Arch Therapeutics, Inc.
Form 10-K
November 15, 2017

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, 2017

OR

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

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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 ¨ (Do not check if a smaller reporting company) 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 7(a)(2)(B) of the Securities Act. ¨

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

EXPLANATORY NOTE

The registrant met the "accelerated filer" requirements as of the end of its 2017 fiscal year pursuant to Rule 12b-2 of the Securities Exchange Act of 1934, as amended. However, pursuant to Rule 12b-2 and SEC Release No. 33-8876, the registrant (as a smaller reporting company transitioning to the larger reporting company system based on its public float as of March 31, 2017) is not required to satisfy the larger reporting company requirements until its first quarterly report on Form 10-Q for the 2018 fiscal year and thus is eligible to check the "Smaller Reporting Company" box on the cover of this Form 10-K.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange 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 $78,000,000. 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 November 14, 2017, 153,935,130 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**" refe to 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 (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.

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 November 14, 2017, we believe that our current cash on hand will meet our anticipated cash requirements into the fourth quarter of Fiscal 2018. 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 To**
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 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’ (Arch) 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.

Clinical Development

In October 2016, we reported that we completed a single-center, randomized, single-blind prospective clinical study (NCT 02704104) of the 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 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.

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 plus a sham. 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.

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.

Preclinical Development

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 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**"). Pursuant to the Project Agreement, NUIG will provide, via the CÚRAM Centre for Research in Medical Devices ("**CÚRAM**"), which is a major national research center headquartered at NUIG established in January 2015 as part of a six-year grant from the Irish government,

personnel, infrastructure support and grant funding in connection with a research program intended to facilitate the continued development of the Company's core technology (the "**Project**"). Under the terms of the Project Agreement, which has a term that will end upon the earlier of the completion of the Project the sixth anniversary of the execution date of the Project Agreement, or termination by either party, we may contribute up to a maximum of two hundred and fifty thousand euro (€250,000) to the Project per year, and NUIG will match such funds at a 2:1 ratio using funds allocated to NUIG by Science Foundation Ireland's ("**SFI**") Research Centres Programme. In addition, while NUIG will initially retain ownership of all intellectual property developed in connection with the Project (collectively, "**Project IP**"), any such Project IP that was either based on or derived from our existing intellectual property ("**Derivative IP**") will be assigned back to us for a nominal fee. For any Project IP that does not constitute Derivative IP ("**Non-Derivative IP**"), we will have a right of first negotiation for an exclusive license to such Non-Derivative IP on customary terms for agreements of that nature including royalties on net sales in the low single-digits, in each case subject to a grant-back to NUIG for research and academic purposes. 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 the 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 a control substance, a saline control substance, a control peptide, and a cautery control substance 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 ill 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 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 formulation material to be used for final 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 decade 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 U.S. Food and Drug Administration ("**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. The Company plans to include data from this trial, as well as data available from the U.S. in a CE mark application that we currently intend to submit in 2018 and approval of which is required in order to market and commercialize AC5 as a medical device in Europe. We also expect to use this data in support of additional U.S. regulatory filings.

We expect that we will pursue approvals for use of AC5 as a hemostatic agent and wound care agent in surgical and dermatological settings, and we may also seek to obtain approvals for additional potential indications for use of the product, which we may pursue either opportunistically or once initial regulatory approval for the product is obtained.

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.

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 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;

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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 November 14, 2017, we believe that our current cash on hand will meet our anticipated cash requirements into the fourth quarter of Fiscal 2018. 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 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 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., Mallinckrodt plc, 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, 2017 was $2,094,795, an increase of $411,496 compared to $1,683,299 for the year ended September 30, 2016. We expect our research and development activities and expenses to increase significantly as we execute on our business plan and commence additional clinical trials.

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 will be 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 will ultimately determine 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. On July 25, 2017, we announced that we had made a 510(k) submission to FDA for our AC5™ Topical Gel. If our 510(k) application is cleared by the FDA, it is expected that the AC5™ Topical Gel will be used for external wounds.

To obtain 510(k) marketing clearance for a medical device, an applicant must submit a premarket notification application to the FDA demonstrating that the device is "substantially equivalent" to a predicate device, 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.

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 and approval 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, an advisory panel of 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 panel's recommendation. 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 that affect the safety or efficacy of the device, 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, and 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 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