Arch Therapeutics, Inc.
Form 10-K
December 12, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549
FORM 10-K

(Mark One)

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

For the fiscal year ended September 30, 2014

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.)
20 William Street, Suite 270 **Wellesley, MA**	**02481**
(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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting 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

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 $18,000,000 For purposes of this calculation, it has been assumed that shares of common stock held by each director, each officer and each person who owns 10% or more of the registrant's outstanding common stock are held by affiliates.

As of December 10, 2014, 76,076,487 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; anti-dilution protection afforded investors in prior financing transactions and restrictions under its existing loan agreement with the Massachusetts Life Sciences Center that may restrict or prohibit Arch's ability to raise capital or borrow funds on terms favorable to the Company and its current stockholders; 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 SEC. Copies of Arch's filings with the Securities and Exchange Commission ("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 pending trademark applications for AC5 Surgical Hemostatic Device™, AC5 Surgical Hemostat™, 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. was incorporated under the laws of the State of Nevada on September 16, 2009 with the name "Almah, Inc." to pursue the business of distributing automobile spare parts online. Effective June 26, 2013, Arch 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"), Arch'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 Arch. Prior to the completion of the Merger, Arch was a "shell company" under applicable rules of the SEC and had no or nominal assets or operations. Upon its acquisition of ABS, Arch abandoned its prior business plan and changed its operations to the business of a life science medical device company.

For financial reporting purposes, the Merger represented a "reverse merger" rather than a business combination and ABS was deemed to be the accounting acquirer in the transaction and the predecessor of Arch. Consequently, the assets, liabilities, deficit accumulated during the development stage and the historical operations that are reflected in the Company's consolidated financial statements are those of ABS. All share information has been restated to reflect the effects of the Merger. The Company's financial information was 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 and will be so replaced in all future filings with the SEC that require financial statements to be included.

ABS was incorporated under the laws of the Commonwealth of Massachusetts on March 6, 2006 as Clear Nano Solutions, Inc., changed its name to Arch Therapeutics, Inc. on April 7, 2008, and changed its name from Arch Therapeutics, Inc. to Arch Biosurgery, Inc. upon the closing of the Merger on June 26, 2013.

Our Current Business

The Company is in the development stage, has generated no operating revenues to date, and is devoting substantially all of its operational efforts toward product research and development. We aim to develop products that make surgery and interventional care faster and safer by using a novel approach to stop bleeding (referenced as “hemostasis”), control leaking (referenced as “sealant”), and provide other advantages during surgery and trauma care. Our core technology is based on a self-assembling peptide that creates a physical, mechanical barrier, which could be applied to seal organs or wounds that are leaking blood and other fluids. 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 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. The Company believes that its current cash and cash equivalents on hand will only be sufficient to meet its anticipated cash requirements into March 2015. The Company will be required to raise additional capital, obtain alternative means of financial support, or both, on or prior to March 2015 in order to continue to fund operations. 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.

Our Core Technology

Our primary product candidate, AC5 Surgical Hemostatic Device™ (“AC5” or “AC5™”), relies on our core technology and is designed to achieve hemostasis in minimally invasive and open surgical procedures, and we hope to develop other products in the future based on our technology platform aimed at stopping bleeding and sealing other leaking fluids during surgical and other procedures. AC5 is a biocompatible synthetic peptide comprising 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. We believe that the results of early data from preclinical animal tests have shown quick and effective hemostasis with the use of AC5 relative to other types of hemostatic agents. AC5 is designed for either direct application as a liquid or application as a spray, which we believe will make it user-friendly and able to conform to irregular wound geometry. Additionally, AC5 is not sticky or glue-like, which we believe will enhance its utility in the setting of minimally invasive and laparoscopic surgeries. Further, AC5 is transparent, which should make it easier for a surgeons or other

healthcare providers to maintain a clear field of vision during a surgical procedure and prophylactically stop bleeding as it starts, which we call Crystal Clear Surgery™. Finally, Arch and an independent third-party research group have each conducted preclinical studies that have provided evidence that AC5 can result in improved average time to hemostasis ("TTH") when applied to animal test subjects, and that TTH was comparable among test subjects regardless of whether such test subject had or had not been treated with therapeutics doses of anticoagulants or antiplatelet medications, commonly called "blood thinners".

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, 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 Arch products, including AC5, 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. Success or failure in both setting and realizing appropriate specifications may directly impact the anticipated clinical trial and subsequent commercialization timelines for AC5 and other planned products.

Preclinical Development

We are advancing through our planned preclinical program for AC5. We are focused on scale-up of selected manufacturing methods and formulation optimization while preparing for our first-in-human clinical trial. In parallel, we are conducting certain preclinical *in vivo* and *in vitro* tests, while additional preclinical testing will occur after completion of the manufacturing scale-up and formulation optimization steps. Self-assembling peptide manufacturing and formulation optimization are challenging, and any delays could negatively impact our anticipated clinical trial and subsequent commercialization timeline. 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 are currently negotiating a potential collaboration agreement with CÚRAM Centre for Research in Medical Devices ("CÚRAM"). CÚRAM is a major new national research center being established at the National University of Ireland Galway ("NUIG") in Galway, Ireland, as part of a six-year grant from the Irish government. Proceeds, which are expected to be released by the Irish government in January 2015, are intended to fund collaborative work performed by CÚRAM and its planned industry partners which, subject to the execution of a definitive collaboration agreement, would include Arch. Industry partners, which will benefit by provision of highly skilled personnel, significant grant funding, and available infrastructure support, will provide capital to match a portion of the government funds designated for their respective R&D programs. There can be no assurance that we will be successful in negotiating a definitive collaboration agreement with CÚRAM. We have also engaged, on a fee for service basis, several private third party facilities in the United States 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 improved average time to hemostasis ("TTH") when applied to animal brains, spinal cords and livers. Those studies have tested TTH when using AC5 during a range of 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 under 15 – 30 seconds when AC5 was applied, compared to a TTH ranging from 80 to significantly more than 300 seconds when various control substances were applied, depending on the nature of the control substance and procedure performed.

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 therapeutics 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.

Finally, in the preclinical tests conducted to date, AC5 has also 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 naturally occurring 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 planning for clinical trial testing of AC5

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 Europe and the U.S. to perform preclinical research and 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 be utilized to produce AC5 and other potential future product candidates rely on synthetic organic chemistry, a detailed, complex and difficult process to manage. Although use of those methods requires that we engage a manufacturer that can employ certain expertise with the technology, skill and know-how involved with those methods, the required manufacturing 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 humans in their natural state. 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

Although the FDA and other regulatory authorities or related bodies will finally determine the classification of AC5, we believe that our primary product candidate meets the criteria for 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 European Union ("EU") and the U.S. are classified along a spectrum. We anticipate that AC5 will be a Class III medical device in these jurisdictions, subject to the process for obtaining a CE mark in the EU and the premarketing authorization process in the U.S. While the Class III status is a higher-level classification than for devices not comprised of novel materials and involves additional procedures and regulatory scrutiny of the product candidate to obtain approvals, we believe that it provides less regulatory ambiguity.

Biocompatibility Tests and Clinical Trials

Before initiating any human clinical trials, we will need to complete the biocompatibility assessment of AC5. Standard required tests to assess biocompatibility, as set forth in ISO 10993 issued by the International Organization for Standardization, 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 are currently engaged in biocompatibility studies for AC5. Following the successful completion of biocompatibility tests for AC5, we expect to focus on conducting required human clinical trials. We currently plan to conduct the first-in-human clinical trial of AC5 in Europe. Assuming successful results of the trial, we expect that we will then pursue a CE mark, the required European approval to market and commercialize a medical device such as AC5, prior to pursuing approval by the U.S. FDA.

We expect that we will pursue approvals for use of AC5 as a hemostatic 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 long-term 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 current general approach and strategy of utilizing the expertise and resources of third party service providers and relatively 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 successful biocompatibility studies and, subsequently, clinical trials on AC5;

- expanding and protecting our intellectual property portfolio;
- developing appropriate third party relationships to manufacture, distribute, market and otherwise commercialize AC5;
- obtaining regulatory approval or certification of AC5 in the European Union ("EU"), the U.S., and other jurisdictions as we may determine;
- 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 to support the milestones described above 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;
- complete the clinical trial protocol and Clinical Investigational Plan with principal investigators for AC5 and submit application to Ethics Committee and required authoritative agencies for our initial clinical trial;
- commence and complete a human clinical trial for AC5, the timeframe for which is dependent upon successful completion of certain manufacturing, regulatory, and biocompatibility activities; based on current expectations, we estimate such a trial could be initiated in the first half of 2015;
- continue to expand and enhance our financial and operational reporting and controls;
- expand and enhance our intellectual property portfolio by filing new patent applications, obtaining allowances on currently filed patent applications, and 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; and
- assess our self-assembling peptide platform in order to identify and select product candidates for advancement into development.

With respect to our objectives relating to AC5, we currently project requiring $5,000,000 - $8,000,000 of additional capital to complete the milestones to obtain regulatory approval in Europe. We expect that obtaining regulatory approvals in the U.S., including conducting additional required clinical trials, would require at least an estimated additional $8,000,000 - $10,000,000 in capital. These estimated amounts could increase by potentially large amounts if any number of risks relating to conducting these activities were to occur, including without limitation those set forth under the heading "Risk Factors" in this Annual Report.

We anticipate that our operating and other expenses will continue to increase as we continue to implement our business plan and pursue and achieve these goals. After giving effect to the funds received in past equity and debt financings and assuming our use of that funding at the rate we presently anticipate, as of the date of this Annual Report on Form 10-K we expect to have sufficient funds to operate our business into March 2015. 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 borrowings and the issuance of convertible debt and units consisting of common stock and warrants, 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. 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 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

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 prevalence of anticoagulant use, which predispose patients to bleeding. .

As a result of this demand, use of hemostatic agents and sealants is increasing. According to MedMarket Diligence, the market for these products achieved approximately $3.4 billion in worldwide sales in 2010 and is projected to reach $5.5 billion in 2015 and surpass $6.5 billion in 2017. Over two-thirds of those sales are for hemostats. Further, the projected growth rate and incremental demand for sealants may be even higher than that for hemostats due to a general lack of available products and potentially larger unmet need.

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 the 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 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 the following as desirable characteristics of a hemostatic agent, which we carefully considered in developing AC5 and which we believe are well satisfied by our primary product candidate:

- laparoscopic friendly;
- easily handled and applied;
- promotes a clear field of vision and does not obstruct view;
- non-viscous and flowable;
- non-sticky (to tissue or equipment);
- permits normal healing;
- indifferent to status of coagulation cascade or “blood thinning” drugs;
- non-toxic; and
- contains neither blood nor tissue components from either humans or other animals.

We hope that AC5 will meet these particular market demands, and we anticipate its use in minimally invasive or laparoscopic surgery as well as open surgery. While open surgery 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 produce 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 required 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 is increasing by approximately 5% annually, and a 2009 report covering U.S. surgical procedures suggests that inpatient surgery volume is 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 includes large companies, such as Johnson & Johnson and its affiliated companies, Covidien plc and Baxter Healthcare Corporation, as well as various smaller companies such

as The Medicines Company and a range of wound care companies.

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 relatively simple and 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.

- We have not completed preclinical and clinical human trials relating to AC5, whereas the competition has done so where required for their marketed products. Accordingly, the safety and efficacy of AC5 has not been demonstrated or accepted by required regulatory agencies, and we will require significant resources in order to conduct the required trials and other tests to attempt to obtain such approvals.

Research and Development Expenditures

Our research and development expenses to date have primarily included costs to develop our core technology and AC5. During the year ended September 30, 2014, we incurred $1,477,479 in research and development expenses, as compared to $218,901 incurred during the year ended September 30, 2013. We expect our research and development activities and expenses to increase significantly as we execute on our business plan and pursue 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 above, 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 anticipate that the FDA will classify it as a Class III medical device.

PMA Approval 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 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 expect that we will need to obtain PMA approval in order to sell AC5 in the U.S., but the FDA will ultimately determine whether a PMA is the appropriate approval to be obtained. We have not submitted to the FDA any PMA covering AC5 or commenced the required clinical trials. If we are able to conduct successful preclinical studies and submit a PMA, the FDA may not grant PMA approval of AC5 for the desired indications of use, on a timely basis, or at all. Our inability to achieve regulatory approval for AC5 in the U.S., 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”).

Prior to conducting a clinical trial, we also would be required to enroll a sufficient number of patients to conduct the trial and obtain 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. 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.

We have not commenced any human clinical trials. We have commenced certain biocompatibility studies, described above under the heading “Development and Commercialization Strategy—Regulatory—Biocompatibility Tests and Clinical Trials”, that are typically completed prior to commencing clinical trials. We will require significant additional funding and preparation before we are able to initiate the first clinical trial for AC5 and in order to complete all required trials to obtain marketing approval in the U.S.

Pre-Marketing Regulation in the EU

Medical Device Classification

Similar to the U.S., the EU recognizes different class 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 (which is a private commercial entity designated by the national government of an EU member state as being competent to make independent judgments about whether a medical device complies with applicable regulatory requirements);
- 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.

We anticipate that AC5 would be classified as a Class III medical device based on the EU’s medical device classes.

CE Mark Approval Process

The EU has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices. Each EU member state has implemented legislation applying these directives and standards at a national level. Other countries outside of the EU have also voluntarily adopted laws and regulations that mirror those of the EU with respect to medical devices.

Under applicable EU medical device directives, a CE mark is a symbol placed on a product that declares the product's compliance 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 have identified several potential countries through which we may pursue a CE mark for AC5.

Clinical Trials

As with U.S. Class III medical device approval, EU Class III medical device approval requires 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 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 r