

Arch Therapeutics, Inc.
Form 8-K
June 26, 2013

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 OR 15(d) of The Securities
Exchange Act of 1934**

Date of report (Date of earliest event reported): June 25, 2013

ARCH THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Nevada **333-178883** **46-0524102**
(State or other jurisdiction (Commission (I.R.S. Employer
of incorporation) File Number) Identification No.)

One Broadway, 14th Floor

Cambridge, Massachusetts **02142**
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (617)
475-5254

Pembroke House

28-32 Pembroke St Upper

Dublin 2, Ireland

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(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements that involve risks, uncertainties and assumptions. If such risks or uncertainties materialize or such assumptions prove incorrect, our results could differ materially from those expressed or implied by such forward-looking statements and assumptions. In some cases, you can identify forward-looking statements by terminology such as “may”, “should”, “expects”, “plan”, “anticipate”, “believe”, “estimate”, “predict”, “potential” or “continue” or the negative of these terms or other comparable terminology. All statements made in this Form 8-K other than statements of historical fact are statements that could be deemed forward-looking statements, including without limitation statements about our business plan, our plan of operations and our need to obtain future financing. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks in the section entitled “Risk Factors” and the risks set out below, any of which may cause our or our industry’s actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. These risks include, by way of example and not in limitation, risks related to:

- General economic and business conditions;
- Our ability to continue as a going concern;
- Our ability to obtain financing necessary to operate our business;
- Our limited operating history;
- Our ability to recruit and retain qualified personnel;
- Our ability to manage future growth;
- Our ability to develop, obtain required approvals for and commercialize our product candidates;
- Our ability to maintain and protect our intellectual property;
- Our ability to successfully complete potential acquisitions and collaborative arrangements; and
- Other factors discussed under the section entitled “Risk Factors”.

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Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity or performance. These forward-looking statements speak only as of the date of this Current Report on Form 8-K. Except as required by applicable law, we do not intend to update any of these forward-looking statements.

As used in this Current Report on Form 8-K, unless otherwise indicated the terms the “Company”, “Arch Therapeutics”, “we”, “us” and “our” refer to Arch Therapeutics, Inc., a Nevada corporation, and its subsidiary, unless the context otherwise requires.

We have pending trademark applications for AC5™, Crystal Clear Surgery™, NanoDrape™ and NanoBioBarrier™. All other trademarks, trade names and service marks included in this Current Report on Form 8-K are the property of their respective owners.

Item 2.01 Completion of Acquisition or Disposition of Assets.

The Merger and Related Transactions

The Merger

As previously disclosed, on May 10, 2013, we entered into an Agreement and Plan of Merger (the “Merger Agreement”) with Arch Biosurgery, Inc. (formerly known as Arch Therapeutics, Inc.), a Massachusetts corporation (“ABS”), and Arch Acquisition Corporation, a Massachusetts corporation and our wholly-owned subsidiary formed for the purpose of the transaction (“Merger Sub”). The Merger Agreement provided for the merger of Merger Sub with and into ABS (the “Merger”), with ABS surviving the Merger as our wholly owned subsidiary, upon the terms and subject to the conditions set forth in the Merger Agreement.

On June 26, 2013, following the satisfaction or waiver of the conditions set forth in and otherwise in accordance with the terms of the Merger Agreement, the Merger was consummated and Merger Sub merged with and into ABS. As a result of the closing of the Merger, we have abandoned our prior business plan and we are now pursuing the operations of ABS as a life science company developing product candidates in the surgical hemostasis field.

The Merger Agreement includes customary representations, warranties and covenants made by us, Merger Sub and ABS as of specific dates. The assertions embodied in those representations and warranties were made solely for purposes of the Merger Agreement and are not intended to provide factual, business, or financial information about us, Merger Sub and ABS. Moreover, some of those representations and warranties (i) may not be accurate or complete as of any specified date, (ii) may be subject to a contractual standard of materiality different from those generally applicable to shareholders or different from what a shareholder might view as material, (iii) may have been used for purposes of allocating risk among us, Merger Sub and ABS, rather than establishing matters as facts, and/or (iv) may have been qualified by certain disclosures not reflected in the Merger Agreement that were made to the other party in connection with the negotiation of the Merger Agreement and generally were solely for the benefit of the parties to the Merger Agreement. The Merger Agreement should not be read alone, but should instead be read in conjunction with the other information regarding us and our business that has been, is or will be contained in, or incorporated by reference into, the Forms 10-K, Forms 10-Q, Forms 8-K, and other documents that we file with the Securities and Exchange Commission (the “SEC”). The description of the Merger Agreement set forth herein is qualified in its entirety by reference to the full text of the Merger Agreement, which is filed as Exhibit 2.1 to the Current Report Form 8-K we filed with the SEC on May 13, 2013 and is incorporated herein by reference.

The Coldstream Financing

In contemplation of the Merger, on April 19, 2013, we entered into a financing agreement (the “Financing Agreement”) with Coldstream Summit Ltd. (“Coldstream”), pursuant to which we agreed to issue and sell, and Coldstream agreed to purchase or assist in securing the purchase of, \$2,000,000 worth of units in a private offering within the 12 month period following the closing of the Merger (the “Coldstream Financing”). Each unit issued in the Coldstream Financing is to be sold at a price of \$0.50 per share and is to consist of (i) one share of our common stock and (ii) one warrant to purchase one share of our common stock at an exercise price of \$0.75 per share and with a term of 12 months. As of the date of this Current Report on Form 8-K, we have issued and sold units consisting of 2,500,000 shares of our common stock and warrants to purchase 2,500,000 shares of our common stock in the Coldstream Financing, for aggregate gross proceeds of \$1,250,000. The proceeds of the Coldstream Financing are being used for the funding of our and ABS’s ongoing business and operations. As previously disclosed, pursuant to the terms of the Merger Agreement, all such proceeds raised to date were advanced to ABS prior to the closing of the Merger.

Post-Merger Company Ownership

As set forth in the Merger Agreement, upon the closing of the Merger, all of the issued and outstanding capital stock and convertible notes and warrants of ABS were cancelled automatically and the holders thereof became entitled to receive an aggregate of 14,645,212 shares of the Company’s common stock. That number of shares was negotiated and agreed to by the Company and ABS prior to entering into the Merger Agreement. Upon the closing of the Merger, the former shareholders of ABS are entitled to receive two and one-half shares of our common stock for each share of common stock of ABS held by them immediately prior to the closing of the Merger. After giving effect to the closing of the Merger and including the shares and warrants issued in the Coldstream Financing as of the date hereof and to be issued in the Coldstream Financing over the 12 month period following the closing of the Merger, the securities of the Company (on a fully diluted basis) are owned as follows:

Former shareholders of ABS hold 5,645,212 shares of the Company's common stock, or approximately 7.8% of the Company on a fully diluted basis;

Former holders of convertible promissory notes of ABS hold 9,000,000 shares of the Company's common stock, or approximately 12.5% of the Company on a fully diluted basis;

Dr. Norchi and Dr. Dhillon, or their respective designees over which they hold a controlling interest, collectively hold 18,579,449 shares of the Company's common stock (including the shares of the Company's common stock they are entitled to receive as former shareholders and noteholders of ABS), or approximately 25.8% of the Company on a fully diluted basis;

7,825,388 shares of the Company's common stock initially reserved for issuance to employees, directors and consultants under the Arch Therapeutics, Inc. 2013 Stock Incentive Plan (the "Plan"), representing approximately 10.9% of the Company on a fully diluted basis;

Stockholders of the Company prior to the closing of the Merger, including consultants of the Company that were issued an aggregate of 1,500,000 shares of our common stock on June 18, 2013 in restricted stock grants outside of the Plan, hold 21,500,000 shares of the Company's common stock, or approximately 29.9% of the Company on a fully diluted basis; and

Current and future investors in the Coldstream Financing will hold 4,000,000 shares of the Company's common stock and warrants to acquire 4,000,000 shares of the Company's common stock, or approximately 11.1% of the Company on a fully diluted basis.

Lock-Up Restrictions

In connection with the Merger, shares of our common stock received by (i) substantially all of ABS's former shareholders and noteholders as a result of the Merger, including all shares held by Dr. Norchi and Dr. Dhillon (and their respective designees) that were received in connection with the Merger, (ii) recipients of restricted stock grants of an aggregate of 1,500,000 shares made outside of our Plan, and (iii) recipients of certain non-qualified stock options granted under our Plan to purchase an aggregate of 3,984,212 shares, are subject to certain lock-up restrictions that restrict the sale or other transfer of such shares for a certain period of time following the closing of the Merger. For the 18 months following the closing of the Merger, all such shares will be subject to those lock-up restrictions. Thereafter, 25% of such shares will be released from the lock-up restrictions every three months, until 100% of the shares are released from the lock-up restrictions.

Accounting Treatment of the Merger

For financial reporting purposes, the Merger represents a “reverse merger” rather than a business combination and ABS is deemed to be the accounting acquirer in the transaction. Consequently, the assets and liabilities and the historical operations that will be reflected in the Company’s future financial statements will be those of ABS. The Company’s assets, liabilities and results of operations will be consolidated with the assets, liabilities and results of operations of ABS after consummation of the Merger, and the historical financial statements of the Company before the Merger will be replaced with the historical financial statements of ABS before the Merger in all future filings with the SEC.

FORM 10 INFORMATION

Immediately prior to the closing of the Merger, we were deemed a shell company as defined in Rule 12b-2 promulgated under the Securities Exchange Act of 1934 (the “Exchange Act”). Item 2.01(f) of Form 8-K requires that, under those circumstances, a registrant must disclose the information that would be required if the registrant were filing a general form for registration of securities on Form 10 under the Exchange Act. Accordingly, we are providing such information for the combined enterprises of the Company and ABS below.

BUSINESS

Corporate Overview

We were incorporated under the laws of State of Nevada on September 16, 2009 as Almah, Inc. On May 10, 2013, we entered into the Merger Agreement with ABS and Arch Acquisition Corporation, our wholly owned subsidiary formed for the purpose of the transaction, pursuant to which Arch Acquisition Corporation merged with and into ABS and ABS thereby became our wholly owned subsidiary. In contemplation of the Merger, effective May 24, 2013 we increased our authorized common stock from 75,000,000 shares to 300,000,000 shares and effected a forward stock split, by way of a stock dividend, of our issued and outstanding shares of common stock at a ratio of 11 shares to each one issued and outstanding share, and effective June 5, 2013, we changed our name from Almah, Inc. to Arch Therapeutics, Inc. and changed the ticker symbol under which our common stock trades on the OTC Bulletin Board from “AACH” to “ARTH”. All share amounts of our common stock referenced in this Current Report on Form 8-K give effect to the 11-for-1 forward stock split described above, including those applicable to periods prior to the forward stock split.

ABS was incorporated under the laws of Commonwealth of Massachusetts on March 6, 2006 as Clear Nano Solutions, Inc. On April 7, 2008, ABS changed its name to Arch Therapeutics, Inc., and on August 28, 2009, ABS increased its authorized common stock, no par value, from 275,000 shares to 1,275,000 shares. Effective upon the closing of the Merger, ABS changed its name from Arch Therapeutics, Inc. to Arch Biosurgery, Inc.

The Merger closed on June 26, 2013, and as a result we have abandoned our prior business plan and are now pursuing the business of ABS as our sole business. The following is a discussion of the business of ABS that we are now pursuing. References to “we”, “us” and “our” in the following discussion refer to the Company and its subsidiary, ABS, as a combined enterprise.

Our Current Business

We are life science medical device company in the development stage with limited operations to date. We aim to develop products that make surgery and interventional care faster and safer by utilizing 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 solution that creates a physical, mechanical barrier, which could be applied to bleeding organs or wounds to seal 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 first product candidate, AC5™, is designed to achieve hemostasis in minimally invasive and open surgical procedures, and we hope to develop other product candidates in the future based on our technology platform aimed at stopping bleeding and sealing other leaking fluids during surgical and other procedures.

Our Core Technology

Our technology platform is based on self-assembling synthetic peptides. Our plan and business model is to develop products that apply that core technology to human bodily fluids and connective tissues.

Our primary product candidate, AC5, relies on this technology to achieve hemostasis during surgical procedures. We envision developing other product candidates in the future based on our core technology, examples of which could include, for instance, products for specialty surgery, burn and trauma care, wound care, military applications, and consumer care.

We have devoted much of our operations to date to the development of our core technology, including selecting our lead product composition, conducting initial safety and other related tests, generating scale-up, reproducibility and

manufacturing methods, and developing and protecting the intellectual property rights underlying our technology platform. We have one key intellectual property licensor, the Massachusetts Institute of Technology (“MIT”), from which we license certain of our important intellectual property rights, and have made, and hope to continue to make, advances on our core technology to further refine and improve its use and functionality, further develop our intellectual property rights, and ultimately produce an expanded portfolio of potential product candidates.

AC5

Our first product in development, 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.

The results of early data from preclinical animal tests have shown that AC5 achieves hemostasis quickly and effectively. AC5 can be directly applied as a liquid or sprayed, making it user-friendly and able to conform to irregular wound geometry, and is not sticky or glue-like, making it ideal for use in the setting of minimally invasive laparoscopic surgeries. Further, AC5 is transparent, which should make it easier for a surgeon 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™.

Completed Preclinical Development

We are in the early stages of our planned clinical program for AC5. To date, only preclinical animal tests have been performed. In order to achieve the approvals and certifications we need to market and sell AC5, significant additional testing, including conducting human clinical trials, will be required.

Preclinical testing to date has been conducted in a number of settings. One of the co-founders of ABS and a co-founding inventor of certain of our technology, Dr. Rutledge Ellis-Behnke, performed a significant portion of the preclinical animal experimentation conducted to date during his time at the Massachusetts Institute of Technology in the Department of Brain and Cognitive Sciences from 2001 through 2005 and the University of Hong Kong Faculty of Medicine in the Department of Anatomy from 2004 through 2009, with overlap between the two institutions in 2004 and 2005. Dr. Ellis-Behnke and his colleagues also outsourced certain experiments to third parties. Some of the most significant findings from Dr. Ellis-Behnke's studies have been published. Additionally, on a fee for service basis, ABS engaged a private third party facility in Massachusetts where certain preclinical animal experiments were performed with the assistance of ABS consultants. ABS also engaged a biomedical animal research company in Massachusetts to perform certain preclinical animal studies. Further, through collaboration with the National University of Ireland system, preclinical animal and tissue experiments have been performed in Dublin and Cork, Ireland.

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 tests 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 seconds when AC5 was applied, compared to a TTH ranging from 80 to 300 seconds when various control substances were applied, depending on the nature of the control substance and procedure performed. In tests 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 body.

Our plans in the near-term are to focus our efforts on the development of AC5 by pursuing additional preclinical studies and preparing for future clinical trials.

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 utilize the services of third party entities that are experts in each aspect of our operations, while preserving capital and efficiencies by avoiding certain internal scale-up costs and duplication of resources.

Research and Development; Manufacturing

Use of Third Party Relationships

To date, we have engaged third party laboratory facilities run by peptide experts in Europe and the U.S. to perform preclinical research and development activities. Those engagement have enabled us to properly develop our primary product candidate, as well as generate appropriate analytical methods, scale-up, and other procedures that we intend to use as a “blueprint” for a third party manufacturer to make the product on a larger scale for purposes of further clinical testing and ultimately commercialization.

We are currently preparing for that transition to traditional contract manufacturing and related organizations. We have commenced discussions with manufacturers operating with the current good manufacturing practices (“cGMP”) required by applicable regulatory agencies, which we would engage to scale up and produce clinical 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 is 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 envision would be utilized to produce AC5 and other potential future product candidates rely on synthetic organic chemistry. The technology, skill and know-how involved with those methods are important, but the required manufacturing equipment is widely available. Furthermore, improvements in relevant synthetic manufacturing techniques in the past several years have reduced their complexity and cost, while increasing large scale cGMP capacity. In addition, as a result of increased demand for amino acids in recent years, the cost of obtaining amino acid raw materials has decreased. Further, our planned product candidates, including AC5, will be synthesized of 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 is often more likely to be categorized as “generally recognized as safe”, or “GRAS”, by the U.S. Food and Drug Administration (“FDA”), and can convey a lower risk of adverse effects.

We believe that our pursued manufacturing methods and ingredients will make our choice of third party manufacturers important, as we will need to select service providers with sufficient expertise with synthetic organic chemistry manufacturing, but will benefit from the lack of expensive equipment, technology and materials required and the naturally occurring ingredients used in the manufacturing process.

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. 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 procedure and regulatory scrutiny of the product candidate to obtain approvals, it provides less regulatory ambiguity.

Biocompatibility Tests and Clinical Trials

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Before initiating any human clinical trials, we will need to assess the biocompatibility 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;
- systemic toxicity; and
- in vitro chromosome aberration assay (structural chromosome changes).

We have not commenced formal biocompatibility studies for AC5. However, Dr. Ellis-Behnke and his colleagues, on a fee for service basis, engaged a third party Massachusetts-based facility to perform certain in vitro and in vivo biocompatibility and toxicology studies on what was an earlier version of our composition; such tests illustrated no evidence of toxicity and portions of the results have been published. Further, with the assistance of ABS personnel and consultants, certain large relative dose pilot tests were performed in rodents at a private third party facility in Massachusetts, and no abnormal behavior or pathology was observed from such tests.

Following completion of biocompatibility tests for AC5, assuming successful results of those tests, we expect that we will focus on conducting required human clinical trials. We currently plan to conduct the First in Human clinical trial on 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. Based on precedent, we believe that the EU will require one clinical trial to obtain a CE mark for AC5.

When properly harmonized, the FDA may accept non-U.S. jurisdiction clinical trial data for a product in support of a FDA application for the same product, and we hope to use the data from our planned initial clinical trial to be conducted in the EU in this fashion. Similarly, any subsequent American clinical trials could help to broaden the scope and indications of any European label for AC5 that we may achieve.

In order to obtain a broad label for AC5 in the U.S., we believe that the FDA will require safety and efficacy data in three different tissue types. We hope to utilize the data from our planned initial clinical trial in the EU to contribute to the satisfaction of some of those FDA requirements.

We also intend to pursue other potential indications for AC5 and/or other potential product candidates based on our technology platform, which we may pursue either opportunistically or once regulatory approval is obtained for our initial surgical hemostasis product candidate.

Commercialization

We are in the process of developing a long-term commercialization plan for our product candidates. That plan could entail entering into one or more strategic partnerships in connection with product commercialization, our direct performance of commercialization activities, or some combination of those alternatives. Based on our current general approach and strategy of utilizing the expertise and resources of third party service providers while maintaining a 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 partnerships or collaboration 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 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 clinical trials on AC5;
- obtaining regulatory approval or certification of AC5 in the EU, the U.S., and other jurisdictions;
- expanding our intellectual property portfolio;
- developing appropriate third party relationships to manufacture, distribute, market and otherwise commercialize AC5; and
- developing additional product candidates in the hemostatic and sealant field.

With respect to our goals relating to AC5, we currently project requiring between \$6,000,000 and \$8,000,000 of additional capital to complete the milestones to obtain regulatory approval in Europe and launch AC5 in the European market. We expect that obtaining regulatory approvals and launching AC5 in the U.S., including conducting additional required clinical trials, would require at least an additional \$9,000,000 in capital.

In furtherance of our long-term business goals, we expect to focus on the following activities during the remainder of calendar year 2013 and calendar year 2014:

- conducting formal biocompatibility studies;
- participating in EU and, subsequently, U.S. regulatory meetings;
- preparing for initial clinical trials, including developing clinical trial protocols;
- engaging a large scale manufacturing partner to produce cGMP product for clinical trials;
- further developing and securing our intellectual property rights; and
- commencing human clinical trials.

We anticipate that our operating and other expenses will increase following the closing of the Merger as we and ABS implement our business plan as a combined enterprise. After giving effect to the funds received in the recent equity and debt financings and certain committed funding over the next 12 months from the Coldstream Financing, and assuming our use of that funding at the rate we presently anticipate, as of the date of this Current Report on Form 8-K we expect to have sufficient funds to operate our business for the next 12 months. 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 that period.

Our estimates of the amount of cash necessary to operate our business and attain our near-term and long-term business goals may prove to be wrong, due to increased costs to achieve milestones and/or additional expenses if we encounter unanticipated difficulties or other reasons, in which case additional funding than projected would be needed. Other than the funding committed under the Coldstream Financing, we have no firm commitments for future capital. Even after giving effect to those additional committed funds, we will require significant additional financing to fund our planned operations, including further research and development relating to our primary product candidate, seeking regulatory approval of that or any other product candidate we may choose to develop, commercializing any product candidate for which we are able to obtain regulatory approval or certification, seeking to license or acquire new assets or business, and maintaining our intellectual property rights and pursuing rights to new technologies. We may not be able to obtain additional financing on commercially reasonable or acceptable terms when needed, or at all. 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 equity and debt financings and we expect to continue to seek to do so in the future. If we obtain additional financing by issuing equity securities, our existing stockholders' ownership will be diluted. 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. We estimate that

20-25% of those surgeries are performed laparoscopically. Additionally, there are many minor procedures and operations that may not be included in those figures. Those surgeries and other procedures could benefit from sealants and hemostatic agents, as 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 of approximately 5%;

· laparoscopic procedure volume growth; and

· efforts to reduce operating room time.

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 2010 worldwide sales and is projected to reach \$4.5 billion in 2013 and surpass \$6.5 billion in 2017. Over two-thirds of those sales are for hemostats. The growth rate for sealants is 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 and sealant agents 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 and sealant agents are the same as those of their first-generation counterparts, as revolutionary advances in underlying technologies have been elusive.

The hemostatic and sealant market is currently comprised of large companies, such as Johnson & Johnson and its affiliated companies, Covidien plc and Baxter Healthcare Corporation, as well as a number of smaller companies. Although some companies are developing new products in the hemostatic and sealant space, they appear to be mostly geared toward focused, niche applications and not on broad surgical applications. For instance, a glue-like composition may be effective for sealing an air leak in the lung or attaching two bleeding blood vessels, but it may not easily stop bleeding and enable normal healing in the liver. AC5 is envisioned as a general hemostatic agent that serves as one tool to replace narrower alternatives.

In the course of developing AC5, we engaged commercial strategy and marketing consultants to understand the routines and needs of potential customers and to assess market preferences. Although better efficacy and reliability were identified as important to those customers, it was discovered that other product features are also critical to achieving broad market acceptance. Surgeons, operating room managers, sales representatives for competitive products, and hospital administrator decision-makers identified the following characteristics as desirable features 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);
- enables normal healing;
- indifferent to status of coagulation cascade or “blood thinning” drugs;
- non-toxic; and
- does not contain human blood product or animal components.

We hope that AC5 will meet particular market demands, and we anticipate its use in laparoscopic surgery as well as open surgery. While open surgery represents the more established market for hemostatic agents, approximately one-quarter of surgeries are laparoscopic, and that number is growing. 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, most 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 laparoscopic procedures. We believe that the novel features and differentiating characteristics of AC5 will make it more suitable for laparoscopic surgeries than presently available alternatives.

Further, there seems to 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 approximately 5% annually, and a 2009 report covering U.S. surgical procedures suggests that inpatient surgery volume is declining 1% per year. A motivating factor of this trend is 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 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 and sealant products that can decrease operating room time for inpatient procedures and help to increase the safety of performing more types of procedures in less expensive outpatient settings.

Commercially available products in the hemostasis field with which we expect AC5 will compete 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 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 AC5 is 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, as well as our planned use of a manufacturing method to produce the product that we expect will be relatively simple and cost effective compared to competing products, which could enable sales 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 expect AC5 will compete are as follows:

The favorable handling characteristics of AC5 are the result of its non-sticky or 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 desired effect.

While we project that AC5 will be relatively economical to manufacture at scale, it will 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 marketed competition has done so. 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, 2011, we incurred \$122,738 on research and development expenses, as compared to \$87,021 incurred during the year ended September 30, 2012. 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 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, 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 it does not depend on a body for metabolic or chemical activity. 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-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 it is based, we anticipate that it will be classified as a Class III medical device by the FDA.

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, and 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 the 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, described below. 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 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 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 obtain the 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. 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 yet commenced any human clinical trials. We also have not yet 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. Medical devices in the EU are classified into one of those classes on the basis of the amount of potential risk to the patient associated with the medical device. Classification involves rules found in the EU's Medical Device Directive. Key questions of relevance include the degree of the device's contact with the patient, invasiveness, active nature, and indications for use. The medical device classes recognized in the EU are as follows:

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

- Class IIa, which are considered low-medium risk devices and require certification by a Notified Body;
- Class IIb, which are considered medium-high risk devices and require certification by a Notified Body; and
- Class III, which are considered high-risk devices and require certification by a Notified Body.

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.

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, a company 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. The CA in each country also designates and regulates Notified Bodies, which are private commercial entities designated by the national government of a member state as being competent to make independent judgments about whether a device complies with applicable regulatory requirements. 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 preliminarily selected Ireland as the country through which we will pursue a CE mark for AC5. The CA in that country has a strong record of compliance, a relatively rapid approval process, and is reputed to be trusted by the FDA. Our hope is that the selection of this country will prove helpful if and when we are able to attain a CE mark for AC5 and subsequently pursue approval with the FDA, by potentially permitting us to include data from the CE mark approval process in a PMA and/or IDE. Alternative countries have also been identified.

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 will be required for AC5 to obtain 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 regulatory requirements continue to 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 one of our approved devices;

- 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 products may have caused or contributed to a death or serious injury or in which a product malfunctioned, and notices of corrections or removals.

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

Regulation by Other Foreign Agencies

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

Other Governmental Regulations and Environmental Matters

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

Intellectual Property

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

We have filed 10 patent applications for self-assembling peptides and methods of use thereof in 5 jurisdictions, all of which are pending. We have also entered into a license agreement with MIT pursuant to which we have been granted exclusive rights under one portfolio of patents and non-exclusive rights under another portfolio of patents. The portfolio exclusively licensed from MIT includes one issued patent in one jurisdiction that expires in 2026, and 18 pending patent applications in 10 jurisdictions. The portfolio non-exclusively licensed from MIT includes 11 issued patents in eight jurisdictions that expire between 2016 and 2026, and six pending patent applications in four jurisdictions.

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

We also have been granted a non-exclusive sub-license of a patent assigned to MIT and in turn licensed by MIT to the sub-licensing third party, which patent is due to expire in 2014. The sub-license is a fully-paid and royalty-free and does not provide any outbound license grant to any ABS owned or exclusively licensed intellectual property. We presently do not anticipate any material impact on our business or operations resulting from the expected expiration of this patent in 2014.

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

Employees

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

Properties

We currently maintain our corporate office at One Broadway, 14th Floor, Cambridge, Massachusetts 02142 under a month-to-month property rental agreement, pursuant to which we are obligated to pay monthly rent of approximately \$2,800. We currently do not own any real property. We believe our present offices are suitable for our current and planned near-term operations.

Legal Proceedings

We are not aware of any material pending legal proceedings to which we or our subsidiary is a party or of which any of our property is the subject.

RISK FACTORS

Investment in our common stock involves a high degree of risk. The risk factors described below summarize some of the material risks inherent in and affecting our business. You should carefully consider the following risk factors before making an investment decision. If any of the following risks and uncertainties