Arch Therapeutics, Inc.
Form 10-K
December 18, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended September 30, 2018

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)

(617) 431-2313

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: **None**

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 x

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 x

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 x 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 x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer x	Smaller reporting company x
	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 2018 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, 2018.

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

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 $42,000,000. 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 17, 2018, 164,441,786 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

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This Annual Report on Form 10-K 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, and in some cases, you can identify these statements by forward-looking words such as "if," "shall," "may," "might," "will likely result," "should," "ex "plan," "anticipate," "believe," "estimate," "project," "intend," "goal," "objective," "predict," "potential" or "continue," or the 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 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 t Arch Therapeutics, Inc. and its consolidated subsidiary, Arch Biosurgery, Inc.

We have either filed or intend to file trademark applications for AC5™ Surgical Hemostatic Device, AC5 Surgical Hemostat™, AC5™ Topical Hemostatic Device, AC5 Topical Hemostat™, AC5 Device™, AC5™, Crystal Clear Surgery™, NanoDrape™ and NanoBioBarrier™. 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. 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.

Our Current Business

We are a biotechnology company in the development stage. We have generated no revenues to date and are devoting substantially all of our operational efforts to the development of our core technology. We are developing a novel approach to stop bleeding ("hemostasis"), control leaking ("sealant") and manage wounds during surgery, trauma and interventional care. Arch is developing products based on an innovative self-assembling barrier technology platform with the goal of making care faster and safer for patients. We believe our technology could support an innovative platform of potential products in the field of stasis and barrier applications. Our plan and business model is to develop products that apply that core technology for use with bodily fluids and tissues.

To date, the Company has principally raised capital through borrowings and the issuance of convertible debt and 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 potential products. As of December 17, 2018, we believe that our current cash on hand will meet our anticipated cash requirements into the third quarter of fiscal 2019. The Company will be required to raise additional capital 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.

Our Core Technology

Our flagship development stage product candidates, known collectively as the AC5™ Devices (which we sometimes refer to as "AC5™", "AC5™ Topical Gel", "AC5™ Surgical Hemostatic Device", "AC5™ Surgical Hemostat", "AC5™ Topi Hemostatic Device", or "AC5™ Topical Hemostat"), are being designed to achieve hemostasis during surgical, wound and interventional care. They rely on our self-assembling peptide ("SAP") technology and are being designed to achieve hemostasis in skin wounds and in minimally invasive and open surgical procedures. We intend to develop other product candidates based on our technology platform for use in a range of indications. AC5 is being designed as a product containing synthetic biocompatible peptides comprising L-amino acids, commonly referred to as naturally occurring amino acids. When applied to a wound, AC5 intercalates into the interstices of the connective tissue where it self-assembles into a physical, mechanical nanoscale structure that provides a barrier to leaking substances, such as blood. AC5 may be applied directly as a liquid, which we believe will make it user-friendly and able to conform to irregular wound geometry. Additionally, AC5 does not possess sticky or glue-like handling characteristics, which we believe will enhance its utility in several settings, including minimally invasive surgical procedures. Further, in certain settings, AC5 lends itself to a concept that we call Crystal Clear Surgery™; the transparency and physical properties of AC5 may enable a surgeon to operate through it in order to maintain a clearer field of vision and prophylactically stop or lessen bleeding as it starts.

We believe that the results of early data from preclinical tests as well as certain clinical investigations have shown quick and effective hemostasis with the use of AC5 relative to that reported with other types of hemostatic agents, and that time to hemostasis is comparable among test subjects regardless of whether such test subject had or had not been treated with therapeutic doses of anticoagulant or antiplatelet medications, commonly called "blood thinners". Based on testing results, we believe that AC5 is biocompatible. Arch Therapeutics' technology has demonstrated hemostasis in liver and other organs in *in vivo* surgical models, including durable hemostasis within 15 seconds. SAP compositions have been tested in small animal organs (i.e. liver, skin, muscle, brain, eye, spine, spleen, arteries and veins). In mammalian vision models (severed hamster optic tract and in our ocular tissue pilot studies), SAPs demonstrated biocompatibility and the ability to rapidly and reliably stop bleeding and limit inflammation.

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 of AC5, developing methods for manufacturing scale-up, reproducibility, and validation, and developing and protecting the intellectual property rights underlying our technology platform. Manufacturing method and formulation optimization and validation are important parts of peptide development. Manufacturing and formulation optimization for our product candidates has been and continues to be done with extensive collaboration among our team and partners. The processes are focused on optimizing traditional product parameters to target specifications covering performance, biocompatibility, physical appearance, stability, and handling characteristics, among others. We and our partners intend to continue to monitor manufacturing processes and formulation methods closely, as success or failure in both setting and realizing appropriate specifications may directly impact our ability to conduct additional preclinical and clinical trials as we establish and execute our commercialization efforts.

Clinical Development

In October 2016, we reported that we completed a single-center, randomized, single-blind prospective clinical study (NCT 02704104) of AC5 previously referred on AC5 Topical Hemostatic Device in skin lesion patients with bleeding wounds. This was the first study assessing the safety and performance of AC5 in humans.

The clinical study enrolled 46 patients, including 10 who were taking antiplatelet monotherapy. 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 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 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 treatment group and the control group were similar. No serious adverse events were reported.

A secondary endpoint was performance as assessed by time to hemostasis. The median time to hemostasis 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 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.

Additionally, the clinical study indicated that AC5 shortened time to hemostasis ("TTH") versus a control whether or not patients were taking antiplatelet therapy, suggesting that AC5 performance is not affected by antiplatelet therapy. The reduced median TTH of the AC5 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 was less than 30 seconds for both the overall study group and for the subset of patients taking antiplatelet therapy.

On September 5, 2018 we announced topline data for the irritation/sensitization patch test study of AC5 Topical Gel that we conducted to address a request by the Food and Drug Administration (FDA or “the Agency”). 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, AC5 on a patch 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 of AC5, and after a two-day rest period, were evaluated over 48 hours.

The results indicated that AC5 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.

Preclinical Development

In a paper presented by Dr. Terrence Norchi and Dr. Rutledge Ellis-Behnke, using the experimental intraocular inflammation model of injected Lipopolysaccharide (“LPS”), an intraocular application of AC5 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 use of AC5 for hemostasis of a wound will also subsequently reduce inflammation.

SAPs may be considered a new class of devices (anti-inflammatory agents) to control ocular inflammation. SAPs have shown a similar effect in other organs, including liver and kidney. SAPs may show promise to control inflammation along with the stabilization of tissue after injury, and may be an important component of field-based wound care and stabilization for transport.

Previously, we completed the components of the planned preclinical program for AC5 that were required before we started our first human safety and performance trial, which was completed in 2016. We are focused on further scale-up of selected manufacturing methods and formulation optimization. In parallel, we are continuing to conduct further in vivo and in vitro tests, while additional testing will continue after completion of manufacturing scale-up and formulation optimization steps and the clinical trial. Self-assembling peptide manufacturing and formulation optimization are challenging, and any delays could negatively impact anticipated clinical trial and subsequent commercialization timelines. In order to market and sell AC5 and other Arch planned products, successful human clinical trials, additional testing, and regulatory approvals and certifications will be required. A co-founding inventor of certain of our technology, Dr. Rutledge Ellis-Behnke, performed a significant portion of the early preclinical animal experimentation conducted on our technology. Some of the most significant findings from Dr. Ellis-Behnke's studies have been published. Additionally, through collaboration with the National University of Ireland system, preclinical bench-top and animal studies have been performed in Dublin and Cork, Ireland. As a continuation of our commitment to our product development we entered into a collaboration agreement with National University of Ireland Galway ("NUIG") in Galway, Ireland on May 28, 2015 (the "Project Agreement") that concluded in the third quarter of fiscal 2018. Pursuant to the Project Agreement, NUIG provided additional research services, via the CÚRAM Centre for Research in Medical Devices ("CÚRAM"), which is a major national research center headquartered at NUIG established in January 2015. We have also engaged, on a fee for service basis, several private third party facilities in the United States and abroad to perform certain preclinical bench-top and animal studies, which are often conducted with assistance from our scientific team, and we continue to engage third parties for such services as needed and as appropriate.

In preclinical animal tests conducted to date, AC5 has demonstrated rapid average time to hemostasis ("TTH") when applied to a range of animal tissues. Certain studies have tested TTH when using AC5 during surgical procedures compared to TTH when using an active control, a saline control, a peptide control, and a cautery control during those same procedures. The results of those tests have shown a TTH of approximately 10 – 30 seconds when AC5 was applied, compared to a TTH ranging from 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 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 achieved hemostasis in significantly less than 30 seconds, whereas the control products took from 50% to over 400% longer than AC5 to achieve hemostasis. Additionally, the preclinical tests that have been conducted to date provide evidence that AC5 can stop bleeding in models of liver bleeding in animals that had been treated with therapeutic amounts of anticoagulant and antiplatelet medications, commonly called "blood thinners." In one preclinical study, an independent third-party research group obtained positive data assessing the use of AC5 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 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 was applied to bleeding liver wounds of animals that had been medicated with anticoagulants 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 in patients on the anticoagulant heparin and in patients on the anti-platelet medication, ticagrelor (Brilinta® in the US, Brilique® in Europe.)

In preclinical tests conducted to date, AC5 has demonstrated biocompatibility and normal healing of tissue treated with the product. Further, animals whose liver, spleen, femoral artery, eye or brain was treated with AC5 have shown no adverse effects We believe that the peptide degrades into the amino acids from which it was originally synthesized, which are molecules that already exist in large quantities in the human body.

Our current and planned near-term activities are focused on continued manufacturing scale-up, formulation optimization, and other preclinical activities, and conducting further clinical trial testing of AC5. In its first clinical study for safety and performance, AC5 was demonstrated to be safe and to reduced TTH in wounds versus controls. Our clinical study also demonstrated that in a subgroup of 10 patients who were taking a prescribed antiplatelet medication, commonly known as a blood thinner, such as aspirin, AC5 had similar effects.

Development and Commercialization Strategy

Our present business model is to operate with a relatively small internal team of key personnel and engage third party service providers to conduct larger scale research, development and manufacturing 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.

Research and Development; Manufacturing

Use of Third Party Relationships

To date, we have engaged third party laboratory facilities run by experts in the U.S. and abroad to perform both research and preclinical and clinical development activities. Those engagements have assisted in our development of our primary product candidate, as well as our generation of appropriate analytical methods, scale-up, and other procedures for use as a “blueprint” for third party manufacturers to produce the product on a larger scale for purposes of further preclinical and clinical testing and ultimately, if required approvals are obtained, commercialization.

We have initiated the transition to traditional contract manufacturing and related organizations. We have commenced relationships and work with manufacturers operating with the current good manufacturing practices (“cGMP”) required by applicable regulatory agencies in order to scale up and produce material to be used for preclinical testing and

clinical trials.

Manufacturing Methods

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 technologies 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 AC5 and other 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 15 years have reduced their complexity and cost, while increasing large-scale cGMP capacity. Moreover, our planned product candidates, including AC5, 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.

Regulatory

Medical Device Classification

In February of 2015, we announced that The British Standards Institution (“BSI”), a 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) in the EU, confirmed that AC5 fulfills the definition of a medical device within the EU and will be classified as such in consideration for CE mark designation. The FDA and other regulatory authorities or related bodies separately determine the classification of AC5. The FDA also determined it to be a medical device. 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. The AC5 mechanism of assembly into a barrier can occur outside of a body and is accordingly consistent with the medical device definition.

Medical devices in the EU and the U.S. are classified along a spectrum. 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. AC5 could be regulated as either a Class III or a Class II medical device in these jurisdictions, depending upon the application, subject to the process for obtaining a CE mark in the EU and the premarketing authorization process in the U.S. It has been determined that our AC5™ Topical Gel used for external wounds will be a Class II medical device.

Biocompatibility Tests and Clinical Trials

Before initiating our European or most other human clinical trials, we are required to have completed the biocompatibility assessment of AC5. Standard required tests to assess biocompatibility, 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 initiate our first human trial of AC5 in Western Europe. We will perform further biocompatibility testing that we deem necessary for additional indications, classifications, jurisdictions, and/or as required by regulatory authorities.

On August 15, 2016, we announced that the AC5 Topical Hemostatic Device met its primary and secondary endpoints in our first clinical trial for safety and performance. On October 31, 2016, the Company further announced that additional analysis of the subgroup of 10 patients who were taking a prescribed antiplatelet medication, commonly known as a blood thinner, such as aspirin, indicated that AC5 had similar effects for this subgroup.

On July 25, 2017, we announced that we had made a 510(k) submission to FDA for our 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 510(k) submission to the FDA for our 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 and initiating the study in the second calendar quarter, and completing the study. On December 17, 2018, we announced that the 510(k) premarket notification for AC5™ Topical Gel has been reviewed and cleared by the FDA, allowing for the product to be marketed.

In addition, we currently anticipate filing our first CE Mark application by the end of calendar year 2018, to subsequently seek regulatory approval for expanded indications, and to pursue internal use commercial opportunities for other AC5-related products through the premarket authorization process.

Commercialization

Our commercialization plan for at least some of our product candidates could entail entering into one or more collaboration agreements or strategic partnerships. Based on our general approach and strategy of utilizing the expertise and resources of third party service providers and maintaining a relatively small internal team, we currently expect that we may pursue some degree of strategic collaborations or partnerships with third parties, which could include licensing arrangements, distribution and supply partnerships, engagement of external regulatory experts and/or marketing and sales teams, among other types of potential relationships. We presently believe that certain relationships could improve our ability to obtain regulatory approval for our product candidates and attain market acceptance for and profitable sales of those product candidates, and that our current and planned activities and milestones relating to AC5 are well-aligned with the needs of the market and potential partners and collaborators that may wish to enter or expand their presence in our target markets.

We envision the potential future customers in the marketplace for AC5 and any other hemostatic or sealant agent we may pursue will include surgeons and other doctors, government agencies such as the Department of Defense, hospital and operating room management and ambulance and other trauma specialists.

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Plan of Operations

Our long-term business plan includes the following goals:

- conducting required biocompatibility studies and, subsequently, additional clinical trials on AC5 and related products;
- expanding and maintaining protection of our intellectual property portfolio;
- developing additional third party relationships to manufacture, distribute, market and otherwise commercialize AC5;
- obtaining regulatory approval or certification of AC5 and related products in the EU, the U.S., and other jurisdictions as we may determine;
- continuing or developing academic, scientific and institutional relationships to collaborate on product research and development; and
- developing additional product candidates in the hemostatic, sealant, and/or other fields.

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 large scale manufacturing partners to scale up production of product compliant with current good manufacturing practices ("cGMP"), which activities will be ongoing as we seek to advance toward, enter into, and, if successful, subsequently increase commercialization activities;
- further clinical development of our product platform;
- pursue regulatory clearance for commercialization;

- continue to expand and enhance our financial and operational reporting and controls;

- seek commercial partnerships;

- 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;

- obtain regulatory input into subsequent clinical trial designs;

- assess our self-assembling peptide platforms in order to identify and select product candidates for advancement into development.

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 17, 2018 we believe that our current cash on hand will meet our anticipated cash requirements into the third quarter of fiscal 2019. We could spend our financial resources much faster than we expect, in which case 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 and the issuance of convertible debt and 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.

Industry and Competition

Arch is developing technology for surgery and trauma care applications. Planned products include, among others, barriers for both bleeding tissues and leaking fluids that create an environment permissive to normal healing. The initial focus has been on procedures and surgeries, with plans to follow with trauma applications. The initial clinical trial assessed AC5's use in an external application, while internal human studies are intended to follow. Our intent is to provide a product set with broad utility and relatively few constraints based on bleeding, leakage, and wound type. 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.

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 U.S. Since the early days of modern minimally invasive surgery in the 1990s, the percent of surgeries performed minimally invasively has increased significantly such that it is now widespread and common. Minimally invasive surgery is often called laparoscopic surgery, although there are additional types. Minimally invasive surgical procedures often present the surgeon with fewer margins for potential error and less capacity to deal with certain risks, such as excessive bleeding, without converting the surgery to a traditional open procedure. We believe that the performance and safety of both minimally invasive and traditional surgeries and other procedures could benefit from newer hemostatic agents and sealants, because surgical and trauma patients are at significant risk for morbidity and mortality from bleeding and/or leaking body fluid.

Additional trends that support a demand for hemostatic and sealant products include the following:

·overall procedure volume growth;

·ambulatory same day surgery volume growth;

·minimally invasive surgery procedure volume growth;

·efforts to reduce operating room time; and

·increased use of anticoagulants, which predispose patients to bleeding.

As a result of this demand, use of hemostatic agents and sealants is increasing. According to a 2015 MedMarket Diligence, LLC report, the market for these products achieved approximately $4.2 billion in worldwide sales in 2015 and is projected to reach $4.8 billion in 2017 and surpass $7.5 billion in 2022. Approximately three quarter of those sales are for hemostats, which are currently growing faster than sealants, as defined in the data survey. However, we believe that due to a currently poorly met need and pent up demand, the projected growth rate for sealants could become greater than that for hemostats once 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.

In the course of developing AC5, 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. As we expected, better efficacy and reliability were identified as product features important to those customers, and we discovered that other product features are important to achieving broad market acceptance. Surgeons, operating room managers, sales representatives for currently available hemostatic products, and hospital decision-makers identified a number of desirable characteristics for a hemostatic agent, which we carefully consider while developing AC5. These features include that a product is:

·laparoscopic friendly;

·easily handled and applied;

· able to promote a clear field of vision and not obstruct view;

· non-viscous and flowable;

· non-sticky (to tissue or equipment);

· able to permit normal healing;

· indifferent to status of coagulation cascade or “blood thinning” drugs;

· non-toxic; and

· not sourced from human or other animal blood or tissue components.

We anticipate that AC5 will meet these particular market demands, and we anticipate its eventual use in minimally invasive or laparoscopic surgery as well as open surgical procedures. While open procedures represents the more established market for hemostatic agents, the number of surgeries performed by minimally invasive techniques, including laparoscopic surgery, has been growing over the past two decades and is significant. Less invasive laparoscopic procedures tend to result in shorter recovery times, faster discharges, less scarring, less pain and less need for pain medications. 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 laparoscopically because they tend to be sticky, powdery, fabric-based or are otherwise difficult to control and/or insert into the small tubes used during many laparoscopic procedures. We believe that the novel features and differentiating characteristics of AC5 will make it more suitable for laparoscopic surgeries than many or most presently available alternatives.

Further, 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 U.S. surgical procedures 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 motivate increased operating room throughput and increased volume of procedures performed in outpatient settings. Both of those trends highlight the need for highly effective hemostatic agents and sealants 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.

Participants in the hemostatic and sealant market currently include large companies, such as Johnson & Johnson and its affiliated companies, C. R. Bard, Inc., 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.

Commercially available products in the hemostasis field with which we would expect AC5 to compete if it obtains 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. Production costs of many of those products are significant, as they may require biotechnology or plasma separation technologies to manufacture, and they may require ingredients or other materials that are expensive to obtain. We believe that, assuming receipt of required regulatory approvals, AC5 will be well positioned to compete against currently available products as a result of its broad applicability in various types of surgical settings and its features that address drawbacks seen in many available hemostatic agents. Furthermore, our planned use of a manufacturing method that we expect will be cost-effective compared to methods used to manufacture many currently available hemostatic products could enable any future sales to be made at competitive price points within the market range.

Potential Disadvantages of AC5 Compared to the Competition

Some potential disadvantages of AC5 compared to the hemostatic agents currently on the market with which we would expect AC5 to compete if it obtains required regulatory approvals are as follows:

- The favorable handling characteristics of AC5 are the result of its 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 in its current form would not achieve that effect.

- While we project that AC5 will be relatively economical to manufacture at scale, it may not be able to compete from a price perspective with inexpensive means to stop bleeding, such as application of pressure or use of bandages or other inexpensive hemostatic agents.

Research and Development Expenditures

Our research and development expenses to date have primarily included labor and third party consulting costs to develop our core technology and AC5. Research and development expense during the year ended September 30, 2018 was $2,884,245, an increase of $789,450 compared to $2,094,795 for the year ended September 30, 2017. We expect our research and development activities and expenses to increase significantly as we execute on our business plan and commence additional clinical trials.

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Regulation by the FDA and Similar Foreign Agencies

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 U.S. and other countries. Most notably, we believe that AC5 will be 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 enforced by foreign agencies in any other countries in which we desire to 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;
- 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.

Pre-Marketing Regulation by the U.S. FDA

Medical Device Classification

As described previously, we expect that AC5 currently is classified as a medical device because its primary desired activity does not depend on metabolic or chemical activity in a body. The FDA classifies medical devices into one of the following three classes on the basis of the amount of risk associated with the medical device and the controls deemed necessary to reasonably ensure their safety and effectiveness:

- 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.

Class III devices are those that are deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or implantable devices, or that have a new intended use or use advanced technology that is not substantially equivalent to that of a legally marketed device. As a result of the intended use of AC5 and the novel technology on which is it based, we further anticipate that AC5 could be regulated as either a Class III or a Class II medical device in these jurisdictions, depending upon the application.

US Regulatory Approval 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 U.S. The FDA ultimately determines the appropriate regulatory path.

We believe that the products we are currently pursuing for internal use will require a PMA approval prior to commercialization. However, we believe that we may commercialize an initial product for external use after clearance 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.

On July 25, 2017, we announced that we had made a 510(k) submission to FDA for our 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 510(k) submission to the FDA for our AC5™ Topical Gel and filed that 510(k) submission during the third calendar quarter of 2018. 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 of 2018, completing the pre-submission process and 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 has been reviewed and cleared by the FDA, allowing for the product to be marketed.

We currently anticipate filing our first CE Mark application by the end of calendar year 2018, to subsequently seek regulatory approval for expanded indications, and to pursue internal use commercial opportunities for other AC5-related products through the premarket authorization process.

A PMA 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. A PMA is required for most Class III medical devices. 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. 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.

The PMA approval process can be lengthy and expensive and requires an applicant to demonstrate the safety and efficacy of the device based, in part, on data obtained from clinical trials. 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.

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. We have not submitted a premarket notification. 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 AC5 for the desired internal use indications, on a timely basis, or at all. Our inability to achieve regulatory approval for AC5 in the U.S. for an internal use product, a large market for hemostatic products, would materially adversely affect our ability to grow our business.

Clinical Trials

Obtaining PMA approval requires the completion of human clinical trials that produce successful results demonstrating the safety and efficacy of the product. Clinical trials for a Class III medical device typically may 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. Human 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").

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 both FDA requirements and 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 the 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.

On December 16, 2015, we announced that we had received clearance from a regulatory authority in Western Europe to initiate a human clinical trial to assess the safety and performance of AC5 in humans. The initial patient was treated in the first quarter of 2016 and on June 6, 2016, we announced we had completed patient enrollment in this study. On August 15, 2016, we announced that the AC5 Topical Hemostatic Device met its primary and secondary endpoints in our first clinical trial. On October 31, 2016, the Company announced that additional analysis of the subgroup of 10 patients who were taking a prescribed antiplatelet medication, commonly known as a blood thinner, such as aspirin, indicated that AC5 had similar effects for this patient population.

Pre-Marketing Regulation in the EU

Medical Device Classification

Similar to the U.S., the EU recognizes different classes of medical devices. The EU recognizes Class I, Class IIa, Class IIb or Class III medical devices, with the classification determination depending on the amount of potential risk to the patient associated with use of the medical device. Classification involves rules found in the EU's Medical Device Directive. Key questions of relevance include the degree of the device's contact with the patient, invasiveness, active nature, and indications for use. The medical device classes recognized in the EU are as follows:

- Class I, which are considered low risk devices, such as wheelchairs and stethoscopes, and require pre-market notification prior to placing the devices onto the EU market;

- 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.

In February of 2015, we announced that BSI confirmed that AC5 fulfills the definition of a medical device within the EU and will be classified as such in consideration for CE mark designation. We anticipate that AC5 could be regulated as either a Class III or a Class II medical device in these jurisdictions, depending upon the application.

CE Mark Approval Process

Approval Process

The EU has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices. Recently, the EU has revised its rules and regulations and have implemented increasingly stringent requirements. In addition, 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.

Under applicable EU medical device directives, a CE mark is a symbol placed on a product that declares that the product is compliant with the essential requirements of applicable EU health, safety and environmental protection legislation. In order to receive a CE mark for a product candidate, the company producing the product candidate must select a country in which to apply. Each country in the EU has one competent authority ("CA") that implements the national regulations by interpreting the EU directives. CAs also designate and regulate Notified Bodies. An assessment by a Notified Body in the selected country within the EU is required in order to commercially distribute the device. In addition, compliance with ISO 13485 issued by the International Organization for Standardization, among other standards, establishes the presumption of conformity with the essential requirements for CE marking. 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.

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 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.

We currently anticipate filing our first CE mark application by the end of the 2018 calendar year. We have identified several potential countries through which we may pursue a CE mark for AC5.

Clinical Trials

As with U.S. Class III and certain Class II medical device approvals, EU Class III and certain Class II medical device approvals require the successful completion of human clinical trials. However, there are several key differences between the jurisdictions with respect to the approvals and processes. Obtaining a CE mark is not equivalent to obtaining FDA clearance or approval, in that a CE mark confirms the safety, but not the effectiveness, of a product. Furthermore, 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. Accordingly, we anticipate that the required EU clinical trial(s) for AC5 will be smaller, faster, and less expensive than what we expect would be required for AC5 to obtain equivalent approvals in the U.S.

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 in the U.S. and

in member states of the EU, 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 or by our third-party manufacturers and 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.

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 November 19, 2018, we either own or license from others a number of U.S. patents, U.S. patent applications, foreign patents and foreign patent applications.

Five patent portfolios assigned to Arch Biosurgery, Inc. include a total of 30 patents and pending applications in a total of nine jurisdictions, including ten patents and pending applications in the US. These portfolios cover self-assembling peptides and methods of use thereof and self-assembling peptidomimetics and methods of use thereof, including five issued US patents (US 9,415,084; US 9,162,005; US 9,789,157; US 9,821,022 and US 9,339,476) that expire between 2026 and 2034 (absent patent term extension), as well as ten 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 23 patents and pending applications drawn to self-assembling peptides and methods of use thereof and self-assembling peptidomimetics and methods of use thereof in a total of nine jurisdictions. The portfolios include four issued US patents (US 9,511,113; US 9,084,837; US 9,327,010; and US 9,364,513) that expire between 2026 and 2027 (absent patent term extension), as well as thirteen 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 2027 (absent patent term extension), as well as four patents that have been either allowed, issued or granted in foreign jurisdictions.

Our license agreement with MIT imposes 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.

We have pending trademark applications for AC5 Surgical Hemostatic Device™, AC5 Surgical Hemostat™, AC5™, Crystal Clear Surgery™, NanoDrape™ and NanoBioBarrier™.

Employees

We presently have eight full-time employees and one part-time employee, 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 following risk factors before making an investment decision. If any of the following risks and uncertainties actually occurs, our business, financial condition, and results of operations could be negatively impacted and you could lose all or part of your investment.

Risks Related to our Business

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

We are a development stage company with no commercial products. Our primary product candidate is in the process of being developed, and will require additional investment before it could potentially be commercialized. As a result, we have not generated any revenue from operations since inception, and we have incurred substantial net losses to date. While as of December 17, 2018, we believe that our current cash on hand will meet our anticipated cash requirements into the third quarter of fiscal 2019, depending upon additional input from EU and US regulatory authorities, we may need to raise additional capital prior to the third quarter of Fiscal 2019. 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 re-file our 510(k) submission for our AC5™ Topical Gel, and filed a 510(k) submission during the third calendar quarter, the resubmission process required us to expend a minimum of $100,000 that we had not previously anticipated spending.

In any event, during or prior to the third quarter of Fiscal 2019, we will need to obtain additional cash to continue operations and fund our planned future operations, which include research and development of our primary product candidate, seeking regulatory approval for that product candidate, and pursuing its commercialization in the U.S., Europe and other markets. Those circumstances raise 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 are a development stage company with no commercial products. 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 operations to date to the research and development of our core technology, including selecting our initial product composition, conducting initial safety and other related tests, generating scale-up, reproducibility and manufacturing and formulation methods, conducting our initial clinical trial for AC5, and developing and protecting the intellectual property rights underlying our technology platform.

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

- develop our principal product candidate, AC5, and the underlying technology, including advancing applications and conducting biocompatibility and other preclinical studies;
- raise capital needed to fund our operations;
- build and enhance investor relations and corporate communications capabilities;
- conduct additional clinical trials relating to AC5 and any other product candidate we seek to develop;
- attempt to gain regulatory approvals for product candidates;
- build relationships with 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 approval; 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 approval for our product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. 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 17, 2018, we believe that our current cash on hand will meet our anticipated cash requirements into the third quarter of fiscal 2019. Notwithstanding that, depending upon additional input from EU and US regulatory authorities, we may need to raise additional capital prior to the third quarter of Fiscal 2019. 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 re-file our 510(k) submission for our AC5™ Topical Gel, and filed a 510(k) submission during the third calendar quarter, the resubmission process required us to expend a minimum of $100,000 that we had not anticipated spending.

In any event, during or prior to the third quarter of Fiscal 2019, we will need to obtain 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 applications and approval of AC5 in the U.S. and Europe 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 approvals 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 have obtained research and development support through collaborative arrangements, such as the Project Agreement that we entered into with the National University of Ireland Galway ("NUIG") on May 28, 2015 and which concluded in the third quarter of fiscal 2018, and we may continue to seek funding through additional 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 ("2017 SPA") and June 28, 2018 (the "2018 SPA") in connection with the registered direct financings that closed on February 24, 2017 ("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 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 including, but not limited to, an equity line of credit or "At-the-Market" financing facility.

As of December 17, 2018, none of the lead investors for either the 2017 Financing or 2018 Financing have exercised or transferred any of their Series F Warrants or Series G Warrants. As defined in both 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 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, obtain regulatory approvals, 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 the Development and Commercialization of our Product Candidates

The Company voluntarily withdrew a 510(k) notification to the FDA on December 18, 2017, and the future success of our business is significantly dependent on the success of our being able to obtain regulatory approval for our flagship development stage product candidates, known collectively as the AC5 devices.

On July 17, 2017, we filed a 510(k) notification with the FDA for our AC5™ Topical Gel. As previously announced on December 18, 2017, we voluntarily withdrew the submission after receiving a communication from 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 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, allowing for the product to be marketed.

In addition to our 510(k) notification, we currently anticipate filing our first CE Mark application by the end of the 2018 calendar year, to subsequently seek regulatory approval for expanded indications, and to pursue internal use commercial opportunities for other AC5-related products through the premarket authorization process.

Our business plan is dependent on the success of our flagship development stage product candidates, known collectively as the AC5 devices.

Our business is currently focused almost entirely on the development and commercialization of our flagship development stage product candidates, known collectively as the AC5 devices. Our reliance on the AC5 devices means that, if we are not able to obtain regulatory approvals and market acceptance of at least one 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 develops and obtains regulatory approval or certification for similar products faster than we can or that is otherwise more attractive to the market than the AC5 devices. Our current dependence on the AC5 devices increases the risk that our business will fail if our development efforts for the AC5 devices 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.

If we are required or voluntarily decide to change manufacturers for commercial or other reasons, the FDA and any other applicable regulatory bodies would also require that we demonstrate structural and functional comparability between the same products manufactured by our current and any new manufacturer and may require comparability studies to be performed before qualifying such new manufacturer.

As noted above, we are dependent on third-party manufacturers, and this dependence exposes us to increased risks associated with delivery schedules, manufacturing capability, quality control, quality assurance and costs. Our contract manufacturers may not perform as agreed. If we are required to or voluntarily decide to find a new contract manufacturer, qualifying such new contract manufacturer may be expensive and time consuming since, among other things, the FDA and any other applicable regulatory bodies would also require that we demonstrate structural and functional comparability between the same products manufactured by our current and any new manufacturer and may require comparability studies to be performed before qualifying such new manufacturer. This qualification process may affect product availability, which may in turn adversely affect our business.

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 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 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) in the EU, confirmed that AC5 fulfills the definition of a medical device within the EU and will be classified as such in consideration for CE mark designation. The FDA and other regulatory authorities or related bodies separately determine the classification of AC5. The FDA also determined our current product to be a medical device. If the FDA or similar foreign agencies or intermediaries deem our product 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 previously approved products.

In the European Union, we are required to comply with applicable medical device directives, including the Medical Devices Directive, and obtain CE Marking 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 regulatory approvals 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 Marking process, data transparency and application review timetables.

If we are not able to secure and maintain relationships with third parties that are capable of conducting clinical trials on our product candidates and support our regulatory submissions, our product development efforts, and subsequent regulatory approvals 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, regulatory approvals 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 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:

- the 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 product candidate;

- subjects experience an unacceptable rate of efficacy of the product candidate;

- subjects experience an unacceptable rate or severity of adverse side effects, demonstrating a lack of safety of the 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 regulatory approval.

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 regulatory approvals, 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 require the process of FDA Premarket Approval (“PMA“) for the product, which is based on novel technologies

and likely will be classified as a Class III medical device. 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 approvals 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 approval of our product candidates would 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 approvals are obtained, commercialize our product candidates.

As demonstrated by the Project Agreement that we entered into with NUIG on May 28, 2015, we are interested in collaborating with physicians, patient advocacy groups, foundations, government agencies, and/or other third parties to assist with the development of our product candidates. If required regulatory approvals are obtained for 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 relationship with NUIG and/or seek additional collaborators in the future but are unable to reach agreements with NUIG and/or 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 recently adopted legislation regarding health insurance. As a result of this new legislation, substantial changes could be made to the current system for paying for healthcare in the U.S., including modifications to the existing system of private payers and government programs, such as Medicare, Medicaid and State Children's Health Insurance Program, creation of a government-sponsored healthcare insurance source, or some combination of those, 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 approved product candidates, 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 recently 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 2019. If the Opponents prevail in the appeal, European Patent No. 1879606 will be fully or partially invalidated, resulting in potential loss of rights. Our licensed MIT Japanese patent No. 5204646 was challenged in a Japanese court. The Japanese Court issued a decision in our favor to maintain the patent in its entirety. The Opponent appealed the decision. On October 30, 2018, the Japanese IP Court issued a decision in our favor to maintain the patent in its entirely. The opponent maintains the right to appeal this decision. If the Opponent prevails in the appeal, Japanese Patent No. 5204646 will be fully or partially invalidated, resulting in potential loss of rights. European patent No. 2581097 has been opposed. If the Opponents prevail, 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 or licensed patent applications are pending, and our patent portfolio includes certain patents and applications that are in-licensed on a non-exclusive basis.

As of November 19, 2018, we either own or license from others a number of U.S. patents, U.S. patent applications, foreign patents and foreign patent applications.

Three patent portfolios assigned to Arch Biosurgery, Inc. include a total of 30 patents and pending applications in a total of nine jurisdictions, including ten patents and pending applications in the US. These portfolios cover self-assembling peptides and methods of use thereof, including five issued US patents (US 9,415,084; US 9,162,005; US 9,789,157; US 9,821,022; and US 9,339,476) that expire between 2026 and 2034 (absent patent term extension) as well as ten 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 23 patents and pending applications drawn to self-assembling peptides and methods of use thereof and self-assembling peptidomimetrics and methods of use thereof in a total of nine jurisdictions. The portfolios include four issued US patents (US 9,511,113; US 9,084,837; US 9,327,010; and US 9,364,513) that expire between 2026 and 2027 (absent patent term extension), as well as thirteen 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 2027 (absent patent term extension), as well as four 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 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 G Warrants, Series F Warrants, Series E Warrants, and/or the Series D Warrants, our existing stockholders will be diluted.

Our articles of incorporation authorize the issuance of up to 300,000,000 shares of Common Stock. 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 17, 2018 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 17, 2018 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 17, 2018 up to 4,214,582 shares may be acquired upon the exercise of the Series E Warrants. Similarly, in connection with our private placement financing that concluded on July 2, 2015 (“2015 Private Placement Financing”), we issued an aggregate of 14,390,754 shares of our Common Stock, which equaled approximately 18% of the 78,766,487 shares of our Common Stock that were issued and outstanding immediately prior to the commencement of the 2015 Private Placement Financing. Upon the closing of the 2015 Private Placement Financing, we also issued Series D Warrants to acquire up to an additional 14,390,754 shares of our Common Stock at an initial exercise price of $0.25 per share. As of December 17, 2018, up to 8,974,389 shares may be acquired upon the exercise of the Series D Warrants.

Additionally, as of December 17, 2018, 20,518,419 shares of Common Stock were reserved for future issuance under the 2013 Plan, of which 15,734,210 shares are subject to outstanding option awards granted under the 2013 Plan at exercise prices ranging from $0.17 to $0.50 per share and with a weighted average exercise price of $0.40 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 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 Series D Warrants granted in connection with the 2015 Private Placement Financing, there are currently outstanding warrants to acquire up to 145,985 shares of our Common Stock. 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 17, 2018 we believe that our current cash on hand will meet our anticipated cash requirements into the third quarter of fiscal 2019. 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.

The Company may have material liabilities that were not discovered before the closing of the Merger.

The Company may have material liabilities that were not discovered before the consummation of the Merger. We could experience losses as a result of any such unasserted liabilities that are eventually found to be incurred, which could materially harm our business and financial condition. Although the Merger Agreement contained customary representations and warranties from the Company concerning its assets, liabilities, financial condition and affairs, there may be limited or no recourse against the Company's prior owners or principals in the event those prove to be untrue. As a result, the stockholders of the Company bear risks relating to any such unknown or unasserted liabilities.

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 17, 2018, 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 13% 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.

Our present management team has limited experience in managing public companies. It will be time consuming, difficult and costly for our management team to acquire additional expertise and experience in operating a public company, and to develop and implement the additional internal controls and reporting procedures required by Sarbanes-Oxley and other applicable securities laws.

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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. We are obligated to pay annual rent of $38,400 during the first year, $39,600 during the second year and $42,000 during the third year. We believe our present offices are suitable for our current and planned near-term operations.

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. 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, any reported sale

prices may not be a true market-based valuation of our Common Stock.

The table below sets forth reported high and low closing bid quotations for our Common Stock for the fiscal quarters indicated as reported on the OTCQB. The quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

	High	Low
Fiscal Year Ending September 30, 2017		
First Quarter ended December 31, 2016	$0.66	$0.56
Second Quarter ended March 31, 2017	$0.78	$0.58
Third Quarter ended June 30, 2017	$0.60	$0.46
Fourth Quarter ended September 30, 2017	$0.86	$0.58
Fiscal Year Ending September 30, 2018		
First Quarter ended December 31, 2017	$0.82	$0.43
Second Quarter ended March 31, 2018	$0.51	$0.28
Third Quarter ended June 30, 2018	$0.66	$0.27
Fourth Quarter ended September 30, 2018	$0.47	$0.37

As of December 17, 2018, 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

On August 9, 2016, we entered into a consulting agreement with an investor relations firm, Acorn Management Partners, LLC (“Acorn”). In consideration of the services to be provided under and in accordance with the terms of the consulting agreement, we issued (i) 225,000 shares of Common Stock under our 2013 Stock Incentive Plan at an agreed upon value of $0.72 per share, which was the closing price of our common stock on August 9, 2016; and (ii) an option under our 2013 Stock Incentive Plan to purchase up to 375,000 shares of Common Stock at an exercise price of price of $0.72 per share, in each case to John R. Exley, Acorn’s Chief Executive Officer and the party designated by Acorn to receive its shares and option. The shares and option are subject to time-based vesting restrictions. Of the 225,000 shares of Common Stock granted to Mr. Exley, 75,000 vest 90 days from the date of the award, 75,000 vest 120 days from the date of the award and the remaining 75,000 shares are scheduled to vest 150 days from the date of

the award. During the year ended September 30, 2017, all 225,000 shares of Common Stock vested. Of the stock options to purchase up to 375,000 shares of Common Stock awarded to Mr. Exley, 125,000 vest 90 days from the date of the award, 125,000 vest 120 days from the date of the award and the remaining 125,000 shares are scheduled to vest 150 days from the date of the award. The issuance and sale of the shares of Common Stock and option to Acorn has not been registered under the Securities Act, and 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 securities were issued and sold in reliance upon an exemption from registration afforded by Section 4(a)(2) of the Securities Act based on the following facts: Acorn has represented that it is an accredited investor as defined in Regulation D promulgated under the Securities Act, that it is acquiring the securities for investment only and not with a view towards, or for resale in connection with, a distribution thereof in violation of applicable securities laws; that it understood that the securities would be issued as restricted securities and as a result, it must bear the economic risk of its investment in the securities for an indefinite period of time.

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, 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," "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 .

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. 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 are in the development stage and have generated no operating revenues to date and do not expect to do so in the foreseeable future due to the early stage nature of our current product candidates. We currently do not have any products that have obtained marketing approval in any jurisdiction. 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, 2018, we had a net loss of $4,814,032 versus a net loss of $7,788,856 in the comparable period in the prior year. The losses for each of the years ended September 30, 2018 and 2017 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 increased $297,315 during the year ended September 30, 2018 to $5,913,563, compared to $5,616,248 for the year ended September 30, 2017. Cash at September 30, 2018 decreased

by $1,326,642 to $4,667,410 compared to $5,994,052 as of September 30, 2017.

Business Overview

We are a biotechnology company in the development stage. We have generated no revenues to date and are devoting substantially all of our operational efforts to the development of our core technology. We are developing a novel approach to stop bleeding ("hemostasis"), control leaking ("sealant") and manage wounds during surgery, trauma and interventional care. Arch is developing products based on an innovative self-assembling barrier technology platform with the goal of making care faster and safer for patients. We believe our technology could support an innovative platform of potential products in the field of stasis and barrier applications. Our plan and business model is to develop products that apply that core technology for use with bodily fluids and tissues.

Our flagship development product candidates, known collectively as the AC5™ Devices (which we sometimes refer to as "AC5™", "AC5™ Topical Gel", "AC5™ Surgical Hemostatic Device", "AC5™ Surgical Hemostat", "AC5™ Topical Hem Device", or "AC5™ Topical Hemostat"), are being designed to achieve hemostasis during surgical, wound and interventional care. They rely on our self-assembling peptide ("SAP") technology and are being designed to achieve hemostasis in skin wounds and in minimally invasive and open surgical procedures. We intend to develop other product candidates based on our technology platform for use in a range of indications. AC5 is being designed as a product containing synthetic biocompatible peptides comprising L amino acids, commonly referred to as naturally occurring amino acids. When applied to a wound, AC5 intercalates into the interstices of the connective tissue where it self-assembles into a physical, mechanical nanoscale structure that provides a barrier to leaking substances, such as blood. AC5 may be applied directly as a liquid, which we believe will make it user-friendly and able to conform to irregular wound geometry. Additionally, AC5 does not possess sticky or glue-like handling characteristics, which we believe will enhance its utility in several settings, including minimally invasive surgical procedures. Further, in certain settings, AC5 lends itself to a concept that we call Crystal Clear Surgery™; the transparency and physical properties of AC5 may enable a surgeon to operate through it in order to maintain a clearer field of vision and prophylactically stop or lessen bleeding as it starts.

We believe that the results of early data from preclinical tests have shown quick and effective hemostasis with the use of AC5 relative to that reported with other types of hemostatic agents, and that time to hemostasis is comparable among test subjects regardless of whether such test subject had or had not been treated with therapeutic doses of anticoagulant or antiplatelet medications, commonly called "blood thinners". Based on testing results to date, we believe that AC5 is biocompatible. Arch Therapeutics' technology has demonstrated hemostasis in liver and other organs in *in vivo* surgical models, including durable hemostasis within 15 seconds. SAP compositions have been tested in small animal organs (i.e. liver, skin, muscle, brain, eye, spine, spleen, arteries and veins). In mammalian vision models (severed hamster optic tract and in our ocular tissue pilot studies, SAPs demonstrated biocompatibility and the ability to rapidly and reliably stop bleeding) and limit inflammation.

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 initial safety and other related tests, conducting an initial human trial for safety and performance of AC5, developing methods for scale-up, reproducibility, manufacturing and formulation, and developing and protecting the intellectual property rights underlying our technology platform. Manufacturing method and formulation optimization are important parts of peptide development. Manufacturing and formulation optimization for our product candidates has been and continues to be done with extensive collaboration among our team and partners. The processes are focused on optimizing traditional product parameters to target specifications covering performance, biocompatibility, physical appearance, stability, and handling characteristics, among others. We and our partners intend to monitor manufacturing processes and formulation methods closely, as success or failure in both setting and realizing appropriate specifications may directly impact our ability to conduct preclinical and clinical trials and our subsequent commercialization timelines.

Our long-term business plan includes the following goals:

- conducting required biocompatibility studies and, subsequently, additional clinical trials on AC5 and related products;
- expanding and maintaining protection of our intellectual property portfolio;
- developing appropriate third-party relationships to manufacture, distribute, market and otherwise commercialize AC5;
- obtaining regulatory approval or certification of AC5 and related products in the EU, the U.S., and other jurisdictions as we may determine;
- continuing or developing academic, scientific and institutional relationships to collaborate on product research and development; and
- developing additional product candidates in the hemostatic, sealant, and/or other fields.

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 large scale manufacturing partners to scale up production of product compliant with current good manufacturing practices ("cGMP"), which activities will be ongoing as we seek to advance toward, enter into, and, if successful, subsequently increase commercialization activities;

- further clinical development of our product platform;

- pursue regulatory clearance for commercialization;

- continue to expand and enhance our financial and operational reporting and controls;

- seek commercial partnerships;

- 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;

- obtain regulatory input into subsequent clinical trial designs;

- assess our self-assembling peptide platforms in order to identify and select product candidates for advancement into development.

We believe that the Company has cash on hand to meet its anticipated cash requirements into the third quarter of fiscal 2019. Notwithstanding this, depending upon additional input from EU and US regulatory authorities, we may need to raise additional capital prior to the third quarter of Fiscal 2019. In addition to the foregoing, our estimated capital requirements potentially could increase significantly if a number of risks relating to conducting these activities were to occur, including without limitation those set forth under the heading "**RISK FACTORS**" in this filing.

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 July 17, 2017, we filed a 510(k) notification with the FDA for our AC5™ Topical Gel. As previously announced on December 18, 2017, we voluntarily withdrew the submission after receiving a communication from 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 FDA to appropriately address the outstanding questions and planed 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 October 1, 2018 the Company announced that it submitted a 510(k) notification to the U.S. Food and Drug Administration (FDA or "the Agency") for its AC5™ Topical Gel (AC5) has received acknowledgement from the Agency 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, allowing for the product to be marketed.

On July 2, 2018, the Company closed on a registered direct offering of 9,070,000 units, each unit consisting of a share of the Company's common stock, and a Series G Warrant ("Series G Warrant") to purchase 0.75 of a share of our

common stock for the combined purchase price of $0.50 per unit. The Series G Warrants have an exercise price of $0.70 per share and are exercisable for a period of five years. The gross proceeds to Arch from the 2018 Financing, were approximately $4.5 million before deducting financing costs of approximately $74,000.

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, 2018 Compared to Year Ended September 30, 2017

	September 30, 2018	September 30, 2017	Increase (Decrease)
Revenue	$ -	$ -	$ -
Operating Expenses			
General and Administrative	4,565,522	5,207,753	(642,231)
Research and Development	2,884,245	2,094,795	789,450
Loss from Operations	(7,449,767)	(7,302,548)	147,219
Other Income (Expense)	2,635,735	(486,308)	(3,122,043)
Net Loss	$ (4,814,032)	$ (7,788,856)	$ (2,974,824)

Revenue

We did not generate any revenue in either of the years ended September 30, 2018 or 2017.

General and Administrative Expense

General and administrative expenses during the fiscal year ended September 30, 2018 were $4,565,522 a decrease of $642,231 compared to $5,207,753 for the fiscal year ended September 30, 2017. The decrease in general and administrative expense is primarily attributable to a decrease in stock based compensation, and by reduced defense of patent and patent prosecution costs. General and administrative expenses are generally expected to increase 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, 2018 was $2,884,245**,** an increase of $789,450 compared to $2,094,795 for the fiscal year ended September 30, 2017. The increase in research and development expense is primarily attributable to an increase in product and development costs, preparation of regulatory filings and new hires and advisors to support these efforts. Research and development expenses are expected to increase 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, 2018 was $2,635,735, an increase of $3,122,043 compared to total other expense of $486,308 for the year ended September 30, 2017. The net increase in other expense was the result of the change in the fair value of derivative liabilities inadditon to a decrease in interest expense. The decrease was the result of the payment in full of a note payable.

Liquidity and Capital Resources

Working Capital

At September 30, 2018, we had total current assets of $4,819,204 (including cash of $4,667,410) and working capital of $4,530,819. Our working capital as of September 30, 2018 and September 30, 2017 is summarized as follows:

	September 30, 2018	September 30, 2017
Total Current Assets	$ 4,819,204	$ 6,079,395
Total Current Liabilities	288,385	433,531
Working Capital	$ 4,530,819	$ 5,645,864

Total current assets as of September 30, 2018 were $4,819,204, a decrease of $1,260,191 compared to $6,079,395 as of September 30, 2017. The decrease in current assets is primarily attributable to an increase in research and development expenses attributable to product development testing and preparation for regulatory filings, in addition to a decrease in the exercise of warrants. Our total current assets as of September 30, 2018 and September 30, 2017 were comprised primarily of cash and prepaid expenses.

Total current liabilities as of September 30, 2018 were $288,385, a decrease of $145,146 compared to $433,531 as of September 30, 2017. The decrease is primarily due to the payment patent prosecution costs. Our total current liabilities as of September 30, 2018 were comprised of accounts payable and accrued expenses. Our total current liabilities as of September 30, 2018 and 2017 were comprised of accounts payable and accrued expenses.

Cash Flow

	September 30, 2018	September 30, 2017
Cash Used in Operating Activities	$ (5,913,563)	$ (5,616,248)
Cash Used in Investing Activities	(15,415)	(8,686)
Cash Provided by Financing Activities	4,602,336	6,582,510
Net (decrease)/increase in cash and cash equivalents	$ (1,326,642)	$ 957,576

Cash Used in Operating Activities

Cash used in operating activities increased $297,315 during the year ended September 30, 2018 to $5,913,563, compared to $5,616,248 during the year ended September 30, 2017. The increase was primarily due to an increase in general and administrative expense primarily attributable to increased intellectual property costs and research and development expenses incurred in connection with activities to develop our primary product candidate.

Cash Used in Investing Activities

Cash used in investing activities increased $6,729 to $15,415 due to the purchase of furniture and fixtures and leasehold improvements, during the year ended September 30, 2018, compared to $8,686 during the year ended September 30, 2017.

Cash Provided by Financing Activities

Cash provided by financing activities decreased $1,980,174 to $4,602,336 during the year ended September 30, 2018, compared to $6,582,510 during the year ended September 30, 2017. For the year ended September 30, 2018, the cash provided by investing activities resulted from (i) net proceeds received of $4,461,248 from 2018 Financing to purchase 9,070,000 shares of our common stock and Series G Warrants to purchase 6,802,500 shares of Common Stock; (ii) $56,818 in proceeds received from the exercise of Series D Warrants to purchase 227,273 shares of our Common Stock; (iii) $6,570 in proceeds received from the exercise of the Series E Warrants to purchase 15,000 shares of our Common Stock; and (iv) $77,700 in proceeds received from the exercise of stock options for 210,000 shares of our Common Stock. For the year ended September 30, 2017, the cash provided by financing resulted from (1) net proceeds received of $5,987,122 from 2017 Financing to purchase 10,166,664 shares of our common stock and Series F Warrants to purchase 5,591,664 shares of Common Stock; (2) $220,000 in proceeds received from the exercise of Series A Warrants to purchase 1,100,000 shares of our Common Stock; (3) $437,500 in proceeds received from the exercise of the Series D Warrants to purchase 1,750,001 shares of our Common Stock; (4) $932,388 in proceeds received from the exercise of the Series E Warrants to purchase 2,128,741 shares of our Common Stock; and (5) $5,500 in proceeds received from the exercise of stock options for 15,000 shares of our Common Stock. The proceeds were partially offset by the payment of $1,000,000 of principal of the Company’s Note Payable.

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 17, 2018, we believe that our current cash on hand will meet our anticipated cash requirements into the third quarter of fiscal 2019. Notwithstanding this, depending upon additional input from EU and US regulatory authorities, we may need to raise additional capital prior to the third quarter of Fiscal 2019. 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.

We are in the development stage and have generated no operating revenues to date. We do not presently have, nor do we expect in the near future to have, revenue to fund our business from our operations, and will need to obtain all of our necessary 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 and 2018 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. The Company anticipates that it will have enough cash on hand into the third quarter of fiscal 2019, however, 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, 2018, 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 and Significant Judgments and Estimates

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

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 is in the development stage and is devoting 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 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 to employees, including grants of employee stock options, to be recognized in the consolidated financial statements

based on their fair values. We account for non-employee stock-based compensation in accordance with the guidance of FASB ASC Topic 505, *Equity* ("FASB ASC Topic 505"), which requires that companies recognize compensation expense based on the estimated fair value of options granted to non-employees over their vesting period, which is generally the period during which services are rendered by such non-employees. FASB ASC Topic 505 requires us to re-measure the fair value of stock options issued to non- employee at each reporting period during the vesting period or until services are complete.

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 is estimated in accordance with ASC 718-10-S99 *Compensation-Stock Compensation* ("ASC 718-10-S99"), using historical volatilities of similar public entities. 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.

On December 22, 2017, the Tax Cuts and Jobs Act ("TCJA") was signed into United States law. The TCJA includes a number of changes to existing tax law, including, among other things, a permanent reduction in the federal corporate income tax rate to a flat rate of 21%, effective January 1, 2018, as well as the elimination of net operating loss carrybacks for losses arising in taxable years beginning after December 31, 2017. Further, operating losses arising in tax years after December 31, 2017, are carried forward indefinitely. Due to the TCJA, the Company's deferred tax assets and liabilities recognized prior to 2017 were revalued at the newly enacted tax rates, which resulted in a corresponding adjustment in the valuation allowance.

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 expected volatility, expected life, yield, and risk-free interest rate.

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 does not believe that this guidance will have a material impact on its consolidated results of operations, financial position or disclosures.

ASU 2016-15, “Statement of Cash Flows (Topic 230) Classification of Certain Cash Receipts and Payments” was issued by the Financial Accounting Standards Board (FASB) in August 2016. The purpose of this amendment is to address eight specific cash flow issues with the objective of reducing the existing diversity in practice. 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, 2017. Early adoption is permitted. The Company does not believe that this guidance will have a material impact on its consolidated results of operations, financial position or disclosure.

ASU 2016-09, “Compensation—Stock Compensation (Topic 718) Improvements to Employee Share-Based Payment Accounting” was issued by the FASB in March 2016. The purpose of this amendment is to simplify several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. 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, 2016. The Company adopted ASU 2016-09 during our first quarter of fiscal year 2018, which had no impact on our consolidated financial statements, and will apply the new guidance in future periods

ASU 2016-02, “Leases (Topic 842)” was issued by the FASB in February. 2016. The purpose of this amendment requires the recognition of lease assets and lease liabilities by lessees for those leases previously classified as operating leases. 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 does not believe that this guidance will have a material impact on its consolidated results of operations, financial position or disclosures.

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, 2018, 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, 2018 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, 2018.

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, 2018, 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	53	April 2013
James R. Sulat	Director	68	August 2015
Punit Dhillon	Director	38	July 2018
Richard E. Davis	Chief Financial Officer	60	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 served as Chief Executive Officer and Chief Financial Officer of Maxygen Inc., a biopharmaceutical company focused on developing improved versions of protein drugs, from October 2009 to June 2013. Prior to this, he was Chief Executive Officer, Chief Financial Officer and a member of the Board of Directors at Memory Pharmaceuticals Corp., which developed innovative drug candidates for the treatment of debilitating central nervous system disorders, from 2005 to 2008. He previously served in senior executive roles for R.R. Donnelley & Sons, Co., Chiron Corporation, Stanford Health Services, Inc., and Esprit de Corp, Inc. He currently serves on the Board of Directors of Momenta Pharmaceuticals, Inc., a biotechnology company focused on the analysis, characterization and design of complex pharmaceutical products. He also currently serves as a member of the Board of Directors of Valneva SE and AMAG Pharmaceuticals, Inc. Mr. Sulat received a BS in Administrative Sciences from Yale University and an MBA and MS in Health Services Administration from Stanford University. Mr. Sulat brings to our Board of Directors extensive experience with public and financial accounting matters, experience as a chief executive officer and chief financial officer, and experience serving on other boards of directors in the biopharmaceutical industry.

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 OncoSec, a biotechnology company pioneering new technologies to stimulate the body's immune system to target and attack cancer. Mr Dhillon is currently a member of the board of directors of OncoSec. 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 currently a director for Emerald Health Sciences, Inc. and Audit Committee Chair of Emerald Health Therapeutics, Inc. (TSXV: EMH) and Nemus 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 the former chairman of the board of directors of the Company, and is a member of the board of directors of OncoSec and Emerald Health Sciences, Inc., both of which are companies for which Dr. Dhillon is the chairman of the board. 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.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors, executive officers, and stockholders beneficially owning more than 10% of our outstanding common stock to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock. Executive officers, directors, and persons who beneficially own more than 10% of our common stock are required by SEC regulations to furnish us with copies of all Section 16(a) reports they file. Based solely on our review of the copies of such reports furnished to us, we believe that during the fiscal year ended September 30, 2018, all executive officers, directors and greater than 10% beneficial owners of our common stock complied with the reporting requirements of Section 16(a).

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, 2018 and September 30, 2017 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 ($) (1)	Option Awards ($) (2)	All other Compensation ($)	Total ($)
Dr. Terrence W. Norchi	2018	425,000	127,500	153,000	123,984		829,484
President and Chief Executive Officer	2017	350,000	97,500	422,500	357,435	—	1,227,435
Richard E. Davis	2018	325,000	81,250	116,875	94,710		617,835
Chief Financial Officer	2017	268,750	62,500	325,000	274,950	—	931,200

(1) Represents the aggregate grant date fair values of restricted stock awards granted during the fiscal year ended September 30, 2018.

(2) Represents the aggregate grant date fair values of awards granted during the fiscal years ended September 30, 2018 and 2017 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 years ended September 30, 2018 and 2017, refer to Note 10 “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 Director’s annual review of Dr. Norchi’s base salary, Dr. Norchi’s annual base salary was increased to $425,000 effective July 1, 2017.

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 Director's

annual review of Mr. Davis' base salary, Mr. Davis' annual base salary was increased to $325,000 effective July 1, 2017.

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, 2018:

	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			
	1,041,667	208,333	(4)	0.39	05/02/2026			
	419,792	230,208	(5)	0.65	02/02/2027			
	105,000	255,000	(6)	0.425	07/18/2028			
						1,030,000	(7)	432,600
						650,000	(8)	273,000
						360,000	(9)	151,200
Richard E. Davis	500,000	-	(10)	0.22	07/06/2024			
	500,000	-	(11)	0.19	01/21/2025			
	175,000	-	(12)	0.28	08/17/2025			
	125,000	25,000	(13)	0.39	05/02/2026			
	322,917	177,083	(14)	0.65	02/02/2027			
	80,208	194,792	(15)	0.425	07/18/2028			
						500,000	(16)	210,000
						275,000	(17)	115,500

(1) Represents an option to purchase 500,000 shares of Common Stock with a grant date of March 23, 2014. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, 25% of the shares shall vest 12 months following the date of grant and 1/24 th of the remaining shares shall vest on each of the monthly anniversaries of the grant date, commencing April 23, 2015.

(2) Represents an option to purchase 400,000 shares of Common Stock with a grant date of January 22, 2015. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, 25% of the shares shall vest 12 months following the date of grant and 1/24 th 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 1/36 th of the remaining shares shall vest on each of the monthly anniversaries of the grant date, commencing September 18, 2015.

(4) Represents an option to purchase 1,250,000 shares of Common Stock granted on May 3, 2016. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vesting immediately, the remaining unvested Shares subject to the Option shall vest on each of the next thirty-six (36) monthly anniversaries of the date of grant.

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

(6) Represents an option to purchase 360,000 shares of Common Stock with a grant date of July 19, 2018. The vesting period of the shares underlying the option commenced on the date of grant, with 25% of the shares vested immediately on the date of grant, and 1/36 th of the remaining shares shall vest on each of the monthly anniversaries of the grant date, commencing August 19, 2018.

(7) Represents a stock award to receive 1,030,000 shares of Common Stock granted on May 3, 2016. 100% of the stock award becomes vested on November 1, 2018.

(8) Represents a stock award to receive 650,000 shares of Common Stock granted on February 3, 2017. 100% of the stock award becomes vested on February 3, 2019.

(9) Represents a stock award to receive 360,000 shares of Common Stock granted on July 19, 2018. 100% of the stock award becomes vested on July 19, 2020.

(10) 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.

(11) 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 1/24 th of the remaining shares shall vest on each of the monthly anniversaries of the grant date, commencing February 22, 2015.

(12) 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 1/36 th of the remaining shares shall vest on each of the monthly anniversaries of the grant date, commencing September 18, 2015.

(13) 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.

(14) 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.

(15) 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.

(16) Represents a stock award to receive 500,000 shares of Common Stock granted on February 3, 2017. 100% of the stock award becomes vested on February 3, 2019.

(17) Represents a stock award to receive 275,000 shares of Common Stock granted on July 19, 2018. 100% of the stock award becomes vested on July 19, 2020.

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, 2018:

Director Compensation Table

	Fees Earned or Paid In Cash ($)	Stock Awards ($)(1)	Option Awards ($)(2)	All other Compensation ($)	Total ($)
Dr. Avtar Dhillon (3)	152,000	93,500	84,455	—	329,958
James R. Sulat (4)	50,000	46,750	37,887	—	134,634
Punit Dhillon (5)	10,000	—	68,885	—	78,880

(1) The values listed represent the aggregate grant date fair values of restricted stock awards granted during the fiscal year ended September 30, 2018.

(2) Represents the aggregate grant date fair values of awards granted during the fiscal year ended September 30, 2018 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 non-employee directors. For information on the valuation assumptions with respect to option grants made during the fiscal years ended September 30, 2018, refer to Note 10 “Stock-Based Compensation” in our consolidated financial statements included in this filing.

(3) The aggregate number of shares of Common Stock underlying option awards and stock awards outstanding as of September 30, 2018 held by Dr. Dhillon was 2,405,000 and 1,357,000, respectively. Dr. Dhillon resigned from the Board effective July 19, 2018.

(4) 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 and stock awards outstanding as of September 30, 2018 held by Mr.

Sulat was 640,000 and 340,000, respectively.

(5) 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, 2018 held by Mr. Dhillon was 200,000.

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, 2018, the Plan has reserved 22,114,256 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, 2018, the number of shares reserved for issuance under the Plan increased by 3,000,000 to 25,114,256. The following table provides information as of September 30, 2018 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	15,684,210	$ 0.40	1,878,980
Equity compensation plans not approved by security holders	—	—	—
Total	15,684,210	$ 0.40	1,878,980

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 164,441,786 shares of our Common Stock outstanding on December 17, 2018. Shares of our Common Stock subject to options, warrants, or other rights currently exercisable or exercisable within 60 days of December 17, 2018 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 (a) the 4.9% ownership limitation (which may waived at the holder's discretion, provided that such waiver will not become effective until the 61 st day after delivery of such waiver notice) to which Tungsten III, LLC ("Tungsten"), an entity controlled by Michael Parker, is subject to under the terms of the Series D Warrants issued to Mr. Parker in the 2015 Private Placement Financing that concluded on July 2, 2015 and subsequently transferred to Tungsten; and (b) the 4.99% ownership limitation (which may be increased to 9.99% at the holder's discretion, *provided that* such increase will not become effective until the 61 st day after delivery of the notice in which the holder informs us of this increase) to which the investors in our 2016 private placement that closed on May 26, 2016 (the "2016 Private Placement Financing") the 2017 Financing and their respective assignees are subject under the terms of the Series E Warrants issued in the 2016 Private Placement Financing and/or Series F Warrants issued in the 2017 Financing. As a result of the foregoing ownership limitations, the table below does not include any of the investors from the Private Placement Financings other than Mr. Parker.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned (1)	
5%+ Stockholders:			
Avtar Dhillon (4)	10,760,498	6.46	%
Twelve Pins Partners (2)	10,000,000	6.08	%
Michael A. Parker (3)	9,676,966	5.89	%
Directors and Executive Officers			
Terrence Norchi (5)	16,608,451	9.92	%
James R. Sulat (6)	2,582,018	1.56	%
Punit Dhillon (7)	100,000	0.00	%
Richard E. Davis (8)	2,671,750	1.61	%
Current Directors and Named Executive Officers as a Group (4 persons)	21,962,219	12.92	%

Shares of our Common Stock subject to options, warrants, or other rights currently exercisable or exercisable within 60 days of November 14, 2018, 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) 1,380,891 shares of Common Stock owned individually by Michael Parker; (ii) 3,296,075 shares of Common Stock owned individually by Ana B Parker, spouse of Michael Parker; 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 June 30, 2020) or 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), 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 17, 2018, Mr. Parker has not waived such limitation."

(4) Represents (a) 8,517,373 shares of our Common Stock; and (b) 2,243,125 shares subject to options exercisable within 60 days after December 17, 2018.

(5) 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; 360,000 shares of restricted stock granted to Dr. Norchi on July 19, 2018; and (e) 3,049,375 shares subject to options exercisable within 60 days after December 17, 2018. Dr. Norchi disclaims beneficial ownership of the securities held by Twelve Pins Partners, LLC except to the extent of his pecuniary interest therein.

(6) 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) 576,875 shares subject to options exercisable within 60 days after December 17, 2018. 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.

(7) Represents 100,000 shares of our Common Stock subject to options exercisable within 60 days after December 17, 2018.

(8) Represents (a) 103,000 of our Common Stock directly held by Mr. Davis; (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) 1,793,750 shares of our Common Stock subject to options exercisable within 60 days after December 17, 2018.

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

Related Party Transactions

During fiscal years 2018 and 2017, 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:

James R. Sulat, who was appointed as a member of our Board of Directors on August 19, 2015, is a co-trustee of the Keyes Sulat Revocable Trust (the "Keyes Sulat Trust"), Brenna Keyes Sulat Irrevocable Trust ("BKS Trust") and Nathaniel Keyes Sulat Irrevocable Trust ("NKS Trust", and together with the Keyes Sulat Trust and BKS Trust, the "Trusts"). In exchange for a payment of (i) $100,000, the Keyes Sulat Trust received 454,546 shares of our Common Stock upon the Initial Closing of the 2015 Private Placement Financing on June 30, 2015, and a Series D Warrant exercisable for the same number of shares at an exercise price of $0.25; (ii) $40,000, the Keyes Sulat Trust received 111,111 shares of our Common Stock upon the closing of the 2016 Private Placement Financing on May 26, 2016, and a Series E Warrant exercisable for 83,333 shares at an exercise price of $0.4380; and (iii) $100,000, the Trusts

received, in the aggregate, 166,655 shares of our Common Stock upon the closing of the 2017 Financing on February 24, 2017, and Series F Warrants exercisable for 91,665 shares of our Common Stock at an exercise price of $0.75 . Regarding the 2016 Private Placement Financing and 2017 Financing, in each case Mr. Sulat disclosed his interest in such financings to the remaining members of the Board, all of whom were disinterested in the transaction (the "Disinterested Directors"), in accordance with the Company's policies governing related party transactions (which is described below), and recused himself from discussing or voting on matters related to either financing. The Disinterested Directors unanimously approved the 2016 Private Placement Financing and 2017 Financing.

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, 2018 and 2017 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, 2018 and 2017:

	2018	2017
Audit Fees	$129,680	$115,600
Audit-Related Fees	-	-
Tax Fees	-	-
All Other Fees	-	10,853
Total	$129,680	$126,453

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. In addition, the amounts include fees for services that are normally provided by the auditor in connection with regulatory filings and engagements for the years identified.

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, 2018 and 2017 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 such as fees incurred in connection with reviewing our registration statements and prospectus supplements.

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 2018 and 2017 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.

			Incorporated By Reference			
Exhibit No.	**Exhibit Title**	**Filed Herewith**	**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
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		8-K	10.1	000-54986	7/8/2013

	William M. Cotter				
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		8-K	10.6	333-178883	6/26/2013

	Agreement dated June 10, 2013 between ABS and the Massachusetts Institute of Technology				
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
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
21.1	List of Subsidiaries	8-K	21.1	333-178883	6/26/2013
23.1	Consent of Independent Registered Public Accounting Firm	X			

Exhibit No.	Exhibit Title	Filed Herewith	Incorporated By Reference			
			Form	Exhibit No.	File No.	Filing Date
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				
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 18, 2018

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 18, 2018
/s/ Richard E. Davis Richard E. Davis	Chief Financial Officer (Principal *Financial and Accounting Officer*)	December 18, 2018
/s/ James R. Sulat James R. Sulat	Director	December 18, 2018
/s/ Punit Dhillon Punit Dhillon	Director	December 18, 2018

ARCH THERAPEUTICS, INC.

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.

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, 2018 and 2017, and the related consolidated statements of operations, changes stockholders' equity, and cash flows for each of the years in the two-year period ended September 30, 2018, 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, 2018 and 2017, and the results of their operations and their cash flows for each of the years in the two-year period ended September 30, 2018, 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 audit, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our 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 18, 2018

Arch Therapeutics, Inc.
Consolidated Balance Sheets
As of September 30, 2018 and 2017

	September 30, 2018	September 30, 2017
ASSETS		
Current assets:		
Cash	$4,667,410	$5,994,052
Prepaid expenses	151,794	85,343
Total current assets	4,819,204	6,079,395
Long-term assets:		
Property and equipment, net	17,261	7,188
Other assets	3,500	3,500
Total long-term assets	20,761	10,688
Total assets	$4,839,965	$6,090,083
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$160,946	$264,876
Accrued expenses and other liabilities	127,439	168,655
Total current liabilities	288,385	433,531
Long-term liabilities:		
Long-term derivative liability	3,191,752	3,430,033
Total long-term liabilities	3,191,752	3,430,033
Total liabilities	3,480,137	3,863,564
Commitments and contingencies (Note 13)		
Stockholders’ equity:		
Common stock, $0.001 par value, 300,000,000 shares authorized, 164,397,013 and 153,692,857 shares issued and outstanding as of September 30, 2018 and September 30, 2017, respectively	159,815	149,943
Additional paid-in capital	35,517,491	31,580,022
Accumulated deficit	(34,317,478)	(29,503,446)
Total stockholders’ equity	1,359,828	2,226,519
Total liabilities and stockholders' equity	$4,839,965	$6,090,083

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

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Arch Therapeutics, Inc.
Consolidated Statements of Operations
For the Years Ended September 30, 2018 and 2017

	Fiscal Year Ended September 30, 2018	Fiscal Year Ended September 30, 2017
Revenues	$ -	$ -
Operating expenses:		
General and administrative expenses	4,565,522	5,207,753
Research and development expenses	2,884,245	2,094,795
Total operating expenses	7,449,767	7,302,548
Operating loss	(7,449,767)	(7,302,548)
Other income (expense):		
(Increase)/decrease to fair value of derivative	2,635,735	(433,923)
Interest expense	-	(52,385)
Total other income (expense)	2,635,735	(486,308)
Net loss	$ (4,814,032)	$ (7,788,856)
Earnings per share - basic and diluted		
Net loss per common share - basic and diluted	$ (0.03)	$ (0.05)
Weighted common shares - basic and diluted	152,712,714	142,722,788

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

Arch Therapeutics, Inc.
Consolidated Statements of Changes in Stockholders' Equity
For the Years Ended Septermber 30. 2018 and 2017

	Common Stock Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at September 30, 2016	134,432,075	$134,432	$24,741,153	$(21,714,590)	$3,160,995
Net loss	-	-	-	(7,788,856)	(7,788,856)
Issuance of restricted stock for services	225,000	225	161,775	-	162,000
Shares issued for the exercise of warrants	4,978,742	4,979	1,584,909	-	1,589,888
Shares issued for the exercise of stock options	15,000	15	5,485	-	5,500
Shares issued for the exercise of stock options - cashless	106,666	106	(106)	-	-
Exercise of Series A Warrants - cashless	18,710	19	(19)	-	-
Issuance of stock in private placement funding	10,166,664	10,167	2,980,845	-	2,991,012
Stock based compensation expense	-	-	2,105,980	-	2,105,980
Balance at September 30, 2017	149,942,857	149,943	31,580,022	(29,503,446)	2,226,519
Net loss	-	-	-	(4,814,032)	(4,814,032)
Shares issued for the exercise of warrants	242,273	242	63,146	-	63,388
Shares issued for the exercise of stock options - Cashless	116,883	117	(117)	-	-
Shares issued for the exercise of stock options	210,000	210	77,490	-	77,700
Issuance of restricted stock	233,000	233	(233)	-	-
Issuance of stock in private placement funding	9,070,000	9,070	2,054,724	-	2,063,794

Stock based compensation expense	-	-	1,742,459	-	1,742,459
Balance at September 30, 2018	159,815,013	$159,815	$35,517,491	$(34,317,478)	$1,359,828

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

Arch Therapeutics, Inc.
Consolidated Statements of Cash Flows
For the Years Ended September 30, 2018 and 2017

	Fiscal Year Ended September 30, 2018	Fiscal Year Ended September 30, 2017
Cash flows from operating activities:		
Net loss	$ (4,814,032)	$ (7,788,856)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	5,342	1,498
Stock-based compensation	1,742,459	2,105,980
Noncash interest expense on notes payable	-	22,118
Issuance of restricted stock for services	-	162,000
(Decrease) increase to fair value of derivative	(2,635,735)	433,923
Changes in operating assets and liabilities:		
(Increase) decrease in:		
Prepaid expenses	(66,451)	22,441
Other Assets	-	(3,500)
Increase (decrease) in:		
Accounts payable	(103,930)	(110,020)
Accrued expenses and other liabilities	(41,216)	(130,832)
Accrued interest	-	(331,000)
Net cash used in operating activities	(5,913,563)	(5,616,248)
Cash flows from investing activities:		
Purchases of property and equipment	(15,415)	(8,686)
Net cash used in investing activities	(15,415)	(8,686)
Cash flows from financing activities:		
Proceeds from exercise of warrants	63,388	1,589,888
Proceeds from issuance of common stock and warrants	4,461,248	5,987,122
Proceeds from exercise of stock options	77,700	5,500
Payments on note payable	-	(1,000,000)
Net cash provided by financing activities	4,602,336	6,582,510
Net (decrease)/increase in cash	(1,326,642)	957,576
Cash, beginning of year	5,994,052	5,036,476
Cash, end of year	$ 4,667,410	$ 5,994,052
Non-cash financing activities:		

Warrant derivative liability	$ 2,397,454	$ 2,996,110
Exercise of stock options - cashless	$ 117	$ 107
Restricted stock - vested	$ 233	$ -
Cash paid for		
Interest on note	$ -	$ 361,268

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.

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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.

The Company is in the development stage and is 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 does not believe that this guidance will have a material impact on its consolidated results of operations, financial position or disclosures.

ASU 2016-15, “Statement of Cash Flows (Topic 230) Classification of Certain Cash Receipts and Payments” was issued by the Financial Accounting Standards Board (FASB) in August 2016. The purpose of this amendment is to address eight specific cash flow issues with the objective of reducing the existing diversity in practice. 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, 2017. Early adoption is permitted. The Company does not believe that this guidance will have a material impact on its consolidated results of operations, financial position or disclosure.

ASU 2016-09, “Compensation—Stock Compensation (Topic 718) Improvements to Employee Share-Based Payment Accounting” was issued by the FASB in March 2016. The purpose of this amendment is to simplify several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. 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, 2016. The Company adopted ASU 2016-09 during our first quarter of fiscal year 2018, which had no impact on our consolidated financial statements, and will apply the guidance in future periods.

ASU 2016-02, “Leases (Topic 842)” was issued by the FASB in February 2016. The purpose of this amendment requires the recognition of lease assets and lease liabilities by lessees for those leases previously classified as operating leases. 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 does not believe that this guidance will have a material impact on its consolidated results of operations, financial position or disclosures.

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, 2018 and September 30, 2017.

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.

Deferred Offering Costs

Deferred Offering Costs consist of fees and expenses incurred in connection with the public offering and sale of the Company’s common stock, including legal, accounting, printing and other related expenses. These costs are netted against the proceeds received as a reduction to additional paid-in capital.

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 Equipment* .. For assets that are to be held and used, impairment is recognized when the estimated undiscounted cash flows associated with the asset or group of assets is less than their carrying value. If impairment exists, an adjustment is made to write the asset down to its fair value, and a loss is recorded as the difference between the carrying value and fair value. Fair values are determined based on quoted market values, discounted cash flows or internal and external appraisals, as applicable. Assets to be disposed of are carried at the lower of carrying value or estimated net realizable value. For the years ended September 30, 2018 and 2017 there has not been any impairment of long-lived assets.

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.

On December 22, 2017, the Tax Cuts and Jobs Act (“TCJA”) was signed into United States law. The TCJA includes a number of changes to existing tax law, including, among other things, a permanent reduction in the federal corporate

income tax rate to a flat rate of 21%, effective January 1, 2018, as well as the elimination of net operating loss carrybacks for losses arising in taxable years beginning after December 31, 2017. Further, operating losses arising in tax years after December 31, 2017, are carried forward indefinitely. Due to the TCJA, the Company's deferred tax assets and liabilities recognized prior to 2017 were revalued at the newly enacted tax rates, which resulted in a corresponding adjustment in the valuation allowance.

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 employee 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 to employees, including grants of employee stock options, to be recognized in the consolidated financial statements based on their fair values. The Company accounts for non-employee stock-based compensation in accordance with the guidance of FASB ASC Topic 505, *Equity* ("FASB ASC Topic 505"), which requires that companies recognize compensation expense based on the estimated fair value of options granted to non-employees over their vesting period, which is generally the period during which services are rendered by such non-employees. FASB ASC Topic 505 requires the Company to re-measure the fair value of stock options issued to non- employee at each reporting period during the vesting period or until services are complete.

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. The Company does not have a sufficient history of market prices of the common stock, and as such volatility is estimated in accordance with ASC 718-10-S99 Staff Accounting Bulletin ("SAB") No. 107, *Share-Based Payment* ("SAB No. 107"), using historical volatilities of similar public entities. 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, 2018 and September 30, 2017, the carrying amounts of cash, accounts payable, accrued expenses and other liabilities, approximate fair value because of their short-term nature.

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, 2018 and ending on December 17, 2018 the date which these consolidated financial statements were issued. The Company disclosed material subsequent events in Note 15.

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, 2018, 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. 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 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 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 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, 2018 and September 30, 2017, property and equipment consisted of:

	Estimated Useful Life	September 30, 2018	September 30, 2017
Furniture and fixtures	5 years	$ 9,357	$ 2,925
Leasehold improvements	3 years	$ 8,983	$ -
Computer equipment	3 years	$ 8,686	$ 8,686
Lab equipment	5 years	$ 1,000	$ 1,000
		28,026	12,611
Less – accumulated depreciation		10,765	5,423
Property and equipment, net		$ 17,261	$ 7,188

For the years ended September 30, 2018 and 2017 depreciation expense recorded was $5,342 and $1,498, respectively.

4. INCOME TAXES

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

	2018	2017
Net operating loss carryforwards	$5,848,080	$7,129,736
Capitalized expenditures	1,486,679	1,511,187
Research and experimentation credit carryforwards	802,765	632,659
Stock based compensation	2,074,247	2,370,477
Property and Equipment	1,235	1,488
Accrued expenses	13,660	20,100
Deferred rent	328	-
Gross deferred tax assets	10,226,994	11,665,647
Deferred tax asset valuation allowance	(10,226,994)	(11,665,647)

Net deferred tax assets	$-	$-

As of September 30, 2018 and 2017, the Company had federal net operating loss carryforwards of approximately $21,770,000 and $17,960,000, respectively, which may be available to offset future taxable income and which would begin to expire in 2026. As of September 30, 2018 and 2017, the Company had federal research and experimentation credit carryforwards of $616,217 and $380,982, respectively, which may be available to offset future income tax liabilities and which would begin to expire in 2029.

As of September 30, 2018 and 2017, the Company had state net operating loss carryforwards of approximately $20,730,000 and $16,771,000, respectively, which may be available to offset future taxable income and which would begin to expire in 2018. As of September 30, 2018 and 2017, the Company had state research and experimentation credit carryforwards of $236,000 and $162,000, 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, 2018 and 2017 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 decreased in 2018 by approximately $1,440,000 and increased in 2017 by approximately $3,041,000. 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, 2018, the Company is open to examination in the U.S. federal and certain state jurisdictions for tax years ended September 30, 2018, 2017, 2016, and 2015.

5. 2014 PRIVATE PLACEMENT FINANCING

On January 30, 2014, the Company entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with nine separate accredited investors ("2014 Investors") providing for the issuance and sale by the Company to the 2014 Investors, in a private placement, of an aggregate of 11,400,000 shares of Common Stock (collectively, the "2014 Shares") at a purchase price of $0.25 per share and three series of warrants, the Series A warrants, the Series B warrants and the Series C warrants, to purchase up to an aggregate of 34,200,000 shares of the Company's Common Stock (collectively, the " 2014 Warrants ," and the shares issuable upon exercise of the 2014 Warrants, collectively, the "2014 Warrant Shares"), for aggregate gross proceeds to the Company of approximately $2,850,000 (the "2014 Private Placement Financing").

Upon the closing of the 2014 Private Placement Financing on February 4, 2014 (the "Closing Date"), the Company entered into a registration rights agreement (the "2014 Registration Rights Agreement) with the 2014 Investors, pursuant to which the Company became obligated, subject to certain conditions, to file with the SEC on or before March 21, 2014 one or more registration statements to register for resale under the Securities Act of 1933, as amended (the "Securities Act"), (i) the 2014 Shares and the 2014 Warrant Shares, plus (ii) an additional number of shares of Common Stock equal to 33% of the total number of 2014 Shares and 2014 Warrant Shares, to account for adjustments, if any, to the number of 2014 Warrant Shares issuable pursuant to the terms of the 2014 Warrants (the securities set forth in this clause (ii), the "Additional Shares"). Under the terms of the 2014 Registration Rights Agreement, the Company was permitted to reduce the number of shares covered by a registration statement if such reduction is required by the SEC as a condition for permitting such registration statement to become effective and treated as a resale registration statement (the "Cutback Provisions"). In response to comments received from the SEC and in accordance with the terms of the 2014 Registration Rights Agreement, the Company reduced the number of shares included in its draft resale registration statement (the "2014 S-1") by the number of Additional Shares. The Company's failure to satisfy certain other obligations and deadlines set forth in the 2014 Registration Rights Agreement may subject the Company to payment of monetary penalties as discussed below. The resale registration statement was declared effective on July 2, 2014. As described below, in the event that we fail to comply with certain requirements in the 2014 Registration Rights Agreement, we may be required to pay liquidated damages to the investors.

The 2014 Registration Rights Agreement also obligated the Company to register the resale of all securities covered by the 2014 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 "2014 S-3") to register the remaining securities covered by the 2014 Registration Rights Agreement, and the 2014 S-3 was declared effective on November 23, 2016. Pursuant to Rule 429 promulgated under the Securities Act, the 2014 S-3 contained a combined prospectus that covered the securities that remained unsold under the 2014 S-1 and also registered those same securities under the 2014 S-3. Under Rule 429, the 2014 S-3 also constituted a

post-effective amendment to the 2014 S-1, which became effective on the date that the 2014 S-3 was declared effective.

The 2014 Warrants were exercisable immediately upon issuance. The Series A warrants had an initial exercise price of $0.30 per share and expire five years from the date of their issuance. The Series B warrants had an initial exercise price of $0.35 per share and expired on the earlier of 12 months after their issuance date or six months after the first date on which the resale of all Registrable Securities (as defined in the 2014 Registration Rights Agreement) is covered by one or more effective registration statements, which occurred on July 2, 2014 (the "2014 Registration Statement Effective Date"). The Series B warrants expired on January 2, 2015. The Series C warrants had an initial exercise price of $0.40 per share and an initial expiration on the earlier of 18 months after their issuance date or nine months after the 2014 Registration Statement Effective Date. As described below, the term of the Series C Warrants was extended to 5:00 p.m., New York time, on July 2, 2016 and, prior to such expiration date, all 11,400,000 shares underlying the Series C Warrants were exercised. The number of shares of the Company's Common Stock into which each of the 2014 Warrants is exercisable and the exercise price therefore were subject to adjustment as set forth in the 2014 Warrants, including, without limitation, adjustment to both the exercise price of the 2014 Warrants in the event of certain subsequent issuances and sales of shares of the Company's Common Stock (or securities convertible or exercisable into shares of Common Stock) at a price per share lower than the then-effective exercise price of the 2014 Warrants, in which case the per share exercise price of the 2014 Warrants would be adjusted to equal such lower price per share and the number of shares issuable upon exercise of the 2014 Warrants would be adjusted accordingly so that the aggregate exercise price upon full exercise of the 2014 Warrants immediately before and immediately after such per share exercise price adjustment were equal (the "Anti-Dilution Provisions"). The 2014 Warrants are also subject to customary adjustments in the event of stock dividends and splits, subsequent rights offerings and pro rata distributions to the Company's common stockholders, and 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 Warrant or any of its affiliates beneficially would then own more than 4.9% of the Company's Common Stock. The Company may be required to make certain payments to the 2014 Investors under certain circumstances in the future pursuant to the terms of the Securities Purchase Agreement and the 2014 Registration Rights Agreement. These potential future payments include: (a) potential partial damages for failure to register the Common Stock issued or issuable upon exercise of 2014 Warrants in a cash amount equal to 1% of the price paid to the Company by each investor in the 2014 Private Placement Financing on the date of and on each 30-day anniversary of such failure until the cure thereof; (b) amounts payable if the Company and its transfer agent fail to timely remove certain restrictive legends from certificates representing shares of Common Stock issued in the 2014 Private Placement Financing or issuable upon exercise of the 2014 Warrants; (c) expense reimbursement for the lead investor in the 2014 Private Placement Financing; and (d) payments in respect of claims for which the Company provides indemnification. There is no cap to the potential consideration.

On December 1, 2014, the Company entered into an agreement with Cranshire Capital Master Fund, Ltd. ("Cranshire"), which was the lead investor in the 2014 Private Placement Financing, to amend certain provisions of the 2014 Warrants (the "December 2014 Amendment"). Under the terms of the December 2014 Amendment, the 2014 Warrants were amended to (i) reduce the exercise price of the Series B Warrants from $0.35 to $0.20; (ii) reduce the exercise price of the Series C Warrants from $0.40 to $0.20; and (iii) clarify that each series of 2014 Warrants may be amended without having to amend all three series of 2014 Warrants. The number of shares of the Company's Common Stock, which may be purchased from the Company upon exercise of each 2014 Warrant, remained unchanged. In conjunction with the December 2014 Amendment, the Company recognized a loss on the modification of 2014 Warrants in the amount of $1,300,170, which was determined using Monte Carlo Simulation valuation model.

As of December 2, 2014, Series B Warrants had been exercised for an aggregate issuance of 4,000,000 shares of the Company's Common Stock resulting in gross proceeds to the Company of $800,000. In conjunction with the exercise of the Series B Warrants, their corresponding fair value at the exercise dates of $224,000 were extinguished from the derivative liabilities balance.

On March 13, 2015, the Company issued unsecured 8% Convertible Notes in the aggregate principal amount of $750,000 - See footnote 6. The Company's issuance of the Notes triggered the Anti-Dilution Provisions of the Series A Warrants and, as a result, the exercise price of the Series A Warrants was reduced to $0.20 per share and the aggregate number of shares issuable under the Series A Warrants increased by 5,700,000 shares from 11,400,000 shares to 17,100,000 shares. In addition, on March 13, 2015 and May 30, 2015, respectively the expiration date of the Series C Warrants was extended to June 2, 2015 and July 2, 2015, respectively. In conjunction with the March 13, 2015 amendment, the Company recognized a loss on the modification of warrants in the amount of $624,016, which was determined using Monte Carlo Simulation.

Prior to June 22, 2015, Series C Warrants had been exercised for an aggregate issuance of 2,255,000 shares of the Company's common stock resulting in gross proceeds to the Company of $451,000. In conjunction with the exercise of the Series C Warrants, their corresponding fair value at the exercise dates of $75,321 were extinguished from the derivative liabilities balance and recognized as a gain in the Company's statements of operations.

On June 22, 2015 the Company entered into an amendment to the Series A Warrants and Series C Warrants to purchase Common Stock (the "June 2015 Amendment"), with Cranshire, to (i) delete the Anti-Dilution Provisions in the Series A Warrants and Series C Warrants; and (ii) extend the expiration date of the Series C Warrants from to 5:00 p.m., New York time, on July 2, 2015 to 5:00 p.m., New York time, on July 2, 2016. In consideration of Cranshire's entrance into the June 2015 Amendment (and for no additional consideration), the Company agreed to issue to the holders of the 2014 Warrants up to 570,000 shares of Company's Common Stock subject to the delivery by each such holder of an investor certificate to the Company (such shares of Common Stock, the "Inducement Shares"). All 570,000 Inducement Shares have been issued. In conjunction with the modifications to the Series A and Series C Warrants in the June 2015 Amendment, the Company recognized a gain on modification of warrants, net of Inducement Shares, in the amount of $927,373 which was determined using the Black Scholes model. As of June 22, 2015, the Company

determined that its Series A and C Warrants were eligible for equity classification due to the elimination of the full ratchet anti-dilution provision. As a result, as of June 22, 2015, the then-current value of the derivative liabilities of $3,263,753 was reclassified as equity within the Company's consolidated financial statements.

During the year ended September 30, 2018, no Series A Warrants had been exercised. During the year ended September 30, 2017, Series A Warrants had been exercised on a cash basis for an aggregate issuance of 1,100,000 shares of the Company's common stock, resulting in gross proceeds to the Company of $220,000. During the year ended September 30, 2016, Series C Warrants had been exercised on a cash basis for an aggregate issuance of 3,400,000 shares of the Company's Common stock, respectively, resulting in gross proceeds to the Company of $680,000. As of September 30, 2018, all Series A Warrants and Series C Warrants have been exercised.

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, as described in Note 5, 2014 Private Placement Financing, 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.

During the year ended September 30, 2018, Series D Warrants had been exercised on a cash basis for an aggregate issuance of 227,273 shares of the Company's Common Stock resulting in gross proceeds to the Company of $56,818. During the year ended September 30, 2017, Series D Warrants had been exercised on a cash basis for an aggregate issuance of 1,750,001 shares of the Company's Common stock resulting in gross proceeds to the Company of $437,500. As of September 30, 2018, up to 8,974,389 shares may be acquired upon the exercise of the Series D Warrants.

Common Stock

At the June 30, 2015 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 are indexed to the Company's stock, they are classified within stockholders' equity 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 61 st day after delivery of such notice.

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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 year ended September 30, 2018, Series E Warrants had been exercised on a cash basis for an aggregate issuance of 15,000 shares of the Company's Common stock resulting in gross proceeds to the Company of $6,570. During the year ended September 30, 2017, Series E Warrants had been exercised on a cash basis for an aggregate issuance of 2,128,741 shares of the Company's Common stock resulting in gross proceeds to the Company of $932,388. As of September 30, 2018, 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 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.

As of September 30, 2018, no Series F Warrants have been exercised. As of September 30, 2018, up to 5,591,664 shares may be acquired upon the exercise of the Series F Warrants.

As noted in Note 12, on September 28, 2016, the Company and the Massachusetts Life Sciences Center ("MLSC") entered into the Amendment. Pursuant to this Amendment, the term "Qualified Financing" was defined to mean one or more financing transactions in which the Company received, in a single transaction or series of transactions, cumulative net proceeds of not less than five million dollars ($5,000,000) at any time after October 3, 2016. On March 3, 2017 approximately $830,000 of the offering proceeds were used to satisfy the Company's outstanding indebtedness to MLSC under the MLSC Loan Agreement.

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, 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 were 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 fiscal years ended September 30, 2018 and 2017, ($2,155,629) and $433,923 was recorded to Increase/(decrease) to fair value of derivative, respectively.

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

	September 30, 2018	September 30, 2017
Beginning balance at beginning of year	$ 3,430,033	$ -
Issuances	-	2,996,110
Adjustments to estimated fair value	(2,155,629)	433,923
Ending balance at end of year	$ 1,274,404	$ 3,430,033

The derivative liabilities were valued as of February 24, 2017, September 30, 2017 and September 30, 2018 using the Black Scholes Model with the following assumptions:

	February 24, 2017	September 30, 2017	September 30, 2018
Closing price per share of common stock	$ 0.68	$ 0.60	$ 0.42
Exercise price per share	$ 0.75	$ 0.75	$ 0.75
Expected volatility	111.84 %	109.77 %	98.43 %
Risk-free interest rate	1.80 %	1.89 %	2.88 %
Dividend yield	—	—	—
Remaining expected term of underlying securities (years)	5.00	4.39	3.38

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.

As of September 30, 2018, no Series G Warrants have been exercised. As of September 30, 2018, 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, they are recorded as liabilities at fair value. They are marked to market each reporting period through the consolidated statement of operations.

On September 30, 2018 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. During the fiscal year ending September 30, 2018, $480,106 was recorded to decrease the fair value of derivative.

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)	September 30, 2018
Balance at September 30, 2017	$ -
Issuances	2,397,454
Adjustments to estimated fair value	(480,106)
Ending balance at September 30, 2018	$ 1,917,348

The derivative liabilities were valued as of June 30, 2018 and September 30, 2018 using the Black Scholes Model with the following assumptions:

	June 30, 2018	September 30, 2018
Closing price per share of common stock	$0.48	$ 0.42
Exercise price per share	$0.70	$ 0.70
Expected volatility	105.94 %	100.18 %
Risk-free interest rate	2.73 %	2.94 %
Dividend yield	—	—
Remaining expected term of underlying securities (years)	5.00	4.74

10. 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, 2018, a maximum number of 22,114,256 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, 2018, the aggregate number of authorized shares under the Plan was further increased by 3,000,000 shares to a total of 25,114,256 shares.

As of September 30, 2018, a total of 15,569,212 options had been issued to employees and directors and 6,027,500 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 fiscal year ended September 30, 2018, the Company granted 1,860,000 options to employees and directors and 745,000 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 fiscal year ended September 30, 2018 was based on the fair market value at period end 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 fiscal year ended September 30, 2018; expected volatility, 93.15% - 119.44%, risk-free interest rate, 1.31% - 2.85%, expected forfeiture rate, 0%, expected dividend yield, 0%, expected term, 6.25 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 is 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, 2018 follows:

	Option Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at September 30, 2017	14,634,210	$ 0.39	4.72	$6,178,263
Awarded	2,605,000	$ 0.45	-	-
Exercised	(435,000)	$ 0.37	-	-
Forfeited/Cancelled	(1,120,000)	$ 0.42	-	-
Outstanding at September 30, 2018	15,684,210	$ 0.41	3.89	$1,142,521
Vested	12,703,439	$ 0.39	4.25	$1,123,133
Vested and expected to vest at September 30, 2018	15,684,210	$ 0.40	3.89	$1,142,521

As of September 30, 2018, 1,878,980 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 years ended September 30, 2018 and 2017 resulting from stock options awarded to the Company’s employees, directors and consultants was approximately $913,000 and $1,343,000, respectively. Of this amount during the years ended

September 30, 2018 and 2017, $349,000 and $374,000, respectively, was recorded to research and development expenses, and $564,000 and $969,000, respectively was recorded in general and administrative expenses in the Company's Consolidated Statements of Operations.

During the year ended September 30, 2018, 225,000 stock options awarded under the 2013 Stock Incentive Plan were exercised on a cashless basis for an aggregate issuance of 116,883 shares of the Company's Common Stock. In addition, during the year ended September 30, 2017, 240,000 stock options awarded under the 2013 Stock Incentive Plan were exercised on a cashless basis for an aggregate issuance of 106,666 shares of the Company's Common Stock.

As of September 30, 2018, there is approximately $754,000 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 1.42 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. Dhillon in his capacity as a consultant. The shares subject to this grant are awarded under the 2013 Plan and 100% 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.

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.

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 are awarded under the 2013 Plan and 100% 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.

On August 9, 2016, we entered 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 the consulting agreement, we issued (i) 225,000 shares of Common Stock under our 2013 Stock Incentive Plan at an agreed upon value of $0.72 per share, which was the closing price of our common stock on August 9, 2016; and (ii) an option under our 2013 Stock Incentive Plan to purchase up to 375,000 shares of Common Stock at an exercise price of price of $0.72 per share, in each case to John R. Exley, Acorn's Chief Executive Officer and the party designated by Acorn to receive its shares and option. The shares and option are subject to time-based vesting restrictions. Of the 225,000 shares of Common Stock granted to Mr. Exley, 75,000 vest 90 days from the date of the award, 75,000 vest 120 days from the date of the award and the remaining 75,000 shares are scheduled to vest 150 days from the date of the award. Of the stock options to purchase up to 375,000 shares of Common Stock awarded to Mr. Exley, 125,000 vest 90 days from the date of the award, 125,000 vest 120 days from the date of the award and the remaining 125,000 shares are scheduled to vest 150 days from the date of the award. The issuance and sale of the shares of Common Stock and option to Acorn has not been registered under the Securities Act, and 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 securities were issued and sold in reliance upon an exemption from registration afforded by Section 4(a)(2) of the Securities Act based on the following facts: Acorn has represented that it is an accredited investor as defined in Regulation D promulgated under the Securities Act, that it is acquiring the securities for investment only and not with a view towards, or for resale in connection with, a distribution thereof in violation of applicable securities laws; that it understood that the securities would be issued as restricted securities and as a result, it must bear the economic risk of its investment in the securities for an indefinite period of time.

Restricted stock activity under the 2013 Plan for the year ended September 30, 2018 and 2017 follows:

	2018	2017
Non Vested at September 30, 2017	1,750,000	225,000
Awarded	1,065,000	1,750,000
Vested	-	(225,000)
Forfeited	-	-
Non Vested at September 30, 2018	2,815,000	1,750,000

The weighted average restricted stock award date fair value information for the year ended September 30, 2018 follows:

	Weighted Average Restricted Stock Award
Non Vested at September 30, 2017	$ 0.65
Awarded	0.43
Vested	-
Forfeited	-
Non Vested at September 30, 2018	$ 0.57

Non-employee restricted shares subject to vesting are revalued at each vesting date and at the end of the reporting period, with all changes in fair value recorded as stock-based compensation expense. For the years ended September 30, 2018 and 2017 compensation expense recorded for the restricted stock awards was approximately $600,000 and $372,000, respectively.

11. 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 100% shall 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 will immediately vest. During the fiscal year ended September 30, 2018, 233,000 shares of restricted stock awarded outside the 2013 Plan vested.

Restricted Stock activity for the years ended September 30, 2018 and 2017 is as follows:

	2018	2017
Non Vested at beginning of year	2,000,000	2,000,000
Awarded	-	-
Vested	(233,000)	-
Forfeited	-	-
Non Vested at end of year	1,767,000	2,000,000

The weighted average restricted stock award date fair value information for the years ended September 30, 2018 and 2017 follows:

	2017	2017
Non Vested at beginning of year	$0.39	$0.39
Awarded	-	-
Vested	0.39	-
Forfeited	-	-
Non Vested at end of year	$0.39	$0.39

For the years ended September 30, 2018 and 2017, compensation expense recorded for the restricted stock awards was approximately $229,000 and $553,000, respectively.

12. NOTE PAYABLE

On September 30, 2013, the Company entered into the Life Sciences Accelerator Funding Agreement (“MLSC Loan Agreement”) with the Massachusetts Life Sciences Center (“MLSC”), pursuant to which MLSC provided an unsecured subordinated loan in the amount of $1,000,000 (“MLSC Loan”). The loan originally bore interest at a rate of 10% per annum, and was originally scheduled to become fully due and payable on the earlier of (i) September 30, 2018, (ii) the occurrence of an event of default under the MLSC Loan Agreement, or (iii) the completion of a sale of substantially all of our assets, a change-of-control transaction (“Qualified Sale”) or one or more financing transactions in which we receive from third parties other than our then existing shareholders net proceeds of $5,000,000 or more in a 12-month period (“Qualified Financing”). The MLSC Loan Agreement includes warrants to purchase 145,985 shares of the Company’s Common Stock at an exercise price of $0.27 per share. None of the warrants, which expire on September 30, 2023, have been exercised as of September 30, 2018.

Of the $1,000,000, the Company allocated $944,707 to the loan and $55,293 to the warrants. The allocation of funds to the warrants resulted in a discount on the loan, which is accreted to interest expense over the life of the loan. For the fiscal year ended September 30, 2018 and 2017, approximately $0 and $22,100, respectively of the loan discount was accreted to interest expense. As of September 30, 2018 and 2017, the balance of the MLSC loan was $0.

On September 28, 2016, the Company and MLSC entered into that certain Amendment Agreement to Arch Therapeutics, Inc. Accelerator Funding Agreement (“Amendment”). Under the terms of the Amendment, (i) interest on the MLSC Loan decreased from 10% per annum to 7% per annum beginning October 3, 2016; and (ii) the MLSC Loan became due and payable on the earlier of October 3, 2017 (“Maturity Date”), the occurrence of a Corporate Event (which was defined as the occurrence of either a Qualified Sale or Qualified Financing), or the occurrence of a Default (as defined in the promissory note issued in connection with the MLSC Loan Agreement). In addition, under the terms of the Amendment, (a) beginning October 3, 2016, the Company began amortizing the principal and accrued interest under the MLSC Loan by making the first of 13 monthly payments of approximately $106,022, with the last payment scheduled to occur on the Maturity Date; and (b) the term “Qualified Financing” was defined to mean one or more financing transactions in which we receive, in a single transaction or series of transactions, cumulative net proceeds of not less than five million dollars ($5,000,000) at any time after October 3, 2016. As a result of the Amendment, the Company expected to reduce interest expenses that would otherwise be incurred under the MLSC Loan Agreement by approximately $232,000 due to the effect of the amortization payments and the lower 7% per annum interest rate. On February 24, 2017, the Company completed a registered direct offering with gross proceeds of approximately $6.1 million, which under the Amendment, qualified as a Corporate Event. On March 3, 2017 approximately $830,000 of the offering proceeds were used to satisfy the outstanding indebtedness to the MLSC under the MLSC Loan Agreement. As a result of the Amendment and the acceleration of the Company’s obligation to repay the MLSC Loan as a result of the offering, the Company reduced interest expense that would otherwise be incurred under the MLSC Loan Agreement by approximately $250,000.

13. 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, 2018 and 2017, 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, 2018 and 2017. For the years ended September 30, 2018 and 2017, 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 thru 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, 2018.

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

We do not own any real property. In October 2013, we entered into a one and one-half year operating sublease agreement pursuant to which we leased the office space of our relocated headquarters in Wellesley, Massachusetts for a base annual rent equal to $5,031 per month. In April 2015, we moved our corporate offices to a property in Framingham, Massachusetts. We entered into a month-to-month operating lease agreement, pursuant to which we are obligated to pay monthly rent of $2,000, with a minimum six month commitment. 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. We are no longer party to the October 2013 lease, and we believe our present offices are suitable for our current and planned near-term operations.

The following table reflects the Company's annual lease commitments:

Year Ending September 30,	
2019	$39,600
2020	42,000
	$81,600

14. Selected Quarterly Financial Data (unaudited)

The following table provides selected quarterly financial data for the fiscal years ended September 30, 2018 and 2017:

	Quarters Ended			
	December 31, 2017	March 31, 2018	June 30, 2018	September 30, 2018
Net sales	$-	$-	$-	$-
Gross profit	$-	$-	$-	$-
Operating income (loss)	$(1,582,373)	$(2,013,845)	$(1,620,134)	$(2,233,415)
Net Income (loss)	$389,176	$(1,555,361)	$(2,212,640)	$(1,435,207)
Net income (loss) per share - basic and diluted	$-	$(0.01)	$(0.01)	$(0.01)
Weighted average shares - basic	150,144,575	150,302,013	150,550,189	159,778,165
Weighted average shares - diluted	163,527,032	150,302,013	150,550,189	159,778,165

	Quarters Ended			
	December 31, 2016	March 31, 2017	June 30, 2017	September 30, 2017
Net sales	$-	$-	$-	$-
Gross profit	$-	$-	$-	$-
Operating (loss)	$(1,375,931)	$(2,204,123)	$(1,841,066)	$(1,881,428)
Net (loss)	$(1,401,501)	$(1,869,432)	$(1,775,740)	$(2,742,183)
Net (loss) per share - basic and diluted	$(0.01)	$(0.01)	$(0.01)	$(0.02)
Weighted average shares - basic and diluted	135,319,847	140,513,488	147,019,042	147,989,550

15. SUBSEQUENT EVENTS

The Company evaluated subsequent events from October 1, 2018 through December 17, 2018, and concluded that no subsequent events have occurred that would require recognition or disclosure in the consolidated financial statements.