

Arch Therapeutics, Inc.
Form 10-Q
August 14, 2013

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2013

Commission File Number: 333-178883

ARCH THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of incorporation or organization)

46-0524102

(I.R.S. Employer Identification No.)

One Broadway, 14th Floor

Cambridge, Massachusetts

(Address of principal executive offices)

02142

(Zip Code)

(617) 475-5254

Registrant's telephone number, including area code

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the 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 T 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 T No

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,” “non-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

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

As of August 13, 2013, there were 59,145,237 shares of the registrant’s common stock outstanding.

ARCH THERAPEUTICS, INC.

(formerly Almah, Inc.)

(A Development Stage Company)

Quarterly Report on Form 10-Q

For the Quarterly Period Ended June 30, 2013

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements (unaudited)**ARCH THERAPEUTICS, INC.****(formerly Almah, Inc.)****(A Development Stage Company)****Consolidated Balance Sheets****As of June 30, 2013 and September 30, 2012**

ASSETS	June 30, 2013	September 30, 2012
Current assets:		
Cash and cash equivalents	\$476,369	\$17,139
Prepaid expenses and other current assets	1,121	3,308
Total current assets	477,490	20,447
Long Term Assets:		
Property and equipment, net	61	908
Total assets	\$477,551	\$21,355
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Current maturities of convertible notes payable	\$-	\$1,395,000
Current maturities of convertible notes payable, related parties	-	105,000
Notes payable, related party	-	275,200
Accounts payable	307,548	258,426
Accrued expenses and other liabilities	111,719	49,510
Accrued interest	-	352,755
Accrued interest to related parties	-	116,548
Total current liabilities	419,267	2,552,439

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Long-term liabilities:		
Convertible notes payable, net of current maturities	-	235,000
Accrued interest	-	6,351
Total long-term liabilities	-	241,351
Total liabilities	419,267	2,793,790
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock, \$0.001 par value, 300,000,000 shares authorized at June 30, 2013 and 75,000,000 at September 30, 2012, 58,645,212 and 5,645,212 shares issued and outstanding at June 30, 2013 and September 30, 2012, respectively	58,646	5,645
Additional paid in capital	3,669,971	-
Deficit accumulated during the development stage	(3,670,333)	(2,778,080)
Total stockholders' equity (deficit)	58,284	(2,772,435)
Total liabilities and stockholders' equity (deficit)	\$477,551	\$21,355

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

ARCH THERAPEUTICS, INC.**(formerly Almah, Inc.)****(A Development Stage Company)****Consolidated Statements of Operations**

	Three months ended June 30, 2013	Three months ended June 30, 2012	Nine months ended June 30, 2013	Nine months ended June 30, 2012	Period from Inception (March 6, 2006) through June 30, 2013
Other revenues	\$-	\$-	\$-	\$-	\$431,461
Operating expenses:					
General and administrative expenses	451,046	118,560	721,565	225,841	2,857,530
Research and development expenses	43,750	18,750	62,356	42,240	710,128
Total operating expenses	494,796	137,310	783,921	268,081	3,567,658
Operating loss	(494,796)	(137,310)	(783,921)	(268,081)	(3,136,197)
Other (expense) income:					
Interest expense	(19,596)	(39,233)	(108,384)	(114,702)	(588,101)
Other income (loss)	32	(290)	51	174	53,965
Total other expense	(19,565)	(39,523)	(108,333)	(114,528)	(534,136)
Net loss	\$(514,361)	\$(176,833)	\$(892,254)	\$(382,609)	\$(3,670,333)
Net loss per common share - basic and diluted	\$(0.06)	\$(0.03)	\$(0.13)	\$(0.07)	
Weighted average number of shares outstanding	8,549,322	5,638,813	6,613,249	5,636,618	

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

ARCH THERAPEUTICS, INC.**(formerly Almah, Inc.)****(A Development Stage Company)****Consolidated Statements of Cash Flows**

	Nine months ended June 30, 2013	Nine months ended June 30, 2012	Period from Inception (March 6, 2006) through June 30, 2013
Cash flows from operating activities:			
Net loss	\$(892,254)	\$(382,609)	\$(3,670,333)
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation expense	847	2,589	18,994
Other noncash adjustments	2,859	-	8,342
Noncash interest expense on convertible notes payable	82,147	86,532	441,253
Noncash interest expense on notes payable to related party	25,599	27,790	142,057
Issuance of common stock for services	-	-	253
Changes in operating assets and liabilities:			
(Increase) decrease in:			
Prepaid expenses and other current assets	2,187	3,955	(1,121)
Increase (decrease) in:			
Accounts payable	49,122	114,885	307,548
Accrued expenses and other liabilities	62,211	(4,768)	111,718
Net cash used in operating activities	(667,281)	(151,625)	(2,641,288)
Cash flows from investing activities:			
Purchases of property and equipment	-	-	(19,054)
Net cash used in investing activities	-	-	(19,054)
Cash flows from financing activities:			
Proceeds from common stock issued in merger	1,250,000	-	1,250,000
Repayment of notes payable and accrued interest to related party	(373,488)	-	(373,488)
Proceeds from issuance of notes payable	-	-	275,200
Proceeds from issuance of convertible notes payable	250,000	135,000	1,985,000
Net cash provided by financing activities	1,126,512	135,000	3,136,712

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Net increase in cash and cash equivalents	459,230	(16,626)	476,369
Cash and cash equivalents, beginning of period	17,139	36,775	-
Cash and cash equivalents, end of period	\$476,369	\$20,149	\$476,369
Supplemental disclosure of cash flow information:			
Cash paid during the period for:			
Interest	\$98,288	\$-	\$98,288
Income taxes	\$-	\$-	\$-

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

ARCH THERAPEUTICS, INC.

(formerly Almah, Inc.)

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

1. BASIS OF PRESENTATION AND DESCRIPTION OF BUSINESS

Organization and Description of Business

Arch Therapeutics, Inc. (the “Company”) was incorporated under the laws of State of Nevada on September 16, 2009 under the name “Almah, Inc.” to pursue the business of distributing automobile spare parts online. Effective June 26, 2013, the Company completed a merger (the “Merger”) with Arch Biosurgery, Inc. (formerly known as Arch Therapeutics, Inc.), a Massachusetts corporation (“ABS”), and Arch Acquisition Corporation (“Merger Sub”), the Company’s wholly owned subsidiary formed for the purpose of the transaction, pursuant to which Merger Sub merged with and into ABS and ABS thereby became the wholly owned subsidiary of the Company. As a result of the acquisition of ABS, the Company has abandoned its prior business plan and has changed its operations to the business of developing polymers comprising synthetic peptides intended to form gel-like barriers over wounds to stop or control bleeding and seal wounds. The Company is in the development stage and has generated no operating revenues to date. The Company is currently devoting substantially all of its efforts toward product research and development. Also in connection with the Merger, we relocated our principal office to Cambridge, Massachusetts.

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. Effective upon the closing of the Merger, ABS changed its name from Arch Therapeutics, Inc. to Arch Biosurgery, Inc.

Basis of Presentation

The accompanying unaudited interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“US GAAP”) for interim financial information and with the instructions to Form 10-Q and Rule 8-03 of Regulation S-X. Accordingly, these interim financial statements do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. In management’s opinion, the interim financial statements and accompanying condensed notes reflect all adjustments,

consisting of normal and recurring adjustments, that are necessary for a fair presentation of these financial statements.

The results of operations for the interim periods are not necessarily indicative of the results to be expected for other interim periods or for the entire year. This information should be read in conjunction with the audited financial statements and notes thereto included as of and for the year ended September 30, 2012 in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on December 31, 2012 and in the Company's Current Report on Form 8-K filed with the SEC on June 26, 2013.

The Company does not currently believe its existing cash resources are sufficient to meet its anticipated needs during the next twelve months. As reflected in the financial statements, the Company has an accumulated deficit, has suffered significant net losses and negative cash flows from operations, and has limited working capital. The Company expects to incur substantial expenditures for the foreseeable future for the research, development and commercialization of its potential products. In addition, the Company will require additional financing in order to seek to license or acquire new assets, research and develop any potential patents and the related compounds, and obtain any further intellectual property that the Company may seek to acquire. The Company does not have sufficient cash and cash equivalents to support its current operating plan. The Company will be required to raise additional capital, obtain alternative means of financial support, or both, in order to continue to fund operations. Therefore, there exists substantial doubt about the Company's ability to continue as a going concern. Historically, the Company has funded its operations primarily through equity and debt financings and it expects that it will continue to fund its operations through equity and debt financing. If the Company raises additional financing by issuing equity securities, its existing stockholders' ownership will be diluted. Obtaining commercial loans, assuming those loans would be available, will increase the Company's liabilities and future cash commitments.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. There is substantial doubt about the Company's ability to continue as a going concern as the continuation of the Company's business is dependent upon obtaining additional financing and the continued support of its stockholders to aid in financing operations. The consolidated financial statements do not include any adjustments that might result from this uncertainty.

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary as of June 26, 2013, ABS. All significant inter-company balances and transactions have been eliminated in consolidation.

2.SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Accounting

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The Company is in development stage and is devoting substantially all of its efforts to raising capital, developing technologies, establishing customer and vendor relationships, and recruiting new employees. Accordingly, the accompanying financial statements are presented under the development stage accounting provisions of the Financial Accounting Standards Board (FASB).

Use of Estimates

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

For a complete summary of our significant accounting policies, refer to Note 2 of our audited financial statements for the fiscal year ended September 30, 2012 in the company's Annual Report on Form 10-K filed with the SEC on December 31, 2012 and in the Company's Current Report on Form 8-K filed with the SEC on June 26, 2013. There have been no material changes to our significant accounting policies during the nine months ended June 30, 2013.

Subsequent Events

The Company evaluated all events or transactions that occurred through August 14, 2013, the date which these consolidated financial statements were available to be issued. The Company disclosed material subsequent events in Note 7.

3. MERGER

On June 26, 2013, a Merger ("the Merger") was completed by Arch Acquisition Corporation, a Massachusetts corporation and the Company's wholly-owned subsidiary formed for the purpose of the transaction ("Merger Sub") and Arch Biosurgery, Inc. (formerly known as Arch Therapeutics, Inc.), a Massachusetts corporation ("ABS") with ABS surviving the Merger as the Company's wholly owned subsidiary. Upon the closing of the Merger, all of the issued and outstanding capital stock and convertible notes of ABS were exchanged for an aggregate of 14,645,212 shares of the Company's common stock. Also, in connection with the Merger, the warrants of ABS were cancelled. 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 consolidated financial statements will be those of ABS. The Company's assets, liabilities and results of operations have been consolidated with the assets, liabilities and results of operations of ABS after consummation of the Merger June 26, 2013, 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.

4. RELATED PARTY TRANSACTIONS

Beginning in June 2006 through December 2008, the Company issued interest bearing convertible notes with related parties for aggregate cash proceeds of \$105,000, of which \$50,000 matured January 1, 2013. The notes were convertible into a number of shares of convertible preferred stock upon the closing of a preferred equity financing of at least \$1,000,000 by dividing the principle and accrued interest by the purchase price of the convertible preferred stock ("conversion price"). In connection with the notes, the Company issued warrants to purchase additional shares of convertible preferred stock at the conversion price equal to an aggregate amount of 20% of the principle balance of the notes. On June 26, 2013, the noteholders agreed to the exchange of the notes, accrued interest and cancel the warrants in exchange for the Company's common stock in connection with the Merger described in Note 3.

5. CONVERTIBLE NOTES PAYABLE

During December 2012 and January 2013 the Company issued convertible notes for cash proceeds of \$250,000. The notes accrued interest at 8% per year. In connection with the notes, the Company issued warrants to purchase shares of convertible preferred stock. The notes were convertible into a number of shares of convertible preferred stock upon the closing of a preferred equity financing of at least \$1,000,000 by dividing the principle and accrued interest by the purchase price of the convertible preferred stock ("conversion price"). In connection with the notes, the Company issued warrants to purchase additional shares of convertible preferred stock at the conversion price equal to an aggregate amount of 20% of the principle balance of the notes. On June 26, 2013, the noteholders agreed to the exchange of the notes (with a total aggregate principal balance of \$1,880,000) and accrued interest and cancel the warrants in exchange for the Company's common stock in in connection with the Merger described in Note 3.

6. COLDSTREAM FINANCING

In contemplation of the Merger, on April 19, 2013, the Company entered into a financing agreement (the "Financing Agreement") with Coldstream Summit Ltd. ("Coldstream") agreeing 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 common stock and (ii) one warrant to purchase one share of common stock at an exercise price of \$0.75 per share and with a term of 12 months. As of June 30, 2013, the Company has issued and sold units consisting of 2,500,000 shares of common stock and warrants to purchase 2,500,000 shares of our common stock in the Coldstream Financing to a foreign accredited investor identified by Coldstream, for gross proceeds of \$1,250,000.

7. SUBSEQUENT EVENTS

On July 1, 2013, pursuant to the Coldstream Financing described in Note 6, the Company issued and sold additional units consisting of 500,000 shares of common stock and warrants to purchase 500,000 shares of common stock to a foreign accredited investor identified by Coldstream for gross proceeds of \$250,000.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read in conjunction with our financial statements and notes thereto included elsewhere in this quarterly report. This section and other sections of this report contain 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," "expect," "plan," "anticipate," "believe," "estimate," "project," "objective," "predict," "potential" or "continue," or the negative of these terms and other comparable terminology. These forward-looking statements, which 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. These statements are only predictions based on our current expectations and projections about future events that we believe to be reasonable. There are important factors that could cause our actual results, level of activity, performance or achievements to differ materially from the historical or future results, level of activity, performance or achievements expressed or implied by such forward-looking statements. These factors include, but are not limited to, those discussed under the caption "Risk Factors" in this report. 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.

Corporate Overview

Arch Therapeutics, Inc. (the "Company") was incorporated under the laws of the State of Nevada on September 16, 2009 under the name "Almah, Inc." to pursue the business of distributing automobile spare parts online. Effective June 26, 2013, the Company completed a merger (the "Merger") with Arch Biosurgery, Inc. (formerly known as Arch Therapeutics, Inc.), a Massachusetts corporation ("ABS"), and Arch Acquisition Corporation ("Merger Sub"), the Company's wholly owned subsidiary formed for the purpose of the transaction, pursuant to which Merger Sub merged with and into ABS and ABS thereby became the wholly owned subsidiary of the Company. As a result of the acquisition of ABS, the Company has abandoned its prior business plan and has changed its operations to the business of developing polymers comprising synthetic peptides intended to form gel-like barriers over wounds to stop or control bleeding and seal wounds. The Company is in the development stage and has generated no operating revenues to date. The Company is currently devoting substantially all of its efforts toward product research and development. Also in connection with the Merger, we relocated our principal office to Cambridge, Massachusetts. 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 consolidated financial statements will be those of ABS. The Company's assets, liabilities and results of operations have been consolidated with the assets, liabilities and results of operations of ABS after consummation of the Merger June 26, 2013, 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.

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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. Effective upon the closing of the Merger, ABS changed its name from Arch Therapeutics, Inc. to Arch Biosurgery, Inc.

In contemplation of the Merger, effective May 24, 2013, the Company increased its 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 its issued and outstanding shares of common stock at a ratio of 11 shares to each one (1) issued and outstanding share. The accompanying consolidated financial statements for interim and annual prior periods presented have been retroactively adjusted to reflect the effects of the forward stock split. Also in contemplation of the Merger, effective June 5, 2013, the Company changed its name from Almah, Inc. to Arch Therapeutics, Inc. and changed the ticker symbol under which its common stock trades on the OTC Bulletin Board from "AACH" to "ARTH".

For a discussion and analysis of the Company's financial condition and results of operations prior to the Merger, please refer to the information set forth under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as the related financial statements, in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2012 filed with the Securities and Exchange Commission ("SEC") on December 31, 2012, in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2013 filed with the SEC on May 20, 2013 and in the Company's Current Report on Form 8-K filed with the SEC on June 26, 2013.

Liquidity

As further discussed in "Liquidity and Capital Resources" below, we will need to raise additional funds in order to continue operating our business. We do not currently believe our existing cash resources are sufficient to meet its anticipated needs during the next twelve months.

Business Overview

We are a 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 that stops bleeding (referenced as “hemostasis”), controls leaking (referenced as “sealant”), and provides 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 hemostatic or sealant product candidates in the future based on our self-assembling peptide technology platform. 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. 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 provider to maintain a clear field of vision during a surgical procedure and prophylactically stop bleeding as it starts, which we call Crystal Clear Surgery™.

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.

Our long-term business plan includes the following goals:

- expanding our intellectual property portfolio;
- conducting successful clinical trials on AC5;
- obtaining regulatory approval or certification of AC5 in the European Union (the “EU”), the U.S., and other jurisdictions;
- developing appropriate third party relationships to manufacture, distribute, market and otherwise commercialize AC5;
- and

develop additional product candidates in the hemostatic and sealant field.

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:

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

Recent Developments

Acquisition of ABS and Related Activities

In contemplation of the Merger, effective May 24, 2013, the Company increased its 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 its issued and outstanding shares of common stock at a ratio of 11 shares to each one (1) issued and outstanding share. Also in contemplation of the Merger, effective June 5, 2013, the Company changed its name from Almah, Inc. to Arch Therapeutics, Inc. and changed the ticker symbol under which its common stock trades on the OTC Bulletin Board from "AACH" to "ARTH".

As described above, effective June 26, 2013, the Company completed the Merger with ABS, pursuant to which ABS became a wholly owned subsidiary of the Company. As a result of the acquisition of ABS, the Company has abandoned its prior business plan and has changed its operations to the business of developing polymers comprising synthetic peptides intended to form gel-like barriers over wounds to stop or control bleeding and seal wounds. The Company is in the development stage and has generated no operating revenues to date. The Company is currently devoting substantially all of its efforts toward product research and development. Also in connection with the Merger, we relocated our principal office to Cambridge, Massachusetts.

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 consolidated financial statements will be those of ABS. The Company’s assets, liabilities and results of operations have been consolidated with the assets, liabilities and results of operations of ABS after consummation of the Merger June 25, 2013, 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.

Coldstream Financing

In contemplation of the Merger, on April 19, 2013, the Company entered into a financing agreement (the “Financing Agreement”) with Coldstream Summit Ltd. (“Coldstream”) agreeing 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 common stock and (ii) one warrant to purchase one share of common stock at an exercise price of \$0.75 per share and with a term of 12 months. As of June 30, 2013, the Company has issued and sold units consisting of 2,500,000 shares of common stock and warrants to purchase 2,500,000 shares of common stock in the Coldstream Financing to a foreign accredited investor identified by Coldstream, for aggregate gross proceeds of \$1,250,000. On July 1, 2013, pursuant to the Coldstream Financing, the Company issued and sold additional units consisting of 500,000 shares of common stock and warrants to purchase 500,000 shares of common stock to a foreign accredited investor identified by Coldstream for gross proceeds of \$250,000 (the “July Closing”). Following the July Closing, the Company may raise an additional \$500,000 in financing pursuant to the Financing Agreement.

Adoption of 2013 Equity Incentive Plan

On June 18, 2013, our Board of Directors adopted the 2013 Equity Incentive Plan (the “Plan”) and reserved 7,825,388 shares of the Company’s common stock for issuance thereunder to employees, officers and consultants of the Company. Also on June 18, 2013, stockholders holding a majority of our outstanding common stock executed a written consent approving and adopting the Plan. Pursuant to the approval of our Board of Directors and our stockholders, the adoption of the Plan became effective on June 18, 2013.

Adoption of Amended and Restated Bylaws

Also on June 18, 2013, our Board of Directors and stockholders holding at least a majority of the outstanding shares of our common stock approved the amendment and restatement of our bylaws (the “Restated Bylaws”). The Restated

Bylaws are different than our prior bylaws in various respects, including with respect to the procedures by which special meetings of stockholders may be called, the prohibition on stockholder actions by written consent, the procedures applicable to stockholder proposals and director nominations, the number of directors that may be elected or appointed to our Board, the procedures applicable to the removal of directors, our ability to issue uncertificated shares of our common stock, our ability to communicate electronically with our stockholders, the indemnification of our directors and officers, future amendments to the Restated Bylaws, and the exclusion of certain provisions of the Nevada Revised Statutes relating to the acquisition of our securities that may constitute a controlling interest, among other substantive and stylistic changes.

Appointment of Chief Operating Officer

Effective July 8, 2013, we appointed Mr. William M. Cotter as our Chief Operating Officer. Mr. Cotter is an industry veteran who brings expertise in operations and product development to his role with the Company. In connection with Mr. Cotter's appointment, the Company has entered into an executive employment agreement with Mr. Cotter. The agreement continues until terminated by the Company or by Mr. Cotter. Pursuant to the terms of the agreement, Mr. Cotter is entitled to an initial annual base salary of \$175,000 and is eligible to receive an annual cash bonus in an amount of up to 20% of Mr. Cotter's then-current annual base salary. Annual bonuses are awarded at the sole discretion of the Company's Board of Directors.

Results of Operations

The following discussion of our results of operations should be read together with the financial statements included in this quarterly report. The period to period comparisons of our interim results of operations that follow are not necessarily indicative of future results.

Three Months Ended June 30, 2012 Compared to Three Months Ended June 30, 2013

	June 30, 2013 (\$)	June 30, 2012 (\$)	Increase (Decrease) (\$)
Revenue	0	0	0
Operating Expenses			
General and Administrative	451,046	118,560	332,486
Research and Development	43,750	18,750	25,000
(Loss) from Operations	(494,796)	(137,310)	357,486
Other income (expense)	(19,565)	(39,523)	(19,958)
Net income (loss)	(514,361)	(176,833)	337,528

Revenue

We did not generate any operating revenue in either of the three months ended June 30, 2013 or 2012.

General and Administrative Expense

We incurred general and administrative expense during the three months ended June 30, 2013 in the amount of \$451,046, compared to general and administrative expense incurred during the three months ended June 30, 2012 in the amount of \$118,560 (an increase of \$332,486). Our general and administrative expenses during those periods primarily included legal fees, patent prosecution costs, payroll related expenses and office overhead. The increase in general and administrative expense period over period is primarily attributable to increased costs associated with legal and accounting fees incurred in connection with the Merger partially offset by a decrease in patent prosecution costs.

General and administrative expenses are generally expected to increase as a result of plans to ramp up operations and requirements to comply with public company reporting obligations. We expect increased expenses related to plans to hire additional personnel and consultants and expected incurrence of additional legal fees.

Research and Development Expense

We incurred research and development expense during the three months ended June 30, 2013 in the amount of \$43,750, compared to research and development expense incurred during the three months ended June 30, 2012 in the amount of \$18,750 (an increase of \$25,000). Our research and development expenses primarily relate to our activities to develop our primary product candidate, and are comprised mostly of payroll related expenses. The increase in research and development expense between periods is primarily attributable to increase in payroll related expenses.

Research and development expenses are expected to increase as a result of plans to pursue additional preclinical and clinical studies and otherwise relating to development of our primary product candidate.

Other Income (Expense)

We incurred total other expenses during the three months ended June 30, 2013 in the amount of \$19,565, compared to total other expenses incurred during the three months ended June 30, 2012 in the amount of \$39,523 (a decrease of \$19,958). Other expenses during those periods were primarily interest accrued on debt. The decrease in other expense between periods is attributable to suspension of interest accrual beyond April 30, 2013 in connection with the exchange of debt in the Merger.

Nine Months Ended June 30, 2012 Compared to Nine Months Ended June 30, 2013

	June 30, 2013	June 30, 2012	Increase (Decrease)
	(\$)	(\$)	(\$)
Revenue	0	0	0
Operating Expenses			
General and Administrative	721,565	225,841	495,724
Research and Development	62,356	42,240	20,116
(Loss) from Operations	(783,921)	(268,081)	515,840
Other income (expense)	(108,333)	(114,528)	(6,195)
Net income (loss)	(892,254)	(382,609)	509,645

Revenue

We did not generate any revenue in either of the nine months ended June 30, 2013 or 2012.

General and Administrative Expense

We incurred general and administrative expense during the nine months ended June 30, 2013 in the amount of \$721,565, compared to general and administrative expense incurred during the nine months ended June 30, 2012 in the amount of \$225,841 (an increase of \$495,724). Our general and administrative expenses during those periods primarily included legal fees, patent prosecution costs, payroll related expenses, license maintenance fees, professional fees and office overhead. The increase in general and administrative expense period over period is primarily attributable to increased costs associated with legal and accounting fees incurred in connection with the Merger partially offset by a decrease in patent prosecution costs.

General and administrative expenses are generally expected to increase as a result of plans to ramp up operations and requirements to comply with public company reporting obligations. We expect increased expenses related to plans to hire additional personnel and consultants and expected incurrence of additional legal fees.

Research and Development Expense

We incurred research and development expense during the nine months ended June 30, 2013 in the amount of \$62,356, compared to research and development expense incurred during the nine months ended June 30, 2012 in the amount of \$42,240 (an increase of \$20,116). Our research and development expenses primarily relate to our activities to develop our primary product candidate, and are comprised of payroll related expenses, advisor fees and cost of materials. The increase in research and development expense between periods is primarily attributable to increases in payroll related expenses.

Research and development expenses are expected to increase as a result of plans to pursue additional preclinical and clinical studies and otherwise relating to development of our primary product candidate.

Other Income (Expense)

We incurred total other expenses during the nine months ended June 30, 2013 in the amount of \$108,333 compared to total other expenses incurred during the nine months ended June 30, 2012 in the amount of \$114,528 (a decrease of \$6,195). Other expenses during those periods were primarily interest accrued on debt. The decrease in other expense between periods is attributable to suspension of interest accrual beyond April 30, 2013 in connection with the exchange of debt in the Merger.

Liquidity and Capital Resources

Working Capital

Our working capital as of June 30, 2013 and September 30, 2012 is summarized as follows:

	June 30, 2013	September 30, 2012
Total Current Assets	\$477,490	\$20,447
Total Current Liabilities	419,267	2,552,439
Working Capital	\$58,223	\$(2,531,992)

As of June 30, 2013, total current assets were \$477,490, compared to total current assets of \$20,447 as of September 30, 2012 (an increase of \$457,043). The increase was due to an increase in cash balances resulting from issuance of convertible debt and funds received in connection with the Merger greater than operating expenditures and repayment of related party debt and accrued interest. Our total current assets as of June 30, 2013 were comprised primarily of cash, cash equivalents and prepaid expenses.

As of June 30, 2013, total current liabilities were \$419,267, compared to total current liabilities of \$2,552,439 as of September 30, 2012 (a decrease of \$2,133,172). The decrease was primarily due to cancellation of current maturities of outstanding debt and accrued interest on debt in connection with the Merger partially offset by an increase in accrued expenses. Our total current liabilities as of June 30, 2013 were comprised primarily of accounts payable and accrued expenses.

As a result, on June 30, 2013, we had working capital of \$58,223.

Cash Flow

Our cash on-hand as of June 30, 2013 was \$476,369, compared to cash on-hand as of September 30, 2012 of \$17,139 (an increase of \$459,230). The increase was primarily due to issuance of convertible debt and funds received in connection with the Merger greater than operating expenditures and repayment of related party debt and accrued interest.

Cash Used in Operating Activities

Cash used in operating activities during the nine months ended June 30, 2013 was \$667,281, compared to cash used in operating activities during the nine months ended June 30, 2012 of \$151,625 (an increase of \$515,656). The increase was primarily due to an increase in general and administrative expense attributable to increased costs associated with legal and accounting fees incurred in connection with the Merger partially offset by a decrease in patent prosecution costs.

Cash Used in Investing Activities

There was no cash used in investing activities during the nine months ended June 30, 2013 or 2012, respectively.

Cash Provided by Financing Activities

Cash provided by financing activities during the nine months ended June 30, 2013 was \$1,126,512, compared to cash provided by financing activities during the nine months ended June 30, 2012 of \$135,000 (an increase of \$991,512). The increase in cash provided by financing activities was obtained from issuances of convertible promissory notes and amounts advanced under the Coldstream Financing reduced by the repayment of certain notes payable to the CEO and accrued interest.

Sources of Capital

Prior to the closing of the Merger, we had primarily funded our operations through the issuance of convertible debt and other promissory notes and related warrants. Other than such financing activities, we have had no sources of material funding to date. Since inception through June 30, 2013, we had received an aggregate of \$1,985,000 from our issuance of the convertible notes and related warrants. In contemplation of the Merger, the Company obtained a commitment under the Coldstream Financing totaling \$2,000,000 to fund our operations. Of that amount, gross proceeds of \$1,250,000 have been received as of June 30, 2013. On July 1, 2013, pursuant to the Coldstream Financing, the Company sold and issued additional units consisting of 500,000 shares of common stock and warrants to purchase 500,000 shares of our common stock to a foreign accredited investor identified by Coldstream for aggregate gross proceeds of \$250,000 (the "July Closing"). Following the July Closing, the Company may raise an additional \$500,000 in financing pursuant to the Financing Agreement.

Cash Requirements

As described above, we anticipate that our operating and other expenses will increase following the closing of the Merger as we implement our business plan. After giving effect to the funds received in the recent equity and debt financings, committed funding under the Coldstream Financing over the next six months and we estimate as of June 30, 2013 we will have sufficient funds to operate the business for the next 9 months' however, based on our current operating expenses and working capital requirements, we do not currently believe our existing cash resources are sufficient to meet our anticipated needs during the next twelve months. In addition to the funds raised or available pursuant to the Coldstream Financing, we will require additional financing to fund our planned future operations, including the continuation of our ongoing research and development efforts, seeking to license or acquire new assets, and researching and developing any potential patents, the related compounds and any further intellectual property that we may acquire. Further, these estimates could differ if we encounter unanticipated difficulties, in which case our current funds may not be sufficient to operate our business for that period. In addition, our estimates of the amount of cash necessary to operate our business may prove to be wrong, and we could spend our available financial resources much faster than we currently expect.

Other than the funding committed under the Coldstream Financing, we do not have any firm commitments for future capital. Even after giving effect to those additional committed funds, significant additional financing will be required to fund our planned operations in the near term and in future periods, including research and development activities relating to our principal product candidate, seeking regulatory approval of that or any other product candidate we may choose to develop, commercializing any product candidate for which we are able to obtain regulatory approval or certification, seeking to license or acquire new assets or business, and maintaining our intellectual property rights and pursuing rights to new technologies. We do not presently have, nor do we expect in the near future to have, revenue to fund our business from our operations, and will need to obtain all of our necessary funding from external sources in the near term. 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 investments.

Going Concern

From inception through June 30, 2013 have not received operating revenues from sales of products or services, and have recurring losses from operations. As of June 30, 2013, we had incurred a net loss of \$3,670,333 since our inception. The continuation of our business as a going concern is dependent upon raising additional capital and eventually attaining and maintaining profitable operations. The financial statements included in this Form 10-Q do not include any adjustments relating to the recoverability of assets that might be necessary should operations discontinue.

Critical Accounting Policies and Significant Judgments and Estimates

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

Basis of Presentation — Development Stage Company

We have not earned any revenue from operations. Accordingly, our activities have been accounted for as those of a “Development Stage Company” as set forth in Financial Accounting Standards Board (“FASB”) ASC 915. Among the disclosures required by ASC 915 are that our financial statements be identified as those of a development stage company, and that the statements of operations, stockholders’ deficit and cash flows disclose activity since the date of our inception.

Income Taxes

In accordance with FASB ASC 740, Income Taxes, we recognize deferred tax assets and liabilities for the expected future tax consequences or events that have been included in our financial statements and/or tax returns. Deferred tax assets and liabilities are based upon the differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities and for loss and credit carryforwards using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

We provide reserves for potential payments of tax to various tax authorities related to uncertain tax positions when management determines that it is probable that a loss will be incurred related to these matters and the amount of the loss is reasonably determinable. We have no reserves related to uncertain tax positions as of June 30, 2013 and September 30, 2012.

Recent Accounting Guidance

Accounting Standards Update (ASU) 2013-11, "Income Taxes (Topic 740) - Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists" was issued in July 2013. The amendments in this Update are effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. Early adoption is permitted. The amendments should be applied prospectively to all unrecognized tax benefits that exist at the effective date. Retrospective application is permitted. The Company does not expect adoption of this ASU to have a material impact on its financial statements.

Off-Balance Sheet Arrangements

We have no significant off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to stockholders.

Item 3.—Quantitative and Qualitative Disclosures about Market Risk

Not applicable

Item 4.—Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer (who is our Principal Executive Officer) and our Chief Financial Officer (who is our Principal

Financial Officer and Principal Accounting Officer), of the effectiveness of the design of our disclosure controls and procedures (as defined by Exchange Act Rules 13a-15(e) or 15d-15(e)) as of June 30, 2013, pursuant to Exchange Act Rule 13a-15. Based upon that evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were not effective as of June 30, 2013 in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission's (the "SEC") rules and forms. This conclusion is based on findings that constituted material weaknesses. A material weakness is a deficiency, or a combination of control deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's interim financial statements will not be prevented or detected on a timely basis.

As of June 30, 2013 management has identified the following material weaknesses:

We have had insufficient quantity of dedicated resources and experienced personnel involved in reviewing and (i) designing internal controls. As a result, a material misstatement of the interim and annual financial statements could occur and not be prevented or detected on a timely basis.

(ii) We have not had personnel with formal training to properly analyze and record complex transactions in accordance with U.S. GAAP.

(iii) We have not achieved the optimal level of segregation of duties relative to key financial reporting functions.

(iv) We do not have an audit committee, which is an important entity-level control over our financial statements and the engagement of our independent auditors.

We did not perform an entity level risk assessment to evaluate the implication of relevant risks on financial reporting, including the impact of potential fraud-related risks and the risks related to non-routine transactions, if (v) any, on our internal control over financial reporting. Lack of an entity-level risk assessment constituted an internal control design deficiency which resulted in more than a remote likelihood that a material error would not have been prevented or detected, and constituted a material weakness.

Remediation

Effective June 26, 2013, the Company completed a Merger with ABS. Also in connection with the Merger, our principal office was relocated to Cambridge, Massachusetts. With the closing of the Merger, we now have adequate resources with the experience to review and design internal controls as well as the experience and formal training to properly analyze and record complex transactions in accordance with U.S. GAAP and to ensure that we have adequate segregation of duties to key financial reporting functions.

We have reviewed our disclosure controls and procedures related to these material weaknesses following the closing of the Merger and expect to implement changes in the near term, including identifying specific areas within our governance, accounting and financial reporting processes that will address our material weaknesses. On an annual basis, management is responsible for performing an entity level risk assessment to evaluate the implication of relevant risks on financial reporting, including the impact of potential fraud-related risks and the risks related to non-routine transactions, if any, on our internal control over financial reporting. This annual assessment is scheduled for the fourth quarter of fiscal year 2013. In lieu of an audit committee, we utilize our board of directors as an important entity-level control over our financial statements and the engagement of our independent auditors. We are currently seeking an external financial expert for our board.

Our management team will continue to monitor and evaluate the effectiveness of our internal controls and procedures and our internal controls over financial reporting on an ongoing basis and is committed to taking further action and implementing additional enhancements or improvements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Changes in Internal Control Over Financial Reporting

Other than the ongoing remediation efforts identified above, there were no changes in our internal controls over financial reporting that occurred during the quarterly period ended June 30, 2013 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting. We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if

any, within any company have been detected.

PART II.—OTHER INFORMATION

Item 1.—Legal Proceedings

From time to time, we may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. The impact and outcome of litigation, if any, is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. We are not currently a party to any proceedings the adverse outcome of which, individually or in the aggregate, would have a material adverse effect on our financial position or results of operations.

Item 1A.—Risk Factors

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 actually occurs, our business, financial condition, and results of operations could be negatively impacted and you could lose all or part of your investment.

Risks Related to our Business

We have incurred significant losses since inception. We expect to continue to incur losses for the foreseeable future as we pursue our operations as a combined enterprise, and we may never generate revenue or achieve or maintain profitability.

We have incurred losses in each year since our inception and we expect that losses will continue to be incurred in the foreseeable future in the operation of our new business. To date, we have financed our operations entirely through investments by founders and other investors, and we expect to continue to do so in the foreseeable future. Losses from operations have resulted principally from costs incurred in research and development programs and from general and administrative expenses, including significant costs associated with establishing and maintaining intellectual property rights, significant legal and accounting costs pertaining to the closing of the Merger and related regulatory filings, and

personnel. We have devoted substantially all of our time, money and efforts to date to the advancement of our technology, and expect to continue to devote significant time, money and efforts to such activities going forward.

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

- develop our principal product candidate, AC5™;
- conduct clinical trials relating to AC5 and any other product candidate we seek to develop;
- attempt to gain regulatory approvals for any product candidate that successfully completes clinical trials;
- invest in product and process development through contract manufacturing partners;
- maintain, expand and protect our intellectual property portfolio;
- seek to commercialize selected product candidates for which we may obtain regulatory approval;
- hire additional regulatory, clinical, quality control, scientific and management consultants and personnel; and support and add operational, financial, accounting, facilities engineering and information systems consultants and personnel to further our operations.

To become and remain profitable, we must succeed in developing and eventually commercializing product candidates with significant market potential. This will require us to be successful in a range of challenging activities, including successfully completing preclinical testing and clinical trials of product candidates, obtaining regulatory approval for our product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of those activities. We may never succeed in those activities and may never generate operating revenues or achieve profitability. Even if we do generate operating revenues sufficient to achieve profitability, we may not be able to sustain or increase profitability. Our failure to generate operating revenues or become and remain profitable would impair our ability to raise capital, expand our business or continue our operations, all of which would depress the price of our common stock. A decline in the prices of our common stock could cause our stockholders to lose all or a part of their investment in the Company.

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

We have not generated any revenue from operations since inception, and we have incurred substantial net losses to date. Further, our operating expenses will likely increase in the foreseeable future, as we seek to increase operations as a life sciences medical device company. Moreover, our cash position is vastly inadequate to support our business plans and substantial additional funding will be needed in order to pursue those plans, which include research and development of our primary product candidate, seeking regulatory approval for that product candidate, and pursuing its commercialization in the U.S., Europe and other markets. Those circumstances raise substantial doubt about our ability to continue as a going concern.

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

We are a development stage company with no commercial products. Our primary product candidate is in the process of being developed, and will require significant additional clinical development and additional investment before it could potentially be commercialized. We anticipate that none of our product candidates may be commercially available for several years, if at all.

We currently believe that proceeds we expect to receive from current funding commitments will be sufficient to meet our anticipated cash requirements for the next 9 months; however, based on our current operating expenses and working capital requirements, we do not currently believe our existing cash resources are sufficient to meet our anticipated needs during the next twelve months. In addition to the funds raised or available pursuant to the Coldstream Financing, we will require additional financing to fund our planned future operations, including the continuation of our ongoing research and development efforts, seeking to license or acquire new assets, and researching and developing any potential patents, the related compounds and any further intellectual property that we may acquire. In addition, our plans may change and/or we may use our capital resources more rapidly than we currently anticipate. We presently expect that our expenses will increase in connection with our ongoing activities, particularly as we commence preclinical and clinical development for our lead product candidate, AC5, and that we will need to raise significant additional funds to continue operations. Our future capital requirements will depend on many factors, including:

- the scope, progress and results of our research and preclinical development activities;

the scope, progress, results, costs, timing and outcomes of any clinical trials conducted for any of our product candidates;

-

the timing of entering into, and the terms of, any collaboration agreements with third parties relating to any of our product candidates;

- the timing of and the costs involved in obtaining regulatory approvals for our product candidates;

the costs of operating, expanding and enhancing our operations to support our clinical activities and, if our product candidates are approved, commercialization activities;

the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities;

operating revenues, if any, received from sales of our product candidates, if any are approved by the FDA or other applicable regulatory agencies;

the cost associated with being a public company, including obligations to regulatory agencies and investor relations; and

the costs of additional general and administrative personnel, including accounting and finance, legal and human resources employees.

As a result of these and other factors, we expect that we will need substantial additional funding in the future. We would likely seek such funding through public or private securities offerings, incurrence of indebtedness, or some combination. We may also seek funding through collaborative arrangements if we determine them to be necessary or appropriate. Additional funding may not be available when needed on acceptable terms, or at all. If we obtain capital through collaborative arrangements, these arrangements could require us to relinquish rights to our technology or product candidates and could result in our receipt of only a portion of the revenues associated with the partnered product. If we raise capital through the sale of equity, or securities convertible into equity, it would result in dilution to our then existing stockholders, which could be significant depending on the price at which we may be able to sell our securities. If we raise additional capital through the incurrence of indebtedness, we would likely become subject to covenants restricting our business activities, and holders of debt instruments may have rights and privileges senior to those of our equity investors. In addition, servicing the interest and principal repayment obligations under debt facilities could divert funds that would otherwise be available to support research and development, clinical or commercialization activities.

If we are unable to obtain adequate financing on a timely basis or on acceptable terms in the future, we would likely be required to delay, reduce or eliminate one or more of our product development activities, which could cause our business to fail.

Our short operating history may hinder our ability to successfully meet our objectives.

We are a development stage company subject to the risks, uncertainties and difficulties frequently encountered by early-stage companies in evolving markets. Our operations to date have been primarily limited to organizing and staffing, developing and securing its technology and undertaking or funding preclinical studies of its lead product candidate. We have not demonstrated our ability to successfully complete large-scale, pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on its behalf, or conduct sales and marketing activities necessary for successful product commercialization.

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

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

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

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

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

We have identified material weaknesses in our internal control over financial reporting which could, if not remediated, result in material misstatements in our financial statements.

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. As disclosed in Item 4 of Part I of this report, management identified material weaknesses in our internal control over financial reporting as of June 30, 2013. A material weakness is defined as a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. As a result of these material weaknesses, our management concluded that our internal control over financial reporting was not effective based on criteria set forth by the Committee of Sponsoring Organization of the Treadway Commission in Internal Control—Integrated Framework. We have developed a remediation plan that is designed to address these material weaknesses. If our remedial measures are insufficient to address the material weaknesses, or if additional material weaknesses or significant deficiencies in our internal control are discovered or occur in the future, our consolidated financial statements may contain material misstatements and we could be required to restate our financial results, which could lead to substantial additional costs for accounting and legal fees and litigation. In addition, even if we are successful in strengthening our controls and procedures, in the future those controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our consolidated financial statements. If we fail to achieve and maintain the adequacy of our internal controls in accordance with applicable standards, we may be unable to conclude on an ongoing basis that we have effective internal controls over financial reporting. If we cannot produce reliable financial reports, our business and financial condition could be harmed, investors could lose confidence in our reported financial information, or the market price of our stock could decline significantly. Moreover, our reputation with lenders, investors, securities analysts and others may be adversely affected.

We may become involved in litigation and administrative proceedings that may materially affect us.

From time to time, we may become involved in various legal proceedings relating to matters incidental to the ordinary course of our business, including commercial, employment, class action, whistleblower and other litigation and claims, and governmental and other regulatory investigations and proceedings. Such matters can be time-consuming, divert management's attention and resources and cause us to incur significant expenses. Furthermore, because litigation is inherently unpredictable, there can be no assurance that the results of any of these actions will not have a material adverse effect on our business, results of operations or financial condition.

Risks Related to the Development and Commercialization of our Product Candidates

Our current business plan is dependent on the success of one product candidate.

Our business is currently focused almost entirely on the development and commercialization of one product candidate, AC5. Our reliance on one primary product candidate means that, if we are not able to obtain regulatory approvals and market acceptance of that product, our chances for success will be significantly reduced. We are also less likely to withstand competitive pressures if any of our competitors develops and obtains regulatory approval or certification for a similar product faster than we can or that is otherwise more attractive to the market than AC5. Our current dependence on one product candidate increases the risk that our business will fail if our development efforts for that product candidate experience delays or other obstacles or are otherwise not successful.

The Chemistry, Manufacturing and Control (“CMC”) Process may be challenging.

Because of the complexity of the Company’s products, the CMC process may be difficult to complete successfully within the parameters required by the FDA. Failure to complete the CMC process successfully will severely limit our long-term viability.

Our principal product candidate is inherently risky because it is based on novel technologies.

We are subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of AC5 creates significant challenges with respect to product development and optimization, manufacturing,

government regulation and approval, third-party reimbursement and market acceptance. Our failure to overcome any one of those challenges could harm our operations and overall chances for success.

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

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

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

The development plan for our initial product candidate is based on our anticipation of pursuing the medical device regulatory pathway. However, the FDA and other applicable foreign agencies will have authority to finally determine the regulatory route for our product candidates in their jurisdictions. If the FDA or similar foreign agencies or intermediaries deem our product to be a member of a category other than a medical device, such as a drug or biologic, or impose additional requirements on our pre-clinical and clinical development, financing needs would increase, the timeline for product approval would lengthen, the program complexity and resource requirements would increase, and the probability of successfully commercializing a product would decrease. Any or all of those circumstances would adversely affect our business.

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

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

Any clinical trials that are conducted on our product candidates may fail.

Clinical trials are lengthy, complex and extremely expensive processes with uncertain expenditures and results and frequent failures. Any clinical trials that are commenced for one of our product candidates could be delayed, limited or fail for a number of reasons, including if:

the FDA or other regulatory authorities do not grant permission to proceed or places a trial on clinical hold due to safety concerns or other reasons;

- sufficient suitable subjects do not enroll or remain in our trials;
- we fail to produce necessary amounts of product candidate;
- subjects experience an unacceptable rate of efficacy of the product candidate;

subjects experience an unacceptable rate or severity of adverse side effects, demonstrating a lack of safety of the product candidate;

- any portion of the trial or related studies produces negative or inconclusive results or other adverse events;
- reports from preclinical or clinical testing on similar technologies and products raise safety and/or efficacy concerns;
- third-party clinical investigators lose their licenses or permits necessary to perform our clinical trials, do not perform their clinical trials on their anticipated schedule or consistent with the clinical trial protocol, GCP or regulatory requirements, or other third parties do not perform data collection and analysis in a timely or accurate manner;
- inspections of clinical trial sites by the FDA or Institutional Review Boards (“IRBs”) or other applicable regulatory authorities find violations that require us to undertake corrective action, suspend or terminate one or more testing sites, or prohibit us from using some or all of the data in support of our marketing applications with the FDA or other applicable agencies;
- manufacturing facilities of our third party manufacturers are ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of cGMP or other applicable requirements;
- third-party contractors become debarred or suspended or otherwise penalized by FDA or other government or regulatory authorities for violations of regulatory requirements;
 - the FDA or other regulatory authorities impose requirements on the design, structure or other features of the clinical trials for our product candidates that we and/or its third party contractors are unable to satisfy;
- one or more IRBs refuses to approve, suspends or terminates a trial at an investigational site, precludes enrollment of additional subjects, or withdraws its approval of the trial;
 - the FDA or other regulatory authorities seek the advice of an advisory committee of physician and patient representatives that may view the risks of our product candidates as outweighing the benefits;
- the FDA or other regulatory authorities require us to expand the size and scope of the clinical trials, which we may not be able to do; or
- the FDA or other regulatory authorities impose prohibitive post-marketing restrictions on any of our product candidates that attains regulatory approval.

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

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

We cannot sell our product candidates in any country until regulatory agencies grant marketing approval or other required certifications. The process of obtaining such approval is lengthy, expensive and uncertain. If we are able to obtain such approvals for our lead product candidate or any other product candidate we may pursue, which we may never be able to do, it would likely be a process that takes many years to achieve.

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

We believe that the pathway to marketing approval in the U.S. for our lead product candidate will likely require the FDA's approval of a PMA for the product, which likely will be classified as a Class III medical device and is based on novel technologies. This approval pathway can be lengthy and expensive, and is estimated to take from one to three years or longer from the time the PMA application is submitted to the FDA until an approval is obtained, if an approval can be obtained at all.

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

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

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

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

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

restrictions on the marketing or distribution of a product, including refusals to permit the import or export of products;

- warning letters or untitled letters;
- warning labels on the products;
- withdrawal or recall of the products from the market;

refusal by the FDA or other regulatory agencies to approve pending applications or supplements to approved applications that we may submit;

- suspension of any ongoing clinical trials;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals or certifications; or
- civil or criminal penalties.

The occurrence of any such consequences if any of our product candidates achieves required regulatory marketing approvals or certifications in the future would materially adversely affect our business and operations.

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

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

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

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

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

We have limited personnel with experience in medical device development and manufacturing, do not own or operate manufacturing facilities, and generally lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We currently intend to outsource all or most of the manufacturing and packaging of our preclinical and clinical product candidates and products to third parties. However, we do not currently have agreements with any third party manufacturers for the supply of any of our product candidates. There are a limited number of manufacturers that operate under cGMP regulations and that are capable of and willing to manufacture our product candidates utilizing the manufacturing methods that are required to produce our lead product candidate, and our product candidates will compete with other product candidates for access to qualified manufacturing facilities. In the near term, if we have difficulty locating third party manufacturers to develop our product candidates for clinical work, then our product development programs will experience delays and otherwise suffer. We may also be unable to enter into agreements for the commercial supply of products with third party manufacturers in the future, or may be unable to do so when needed or on acceptable terms. Any such results could materially harm our business.

Reliance on third party manufacturers entails risks to our business, including:

the failure of the third party to maintain regulatory compliance, quality assurance, and general expertise in advanced manufacturing techniques and processes that may be necessary for the manufacture of our product candidates;

- limitations on supply availability resulting from capacity and scheduling constraints of the third parties;

failure of the third party manufacturers to meet the demand for the product candidate, either from future customers or for clinical trial needs;

- the possible breach of the manufacturing agreement by the third party; and

the possible termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient for us.

The failure of any of our contract manufacturers to maintain high manufacturing standards could result in harm to clinical trial participants or patients using products. Such failure could also result in product liability claims, product recalls, product seizures or withdrawals, delays or failures in testing or delivery, cost overruns or other problems that could seriously harm our business or profitability. Further, our contract manufacturers will be required to adhere to FDA and other applicable regulations relating to manufacturing practices. Those regulations cover all aspects of the manufacturing, testing, quality control and recordkeeping relating to our product candidates and any products that we may commercialize in the future. The failure of our third party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval or other required certifications of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business, financial condition and operations.

Materials necessary to manufacture our product candidates may not be available on commercially reasonable terms, or at all, which may delay or otherwise hinder the development and commercialization of those product candidates.

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

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

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

We compete with other pharmaceutical and medical device companies, including companies that may develop products that make our product candidates less attractive or obsolete.

The medical device, pharmaceutical and biotechnology industries are highly competitive. If our product candidates become available for commercial sale, we will compete in that competitive marketplace. There are several products on the market or in development that could be competitors with our lead current product candidate. While our management, which is familiar with these other products, believes that our lead product candidate could be safer and possibly more effective than those competitors, those beliefs may turn out to be wrong. Further, most of our competitors have greater resources or capabilities and greater experience in the development, approval and commercialization of medical devices or other products than we do. We may not be able to compete successfully against them. We also compete for funding with other companies in our industry that are focused on discovering and developing novel improvements in surgical bleeding prevention.

We anticipate that competition in our industry will increase. In addition, the healthcare industry is characterized by rapid technological change, resulting in new product introductions and other technological advancements. Our competitors may develop and market products that render our lead product candidate or any future product non-competitive or otherwise obsolete. Any such circumstances could cause our operations to suffer.

If we fail to generate market acceptance of our product candidates and establish programs to educate and train surgeons as to the distinctive characteristics of our product candidates, we will not be able to generate revenues on those product candidates.

Acceptance in the marketplace of our lead product candidate depends in part on our and our third party contractors' ability to establish programs for the training of surgeons in the proper usage of that product candidate, which will require significant expenditure of resources. Convincing surgeons to dedicate the time and energy necessary to properly train to use new products and techniques is challenging, and we may not be successful in those efforts. If surgeons are not properly trained, they may ineffectively use our product candidates. Such misuse could result in unsatisfactory patient outcomes, patient injury, negative publicity or lawsuits against us. Accordingly, even if our product candidates are superior to alternative treatments, our success will depend on our ability to gain and maintain market acceptance for those product candidates among certain select groups of the population that will use those products. If we fail to do so, we will not be able to generate revenue from product sales and our business, financial condition and results of operations will be adversely affected.

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

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

In addition, the U.S. Congress recently adopted legislation regarding health insurance. As a result of this new legislation, substantial changes could be made to the current system for paying for healthcare in the U.S., including modifications to the existing system of private payors and government programs, such as Medicare, Medicaid and State Children's Health Insurance Program, creation of a government-sponsored healthcare insurance source, or some combination of those, as well as other changes. Restructuring the coverage of medical care in the U.S. could impact the reimbursement for medical devices such as our product candidates. If reimbursement for our approved product candidates, if any, is substantially less than we expect, or rebate obligations associated with them are substantially increased, our business could be materially and adversely impacted.

The use of our product candidates in human subjects may expose us to product liability claims, and we may not be able to obtain adequate insurance or otherwise defend against any such claims.

We face an inherent risk of product liability claims and do not currently have product liability insurance coverage. We will need to obtain insurance coverage if and when we begin clinical trials and commercialization of any of our product candidates. We may not be able to obtain or maintain product liability insurance on acceptable terms with adequate coverage. If claims against us exceed any applicable insurance coverage we may obtain, then our business could be adversely impacted. Regardless of whether we would be ultimately successful in any product liability litigation, such litigation could consume substantial amounts of our financial and managerial resources, which could significantly harm our business.

Risks Related to our Intellectual Property

If we are unable to obtain and maintain protection for our intellectual property rights, the value of our technology and products will be adversely affected.

Our success will depend in large part on our ability to obtain and maintain protection in the U.S. and other countries for the intellectual property rights covering or incorporated into our technology and products. The patent situation in the field of medical devices generally is highly uncertain and involves complex legal, technical, scientific and factual questions. We may not be able to obtain and maintain patent protection relating to our technology or products. Even if issued, patents issued or licensed to us may be challenged, narrowed, invalidated, held to be unenforceable or circumvented, or determined not to cover our product candidates or our competitors' products, which could limit our ability to stop competitors from marketing identical or similar products. Further, we cannot be certain that we were the first to make the inventions claimed in the patents we own or license, or that protection of the inventions set forth in those patents was the first to be filed in the U.S. Third parties that have filed patents or patent applications covering similar technologies or processes may challenge our claim of sole right to use the intellectual property rights covered by the patents we own or exclusively license. Moreover, changes in applicable intellectual property laws or interpretations thereof in the U.S. and other countries may diminish the value of our intellectual property rights or narrow the scope of our patent protection. Any failure to obtain or maintain adequate protection for the intellectual property rights we use would materially harm our business, product development programs and prospects.

In addition, our proprietary information, trade secrets and know-how are important components of our intellectual property rights. We seek to protect our proprietary information, trade secrets, know-how and confidential information, in part, with confidentiality agreements with our employees, corporate partners, outside scientific collaborators, sponsored researchers, consultants and other advisors. We also have confidentiality and invention or patent assignment agreements with our employees and certain consultants and advisors. If our employees or consultants breach those agreements, we may not have adequate remedies for any of those breaches. In addition, our proprietary information, trade secrets and know-how may otherwise become known to or be independently developed by others. Enforcing a claim that a party illegally obtained and is using our proprietary information, trade secrets and know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect trade secrets. Costly and time consuming litigation could be necessary to seek to enforce and determine the scope of our intellectual property rights, and failure to obtain or maintain protection thereof could adversely affect our competitive business position and results of operations.

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

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

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

Our research, development and commercialization activities, as well as any product candidates or products resulting from those activities, may infringe or be accused of infringing a patent or other intellectual property under which we do not hold a license or other rights. Third parties may own or control those patents or other rights in the U.S. or abroad. The third parties that own or control those intellectual property rights could bring claims against us that would cause us to incur substantial time, expense, and diversion of management attention. If a patent or other intellectual property infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales, if any, of the applicable product or product candidate that is the subject of the suit. In order to

avoid or settle potential claims with respect to any of the patent or other intellectual property rights of third parties, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both. Any such license may not be available on acceptable terms, or at all. Even if we or our future collaborators were able to obtain a license, the rights granted to us could be non-exclusive, which could result in our competitors gaining access to the same intellectual property rights and materially negatively affecting the commercialization potential of our planned products. Ultimately, we could be prevented from commercializing one or more product candidates, or be forced to cease some aspects of our business operations, if, as a result of actual or threatened infringement claims, we are unable to enter into licenses on acceptable terms or at all or otherwise settle such claims. Further, if any such claims were successful against us, we could be forced to pay substantial damages. Any of those results could significantly harm our business, prospects and operations.

Risks Related to the Merger and our Common Stock

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

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

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

Certain of our executive officers and directors own a significant percentage of our outstanding capital stock following the closing of the Merger. Dr. Terrence W. Norchi, our President, Chief Executive Officer and a director, and Dr. Avtar Dhillon, the Chairman of our Board of Directors, collectively hold or control over 25% of our outstanding shares of common stock. Accordingly, these members of our Board of Directors and management team have substantial voting power to approve matters requiring stockholder approval, including without limitation the election of directors in the future, and have significant influence over our affairs. This concentration of ownership could have the effect of delaying or preventing a change in control of the Company after the Merger.

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

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

We do not now, and are not expected to in the foreseeable future, meet the initial listing standards of the Nasdaq Stock Market or any other national securities exchange. We presently anticipate that our common stock will continue to be quoted on the OTCBB or another over-the-counter quotation system. In those venues, our stockholders may find it difficult to obtain accurate quotations as to the market value of their shares of our common stock, and may find few buyers to purchase their stock and few market makers to support its price.

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

Our common stock is a “penny stock.”

The SEC has adopted regulations that generally define “penny stock” as an equity security that has a market price of less than \$5.00 per share, subject to specific exemptions. The market price of our common stock is, and is expected to continue to be in the near term, less than \$5.00 per share and is therefore a “penny stock.” Brokers and dealers effecting transactions in “penny stock” must disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities. Those rules may restrict the ability of brokers or dealers to sell our common stock and may affect the ability of our stockholders to sell their shares of our common stock. In addition, if our common stock continues to be quoted on the OTCBB as we expect, then our stockholders may find it difficult to obtain accurate quotations for our stock, and may find few buyers to purchase our stock and few market makers to support its price.

If we issue additional shares in the future, our existing shareholders will be diluted.

Our articles of incorporation authorize the issuance of up to 300,000,000 shares of common stock. In addition to capital raising activities, other possible business and financial uses for our authorized common stock include, without limitation, future stock splits, acquiring other companies, businesses or products in exchange for shares of common stock, issuing shares of our common stock to partners in connection with strategic alliances, attracting and retaining employees by the issuance of additional securities under our various equity compensation plans, or other transactions and corporate purposes that our Board of Directors deems are in the Company’s best interest. Additionally, shares of common stock could be used for anti-takeover purposes or to delay or prevent changes in control or management of the Company. We cannot provide assurances that any issuances of common stock will be consummated on favorable terms or at all, that they will enhance stockholder value, or that they will not adversely affect our business or the trading price of our common stock. The issuance of any such shares will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our common stock. If we issue any such additional shares, such issuance will reduce the proportionate ownership and voting power of all current shareholders. Further, such issuance may result in a change of control of our corporation.

FINRA sales practice requirements may limit a stockholder's ability to buy and sell our stock.

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

There may be additional risks because we recently completed a reverse merger transaction.

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

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

Our Articles of Incorporation eliminates the personal liability of our directors and officers to our Company and our stockholders for damages for breach of fiduciary duty as a director or officer to the extent permissible under Nevada law. Further, our amended and restated bylaws provide that we are obligated to indemnify any of our directors or officers to the fullest extent authorized by the Nevada law and, subject to certain conditions, advance the expenses incurred by any director or officer or director in defending any action, suit or proceeding prior to its final disposition. Those indemnification obligations could result in the Company incurring substantial expenditures to cover the cost of settlement or damage awards against our directors or officers, which we may be unable to recoup. These provisions and resultant costs may also discourage us from bringing a lawsuit against any of our current or former directors or officers for breaches of their fiduciary duties, and may similarly discourage the filing of derivative litigation by our stockholders against our directors and officers even though such actions, if successful, might otherwise benefit us or our stockholders.

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

We are a public reporting company in the U.S., and, accordingly, are subject to the information and reporting requirements of the Exchange Act and other federal securities laws, including the obligations imposed by the Sarbanes-Oxley Act. The costs associated with preparing and filing annual, quarterly and current reports, proxy statements and other information with the SEC in the ordinary course, as well as preparing and filing audited financial statements, will cause our operational expenses to be higher especially considering that we have significantly increased our operating activities as a result of the Merger and the change of our business plan.

Our present management team, which consists of ABS's former management team, has only limited publicly-traded company experience. It will be time consuming, difficult and costly for our management team to acquire additional expertise and experience in operating a public company, and to develop and implement the internal controls and reporting procedures required by Sarbanes-Oxley and other applicable securities laws. We will need to hire additional financial reporting, internal controls and other finance staff in order to completely develop and implement appropriate internal controls and reporting procedures as required by applicable securities regulations for public companies, which we may not be able to do on a timely basis or at all.

Shares of our common stock that have not been registered under federal securities laws, regardless of whether such shares are restricted or unrestricted, are subject to resale restrictions imposed by Rule 144, including those set forth in Rule 144(i) which apply to a "shell company." In addition, any shares of our common stock that are held by affiliates, including any received in a registered offering, will be subject to the resale restrictions of Rule 144(i).

Pursuant to Rule 144 (“Rule 144”) of the Securities Act of 1933, as amended (the “Securities Act”), a “shell company” is defined as a company that has no or nominal operations and either no or nominal assets; assets consisting solely of cash and cash equivalents; or assets consisting of any amount of cash and cash equivalents and nominal other assets. As such, we may be deemed a “shell company” pursuant to Rule 144 prior to the closing of the Merger, and as such, sales of our securities pursuant to Rule 144 are not permitted until a period of at least 12 months has elapsed from June 26, 2013, the date on which our Current Report on Form 8-K, reflecting our status as a non-“shell company”, was filed with the SEC. Therefore, any restricted securities we sell in the future or issue to consultants or employees in consideration for services rendered or for any other purpose will have no liquidity until and unless such securities are registered under the Securities Act and/or until June 26, 2014, provided that we and the selling stockholder are in compliance with the other requirements of Rule 144. As a result, it will be more difficult for us to raise funding to support our operations through the sale of debt or equity securities unless we agree to register such securities under the Securities Act, which could cause us to expend additional time and cash resources. Further, it may be more difficult for us to compensate our employees and consultants with our securities instead of cash. Our previous status as a “shell company” could also limit our use of our securities to pay for any acquisitions we may seek to pursue in the future (although none are currently planned), which could cause the value of our securities, if any, to decline in value or become worthless. In addition, any shares held by affiliates, including shares received in any registered offering, will be subject to the resale restrictions of Rule 144(i).

We do not intend to pay cash dividends on our capital stock in the foreseeable future.

We have never declared or paid any dividends on our shares and do not anticipate paying any such dividends in the foreseeable future. Any future payment of cash dividends would depend on our financial condition, contractual restrictions, solvency tests imposed by applicable corporate laws, results of operations, anticipated cash requirements and other factors and will be at the discretion of the our Board of Directors. Our stockholders should not expect that we will ever pay cash or other dividends on our outstanding capital stock.

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

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

Item 2.—Unregistered Sales of Equity Securities and Use of Proceeds

On July 1, 2013, we issued and sold units consisting of 500,000 shares of our common stock and warrant to purchase 500,000 shares of our common stock in the Coldstream Financing to a foreign accredited investor identified by Coldstream, for aggregate gross proceeds of \$250,000, and pursuant to a Securities Purchase Agreement and warrant in substantially the same forms that were executed previously in connection with the Coldstream Financing. The issuance of securities in the Coldstream Financing has not been registered under the Securities Act, and such securities have been issued in reliance upon an exemption from registration under Section 4(2) of the Securities Act and Regulation S promulgated thereunder. Such securities may not be offered or sold in the United States absent registration under or exemption from the Securities Act and any applicable state securities laws. In determining that the issuance of such securities qualifies for an exemption under Section 4(2) of the Securities Act and Regulation S promulgated thereunder, we have relied on the following facts: the recipients of the securities represented that they are not a “U.S. Person” as defined in as defined in Rule 902 promulgated under the Securities Act and are “accredited investors” as defined in Rule 501 under the Securities Act; and the securities were issued as restricted securities

Item 5. Other Information

Concurrently with the closing of the Merger, effective, June 24, 2013, we amended and restated our bylaws. Our restated bylaws include changes to the procedures by which our stockholders may recommend nominees to our Board of Directors.

Director candidates are considered based upon various criteria, including without limitation their broad-based business and professional skills and experiences, their knowledge of the industry in which we operate and ability to add perspectives relating to that industry, concern for the long-term interests of our stockholders, diversity, and personal integrity and judgment. In addition, directors must have time available to devote to the activities of our Board of Directors and to understand and enhance their knowledge of our industry and business plans. Our Board of Directors has a critical role in guiding our strategic direction and overseeing the management of the Company, and accordingly we seek to attract and retain highly qualified directors who have sufficient time to attend to their substantial duties and responsibilities as a director of the Company.

In carrying out its responsibilities, our Board of Directors will consider director candidates suggested by stockholders. If a stockholder wishes to formally place a director candidate’s name in nomination, then he or she must do so in accordance with the provisions of our amended and restated bylaws, which provide certain advance notice and other requirements in order for our stockholders to nominate a director candidate. Proposed nominations of director candidates must be timely sent to the Secretary of the Company, c/o Arch Therapeutics, Inc., One Broadway, 14th Floor, Cambridge, Massachusetts 02142. To be timely, notice of a proposed director nominee must be delivered to or

mailed and received at the Company's address set forth above not less than 90 days prior to the date of the meeting at which the proposed director nominee would be up for election. Further, the stockholder's notice relating to a director nomination must set forth the following information about each person whom the stockholder proposes to nominate for election or re-election as a director: (i) the name, age, business address and residence address of the person, (ii) the principal occupation or employment of the person, (iii) the class and number of shares of our common stock that are beneficially owned by the person, and (iv) any other information relating to the person that is required to be disclosed in solicitations for proxies for election of directors pursuant to Regulation 14A under the Exchange Act. Further, the stockholder must also provide the following information about itself and certain of persons associated with, controlling, controlled by or acting on concert with the stockholder: (i) the name and record address of the stockholder, (ii) the class and number of shares of our common stock which are beneficially owned by the stockholder; and (iii) certain information specified in our amended and restated bylaws regarding any hedge transactions entered into, derivative instruments beneficially owned by, or rights to dividends on the shares of our common stock beneficially owned by such persons. Pursuant to the terms of our amended and restated bylaws, the Company may also require any proposed nominee to furnish such other information as may reasonably be required by the Corporation to determine the eligibility of such proposed nominee to serve as a director on our Board of Directors.

Item 6. Exhibits

Exhibit	Description
2.1	Agreement and Plan of Merger dated May 10, 2013, by and among Almah, Inc., Arch Acquisition Corporation, and Arch Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed by the Company with the SEC on May 13, 2013)
3.1	Articles of Incorporation of Arch Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Registration Statement on Form S-1 filed by the Company with the SEC on January 5, 2012)
3.2	Certificate of Amendment to Articles of Incorporation of Arch Therapeutics, Inc. (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K filed by the Company with the SEC on June 5, 2013)
3.3	Amended and Restated Bylaws of Arch Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed by the Company with the SEC on June 24, 2013)
10.1	Binding Letter of Intent by and between Almah, Inc. and Arch Therapeutics, Inc. dated April 19, 2013 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Company with the SEC on April 25, 2013)
10.2	Promissory Note by and between Almah, Inc. and Arch Therapeutics, Inc. dated April 19, 2013 (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed by the Company with the SEC on April 25, 2013)
10.3	Financing Agreement by and between Almah, Inc. and Coldstream Summit Ltd. dated April 19, 2013 (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed by the Company with the SEC on April 25, 2013)
10.4	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed by the Company with the SEC on April 25, 2013)
10.5	Form of Warrant (incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K filed by the Company with the SEC on April 25, 2013)
10.6	Amended and Restated Exclusive Patent License Agreement dated May 23, 2011 between ABS and the Massachusetts Institute of Technology, as amended by the First Amendment to Amended and Restated Exclusive Patent License Agreement dated May 15, 2012 between ABS and the Massachusetts Institute of Technology, and further amended by the Second Amendment to Amended and Restated Exclusive Patent License Agreement dated February 1, 2013 between ABS and the Massachusetts Institute of Technology, as further amended by the Third Amendment to Amended and Restated Exclusive Patent License Agreement dated April 30, 2013 between ABS and the Massachusetts Institute of Technology, and as further amended by the Letter Agreement dated June 10, 2013 between ABS and the Massachusetts Institute of Technology (incorporated by reference to Exhibit 10.6 to the Current Report on Form 8-K filed by the Company with the SEC on June 26, 2013)
10.7	Termination Agreement and Release dated June 25, 2013, between ABS and Terrence W. Norchi (incorporated by reference to Exhibit 10.7 to the Current Report on Form 8-K filed by the Company with the SEC on June 26, 2013)
10.8	Executive Employment Agreement dated June 26, 2013 between Arch Therapeutics, Inc. and Terrence W. Norchi (incorporated by reference to Exhibit 10.8 to the Current Report on Form 8-K filed by the Company with the SEC on June 26, 2013)
10.9	Executive Employment Agreement dated June 26, 2013 between Arch Therapeutics, Inc. and Alan T. Barber (incorporated by reference to Exhibit 10.9 to the Current Report on Form 8-K filed by the Company with the SEC on June 26, 2013)
10.10	

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- Executive Employment Agreement, effective July 8, 2013, by and between Arch Therapeutics, Inc. and William M. Cotter (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Company with the SEC on July 8, 2013)
- 10.11* Amendment No. 1 to Agreement and Plan of Merger, dated May 23, 2013, by and among Almah, Inc., Arch Acquisition Corporation, and Arch Therapeutics, Inc.
- 10.12 Arch Therapeutics, Inc. 2013 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Company with the SEC on June 24, 2013)
- 10.13* Form of Stock Option Award Agreement under Arch Therapeutics, Inc. 2013 Stock Incentive Plan
- 10.14* Form of Restricted Stock Unit Award Agreement under Arch Therapeutics, Inc. 2013 Stock Incentive Plan
- 10.15* Form of Restricted Stock Bonus Award Agreement under Arch Therapeutics, Inc. 2013 Stock Incentive Plan
- 31.1* Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities and Exchange Act of 1934
- 31.2* Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities and Exchange Act of 1934
- 32.1* Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, executed by Terrence W. Norchi, President and Chief Executive Officer, and Alan T. Barber, Chief Financial Officer
- 101.INS*[^] XBRL Instance Document
- 101.SCH*[^] XBRL Taxonomy Extension Schema Document
- 101.CAL*[^] XBRL Taxonomy Extension Calculation Linkbase Document
- 101.DEF*[^] XBRL Taxonomy Extension Definition Linkbase Document
- 101.LAB*[^] XBRL Taxonomy Extension Label Linkbase Document
- 101.PRE*[^] XBRL Taxonomy Extension Presentation Linkbase Document
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* Filed herewith.

[^] In accordance with Rule 406T of Regulation S-T, the information in these exhibits shall not be deemed to be “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to liability under that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, except as expressly set forth by specific reference in such filing.

SIGNATURE

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ARCH THERAPEUTICS, INC.

Date: August 14, 2013 By: /s/ TERRENCE W. NORCHI

Terrence W. Norchi

President and Chief Executive Officer (Principal Executive Officer)

Date: August 14, 2013 By: /s/ ALAN T. BARBER

Alan T. Barber

Chief Financial Officer

(Principal Financial and Accounting Officer)