430,208 shares of our Common Stock subject to options exercisable within 60 days after December 10, 2020.

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

Related Party Transactions

During fiscal years 2020 and 2019, other than with respect to matters relating to the Company's compensation arrangements with its executive officers, there were no transactions between the Company or any of its subsidiaries and any "Related Person" (as that term is defined in Item 404 of Regulation S-K) that would be required to be

reported pursuant to Item 404 of Regulation S-K other than the following:

On June 22, 2020, the Company entered into a Series J Warrant Issuance Agreement (the "Keyes Sulat Agreement") with the Keyes Sulat Revocable Trust (the "Trust"), also a holder of outstanding Series D Warrants, resulting in approximately $82,000 of proceeds as a result of the full exercise of the Trust's Series D Warrants. Under the terms of the Keyes Sulat Agreement, in exchange for fully exercising the Trust's remaining Series D Warrants for 454,546 shares of common stock on June 22, 2020, the Trust was issued Series J Warrants to purchase 340,910 shares of common stock at an exercise price of $0.25 over a 1 year term. James R. Sulat, a member of the Board, is a co-trustee of the Trust, of which members of Mr. Sulat's immediate family are beneficiaries. Mr. Sulat disclosed his interest in the Trust to the Board prior to its approval of the transaction and abstained from voting on the transaction.

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. James R. Sulat and Mr. Punit Dhillon would qualify as "independent" as that term is defined by Nasdaq Listing Rule 5605(a)(2). Further, although we have not established separately designated audit, nominating or compensation board committees, Mr. Sulat and Mr. Dhillon would 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, 2020 and 2019 and all other fees paid by us for services rendered by Moody, Famiglietti & Andronico LLP, our current principal accountant, during the fiscal years ended September 30, 2020 and 2019:

	2020	2019
Audit Fees	$ 129,000	$ 110,350
Audit-Related Fees	-	-
Tax Fees	-	-
All Other Fees	-	-
Total	$ 129,000	$ 110,350

Audit Fees. The fees identified under this caption were for professional services rendered by Moody, Famiglietti & Andronico LLP for the audit of our annual financial statements. The fees identified under this caption also include fees for professional services rendered by Moody, Famiglietti & Andronico LLP for the review of the 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, 2020 and 2019 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.

Pre-Approval Policy

As our Board of Directors has not established a separate standing audit committee, all engagements of our independent registered public accounting firm for 2020 and 2019 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 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-K	3.1	000-54986	12/12/2014
3.2	Amended and Restated Bylaws of Arch Therapeutics, Inc.		8-K	3.1	333-178883	6/24/2013
4.1	Description of Securities	X				
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

Exhibit No.	Exhibit Title	Filed Herewith	Incorporated By Reference			
			Form	Exhibit No.	File No.	Filing Date
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	9/9/2015

Exhibit No.	Exhibit Title	Filed Herewith	Incorporated By Reference			
			Form	Exhibit No.	File No.	Filing Date
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		10-Q	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	Form of Subscription Agreement		8-K	10.1	000-54986	6/2/2016

10.42	Form of Series E Warrants		8-K	10.2	000-54986	6/2/2016
10.43	Registration Rights Agreement dated May 26, 2016, by and among Arch Therapeutics, Inc. and the Purchasers set forth on the signature pages thereto		8-K	10.3	000-54986	6/2/2016
10.44	Securities Purchase Agreement		8-K	10.1	000-54986	02/21/2017

Exhibit No.	Exhibit Title	Filed Herewith	Incorporated By Reference			
			Form	Exhibit No.	File No.	Filing Date
10.45	Form of Series F Warrants		8-K	10.2	000-54986	02/21/2017
10.46	Securities Purchase Agreement		8-K	10.1	000-54986	06/29/2018
10.47	Form of Series G Warrants		8-K	10.2	000-54986	06/29/2018
10.48#	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
10.49#	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
10.50	Securities Purchase Agreement		8-K	10.1	000-54986	05/13/2019
10.51	Form of Series H Warrants		8-K	10.2	000-54986	05/13/2019
10.52	Form of Securities Purchase Agreement		8-K	10.1	000-54986	10/18/2019
10.53	Form of Series I Warrants		8-K	10.2	000-54986	10/18/2019
10.54	Engagement Agreement		8-K	10.3	000-54986	10/18/2019
10.55	Form of Placement Agent Warrant		8-K	10.4	000-54986	10/18/2019
10.56	PPP Note		8-K	10.1	000-54986	04/27/2020
10.57	Form of Amendment to Series D Warrants to Purchase Common Stock		8-K	10.1	000-54986	06/05/2020
10.58	Form of Series J Warrant		8-K	10.2	000-54986	06/05/2020
10.59	Form of Convertible Notes		8-K	10.3	000-54986	06/05/2020
21.1	List of Subsidiaries		8-K	21.1	333-178883	6/26/2013
23.1	Consent of Independent Registered Public Accounting Firm	X				
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 Richard E. Davis, Chief Financial Officer and Treasurer	X				
101.INS	XBRL Instance Document	X				
101.SCH	XBRL Taxonomy Extension Schema Document	X				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	X				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	X				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	X				

Exhibit No.	Exhibit Title	Filed Herewith	Incorporated By Reference			
			Form	Exhibit No.	File No.	Filing Date
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					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.

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

Date: December 11, 2020

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Terrence W. Norchi as his or her true and lawful attorney-in-fact and agent, each with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this report and to file the same, with all exhibits thereto and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that such attorney-in-fact and agent, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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*)	December 11, 2020
/s/ Richard E. Davis Richard E. Davis	Chief Financial Officer (Principal *Financial and Accounting Officer*)	December 11, 2020
/s/ James R. Sulat James R. Sulat	Director	December 11, 2020
/s/ Punit Dhillon Punit Dhillon	Director	December 11, 2020

ARCH THERAPEUTICS, INC. AND SUBSIDIARY

CONSOLIDATED FINANCIAL STATEMENTS

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Arch Therapeutics, Inc. and Subsidiary (the "Company") as of September 30, 2020 and 2019, and the related consolidated statements of operations, changes in stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended September 30, 2020, and the related notes (collectively referred to as the 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, 2020 and 2019, and the results of their operations and their cash flows for each of the years in the two-year period ended September 30, 2020, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

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

Basis for Opinion

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

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

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

/s/ Moody, Famiglietti & Andronico, LLP

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

Tewksbury, Massachusetts

December 11, 2020

Arch Therapeutics, Inc. and Subsidiaries
Consolidated Balance Sheets
As of September 30, 2020 and 2019

ASSETS	September 30, 2020	September 30, 2019
Current assets:		
Cash	$ 959,309	$ 2,180,329
Inventory, net	967,993	346,647
Prepaid expenses and other current assets	215,673	362,705
Total current assets	2,142,975	2,889,681
Long-term assets:		
Property and equipment, net	4,552	9,023
Other assets	3,500	3,500
Total long-term assets	8,052	12,523
Total assets	$ 2,151,027	$ 2,902,204
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 342,050	$ 533,555
Accrued expenses and other liabilities	266,749	180,256
Current portion of PPP Loan	37,442	-
Total current liabilities	646,241	713,811
Long-term liabilities:		
Long-tem portion of PPP loan	138,858	-
Promissory convertible debt	550,000	-
Derivative liability	2,316,419	2,995,690
Total long-term liabilities	3,005,277	2,995,690
Total liabilities	3,651,518	3,709,501
Commitments and contingencies (Note 16)	-	-
Stockholders' deficit :		

Common stock, $0.001 par value, 800,000,000 and 300,000,000 shares authorized as of September 30, 2020 and 2019, respectively, 193,044,766 and 173,577,233 shares issued and outstanding as of September 30, 2020 and September 30, 2019, respectively	193,045	172,612
Additional paid-in capital	41,862,901	37,885,151
Accumulated deficit	(43,556,437)	(38,865,060)
Total stockholders' deficit	(1,500,491)	(807,297)
Total liabilities and stockholders' equity (deficit)	$ 2,151,027	$ 2,902,204

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

Arch Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Operations
For the Years Ended September 30, 2020 and 2019

	Fiscal Year Ended September 30, 2020	Fiscal Year Ended September 30, 2019
Revenues	$ -	$ -
Operating expenses:		
General and administrative expenses	3,759,554	3,974,919
Research and development expenses	1,611,094	2,396,838
Total operating expenses	5,370,648	6,371,757
Operating loss	(5,370,648)	(6,371,757)
Other income		
Decrease to fair value of derivative	679,271	1,824,175
Total other income	679,271	1,824,175
Net loss	$ (4,691,377)	$ (4,547,582)
Earnings per share - basic and diluted		
Net loss per common share - basic and diluted	$ (0.02)	$ (0.03)
Weighted common shares - basic and diluted	188,051,683	166,339,862

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

Arch Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Changes in Stockholders' Equity (Deficit)
For the Years Ended September 30, 2020 and 2019

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance at September 30, 2018	159,815,013	$ 159,815	$ 35,517,491	$ (34,317,478)	$ 1,359,828
Net loss	-	-	-	(4,547,582)	(4,547,582)
Issuance of common stock and warrants, net of financing costs	8,615,384	8,615	1,112,093	-	1,120,708
Shares issued for the exercise of stock options - cashless	477,269	477	(477)	-	-
Shares issued for the exercise of stock options	87,567	88	32,312	-	32,400
Issuance of restricted stock	3,517,000	3,517	(3,517)	-	-
Issuance of restricted stock for services	100,000	100	42,900	-	43,000
Stock based compensation expense	-	-	1,184,349	-	1,184,349
Balance September 30, 2019	172,612,233	$ 172,612	$ 37,885,151	$ (38,865,060)	$ (807,297)
Net loss	-	-	-	(4,691,377)	(4,691,377)
Shares issued for the exercise of warrants	5,181,819	5,182	927,546	-	932,728

Issuance of common stock and warrants, net of financing costs	14,285,714	14,286	2,152,876	-	2,167,162
Issuance of restricted stock	965,000	965	(965)		-
Stock based compensation expense	-	-	898,293	-	898,293
Balance at September 30, 2020	193,044,766	$ 193,045	$ 41,862,901	$ (43,556,437)	$ (1,500,491)

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

Arch Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Cash Flows
For the Fiscal Years Ended September 30, 2020 and 2019

	Fiscal Year Ended September 30, 2020	Fiscal Year Ended September 30, 2019
Cash flows from operating activities:		
Net loss	$ (4,691,377)	$ (4,547,582)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	6,926	8,238
Stock-based compensation	898,293	1,184,349
Issuance of restricted stock for services	-	43,000
Increase in inventory reserve	60,385	-
Decrease to fair value of derivative	(679,271)	(1,824,175)
Changes in operating assets and liabilities:		
(Increase) decrease in:		
Inventory	(681,731)	(346,647)
Prepaid expenses and other current assets	147,032	(210,911)
Increase (decrease) in:		
Accounts payable	(191,505)	372,609
Accrued expenses and other liabilities	86,493	52,817
Net cash used in operating activities	(5,044,755)	(5,268,302)
Cash flows from investing activities:		
Purchases of property and equipment	(2,455)	-
Net cash used in investing activities	(2,455)	-
Cash flows from financing activities:		
Proceeds received from PPP loan	176,300	-
Proceeds received from promissory convertible debt	550,000	-
Proceeds from issued common stock and warrants, net of financing costs	2,167,162	2,748,821
Proceeds from exercise of warrants	932,728	-
Proceeds from exercise of stock options	-	32,400
Net cash provided by financing activities	3,826,190	2,781,221
Net decrease in cash	(1,221,020)	(2,487,081)
Cash, beginning of year	2,180,329	4,667,410
Cash, end of year	$ 959,309	$ 2,180,329
Non-cash financing activities:		
Warrant derivative liability	$ -	$ 1,628,113
Exercise of stock options - cashless	$ -	$ 477
Issuance of restricted stock	$ 965	$ 3,517
Issuance of restricted stock for services	$ 93,500	$ 43,000
Series J Warrants issuance cost	$ 219,737	$ -

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

Notes to the Consolidated Financial Statements

1. DESCRIPTION OF BUSINESS

Arch Therapeutics, Inc., (together with its subsidiary, the "Company" or "Arch") was incorporated under the laws of the State of Nevada on September 16, 2009, under the name "Almah, Inc.". Effective June 26, 2013, the Company completed a merger (the "Merger") with Arch Biosurgery, Inc. (formerly known as Arch Therapeutics, Inc.), a

Massachusetts corporation ("ABS"), and Arch Acquisition Corporation ("Merger Sub"), the Company's wholly owned subsidiary formed for the purpose of the transaction, pursuant to which Merger Sub merged with and into ABS and ABS thereby became the wholly owned subsidiary of the Company. As a result of the acquisition of ABS, the Company abandoned its prior business plan and changed its operations to the business of a biotechnology company. Our principal offices are located in Framingham, Massachusetts.

For financial reporting purposes, the Merger represented a "reverse merger". ABS was deemed to be the accounting acquirer in the transaction and the predecessor of Arch. Consequently, the accumulated deficit and the historical operations that are reflected in the Company's consolidated financial statements prior to the Merger are those of ABS. All share information has been restated to reflect the effects of the Merger. The Company's financial information has been consolidated with that of ABS after consummation of the Merger on June 26, 2013, and the historical financial statements of the Company before the Merger have been replaced with the historical financial statements of ABS before the Merger in this report.

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

The Company has generated no operating revenues to date and is devoting substantially all of its efforts toward product research and development. To date, the Company has principally raised capital through debt borrowings, the issuance of convertible debt, and the issuance of units consisting of common stock and warrants.

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

Basis of Presentation

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

We are a biotechnology company marketing or developing a number of products and are devoting substantially all of its efforts to developing technologies, raising capital, establishing customer and vendor relationships, and recruiting and retaining new employees.

Use of Estimates

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

Recently Issued Accounting Guidance

Accounting Standards Update (ASU) 2018-07, *Compensation—Stock Compensation (Topic 718) Improvements to Nonemployee Share-Based Payment Accounting* was issued by the Financial Accounting Standards Board (FASB) in June 2018. The purpose of this amendment is to address aspects of the accounting for nonemployee share-based payment transactions. The amendments in this Update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted. The Company adopted ASU 2018-07 during our first quarter of fiscal year 2020, and the impact was considered immaterial on our consolidated financial statements.

ASU 2016-02, *Leases (Topic 842)* was issued by the FASB in February 2016. The purpose of this amendment is to recognize most operating leases by recording a right-to-use asset and corresponding lease liability. The amendments in this Update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2018. The Company adopted ASU 2016-02 during our first quarter of fiscal year 2020, and the impact has been recorded within the consolidated financial statement using the modified retrospective method.

Cash

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, 2020 and September 30, 2019.

Inventories

Inventories are stated at the lower of cost or net realizable value. The cost of inventories comprises expenditures incurred in acquiring the inventories, the cost of conversion and other costs incurred in bringing them to their existing location and condition. The cost of raw materials, goods-in-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. Inventory reserves are included in research and development expenses for the fiscal year ended September 30, 2020.

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 ASC 360*Property, Plant*

*and Equipmen*t. For assets that are to be held and used, impairment is recognized when the estimated undiscounted cash flows associated with the asset or group of assets is less than their carrying value. If impairment exists, an adjustment is made to write the asset down to its fair value, and a loss is recorded as the difference between the carrying value and fair value. Fair values are determined based on quoted market values, discounted cash flows or internal and external appraisals, as applicable. Assets to be disposed of are carried at the lower of carrying value or estimated net realizable value. For the years ended September 30, 2020 and 2019 there has not been any impairment of long-lived assets.

Leases

The Company determines if an arrangement is a lease at its inception. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As our lease does not provide an implicit interest rate, we use 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. As of September 30, 2020, our ROU asset is included in prepaid expenses and other current assets and the lease obligations is included in accrued expenses and other current liabilities on our consolidated balance sheets. The impact upon adoption was considered immaterial to the consolidated financial statements. As of September 30, 2020, the right-of-use ("ROU") asset of approximately $39,000 represents our right to use an underlying asset for the lease term and the lease liabilities of approximately $39,000 represents our obligation to make lease payments arising from the lease.

Income Taxes

In accordance with FASB ASC 740,*Income Taxes*, we recognize 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.

We provide reserves for potential payments of tax to various tax authorities related to uncertain tax positions when management determines that it is probable 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.

Accounting for Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with the guidance of FASB ASC Topic 718,*Compensation-Stock Compensation* ("FASB ASC Topic 718"), which requires all share-based payments be recognized in the consolidated financial statements based on their fair values. In accordance with FASB ASC Topic 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. Prior to January 1, 2018, the Company's expected volatility was derived from the historical daily change in the market price of its common stock since it exited shell company status, as well as the historical daily change in the market price for the peer group as determined by the Company. Effective January 1, 2018, the Company's expected volatility is derived from the historical daily change in the market price of its common stock since it exited shell company status. The life term for awards uses 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. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Stock-based compensation expense, when recognized in the consolidated financial statements, is based on awards that are ultimately expected to vest.

Fair Value Measurements

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

At September 30, 2020 and September 30, 2019, the carrying amounts of cash, accounts payable, accrued expenses and other liabilities, approximate fair value because of their short-term nature. The carrying amounts for the PPP Loan and the Promissory convertible debt approximate fair value.

Derivative Liabilities

The Company accounts for its warrants and other derivative financial instruments as either equity or liabilities based upon the characteristics and provisions of each instrument, in accordance with FASB ASC Topic 815, *Derivatives and Hedging*. 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.

Subsequent Events

The Company evaluated all events or transactions that occurred commencing from October 1, 2020 and ending on December 10, 2020 the date which these consolidated financial statements were issued. The Company disclosed material subsequent events in Note 20.

Going Concern Basis of Accounting

As reflected in the consolidated financial statements, the Company has an accumulated deficit, has suffered significant net losses and negative cash flows from operations, has not generated operating revenues, and has limited working capital. The continuation of our business as a going concern is dependent upon raising additional capital and eventually attaining and maintaining profitable operations. In particular, as of September 30, 2020, the Company will be required to raise additional capital, obtain alternative means of financial support, or both, in order to continue to fund operations, and therefore there is substantial doubt about our ability to continue as a going concern. The Company expects to incur substantial expenses into the foreseeable future for the research, development and commercialization of its potential products. In addition, the Company will require additional financing in order to seek to license or acquire new assets, research and develop any potential patents and the related compounds, and obtain any further intellectual property that the Company may seek to acquire. Finally, some of our product candidates or the materials contained therein (such as the Active Pharmaceutical Ingredients ("APIs") for our AC5® product line), are manufactured from facilities in areas impacted by the outbreak of the coronavirus, which could result in shortages due to ongoing efforts to address the outbreak. Historically, the Company has principally funded operations through debt borrowings, the issuance of convertible debt, and the issuance of units consisting of common stock and warrants. Provisions in the Securities Purchase Agreements that the Company entered into on February 20, 2017 ("2017 SPA") and on June 28, 2018 ("2018 SPA") restrict the Company's ability to effect or enter into an agreement to effect any issuance by the Company its subsidiary of Common Stock or securities convertible, exercisable or exchangeable for Common Stock (or a combination of units thereof) involving a Variable Rate Transaction (as defined in the 2017 SPA and 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 2017 Financing and the institutional investors in the 2018 SPA collectively own less than 20% of the Series F Warrants and the Series G Warrants purchased by them pursuant to the 2017 SPA and 2018 SPA, respectively. The continued spread of coronavirus and uncertain market conditions may also limit the Company's ability to access capital. If the Company is unable to obtain adequate capital, the Company may be required to reduce the scope, delay, or eliminate some or all of its planned commercial activities. These conditions, in the aggregate, raise substantial doubt as to the Company's ability to continue as a going concern.

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

3. PROPERTY AND EQUIPMENT

At September 30, 2020 and September 30, 2019, property and equipment consisted of:

	Estimated Useful Life	September 30, 2020	September 30, 2019
Furniture and fixtures	5 years	$ 9,357	$ 9,357
Leasehold improvements	Life of Lease	$ 8,983	$ 8,983
Computer equipment	3 years	$ 11,141	$ 8,686
Lab equipment	5 years	$ 1,000	$ 1,000
		30,481	28,026
Less – accumulated depreciation		25,929	19,003
Property and equipment, net		$ 4,552	$ 9,023

For the years ended September 30, 2020 and 2019 depreciation expense recorded was $6,926 and $8,238, respectively.

4. INCOME TAXES

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

	2020	2019
Net operating loss carryforwards	$ 8,451,214	$ 7,291,333
Capitalized expenditures	1,782,185	1,717,025
Research and experimentation credit carryforwards	928,734	898,610
Stock based compensation	2,321,519	2,139,119
Property and Equipment	3,152	2,234
Accrued expenses	18,518	13,660
Inventory allowance	16,497	-
Deferred rent	-	492
Gross deferred tax assets	13,521,819	12,062,473
Deferred tax asset valuation allowance	(13,521,819)	(12,062,473)
Net deferred tax assets	$ -	$ -

As of September 30, 2020 and 2019, the Company had federal net operating loss carryforwards of approximately $31,157,000 and $26,890,000, respectively, which may be available to offset future taxable income and which would begin to expire in 2026. As of September 30, 2020 and 2019, the Company had federal research and experimentation credit carryforwards of $657,000 and $542,000, respectively, which may be available to offset future income tax liabilities and which would begin to expire in 2029.

As of September 30, 2020 and 2019, the Company had state net operating loss carryforwards of approximately $30,737,000 and $26,560,000, respectively, which may be available to offset future taxable income and which would begin to expire in 2030. As of September 30, 2020 and 2019, the Company had state research and experimentation credit carryforwards of $345,000 and $305,000, respectively, which may be able to offset future income tax liabilities and which would begin to expire in 2023.

As the Company has not yet achieved profitable operations, management believes the tax benefits as of September 30, 2020 and 2019 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 2020 by approximately $1,459,000 and increased in 2019 by approximately $1,835,000. 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.

As of September 30, 2020, the Company is open to examination in the U.S. federal and certain state jurisdictions for tax years ended September 30, 2020, 2019, 2018 and 2017. 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 2019 remain open for examination by the IRS.

5. INVENTORIES

Inventories consist of the following:

	September 30, 2020	September 30, 2019
Goods-in-process	$ 1,028,378	$ 328,500
Raw Material	-	18,147
Inventory Reserves	(60,385)	—
Total	$ 967,993	$ 346,647

The increase in inventory is due to continued manufacturing and receipt of product in preparation for commercialization. There was no reserve as of September 30, 2019. Included in research and development expense for the year ended September 30, 2020 is an increase to the inventory reserve of $60,385 which the majority of which is attributable to required product testing during the manufacturing process. In determining net realizable value, appropriate consideration is given to obsolescence, excessive levels, deterioration, and other factors in evaluating net realizable value.

6. 2015 PRIVATE PLACEMENT FINANCING

Beginning June 22, 2015 and through June 30, 2015, the Company entered into a series of substantially similar subscription agreements (each a "Subscription Agreement") with 20 accredited investors (collectively, the "2015 Investors") providing for the issuance and sale by the Company to the 2015 Investors, in a private placement, of an aggregate of 14,390,754 Units ("Unit") at a purchase price of $0.22 per Unit (the "2015 Private Placement Financing"). Each Unit consisted of a share of Common Stock (the "2015 Shares") and a Series D Warrant to purchase a share of Common Stock at an exercise price of $0.25 per share at any time prior to the fifth anniversary of the issuance date of the Series D Warrant (the "Series D Warrants" and the shares issuable upon exercise of the Series D Warrants, collectively, the "2015 Warrant Shares"). The Company did not engage any underwriter or placement agent in connection with the 2015 Private Placement Financing, and the aggregate gross proceeds raised by the Company in the 2015 Private Placement Financing totaled approximately $3,200,000.

The Company's obligation to issue and sell the 2015 Shares and the Series D Warrants and the corresponding obligation of the 2015 Investors to purchase such 2015 Shares and Series D Warrants were subject to a number of conditions precedent including, but not limited to, the amendment of the Company's Series A Warrants and Series C Warrants to delete certain of the anti-dilution provisions contained therein, and other customary closing conditions. The conditions precedent were satisfied June 30, 2015 (the "Initial Closing Date"), and the Company conducted an initial closing (the "Initial Closing") pursuant to which it sold and 19 of the 2015 Investors (the "Initial Investors") purchased 13,936,367 Units at an aggregate purchase price of $3,066,000. On July 2, 2015, the Company conducted a second closing (the "Second Closing" and together with the Initial Closing, the "Closings") pursuant to which it sold, and one of the 2015 Investors purchased 454,387 Units at an aggregate purchase price of $100,000.

On the Initial Closing Date, the Company entered into a registration rights agreement with the Initial Investors (the "2015 Registration Rights Agreement"), pursuant to which the Company was obligated, subject to certain conditions, to file with the Securities and Exchange Commission within 90 days after the closing of the 2015 Private Placement Financing one or more registration statements (any such registration statement, a "Resale Registration Statement") to register the 2015 Shares and the 2015 Warrant Shares for resale under the Securities Act. The remaining 2015 Investor became a party to the 2015 Registration Rights Agreement upon the consummation of the Second Closing. The Company's failure to satisfy certain filing and effectiveness deadlines with respect to a Resale Registration Statement and certain other requirements set forth in the 2015 Registration Rights Agreement may subject the Company to payment of monetary penalties. On October 27, 2015, we received from the SEC a Notice of Effectiveness of our Registration Statement related to the 2015 Private Placement Financing (the "2015 S-1") which satisfied some of our obligation to register these securities with the SEC.

The 2015 Registration Rights Agreement also obligated the Company to register the resale of all securities covered by the 2015 Registration Rights Agreement on a short-form registration statement on Form S-3 as soon as the Company becomes eligible to use Form S-3. On October 31, 2016, the Company filed a resale registration statement on Form S-3 (the "2015 S-3") to register the remaining securities covered by the 2015 Registration Rights Agreement, and the 2015 S-3 was declared effective on November 23, 2016. Pursuant to Rule 429 promulgated under the Securities Act, the 2015 S-3 contained a combined prospectus that covered the securities that remained unsold under the 2015 S-1 and also registered those same securities under the 2015 S-3. Under Rule 429, the 2015 S-3 also constituted a post-effective amendment to the 2015 S-1, which became effective on the date that the 2015 S-3 was declared effective.

Following each Closing, each 2015 Investor was also issued Series D Warrants to purchase shares of the Company's Common Stock up to 100% of the 2015 Shares purchased by such 2015 Investor under such 2015 Investor's Subscription Agreement. The Series D Warrants have an exercise price of $0.25 per share, are exercisable immediately after their issuance and have a term of exercise equal to five years after their issuance date. The number of shares of the Company's Common Stock into which each of the Series D Warrants is exercisable and the exercise price therefore are subject to adjustment, as set forth in the Series D Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise). In addition, at any time during the term of the Series D Warrants, the Company may reduce the then-current exercise price to any amount and for any period of time deemed appropriate by the Board of the Company.

On June 3, 2020, the Company entered into an agreement (the "**Agreement**") with the holders of a majority (the "**Majority Holders**") of the outstanding Series D Warrants (the "**Warrant**") resulting in approximately $850,000 of proceeds as a result of the full exercise of their Warrants. The Agreement provides for the reduction of the Series D Warrant exercise price from $0.25 to $0.18 per share, and the elimination of a provision that prevents the Series D Warrants from being exercised if the holder's beneficial ownership would exceed 4.9% as a result. Under the terms of the Agreement, in exchange for fully exercising their remaining Warrants for 4,727,273 shares of common stock on June 4, 2020, the Majority Holders were issued Series J Warrants to purchase 3,545,454 shares of common stock at an exercise price of $0.25 over a 1 year term.

On June 22, 2020, the Company entered into a Series J Warrant Issuance Agreement (the "Keyes Sulat Agreement") with the Keyes Sulat Revocable Trust (the **Trust**"), also a holder of outstanding Series D Warrants, resulting in approximately $82,000 of proceeds as a result of the full exercise of the Trust's Warrants. Under the terms of the Keyes Sulat Agreement, in exchange for fully exercising the Trust's remaining Warrants for 454,546 shares of common stock on June 22, 2020, the Trust was issued Series J Warrants to purchase 340,910 shares of common stock at an exercise price of $0.25 over a 1 year term. James R. Sulat, a member of the Board, is a co-trustee of the Trust, of which members of Mr. Sulat's immediate family are beneficiaries. Mr. Sulat disclosed his interest in the Trust to the Board prior to its approval of the transaction and abstained from voting on the transaction.

As a result of the issuance of the Series J Warrants, in conjunction with the exercise of the Series D Warrants, the Company recorded in equity a noncash equity issuance cost valued at approximately $220,000. This charge was estimated using the Black-Scholes Option Pricing Model with the following assumptions; expected volatility, 88.15%, risk-free interest rate, 0.16%, expected forfeiture rate, 0%, expected dividend yield, 0%, expected term, 1.08 years. The series J Warrants are indexed to the Company's stock and are

classified as equity.

During the fiscal year ended September 30, 2020, Series D Warrants had been exercised on a cash basis for an aggregate issuance of 5,181,819 shares of the Company's common stock resulting in gross proceeds to the Company of $932,728. During the fiscal year ended September 30, 2019, no Series D Warrants had been exercised. As of September 30, 2020, 3,792,570 Series D Warrants expired.

Common Stock

At June 30, 2015 the Initial Closing Date of the 2015 Private Placement Financing, the Company issued 13,936,367 shares of Common Stock. On July 2, 2015, the Company conducted the Second Closing pursuant to which it sold and one of the 2015 Investors purchased 454,387 shares of Common Stock.

Equity Value of Warrants

The Company accounted for the Series D Warrants relating to the aforementioned 2015 Private Placement Financing in accordance with ASC 815-40,*Derivatives and Hedging*. Because the Series D Warrants and the Series J Warrants are indexed to the Company's stock, they are classified within stockholders' equity (deficit) in the accompanying consolidated financial statements.

7. 2016 PRIVATE PLACEMENT FINANCING

Beginning May 24, 2016 and through May 26, 2016, we entered into a series of substantially similar subscription agreements (each a "2016 Subscription Agreement") with 18 accredited investors (collectively, the "2016 Investors") providing for the issuance and sale by the Company to the 2016 Investors, in a private placement, of an aggregate of 9,418,334 Units at a purchase price of $0.36 per Unit (the "2016 Private Placement Financing"). Each Unit consisted of a share of Common Stock, and a Series E Warrant to purchase 0.75 shares of Common Stock at an exercise price of $0.4380 per share at any time prior to the fifth anniversary of the issuance date of the Series E Warrant (the "Series E Warrants" and the shares issuable upon exercise of the Series E Warrants, collectively, the "Series E Warrant Shares"). The exercise price of the Series E Warrants was set to equal the closing price of our Common Stock on the date of their issuance (May 26, 2016), which was $0.4380, and therefore the Series E Warrants were not issued at a discount to the market price of our Common Stock as of such date. The gross proceeds to Arch were approximately $3.4 million before deducting financing costs of approximately $281,000.

The number of shares of Common Stock into which each of the Series E Warrants is exercisable and the exercise price therefor are subject to adjustment as set forth in the Series E Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise). In addition, (i) at any time during the term of the Series E Warrants, we may reduce the then-current exercise price to any amount and for any period of time deemed appropriate by our Board of Directors (the "Board"); and (ii) certain of the Series E Warrants provide that they shall not be exercisable in the event and to the extent that the exercise thereof would result in the holder of the Series E Warrant, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder's, would be deemed to beneficially own more than 4.99% of the Common Stock; *provided, however* , the holder, upon notice to us, may increase or decrease the ownership limitation, *provided that* any increase is limited to a maximum of 9.99% of the Company's Common Stock, and any increase in the ownership limitation will not become effective until the 61st day after delivery of such notice.

We engaged Maxim Group LLC ("Maxim") as our exclusive institutional investor placement agent in connection with the 2016 Private Placement Financing, and in consideration for the services provided by it, Maxim was entitled to receive cash fees equal to 8.2% of the gross proceeds received by us from certain institutional investors participating in the 2016 Private Placement Financing (the "Maxim Investors"), as well as reimbursement for all reasonable expenses incurred by it in connection with its engagement. We received gross proceeds of approximately $3,390,600 in the aggregate, of which approximately $2,084,000 was attributable to the Maxim Investors, resulting in a fee of approximately $171,000.On May 26, 2016, we entered into a registration rights agreement with the 2016 Investors (the "2016 Registration Rights Agreement"), pursuant to which we became obligated, subject to certain conditions, to file with the Securities and Exchange Commission (the "SEC") within 45 days after the closing of the 2016 Private Placement Financing one or more registration statements (the "2016 S-1") to register the shares of Common Stock issued in the Closings and the Series E Warrant Shares for resale under the Securities Act of 1933, as amended (the "Securities Act"). As a result, we registered for resale under the 2016 S-1 an aggregate of 16,482,082 shares of Common Stock, representing the 9,418,334 shares issued at the closing of the 2016 Private Placement Financing and the 7,063,748 shares underlying the Series E Warrants. On July 13, 2016, we received from the SEC a Notice of Effectiveness of the 2016 S-1, which satisfied some of our obligation to register these securities with the SEC.

The 2016 Registration Rights Agreement also obligated the Company to register the resale of all securities covered by the 2016 Registration Rights Agreement on a short-form registration statement on Form S-3 as soon as the Company becomes eligible to use Form S-3. On October 31, 2016, the Company filed a resale registration statement on Form S-3 (the "2016 S-3") to register the remaining securities covered by the 2016 Registration Rights Agreement, and the 2016 S-3 was declared effective on November 23, 2016. Pursuant to Rule 429 promulgated under the Securities Act, the 2016 S-3 contained a combined prospectus that covered the securities that remained unsold under the 2016 S-1 and also registered those same securities under the 2016 S-3. Under Rule 429, the 2016 S-3 also constituted a post-effective amendment to the 2016 S-1, which became effective on the date that the 2016 S-3 was declared effective.

Following the Closing, each 2016 Investor was also issued Series E Warrants to purchase shares of the Company's Common Stock up to 75% of the 2016 Shares purchased by such 2016 Investor under such 2016 Investor's Subscription Agreement. The Series E Warrants have an exercise price of $0.438 per share, are exercisable immediately after their issuance and have a term of exercise equal to five years after their issuance date. The number of shares of the Company's Common Stock into which each of the Series E Warrants is exercisable and the exercise price therefore are subject to adjustment, as set forth in the Series E Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise). In addition, at any time during the term of the Series E Warrants, the Company may reduce the then-current exercise price to any amount and for any period of time deemed appropriate by the Board of the Company.

During the fiscal years ended September 30, 2020 and 2019, no Series E Warrants had been exercised. As of September 30, 2020, up to 4,214,582 shares may be acquired upon the exercise of the Series E Warrants.

Common Stock

At May 26, 2016, the Closing Date of the 2016 Private Placement Financing, the Company issued 9,418,334 shares of Common Stock.

Equity Value of Warrants

The Company accounted for the Series E Warrants relating to the aforementioned 2016 Private Placement Financing in accordance with ASC 815-40,*Derivatives and Hedging.* Because the Series E Warrants are indexed to the Company's stock, they are classified within stockholders' equity (deficit) in the accompanying consolidated financial statements.

8. 2017 REGISTERED DIRECT OFFERING

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

On February 20, 2017, the Company entered into Securities Purchase Agreement (the "2017 SPA") with 6 accredited investors (collectively, the "2017 Investors") providing for the issuance and sale by the Company to the 2017 Investors of an aggregate of 10,166,664 units at a purchase price of $0.60 per Unit in a registered offering (the "2017 Financing"). The securities comprising the units sold in the 2017 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, and 0.55 of a Series F Warrant to purchase one share of Common Stock at an exercise price of $0.75 per share at any time prior to the fifth anniversary of the issuance date of the Series F Warrant subject to certain restrictions on exercise (the "2017 Warrants" and the shares issuable upon exercise of the 2017 Warrants, collectively, the "2017 Warrant Shares"). Provisions in the 2017 SPA restrict the Company's 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 2017 SPA) including, but not limited to, an equity line of credit or "At-the-Market" financing facility until the three lead investors in the 2017 Financing collectively own less than 20% of the Series F Warrants purchased by them pursuant to the 2017 SPA. The gross proceeds to Arch from the 2017 Financing, which closed on February 24, 2017, were approximately $6.1 million before deducting financing costs of approximately $112,000.

The number of shares of the Company's Common Stock into which each of the Series F Warrants is exercisable and the exercise price therefore are subject to adjustment, as set forth in the Series F Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise). In addition, at any time during the term of the Series F Warrants, the Company may reduce the then-current exercise price to any amount and for any period of time deemed appropriate by the Board of the Company. In addition, if the Company undergoes a change of control or is involved in a similar transaction, the holder may cause the Company or any successor entity to purchase its Series F Warrant for an amount of cash equal to $0.18 for each share of Common Stock underlying the Series F Warrant.

During the fiscal years ended September 30, 2020 and 2019, no Series F Warrants had been exercised. As of September 30, 2020, up to 5,591,664 shares may be acquired upon the exercise of the Series F Warrants.

Common Stock

At February 24, 2017, the Closing Date of the 2017 Financing, the Company issued 10,166,664 shares of Common Stock.

Derivative Liabilities

The Company accounted for the Series F Warrants relating to the aforementioned 2017 Financing in accordance with ASC 815-10,*Derivatives and Hedging*. Since the Company may be required to purchase its Series F Warrants for an amount of cash equal to $0.18 for each share of Common Stock the underlying Series F Warrants are not classified within stockholders' equity (deficit), they are recorded as liabilities at fair value. They are marked to market each reporting period through the consolidated statement of operations.

On the Closing Date, the derivative liabilities were recorded at fair value of $2,996,110. Given that the fair value of the derivative liabilities was less than the net proceeds of the 2017 Financing of $5,987,122, the remaining proceeds of $2,991,012 were allocated to the Common Stock and additional paid-in capital. During the years ended September 30, 2020 and 2019, $0 and $274,404 were recorded to decrease the fair value of derivative, respectively.

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)	**September 30, 2020**	**September 30, 2019**
Beginning balance at beginning of year	$ 1,000,000	$ 1,274,404
Issuances	—	—
Adjustments to estimated fair value	—	(274,404)
Ending balance at end of year	$ 1,000,000	$ 1,000,000

The derivative liabilities were valued as of September 30, 2020 and September 30, 2019 using the Black Scholes Model with the following assumptions:

	September 30, 2020	**September 30, 2019**
Closing price per share of common stock	$ 0.17	$ 0.24
Exercise price per share	$ 0.75	$ 0.75
Expected volatility	84.17%	78.15%
Risk-free interest rate	0.13%	1.60%
Dividend yield	—	—
Remaining expected term of underlying securities (years)	1.35	2.37

9. 2018 REGISTERED DIRECT OFFERING

On June 28, 2018, the Company entered into a Securities Purchase Agreement ("2018 SPA") with 8 accredited investors ("2018 Investors") providing for the issuance and sale by the Company to the 2018 Investors of an aggregate of 9,070,000 units at a purchase price of $0.50 per Unit in a registered offering ("2018 Financing"). The securities comprising the units sold in the 2018 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, and 0.75 of a Series G Warrant to purchase one share of Common Stock at an exercise price of $0.70 per share at any time prior to the fifth anniversary of the issuance date of the Series G Warrant subject to certain restrictions on exercise ("2018 Warrants") and the shares issuable upon exercise of the 2018 Warrants, ("2018 Warrant Shares"). On June 30, 2018 the shares were recorded as subscribed but not issued. On July 2, 2018, the Closing Date of the 2018 Financing, the Company issued 9,070,000 shares of Common Stock.

The 2018 SPA contains certain restrictions in the Company's ability to conduct subsequent sales of its equity securities. In particular, subject to certain customary exemptions, from June 28, 2018 until 90 days after July 2, 2018 (i.e. September 30, 2018), neither the Company nor any subsidiary shall issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of Common Stock or securities convertible, exercisable or exchangeable for Common Stock. Similarly, until such time the three lead investors collectively own less than 20% of the Series G Warrants purchased by them pursuant to the 2018 SPA, the Company is prohibited from effecting or entering into an agreement to effect any issuance by the Company or 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. The gross proceeds to Arch from the 2018 Financing, which were received as of June 29, 2018, were approximately $4.5 million before deducting financing costs of approximately $74,000.

The number of shares of the Company's Common Stock into which each of the Series G Warrants is exercisable and the exercise price therefore are subject to adjustment, as set forth in the Series G Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise). In addition, if the Company undergoes a change of control or is involved in a similar transaction, the holder may cause the Company or any successor entity to purchase its Series G Warrant for an amount of cash equal to $0.11 for each share of Common Stock underlying the Series G Warrant. During the years

ended September 30, 2020 and 2019, no Series G Warrants had been exercised. As of September 30, 2020, up to 6,802,500 shares may be acquired upon the exercise of the Series G Warrants.

Common Stock

On June 30, 2018 the shares were recorded as subscribed but not issued. On July 2, 2018, the Closing Date of the 2018 Financing, the Company issued 9,070,000 shares of Common Stock.

Derivative Liabilities

The Company accounted for the Series G Warrants relating to the aforementioned 2018 Financing in accordance with ASC 815-10,*Derivatives and Hedging*. Since the Company may be required to purchase its Series G Warrants for an amount of cash equal to $0.11 for each share of Common Stock and the underlying Series G Warrants are not classified within stockholders' equity (deficit), they are recorded as liabilities at fair value. They are marked to market each reporting period through the consolidated statement of operations.

On the Closing Date, the derivative liabilities were recorded at fair value of $2,397,454. Given that the fair value of the derivative liabilities were less than the net proceeds of the 2018 Financing of $4,461,248, the remaining proceeds of $2,063,794 were allocated to the Common Stock Subscribed but Unissued and additional paid-in capital. On July 2, 2018 the Common Stock subscribed but Unissued was recorded as Common Stock. During the years ended September 30, 2020 and 2019, $0 and $1,169,073 were recorded to decrease the fair value of derivative, respectively

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)	**September 30, 2020**	**September 30, 2019**
Beginning balance at beginning of year	$ 748,275	$ 1,917,348
Issuances	—	—
Adjustments to estimated fair value	—	(1,169,073)
Ending balance at end of year	$ 748,275	$ 748,275

The derivative liabilities were valued as of September 30, 2020 and September 30, 2019 using the Black Scholes Model with the following assumptions:

	September 30, 2020	**September 30, 2019**
Closing price per share of common stock	$ 0.17	$ 0.24
Exercise price per share	$ 0.70	$ 0.70
Expected volatility	83.31%	78.72%
Risk-free interest rate	0.15%	1.56%
Dividend yield	—	—
Remaining expected term of underlying securities (years)	2.71	3.73

10. 2019 REGISTERED DIRECT OFFERING

On May 12, 2019, the Company entered into a Securities Purchase Agreement ("2019 SPA") with 5 accredited investors ("2019 Investors") providing for the issuance and sale by the Company to the 2019 Investors of an aggregate of 8,615,384 units at a purchase price of $0.325 per Unit in a registered offering ("2019 Financing"). The securities comprising the units sold in the 2019 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, and a Series H Warrant to purchase one share of Common Stock at an exercise price of $0.40 per share at any time prior to the fifth anniversary of the issuance date of the Series H Warrant subject to certain restrictions on exercise ("2019 Warrants") and the shares issuable upon exercise of the 2019 Warrants, ("2019 Warrant Shares"). As of May 14, 2019, the Company recorded the 8,615,384 shares as Common Stock.

The gross proceeds to Arch from the 2019 Financing, which were received as of May 13, 2019, were approximately $2.8 million before deducting financing costs of approximately $51,200. The number of shares of the Company's Common Stock into which each of the Series H Warrants is exercisable and the exercise price therefore are subject to adjustment, as set forth in the Series H Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise). In addition, if the Company undergoes a change of control or is involved in a similar transaction, the holder may cause the Company or any successor entity to purchase its Series H Warrant for an amount of cash equal to $0.0533 for each share of Common Stock underlying the Series H Warrant. During the fiscal years ended September 30, 2020 and 2019, no Series H Warrants had been exercised. As of September 30, 2020, up to 8,615,384 shares may be acquired upon the exercise of the Series H Warrants.

Common Stock

At May 14, 2019 the Closing Date of the 2019 Financing, the Company issued 8,615,384 shares of Common Stock.

Derivative Liabilities

The Company accounted for the Series H Warrants relating to the aforementioned 2019 Financing in accordance with ASC 815-10,*Derivatives and Hedging*. Since the Company may be required to purchase its Series H Warrants for an amount of cash equal to $0.0533 for each share of Common Stock and the underlying Series H Warrants are not classified within stockholders' equity (deficit), they are recorded as liabilities at fair value. They are marked to market each reporting period through the consolidated statement of operations.

On the Closing Date, the derivative liabilities were recorded at fair value of $1,628,113. Given that the fair value of the derivative liabilities were less than the net proceeds of the 2019 Financing of $2,748,821, the remaining proceeds of $1,120,708 were allocated to the Common Stock and additional-paid-in-capital. During the years ended September 30, 2020 and 2019, $679,271 and $380,698, respectively, was recorded to decrease the fair value of derivative.

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)	**September 30, 2020**	**September 30, 2019**

Beginning balance at beginning of year	$ 1,247,415	$ —
Issuances	—	1,628,113
Adjustments to estimated fair value	(679,271)	(380,698)
Ending balance at end of year	$ 568,144	$ 1,247,415

The derivative liabilities were valued as of September 30, 2020, September 30, 2019 and May 14, 2019 using the Black Scholes Model with the following assumptions:

	September 30, 2020	September 30, 2019	May 14, 2019
Closing price per share of common stock	$ 0.17	$ 0.24	$ 0.283
Exercise price per share	$ 0.40	$ 0.40	$ 0.40
Expected volatility	82.24%	92.11%	93.44%
Risk-free interest rate	0.22%	1.55%	2.20%
Dividend yield	—	—	—
Remaining expected term of underlying securities (years)	3.60	4.61	5.00

11. OCTOBER 2019 REGISTERED DIRECT OFFERING

On October 16, 2019, the Company entered into a Securities Purchase Agreement ("October 2019 SPA") with 7 accredited investors ("October 2019 Investors") providing for the issuance and sale by the Company to the 2019 Investors of an aggregate of 14,285,714 units at a purchase price of $0.175 per Unit in a registered offering ("October 2019 Financing"). The securities comprising the units sold in the October 2019 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, and a Series I Warrant to purchase one share of Common Stock at an exercise price of $0.22 per share at any time prior to the fifth anniversary of the issuance date of the Series I Warrant subject to certain restrictions on exercise ("October 2019 Warrants") and the shares issuable upon exercise of the October 2019 Warrants, ("October 2019 Warrant Shares"). As of October 18, 2019, the Company recorded the 14,285,714 shares as Common Stock. Pursuant to the Engagement Agreement (as defined below), the Company also agreed to issue to the Placement Agent, or its designees, warrants to purchase up to 1,071,429 shares (the "Placement Agent Warrants"). The Placement Agent Warrants have substantially the same terms as the Series I Warrants, except that the exercise price of the Placement Agent Warrants is $0.21875 per share and the term of the Placement Agent Warrants is five years.

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

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

During the year ended September 30, 2020, no Series I Warrants or Placement Agent Warrants had been exercised. As of September 30, 2020, up to 14,285,714 and 1,071,429 shares may be acquired upon the exercise of the Series I Warrants and Placement Agent Warrants, respectively.

Common Stock

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

Equity Value of Warrants

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

12. CONVERTIBLE NOTES

On June 4, 2020, the Company issued unsecured 10% Convertible Notes in the aggregate principal amount of $550,000. The Series 1 Convertible Notes provide, among other things, for (i) a term of approximately three (3) years; (ii) the Company's ability to prepay the Series 1 Convertible Notes, in whole or in part, at any time; (iii) the automatic conversion of the Series 1 Convertible Notes upon a Change of Control (all capitalized terms not otherwise defined to have the meaning ascribed to such terms in the Series 1Convertible Notes) into shares of the Company's common stock, par value $0.001 per share (Common Stock), at a per share price of $0.27 (the "**Conversion Price**"); (iv) the ability of a holder of a Convertible Note (a "**Holder**") to convert the Series 1 Convertible Note and accrued interest, in whole or in part, into shares of Common Stock at the Conversion Price; (v) the Company's ability to convert all Note Obligations outstanding upon a Qualified Equity Financing into shares of Common Stock at the Conversion Price; (vi) the Company's ability to convert Series 1Convertible Notes and accrued interest, in whole or in part, into shares of Common Stock at the Conversion Price in the event the volume weighted average price ("VWAP") of the Common Stock equals or exceeds $0.32 per share for at least fifteen (15) consecutive Trading Days; (vii) the Company's ability to convert all outstanding Note Obligations into shares of Common Stock at the Conversion Price (an "**In-Kind Note Repayment**") in lieu of repaying the Note Obligations outstanding on the Maturity Date, June 30, 2023; provided, however, that in the case of an In-Kind Note Repayment, the outstanding Note Obligations will be calculated by increasing by thirty-five percent (35%) the aggregate sum of the unpaid Principal Amount held by each Holder and the accrued interest at a rate of ten percent (10%) per annum, subject to, with respect to any portion of the Principal Amount that is converted or prepaid before the twelve month anniversary of the Issuance Date, a minimum interest payment equal to ten percent (10%) of the amount that is converted or prepaid.

During the year ended September 30, 2020, the Company recorded interest expense as part of general and administrative expenses of approximately $18,000.

13. PAYROLL PROTECTION PROGRAM LOAN

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

The PPP Loan has a two-year term and bears interest at a rate of 1.00% per annum. Monthly principal and interest payments are deferred until the earliest of ten months after

the end of our covered period or the date the SBA makes a decision on our loan forgiveness application. Unless the PPP Loan is forgiven, the Company will be required to make monthly payments of principal and interest of approximately $20,000 to the Lender.

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

Under the terms of the CARES Act, PPP Loan recipients can apply for and be granted forgiveness for all or a portion of loan granted under the PPP. Such forgiveness will be determined, subject to limitations, based on the use of loan proceeds for payment of payroll costs and any payments of mortgage interest, rent, and utilities. However, no assurance is provided that forgiveness for any portion of the PPP Loan will be obtained. During November 2020, the Company applied for forgiveness of the PPP Loan.

14. STOCK-BASED COMPENSATION

2013 Stock Incentive Plan

On June 18, 2013, the Company established the 2013 Stock Incentive Plan (the "2013 Plan"). Under the 2013 Plan, during the fiscal year ended September 30, 2020, a maximum number of 28,114,256 shares of the Company's authorized and available common stock could be issued in the form of options, stock appreciation rights, sales or bonuses of restricted stock, restricted stock units or dividend equivalent rights, and an award may consist of one such security or benefit, or two or more of them in any combination or alternative. The 2013 Plan provides that on the first business day of each fiscal year commencing with fiscal year 2014, the number of shares of our common stock reserved for issuance under the 2013 Plan for all awards except for incentive stock option awards will be subject to increase by an amount equal to the lesser of (A) 3,000,000 Shares, (B) four (4) percent of the number of shares outstanding on the last day of the immediately preceding fiscal year of the Company, or (C) such lesser number of shares as determined by the Company's Board of Directors (the "Board"). The exercise price of each option shall be the fair value as determined in good faith by the Board at the time each option is granted. On October 1, 2020, the aggregate number of authorized shares under the Plan was further increased by 3,000,000 shares to a total of 31,114,256 shares.

As of September 30, 2020, a total of 19,179,212 options had been issued to employees and directors and 7,717,500 options had been issued to consultants. The exercise price of each option has either been equal to the closing price of a share of our common stock on the date of grant or has been determined to be in compliance with Internal Revenue Section 409A.

Share-based awards

During the year ended September 30, 2020, the Company granted 2,685,000 options to employees and directors and 690,000 options to consultants to purchase shares of common stock under the 2013 Plan**.**

The Company recognizes compensation expense for stock option awards on a straight-line basis over the applicable service period of the award. The service period is generally the vesting period, with the exception of options granted subject to a consulting agreement, whereby the option vesting period and the service period are defined pursuant to the terms of the consulting agreement. Share-based compensation expense for awards granted during the year ended September 30, 2020 was based on the fair market value or grant date fair value estimated using the Black-Scholes Option Pricing Model. The following assumptions were used to calculate the fair value of share based compensation for the year ended September 30, 2020; expected volatility, 79.44% - 119.44%, risk-free interest rate, 0.13% - 3.23%, expected forfeiture rate, 0%, expected dividend yield, 0%, expected term, 5.6 years. Expected price volatility is the measure by which the Company's stock price is expected to fluctuate during the expected term of an option. The Company exited shell company status on June 26, 2013. In situations where a newly public entity has limited historical data on the price of its publicly traded shares and no other traded financial instruments, authoritative guidance is provided on estimating this assumption by basing its expected volatility on the historical, expected, or implied volatility of similar entities whose share option prices are publicly available. In making the determination as to similarity, the guidance recommends the consideration of industry, stage of life cycle, size and financial leverage of such other entities. Prior to January 1, 2018, the Company's expected volatility was derived from the historical daily change in the market price of its common stock since it exited shell company status, as well as the historical daily change in the market price for the peer group as determined by the Company. Effective January 1, 2018, the Company's expected volatility is derived from the historical daily change in the market price of its common stock since it exited shell company status.

For so called "plain vanilla" options granted to employees, the expected term of the options is based upon the simplified method as defined in ASC 718-10-S99 which averages an award's weighted-average vesting period and the contractual term for share options. The Company will continue to use the simplified method until it has the historical data necessary to provide a reasonable estimate of expected life in accordance with ASC Topic 718. The Company's estimation of the expected term for stock options not subject to the simplified method is based upon the contractual term of the option award. For the purposes of estimating the fair value of stock option awards, the risk-free interest rate used in the Black-Scholes calculation is based on the prevailing U.S. Treasury yield. The Company has never paid any dividends on its common stock and does not anticipate paying dividends on its common stock in the foreseeable future.

Stock-based compensation expense recognized in the Company's consolidated statements of operations is based on awards ultimately expected to vest, reduced for estimated forfeitures. Authoritative guidance requires forfeitures to be estimated at the time of grant, and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Since the Company has a limited history of occurrences of stock option forfeitures and a small number of employees it continues to estimate the forfeiture rate of its outstanding stock options as zero but will continually evaluate its historical data as a basis for determining expected forfeitures.

Common Stock Options

Stock compensation activity under the 2013 Plan for the year ended September 30, 2020 follows:

	Option Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at September 30, 2019	15,807,911	$ 0.40	3.14	$ 142,810
Awarded	3,375,000	$ 0.22	—	—
Forfeited/Cancelled	(934,565)	$ 0.44	—	—
Outstanding at September 30, 2020	18,248,346	$ 0.36	2.59	$ 79,330
Vested at September 30, 2020	16,077,006	$ 0.38	2.78	$ 69,305
Vested and expected to vest at September 30, 2020	18,248,346	$ 0.36	2.59	$ 79,330

As of September 30, 2020, 4,750,008 shares are available for future grants under the 2013 Plan. Share-based compensation expense recorded in the Company's Consolidated Statements of Operations for the year ended September 30, 2020 and 2019 resulting from stock options awarded to the Company's employees, directors and consultants was approximately $678,000 and $830,000, respectively. Of this amount during the years ended September 30, 2020 and 2019, $288,000 and $483,000, respectively, were recorded as research and development expenses, and $390,000 and $347,000, respectively were recorded as general and administrative expenses in the Company's Consolidated Statements of Operations.

During the year ended September 30, 2020, no stock options awarded under the 2013 Stock Incentive Plan were exercised for cash. During the year ended September 30, 2019, 87,567 stock options awarded under the 2013 Stock Incentive Plan were exercised for cash resulting in proceeds to the Company of $32,400. During the year ended September 30, 2020, no stock options awarded under the 2013 Stock Incentive Plan were exercised on a cashless basis. During the year ended September 30, 2019, 1,437,433 stock options awarded under the 2013 Stock Incentive Plan were exercised on a cashless basis for an aggregate issuance of 477,269 shares of the Company's Common Stock.

As of September 30, 2020, there is approximately $268,000 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.

Restricted Stock

On July 19, 2018, the Company awarded 745,000 shares of Restricted Stock to members of the Board of Directors and management and 220,000 shares of Restricted Stock to Dr. Avtar Dhillon in his capacity as a consultant. The shares subject to this grant are awarded under the 2013 Plan and shall fully vest on the second anniversary of the date of grant. In addition, in the event of a Change of Control (as such term is defined in the 2013 Plan), 100% of the grants will immediately vest. As of September 30, 2020, all restricted shares have vested.

On September 5, 2018, the Company awarded 100,000 shares of Restricted Stock to a consultant. The shares subject to this grant are awarded under the 2013 Plan and 50,000 vest 90 days from the date of the award and 50,000 vest 365 days from the date of the award. In addition, in the event of a Change of Control (as such term is defined in the 2013 Plan), 100% of the grants will immediately vest. As of September 30, 2020, all restricted shares have vested.

On February 3, 2017, the Company awarded 1,750,000 shares of Restricted Stock to members of the Board of Directors and management. The shares subject to this grant were awarded under the 2013 Plan and fully vested on the second anniversary of the date of grant. In addition, in the event of a Change of Control (as such term is defined in the 2013 Plan), 100% of the grants would have immediately vested.

Restricted stock activity in shares under the 2013 Plan for the years ended September 30, 2020 and 2019 follows:

	2020	2019
Non Vested at September 30, 2019 and 2018	965,000	2,815,000
Awarded	-	—
Vested	(965,000)	(1,850,000)
Forfeited	—	—
Non Vested at September 30, 2020 and 2019	-	965,000

The weighted average restricted stock award date fair value information for the years ended September 30, 2020 and 2019 follows:

	2020	2019
Non Vested at September 30, 2019 and 2018	$ 0.43	$ 0.57
Awarded	—	—
Vested	(0.43)	(0.64)
Forfeited	—	—
Non Vested at September 30, 2020 and 2019	$ -	$ 0.43

For the years ended September 30, 2020 and 2019 compensation expense recorded for the restricted stock awards was approximately $220,000 and $397,000, respectively.

15. RESTRICTED STOCK AWARDED OUTSIDE THE 2013 STOCK INCENTIVE PLAN

On May 3, 2016, the Company awarded 2,000,000 shares of Restricted Stock to members of the Board of Directors and management in a private placement in reliance upon an exemption from registration afforded by Section 4(a)(2) of the Securities Act. The shares subject to this grant are outside the 2013 Plan and were scheduled to fully vest on the second anniversary of the date of grant. On May 1, 2018, the vesting date for 1,767,000 shares was amended to November 2018. In addition, in the event of a Change of Control (as such term is defined in the 2013 Plan), 100% of the grants would have immediately vested. During the year ended September 30, 2020 and 2019, 0 and 1,767,000 shares of restricted stock, respectively, awarded outside the 2013 Plan vested.

Restricted Stock activity in shares for the year ended September 30, 2020 and 2019 is as follows:

	2019
Non Vested at September 30, 2019 and 2018	1,767,000
Awarded	—
Vested	(1,767,000)
Forfeited	—
Non Vested at September 30, 2020 and 2019	—

The weighted average restricted stock award date fair value information for the year ended September 30, 2020 and 2019 follows:

	2019
Non Vested at September 30, 2019 and 2018	$ 0.39
Awarded	—
Vested	0.39
Forfeited	—
Non Vested at September 30, 2020 and 2019	$ —

For both of the years ended September 30, 2020 and 2019, compensation expense recorded for the restricted stock awards was $0.

16. 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, 2020 and 2019, 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, 2020 and 2019. For the years ended September 30, 2020 and 2019, 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, 2020.

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

Leases

The Company's corporate offices are located in Framingham, MA. During July 2017, we entered into a three year operating lease commencing October 1, 2017 and ending on September 30, 2020 at our current location. Pursuant to which we are obliged to pay annual rent of $38,400 during the first year, $39,600 during the second year and $42,000 during the third year. During August 2020, we extended the lease through September 30, 2021 at our current location pursuant to which we are obligated to pay annual rent of $42,000. As of September 30, 2020, the right-of-use ("ROU") asset of approximately $39,000 represents our right to use an underlying asset for the lease term and the lease liabilities of approximately $39,000 represents our obligation to make lease payments arising from the lease. Our ROU asset is included in prepaid expenses and other current assets and the lease obligations is included in accrued expenses and other current liabilities on our consolidated balance sheets. The impact upon adoption was considered immaterial to the consolidated financial statements. We believe our present offices are suitable for our current and planned near-term operations. For the fiscal year ending September 30, 2021 the Company's annual lease commitment is $42,000.

17. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

The following table provides selected quarterly financial data for the fiscal years ended September 30, 2020 and 2019:

	Quarters Ended			
	December 31, 2019	March 31, 2020	June 30, 2020	September 30, 2020
Net sales	$ -	$ -	$ -	$ -
Gross profit	$ -	$ -	$ -	$ -
Operating loss	$ (1,619,567)	$ (1,154,569)	$ (1,241,700)	(1,354,812)
Net loss	$ (1,659,754)	$ (731,884)	$ (904,367)	$ (1,395,373)
Net income (loss) per share - basic and diluted	$ (0.01)	$ -	$ (0.01)	$ -
Weighted average shares – basic and diluted	184,102,916	186,897,947	188,340,505	192,855,962

	Quarters Ended			
	December 31, 2018	March 31, 2019	June 30, 2019	September 30, 2019
Net sales	$ -	$ -	$ -	$ -
Gross profit	$ -	$ -	$ -	$ -
Operating loss	$ (1,767,824)	$ (1,507,366)	$ (1,572,261)	$ (1,524,305)
Net loss	$ (2,600,237)	$ 169,962	$ (1,289,162)	$ (828,144)
Net (loss) per share - basic and diluted	$ (0.02)	$ -	$ (0.01)	$ (0.01)
Weighted average shares - basic	161,057,300	163,285,738	168,396,553	172,575,820
Weighted average shares - diluted	161,057,300	163,620,980	168,396,553	172,575,820

18. Risks and Uncertainties – COVID-19

The Company sources its materials and services for its products and product candidates from facilities in areas impacted or which may be impacted by the outbreak of the coronavirus. This may impact the Company's ability to obtain future inventory and impact the company's revenue stream as efforts to address this worldwide outbreak are undertaken. In addition, the Company has historically and principally funded its operations through debt borrowings, the issuance of convertible debt, and the issuance of units consisting of common stock and warrants which may also be impacted by economic conditions beyond the Company's control. To the extent in which the coronavirus will impact the global economy and the Company is uncertain and cannot be reasonably measured.

19. Authorized Common Stock

On July 1, 2020, a special meeting of the Company was held. At the meeting, the stockholders approved an increase to the number of authorized shares of our common stock, par value $0.001 per share ("Common Stock"), from 300,000,000 to 800,000,000 shares. The results of the stockholders' vote were 103,553,044 votes for, 33,707,332 votes against and 3,678519 abstained.

20. SUBSEQUENT EVENTS

The Company evaluated all events or transactions that occurred through December 10, 2020, the date which these consolidated financial statements were available to be issued. On November 6, 2020, the Company issued unsecured 10% Series 2 Convertible Notes in the aggregate principal amount of $1,050,000. The Series 2 Convertible Notes provide, among other things, for (i) a term of approximately three (3) years; (ii) the Company's ability to prepay the Series 2 Convertible Notes, in whole or in part, at any time; (iii) the automatic conversion of the Convertible Notes upon a Change of Control (all capitalized terms not otherwise defined to have the meaning ascribed to such terms in the Convertible Notes) into shares of the Company's common stock, par value $0.001 per share (Common Stock), at a per share price of $0.25 (the "**Conversion Price**"); (iv) the ability of a holder of a Series 2 Convertible Note (a "**Holder**") to convert the Series 2 Convertible Note and accrued interest, in whole or in part, into shares of Common Stock at the Conversion Price; (v) the Company's ability to convert all Note Obligations outstanding upon a Qualified Equity Financing into shares of Common Stock at the Conversion Price; (vi) the Company's ability to convert Series 2 Convertible Notes and accrued interest, in whole or in part, into shares of Common Stock at the Conversion Price in the event the volume weighted average price ("VWAP") of the Common Stock equals or exceeds $0.32 per share for at least fifteen (15) consecutive Trading Days; (vii) the Company's ability to convert all outstanding Note Obligations into shares of Common Stock at the Conversion Price (an "**In-Kind Note Repayment**") in lieu of repaying the Note Obligations outstanding on the Maturity Date, November 30, 2023; provided, however, that in the case of an In-Kind Note Repayment, the outstanding Note Obligations will be calculated by increasing by thirty-five percent (35%) the aggregate sum of the unpaid Principal Amount held by each Holder and the accrued interest at a rate of ten percent (10%) per annum, subject to, with respect to any portion of the Principal Amount that is converted or prepaid before the twelve month anniversary of the Issuance Date, a minimum interest payment equal to ten percent (10%) of the amount that is converted or prepaid.

In addition, on November 6, 2020, as consideration for investment in the Convertible Notes, the Company entered into that certain Amendment to Series J Warrant to Purchase Common Stock, a holder of a Series J Warrant exercisable for up to 3,375,000 shares of Common Stock, to extend the term of the Series J Warrant from one (1) year to thirty (30) months.

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of November 18, 2020, Arch Therapeutics, Inc. had one class of common stock registered under Section 12 of the Securities Exchange Act of 1934, as amended.

The following description of our common stock, par value $0.001 per share ("**Common Stock**") is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our amended and restated Articles of Incorporation (the "**Articles of Incorporation**") and our amended and restated bylaws (the "**Bylaws**"), each of which is incorporated herein by reference as an exhibit to the Annual Report on Form 10-K filed with the Securities and Exchange Commission, of which this Exhibit 4.1 is a part. We encourage you to read our Certificate of Incorporation, our Bylaws and the applicable provisions of the Nevada Revised Statutes ("**NRS**").

Authorized Capital Stock

Effective May 24, 2013, we amended our Articles of Incorporation to increase our authorized Common Stock from 75,000,000 shares to 300,000,000 shares. Other than our Common Stock, we have no other class or series of authorized capital stock.

Also on May 24, 2013, we effected a forward stock split, by way of a stock dividend, of our issued and outstanding shares of Common Stock at a ratio of 11 shares to each one issued and outstanding share. As a result, our outstanding Common Stock increased from 3,960,000 shares to 43,560,000 shares immediately following the forward stock split.

On July 1, 2020, a special meeting of the Company was held. At the meeting, the stockholders approved an increase to the number of authorized shares of our Common Stock from 300,000,000 to 800,000,000 shares.

Description of Common Stock

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

Transfer Agent

The transfer agent for our Common Stock is Empire Stock Transfer. Our transfer agent's address is 1859 Whitney Mesa Drive, Henderson, Nevada 89014.

Anti-Takeover Provisions Of Nevada State Law

Some features of the NRS which are further described below, may have the effect of deterring third parties from making takeover bids for control of us or may be used to hinder or delay a takeover bid. This would decrease the chance that our stockholders would realize a premium over market price for their shares of Common Stock as a result of a takeover bid.

Acquisition of Controlling Interest

The NRS contain provisions governing acquisition of a controlling interest of a Nevada corporation. These provisions provide generally that any person or entity that acquires a certain percentage of the outstanding voting shares of a Nevada corporation may be denied voting rights with respect to the acquired shares, unless certain criteria are satisfied. Our Bylaws provide that these provisions will not apply to us or to any existing or future stockholder or stockholders.

Combination with Interested Stockholder

The NRS contain provisions governing combinations of a Nevada corporation that has 200 or more stockholders of record with an "interested stockholder." These provisions only apply to a Nevada corporation that, at the time the potential acquirer became an interested stockholder, has a class or series of voting shares listed on a national securities exchange, or has a class or series of voting shares traded in an "organized market" and satisfies certain specified public float and stockholder levels. As we do not now meet those requirements, we do not believe that these provisions are currently applicable to us. However, to the extent they become applicable to us in the future, they may have the effect of delaying or making it more difficult to affect a change in control of the Company in the future.

A corporation affected by these provisions may not engage in a combination within two years after the interested stockholder acquires his, her or its shares unless the combination or purchase is approved by the board of directors before the interested stockholder acquired such shares. Generally, if approval is not obtained, then after the expiration of the two-year period, the business combination may be consummated with the approval of the board of directors before the person became an interested stockholder or a majority of the voting power held by disinterested stockholders, or if the consideration to be received per share by disinterested stockholders is at least equal to the highest of:

- the highest price per share paid by the interested stockholder within the three years immediately preceding the date of the announcement of the combination or within three years immediately before, or in, the transaction in which he, she or it became an interested stockholder, whichever is higher;
- the market value per share on the date of announcement of the combination or the date the person became an interested stockholder, whichever is higher; or
- if higher for the holders of preferred stock, the highest liquidation value of the preferred stock, if any.

Generally, these provisions define an interested stockholder as a person who is the beneficial owner, directly or indirectly of 10% or more of the voting power of the outstanding voting shares of a corporation, and define combination to include any merger or consolidation with an interested stockholder, or any sale, lease, exchange, mortgage, pledge, transfer or other disposition, in one transaction or a series of transactions with an interested stockholder of assets of the corporation:

- having an aggregate market value equal to 5% or more of the aggregate market value of the assets of the corporation;
- having an aggregate market value equal to 5% or more of the aggregate market value of all outstanding shares of the corporation; or
- representing 10% or more of the earning power or net income of the corporation.

Liability And Indemnification Of Directors And Officers

The NRS empower us to indemnify our directors and officers against expenses relating to certain actions, suits or proceedings as provided for therein. In order for such indemnification to be available, the applicable director or officer must not have acted in a manner that constituted a breach of his or her fiduciary duties and involved intentional misconduct, fraud or a knowing violation of law, or must have acted in good faith and reasonably believed that his or her conduct was in, or not opposed to, our best interests. In the event of a criminal action, the applicable director or officer must not have had reasonable cause to believe his or her conduct was unlawful.

We have not entered into separate indemnification agreements with our directors and officers. Our Bylaws provide that we shall indemnify any director or officer to the fullest extent authorized by the laws of the State of Nevada. Our Bylaws further provide that we shall pay the expenses incurred by an officer or director (acting in his capacity as such) in defending any action, suit or proceeding in advance of the final disposition of such action, suit or proceeding, subject to the delivery to us by or on behalf of such director or officer of an undertaking to repay the amount of such expenses if it shall ultimately be determined that he or she is not entitled to be indemnified by us as authorized in our bylaws or otherwise.

The NRS further provide that a corporation may purchase and maintain insurance or make other financial arrangements on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise for any liability asserted against him and liability and expenses incurred by him in his capacity as a director, officer, employee or agent, or arising out of his status as such, whether or not the corporation has the authority to indemnify him against such liability and expenses. We have secured a directors' and officers' liability insurance policy. We expect that we will continue to maintain such a policy.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended (the "Securities Act"), may be permitted for our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors
Arch Therapeutics, Inc. and Subsidiary
Framingham, MA

We hereby consent to the incorporation by reference in the Registration Statement (No. 333-234811) on Forms S-1, Registration Statements (Nos. 333-213878; 333-214347; 333-214349; and 333-214350) on Form S-3 and the Registration Statements (Nos. 333-193516; 333-201229; 333-207314; 333-214429; 333-220918; 333-228886 and 333-235715) on Forms S-8 of our report dated December 11, 2020, relating to the consolidated financial statements of Arch Therapeutics, Inc. and Subsidiary, as of and for the years ending September 30, 2020 and 2019.

We also consent to the reference to us under the heading "Experts" in such Registration Statements.

/s/ Moody, Famiglietti & Andronico, LLP
Tewksbury, Massachusetts
December 11, 2020

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):

   (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

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

December 11, 2020

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

Exhibit 31.2

CERTIFICATIONS

I, Richard E. Davis, 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):

   (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

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

December 11, 2020

/s/ Richard E. Davis
Richard E. Davis
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.

Dated: December 11, 2020

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

By: /s/ Richard E. Davis
Richard E. Davis
Chief Financial Officer and Treasurer
(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.