Arch Therapeutics, Inc.
Form 10-Q
February 14, 2014

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 December 31, 2013

Commission File Number: **333-178883**

ARCH THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Nevada	**46-0524102**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
20 William Street, Suite 270 **Wellesley, MA**	**02481**
(Address of principal executive offices)	(Zip Code)

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

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 x

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 February 13, 2014, there were 71,545,237 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 December 31, 2013

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PART I FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements (unaudited)

Arch Therapeutics, Inc.
(A Development Stage Company)
Consolidated Balance Sheets
December 31 (unaudited) and September 30, 2013

	December 31, 2013 (unaudited)	September 30, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 945,398	$ 557,319
Promissory note receivable	-	1,000,000
Prepaid expenses and other current assets	39,629	19,629
Total current assets	985,027	1,576,948
Long-term Assets:		
Property and equipment, net	322	322
Other assets	10,062	10,062
Total long-term assets	10,384	10,384
Total assets	$ 995,411	$ 1,587,332
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	$ 309,571	$ 314,769
Accrued expenses and other liabilities	203,230	140,840
Total current liabilities	512,801	455,609
Long-term liabilities:		
Note payable	947,472	944,707
Accrued interest	25,000	-
Total long-term liabilities	972,472	944,707
Total liabilities	1,485,273	1,400,316
Commitments and contingencies		
Stockholders' (deficit) equity:		
Common stock, $0.001 par value, 300,000,000 shares authorized and 60,145,237 shares issued and outstanding as of December 31 and September 30, 2013	60,145	60,145
Additional paid in capital	4,890,305	4,758,742

Deficit accumulated during the development stage	(5,440,312)	(4,631,871)
Total stockholders' (deficit) equity	(489,862)	187,016
Total liabilities and stockholders' (deficit) equity:	$ 995,411	$ 1,587,332

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

Arch Therapeutics, Inc.
(A Development Stage Company)
Consolidated Statements of Operations (Unaudited)
Three Months Ended December 31, 2013 and 2012 and the
Period from Inception (March 6, 2006) through December 31, 2013

	Three Months ended December 31, 2013	Three Months ended December 31, 2012	Period from Inception (March 6, 2006) through December 31, 2013
Other Revenues	$ -	$ -	$ 431,461
Operating expenses:			
General and administrative expenses	523,443	161,974	4,185,484
Research and development expenses	257,233	-	1,123,906
Total operating expenses	780,676	161,974	5,309,390
Operating loss	(780,676)	(161,974)	(4,877,929)
Other (expense) income:			
Interest expense	(27,765)	(42,981)	(616,361)
Other income	-	-	53,978
Total other expense	(27,765)	(42,981)	(562,383)
Net loss	$ (808,441)	$ (204,955)	$ (5,440,312)
Net loss per common share basic and diluted	$ (0.01)	$ (0.04)	
Weighted average number of shares outstanding	60,145,237	5,645,212	

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

Arch Therapeutics, Inc.
(A Development Stage Company)
Consolidated Statement of Cash Flows (Unaudited)
Three Months Ended December 31, 2013 and 2012 and the
Period from Inception (March 6, 2006) through December 31, 2013

	Three Months ended December 31, 2013	Three Months ended December 31, 2012	Period from Inception (March 6, 2006) through December 31, 2013
Cash flows from operating activities:			
Net loss	$ (808,441)	$ (204,955)	$ (5,440,312)
Adjustments to reconcile net loss to cash used in operating activities:			
Stock based compensation	131,563	-	419,490
Noncash interest expense on notes payable	27,765	33,061	469,018
Noncash interest expense on notes payable to related party	-	9,241	142,057
Depreciation expense	-	522	18,371
Other noncash adjustments	-	-	5,753
Issuance of common stock for services	-	-	253
Changes in operating assets and liabilities:			
(Increase) decrease in:			
Prepaid expenses and other current assets	(20,000)	286	(39,629)
Other Assets	-	-	(10,062)
Increase (decrease) in:			
Accounts payable	(5,198)	50,832	309,571
Accrued expenses and other liabilities	62,390	(22,009)	203,230
Net cash used in operating activities	(611,921)	(133,022)	(3,922,260)
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 issuance of common stock and warrants	-	-	2,000,000
Repayment of notes payable and accrued interest to related party	-	-	(373,488)
Proceeds from issuance of notes payable to related party	-	-	275,200
Proceeds from issuance of convertible notes payable to related party	-	-	105,000
Proceeds from issuance of notes payable	1,000,000	125,000	2,880,000
Net cash provided by financing activities	1,000,000	125,000	4,886,712
Net increase (decrease) in cash and cash equivalents	388,079	(8,022)	945,398
Cash and cash equivalents, beginning of period	557,319	17,139	-

Cash and cash equivalents, end of period	$ 945,398	$ 9,117	$ 945,398
Supplemental disclosure of cash flow information and non-cash financing activities			
Cash paid during the period for:			
Interest	$ -	$ -	$ 98,288
Income taxes	$ -	$ -	$ -

The accompanying notes are an integral part of these unaudited 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. and subsidiary (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. Subsequent to the Merger, we relocated our principal office to Wellesley, Massachusetts.

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

The Company is in the development stage and is devoting substantially all of its efforts toward product research and development. The Company has incurred losses of $5,440,312 since inception. To date, the Company has principally raised capital through the issuance of debt, convertible debt and the sale of investment units consisting of common stock and warrants.

The Company expects to incur substantial expenses for the foreseeable future relating to the research, development and commercialization of its potential products. 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. However, there can be no assurance that the Company will be successful in securing additional resources on terms acceptable to the Company, if at all. Therefore, there exists substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might be necessary despite this uncertainty.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accompanying unaudited interim consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP"). The interim consolidated financial statements included herein are unaudited; however, they contain all normal recurring accruals and adjustments that, in the opinion of management, are necessary to present fairly our results of operations and financial position for the interim periods.

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Although the Company believes that the disclosures in these unaudited interim consolidated financial statements are adequate to make the information presented not misleading, certain information normally included in the footnotes prepared in accordance with US GAAP has been omitted as permitted by the rules and regulations of the Securities and Exchange Commission ("SEC"). These unaudited interim consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2013 filed with the SEC on December 27, 2013.

For a complete summary of our significant accounting policies, please refer to Note 2 included in Item 8 of our Form 10-K for the fiscal year ended September 30, 2013. There have been no material changes to our significant accounting policies during the three months ended December 31, 2013.

Basis of Accounting

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.

Recently Issued 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 adoption of this ASU has not had a material impact on the Company's financial statements.

Subsequent Events

The Company evaluated all events or transactions that occurred through February 14, 2014, the date which these consolidated financial statements were available to be issued. The Company disclosed material subsequent events in Note 6.

3. STOCK-BASED COMPENSATION

2013 Stock Incentive Plan

On June 18, 2013, the Company established the 2013 Stock Incentive Plan (the "2013 Plan"). Under the 2013 Plan, a maximum number of 7,825,388 shares of the Company's authorized and available common stock could be issued in the form of: Options, Stock Appreciation Rights, sales or bonuses of restricted stock, restricted stock units or dividend equivalent rights, and an award may consist of one such security or benefit, or two or more of them in any combination or alternative. Commencing with the first business day of each fiscal year of the Company beginning in 2013, such maximum aggregate number of Shares shall be increased by a number equal to the lesser of (A) 3,000,000

Shares, (B) four (4) percent of the number of shares outstanding on the last day of the immediately preceding fiscal year of the Company, or (C) such lesser number of shares as determined by the Company's Board of Directors (the "Board"). The exercise price of each stock option shall be the fair market value as determined in good faith by the Board at the time each option is granted. On October 1, 2013 the aggregate number of authorized shares under the Plan was increased by 2,405,809 shares to total of 10,231,197 shares.

Share-based awards

During the quarter ended December 31, 2013, the Company granted options to purchase 220,000 shares of the Company's common stock to consultants under the 2013 Plan. The options have a term of 10 years, subject to vesting terms over 3 years and have exercise prices of $0.19 and $0.20.

The Company recognizes compensation expense for stock option awards on a straight-line basis over the applicable service period of the award. The service period is generally the vesting period, with the exception of options granted subject to a consulting agreement, whereby the option vesting period and the service period are defined pursuant to the terms of the consulting agreement. Share-based compensation expense for awards granted during the quarter ended December 31, 2013 were based on the grant date fair value estimated using the Black-Scholes Option Pricing Model. The following assumptions were used to calculate the fair value of share based compensation for the quarter ended December 31, 2013; Expected volatility, 113%, Risk-free interest rate, 2.80% - 3.04%, Expected forfeiture rate, 0.00%, Expected dividend yield, 0.00%, Expected term, 9.7 to 10 years.

Expected price volatility is the measure by which the Company's stock price is expected to fluctuate during the expected term of an option. The Company exited shell status on June 26, 2013. In situations where a newly public entity has limited historical data on the price of its publicly traded shares and no other traded financial instruments, authoritative guidance is provided on estimating this assumption by basing its expected volatility on the historical, expected, or implied volatility of similar entities whose share option prices are publicly available. In making the determination as to similarity, the guidance recommends the consideration of industry, stage of life cycle, size and financial leverage of such other entities. The Company's expected volatility is derived from the historical daily change in the market price of its common stock since it exited shell status, as well as the historical daily changes in the market price for the peer group as determined by the Company.

For so called "plain vanilla" options granted to employees, the expected term of the options is based upon the simplified method as defined in ASC 718-10-S99 which averages an award's weighted-average vesting period and the contractual term for share options. The Company will continue to use the simplified method until it has the historical data necessary to provide a reasonable estimate of expected life in accordance with ASC Topic 718, as amended by ASC 718-10-S99. The Company's estimation of the expected term for stock options not subject to the simplified method is based upon the contractual term of the option award. For the purposes of estimating the fair value of stock option awards, the risk-free interest rate used in the Black-Scholes calculation is based on the prevailing U.S. Treasury yield. The Company has never paid any dividends on its common stock and does not anticipate paying dividends on its common stock in the foreseeable future.

Stock-based compensation expense recognized in the Company's consolidated statements of operations is based on awards ultimately expected to vest, reduced for estimated forfeitures. Authoritative guidance requires forfeitures to be estimated at the time of grant, and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Due to the Company's minimal stock-based compensation activity, the Company has not had significant forfeitures of stock options granted to employees and directors. Therefore, the Company has estimated the forfeiture rate of its outstanding stock options as zero, but will continually evaluate its historical data as a basis for determining expected forfeitures.

Stock compensation plan activity for the quarter ended December 31, 2013 follows:

Common Stock Options

Stock compensation activity under the 2013 Plan for the quarter ended December 31, 2013 follows:

	Option Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at October 1, 2013	3,000,000			
Awarded	220,000	$ 0.20	-	
Exercised	-	-	-	
Forfeited	-	-	-	
Outstanding at December 31, 2013	3,220,000	$ 0.37	5.00	$ 27,400
Vested	1,555,000	$ 0.37	3.90	$ 6,850
Vested and expected to vest at December 31, 2013	3,220,000	$ 0.37	5.00	$ 27,400

As of December 31, 2013, 7,011,197 shares are available for future grants under the 2013 Plan. Share-based compensation expense recorded in the Company's consolidated statement of operations for the quarter ended December 31, 2013 resulting from stock options awarded to the Company's employees, directors and consultants was $131,563. Of this amount during the quarter ended December 31, 2013, $85,999 was recorded to Research and Development expenses, and $45,564 was recorded in General and Administrative expenses in the Company's consolidated statement of operations.

As of December 31, 2013, there is approximately $915,000 of unrecognized compensation expense related to unvested stock-based compensation arrangements granted under the 2013 Plan. That cost is expected to be recognized over a weighted average period of 2.59 years.

For the quarter ended December 31, 2012, the Company did not recognize any stock based compensation expense.

4. NOTE PAYABLE

On September 30, 2013, the Company entered into the Life Sciences Accelerator Funding Agreement (the "Loan Agreement") with the Massachusetts Life Sciences Center ("MLSC"), pursuant to which MLSC provided an unsecured subordinated loan in the amount of $1,000,000. The loan bears interest at a rate of 10% per annum, and will become fully due and payable on the earlier of (i) September 30, 2018, (ii) the occurrence of an event of default under the MLSC Loan Agreement, or (iii) the completion of a sale of substantially all of our assets, a change-of-control transaction or one or more financing transactions in which we receive net proceeds of $5,000,000 or more in a 12-month period. The Loan Agreement includes warrants to purchase 145,985 shares of the Company's common stock at an exercise price of $0.27 per share. The warrants expire on September 30, 2023. No warrants have been exercised as of December 31, 2013.

Of the $1,000,000, the Company allocated $944,707 to the loan and $55,293 to the warrants. The warrant valuation was derived with the Black-Scholes option pricing model with the following assumptions: risk free rate 2.64%, dividend yield 0.0%, expected life of 10 years, and volatility 114%. The fair value of the warrant was recorded as an increase in the Additional Paid-In Capital account. The allocation of funds to the warrants resulted in a discount on

the loan, which will be amortized to Interest Expense over the life of the loan. The amount amortized to Interest Expense in the Company's consolidated statement of operations for the quarter ended December 31, 2013 was $2,765.

5. CONVERTIBLE NOTES PAYABLE

From March 2006 through December 31, 2013, the Company issued convertible notes for aggregate cash proceeds of $1,735,000. The notes accrued interest at various rates ranging from 6 % to 10 % per year and had an original maturity date of two years from issuance. The notes were originally convertible into the number of shares of convertible preferred stock upon the closing of a preferred equity financing of at least $1,000,000 by dividing the principal and accrued interest by the purchase price of the convertible preferred stock. 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 ranging from 10 % to up to 50 % of the principal balance of the note. The warrants had various expiration dates through January 2015.

The Company held $1,245,000 of notes that had matured as of September 30, 2012. An additional $50,000 matured during October 2012 bringing the total to $1,295,000. Each of the holders of the matured notes entered into an agreement of forbearance with the Company extending the time to repay the matured notes and the accrued interest for an unspecified period of time. Under the terms of the agreement, interest continued to accrue at the rate in effect at the time of maturity.

On April 20, 2013, the convertible noteholders and the Company entered into an agreement to cancel the warrants and exchange the notes (with a total aggregate principal balance of $1,880,000) and the interest accrued through April 30, 2013 for the Company's common stock upon the completion of the Merger completed on June 26, 2013.

6. SUBSEQUENT EVENTS

Private Placement Financing

On January 30, 2014, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with a group of investors ("Investors") providing for the issuance and sale by the Company to the Investors, in a private placement, of an aggregate of 11,400,000 shares of the Company's common stock (collectively, the "Shares") at a purchase price of $0.25 per share and three series of warrants, the Series A Warrants, the Series B Warrants and the Series C Warrants, to purchase up to an aggregate of 34,200,000 shares of the Company's common stock (collectively, the "Warrants," and the shares issuable upon exercise of the Warrants, collectively, the "Warrant Shares"), for aggregate gross proceeds to the Company of approximately $2.85 million (the "Private Placement Financing").

Upon the closing of the Private Placement Financing on February 4, 2014, the Company entered into a registration rights agreement with the Investors (the "Registration Rights Agreement"), pursuant to which the Company will be obligated, subject to certain conditions, to file with the Securities and Exchange Commission within 45 days one or more registration statements (any such registration statement, a "Resale Registration Statement") to register the Shares and the Warrant Shares for resale under the Securities Act of 1933, as amended (the "Securities Act"). The Company's failure to satisfy certain filing and effectiveness deadlines with respect to a Resale Registration Statement and certain other requirements set forth in the Registration Rights Agreement may subject the Company to payment of monetary penalties.

The Warrants are exercisable upon issuance. The Series A Warrants have an exercise price of $0.30 per share and have a term of exercise equal to five years from their issuance. The Series B Warrants have an exercise price of $0.35 per share and have a term of exercise equal to the shorter of twelve months from their issuance and six months after the effective date of a Resale Registration Statement. The Series C Warrants have an exercise price of $0.40 per share and have a term of exercise equal to the shorter of 18 months after their issuance and nine months after the effective date of a Resale Registration Statement. The number of shares of the Company's common stock into which each of the Warrants is exercisable and the exercise price therefore are subject to adjustment as set forth in the Warrants,

including, without limitation, full ratchet anti-dilution protection in the event of certain dilutive issuances of the Company's equity securities following the issuance date of the Warrants. The exercisability of the Warrants may be limited if, upon exercise, the holder or any of its affiliates would beneficially own more than 4.9% of the Company's common stock.

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. (as used in this report on Form 10-Q, unless otherwise indicated, "Company", "we", "us", "our", and "Arch" refer to Arch Therapeutics, Inc. and its consolidated subsidiary, Arch Biosurgery, Inc.) was incorporated under the laws of the State of Nevada on September 16, 2009 with the name "Almah, Inc." to pursue the business of distributing automobile spare parts online. Effective June 26, 2013, Arch completed a merger (the "Merger") with Arch Biosurgery, Inc. (formerly known as Arch Therapeutics, Inc.), a Massachusetts corporation ("ABS"), and Arch Acquisition Corporation ("Merger Sub"), Arch's wholly owned subsidiary formed for the purpose of the transaction, pursuant to which Merger Sub merged with and into ABS and ABS thereby became the wholly owned subsidiary of Arch. Prior to the completion of the Merger, Arch was a "shell company" under applicable rules of the Securities and Exchange Commission (the "SEC") and had no or nominal assets or operations. Upon its acquisition of ABS, Arch abandoned its prior business plan and changed its operations to the business of a life science medical device company. For financial reporting purposes, the Merger represents a "reverse merger" rather than a business combination and ABS is deemed to be the accounting acquirer in the transaction and the predecessor of Arch. Consequently, the assets, liabilities, deficit accumulated during the development stage and the historical operations that are reflected in the Company's consolidated financial statements are those of ABS. All share information has been restated to reflect the effects of the Merger. The Company's financial information has been consolidated with that of ABS after consummation of the Merger on June 26, 2013, and the historical financial statements of the Company before the Merger will be replaced with the historical financial statements of ABS before the Merger in this filing and all future filings with the SEC that require financial statements to be included.

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

Liquidity

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. As further discussed in "Liquidity and Capital Resources" below, we will need to raise substantial additional funds in order to continue operating our business.

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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 use with human bodily fluids and connective tissues.

Our primary product candidate, AC5, relies on this technology and is designed 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. We believe that the results of early data from preclinical animal tests have shown quick and effective hemostasis with the use of AC5 relative to other types of hemostatic agents. AC5 is designed for either direct application as a liquid or application as a spray, which we believe will make it user-friendly and able to conform to irregular wound geometry. Additionally, AC5 is not sticky or glue-like, which we believe will enhance its utility in the setting of minimally invasive and laparoscopic surgeries. Further, AC5 is transparent, which should make it easier for a surgeon or other healthcare providers to maintain a clear field of vision during a surgical procedure and prophylactically stop bleeding as it starts, which we call Crystal Clear Surgery .

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 and formulation methods, and developing and protecting the intellectual property rights underlying our technology platform. Formulation optimization is an important part of peptide development. AC5 formulation optimization, which is done with extensive collaboration among our team and partners, is focused on optimizing traditional product parameters to target specifications covering performance, physical appearance, stability, and handling characteristics, among others. Arch intends to monitor formulation optimization closely, as success or failure in setting and realizing appropriate specifications may directly impact our anticipated clinical trial and subsequent commercialization timeline.

Our long-term business plan includes the following goals:

- conducting successful biocompatibility studies and, subsequently, clinical trials on AC5;
- obtaining regulatory approval or certification of AC5 in the EU, the U.S., and other jurisdictions as we may determine;
- expanding our intellectual property portfolio;
- developing appropriate third party relationships to manufacture, distribute, market and otherwise commercialize AC5; and
- developing additional product candidates in the hemostatic and sealant field.

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

- finalizing the composition of our lead product candidate;
- 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 initial human clinical trials.

Recent Developments

Merger with ABS and Related Activities

On 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 that of a life science medical device company. 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.

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 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”.

In connection with the Merger, our Board of Directors and management team has undergone significant changes in connection with the appointment of ABS’s management team to similar roles with our Company. On April 23, 2013, our former President, Chief Executive Officer and sole director Joey Power resigned from all of his positions with the Company, and Dr. Terrence W. Norchi was appointed as our President and Chief Executive Officer and a member of our Board of Directors and Dr. Avtar Dhillon was appointed as an independent member of our Board of Directors. On June 26, 2013, Alan T. Barber was appointed as our Chief Financial Officer and Dr. Arthur L. Rosenthal was appointed as an independent member of our Board of Directors. On July 8, 2013, William Cotter was appointed as our Chief Operating Officer. All of those individuals held the same or similar positions with ABS prior to the completion of the Merger.

MLSC Loan Agreement and Warrant

On September 30, 2013, we entered into the Life Sciences Accelerator Funding Agreement (the “MLSC Loan Agreement”) with the Massachusetts Life Sciences Center (“MLSC”), pursuant to which MLSC agreed to provide us an unsecured subordinated loan, and we issued to MLSC a related promissory note, in principal amount of $1,000,000 (such loan, the “MLSC Loan”). We received the full amount of the MLSC Loan on October 4, 2013. The MLSC Loan bears interest at a rate of 10% per annum, and will become fully due and payable on the earlier of (i) September 30, 2018, (ii) the occurrence of an event of default under the MLSC Loan Agreement, or (iii) the completion of a sale of substantially all of our assets, a change-of-control transaction or one or more financing transactions in which we receive net proceeds of $5,000,000 or more in a 12-month period. We may, at our election and without penalty, repay the MLSC Loan in whole or in part at any time prior to its maturity date. Pursuant to the terms of the MLSC Loan Agreement, we may use the proceeds of the MLSC Loan solely to fund working capital requirements and/or the purchase of capital assets in the life sciences field, and we are expressly prohibited from using any such proceeds for any severance payment, investment in certain securities or payment for goods or services to a related party of the Company. The MLSC Loan Agreement also provides that, for so long as any of the MLSC Loan remains outstanding, our headquarters and at least a majority of our employees must be located in Massachusetts and we must not take certain actions without obtaining MLSC’s prior consent, including without limitation paying dividends on our capital stock, redeeming any of our outstanding securities, incurring certain types and amounts of additional indebtedness, and completing a sale of substantially all of our assets or a change-of-control transaction.

In connection with and as a condition of the MLSC Loan Agreement, on September 30, 2013, we issued to MLSC a warrant (the “MLSC Warrant”) to purchase 145,985 shares of our common stock at an exercise price of $0.274 per share. The MLSC Warrant has been issued as partial consideration for the funding provided under the MLSC Loan

Agreement and for no separate consideration. The MLSC Warrant is exercisable immediately upon its issuance and expires on the earlier of September 30, 2023 and the completion of a sale of substantially all of our assets or a change-of-control transaction.

Private Placement Financing

On January 30, 2014, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with a group of investors ("Investors") providing for the issuance and sale by the Company to the Investors, in a private placement, of an aggregate of 11,400,000 shares of the Company's common stock (collectively, the "Shares") at a purchase price of $0.25 per share and three series of warrants, the Series A Warrants, the Series B Warrants and the Series C Warrants, to purchase up to an aggregate of 34,200,000 shares of the Company's common stock (collectively, the "Warrants," and the shares issuable upon exercise of the Warrants, collectively, the "Warrant Shares"), for aggregate gross proceeds to the Company of approximately $2.85 million (the "Private Placement Financing"). After deducting for estimated fees and expenses, the aggregate net proceeds to the Company from the sale of the Shares and the Warrants are expected to be approximately $2.77 million. The Company did not engage any underwriter or placement agent in connection with the Private Placement Financing.

Upon the closing of the Private Placement Financing on February 4, 2014, the Company entered into a registration rights agreement with the Investors (the "Registration Rights Agreement"), pursuant to which the Company will be obligated, subject to certain conditions, to file with the Securities and Exchange Commission within 45 days one or more registration statements (any such registration statement, a "Resale Registration Statement") to register the Shares and the Warrant Shares for resale under the Securities Act of 1933, as amended (the "Securities Act"). The Company's failure to satisfy certain filing and effectiveness deadlines with respect to a Resale Registration Statement and certain other requirements set forth in the Registration Rights Agreement may subject the Company to payment of monetary penalties.

Also upon the closing of the Private Placement Financing, each Investor was issued a Series A Warrant, a Series B Warrant and a Series C Warrant, each to purchase up to a number of shares of the Company's common stock equal to 100% of the Shares purchased by such Investor under the Securities Purchase Agreement. The Warrants are all exercisable upon their issuance. The Series A Warrants have an exercise price of $0.30 per share and have a term of exercise equal to five years from their issuance. The Series B Warrants have an exercise price of $0.35 per share and have a term of exercise equal to the shorter of 12 months from their issuance and six months after the effective date of a Resale Registration Statement. The Series C Warrants have an exercise price of $0.40 per share and have a term of exercise equal to the shorter of 18 months after their issuance and nine months after the effective date of a Resale Registration Statement. The number of shares of the Company's common stock into which each of the Warrants is exercisable and the exercise price therefor are subject to adjustment as set forth in the Warrants, including, without limitation, full ratchet anti-dilution protection in the event of certain dilutive issuances of the Company's equity securities following the issuance date of the Warrants. The exercisability of the Warrants may be limited if, upon exercise, the holder or any of its affiliates would beneficially own more than 4.9% of the Company's common stock.

The issuance and sale of the Shares, Warrants and Warrant Shares (collectively, the "Securities") has not been registered under the Securities Act, and the Securities may not be offered or sold in the United States absent registration under or exemption from the Securities Act and any applicable state securities laws. The Securities will be issued and sold in reliance upon an exemption from registration afforded by Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated under the Securities Act, based on the following facts: each of the Investors has represented that it is an accredited investor as defined in Rule 501 promulgated under the Securities Act, that it is acquiring the Securities for investment only and not with a view towards, or for resale in connection with, the public sale or distribution thereof in violation of applicable securities laws and that it has sufficient investment experience to evaluate the risks of the investment; the Company used no advertising or general solicitation in connection with the issuance and sale of the Securities to the Investors; and the Securities will be issued as restricted securities.

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 December 31, 2013 Compared to Three Months Ended December 31, 2012

	December 31, 2013 ($)	December 31, 2012 ($)	Increase (Decrease) ($)
Revenue	$ -	$ -	$ -
Operating Expenses			
General and Administrative	523,443	161,974	361,469
Research and Development	257,233	-	253,233
(Loss) from Operations	(780,676)	(161,974)	685,402
Other income (expense)	(27,765)	(42,981)	(15,216)
Net income (loss)	$ (804,441)	$ (204,955)	$ 599,486

Revenue

We did not generate revenue in either of the three months ended December 31, 2013 or 2012.

General and Administrative Expense

We incurred general and administrative expenses during the three months ended December 31, 2013 in the amount of $523,443, compared to general and administrative expenses incurred during the three months ended December 31, 2012 in the amount of $161,974 (an increase of $361,469). General and administrative expenses during the three months ended December 31, 2013 primarily included legal fees, patent prosecution costs, payroll related expenses, stock based compensation and office overhead. General and administrative expenses during the three months ended December 31, 2012 primarily included legal fees, patent prosecution costs, and office overhead. The increase in general and administrative expense period over period is primarily attributable to increased costs associated with legal fees, accounting fees and investor relations expenses incurred in connection with being a public company, which were 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 expenses during the three months ended December 31, 2013 in the amount of $257,233. Due to limited resources, we did not incur research and development expenses during the three months ended December 31, 2012. Research and development expenses primarily relate to our activities to develop our primary product candidate, and are comprised mostly of payroll related expenses stock based compensation and formulation contractors.

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 December 31, 2013 in the amount of $27,765, compared to total other expenses incurred during the three months ended December 31, 2012 in the amount of $42,981 (a decrease of $15,216). Other expenses during those periods were primarily interest accrued on debt. The

decrease in other expense between periods is attributable to the repayment of related party notes payable and conversion of other notes into equity in connection with the Merger, both of which were partially offset by interest on the loan obtained from MLSC.

Liquidity and Capital Resources

Working Capital

As of December 31, 2013, total current assets were $985,027, compared to total current assets of $1,576,948 as of September 30, 2013 (a decrease of $591,921). The decrease was primarily due to the use of cash to pay operating expenses incurred during the quarter. Our total current assets as of December 31, 2013 were comprised primarily of cash and prepaid expenses.

As of December 31, 2013, total current liabilities were $512,801, compared to total current liabilities of $455,609 as of September 30, 2013 (an increase of $57,192). The increase was primarily due to an increase in accrued expenses related to legal and accounting fees associated with being a public reporting entity, directors' fees and consulting fees. Our total current liabilities as of December 31, 2013 were comprised primarily of accounts payable and accrued expenses.

As a result, on December 31, 2013, we had positive working capital of $472,226, compared with positive working capital as of September 30, 2013 of $1,121,339.

Cash Flow

Our cash on-hand as of December 31, 2013 was $945,398, compared to cash on-hand as of September 30, 2013 of $557,319 (an increase of $389,079). The increase was primarily due to receipt of funds under the MLSC offset by operating expenditures during the quarter.

Cash Used in Operating Activities

Cash used in operating activities during the three months ended December 31, 2013 was $611,921, compared to cash used in operating activities during the three months ended December 31, 2012 of $133,022 (an increase of $478,899). 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 being a public reporting entity and research and development expense in connection with activities to develop our primary product candidate.

Cash Used in Investing Activities

There was no cash used in investing activities during the three months ended December 31, 2013 or 2012, respectively.

Cash Provided by Financing Activities

Cash provided by financing activities during the three months ended December 31, 2013 was $1,000,000 compared to cash provided by financing activities during the three months ended December 31, 2012 of $125,000 (an increase of $875,000). The increase in cash provided by financing activities was a result of increased financing from the MLSC loan of $1,000,000 during the three months ended December 31, 2013 as compared to convertible notes of $125,000 from issuance of convertible notes to existing investors during the three months ended December 31, 2012.

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, from which we received an aggregate of $1,985,000 in exchange for such issuances from inception through the closing of the Merger on June 26, 2013. All of such convertible notes and

related warrants were cancelled in exchange for shares of our common stock in connection with the closing of the Merger. Subsequent to the Merger, we have funded our operations through the issuance and sale of shares of our common stock and warrants to acquire shares of our common stock for a total of $4,850,000 including the Private Placement Financing entered into on January 30, 2014 and $1,000,000 of indebtedness under the MLSC Loan Agreement. We have no contractual commitments for any further funding from those or any other parties.

Cash Requirements

As described above, we anticipate that our operating and other expenses will increase as we continue to implement our business plan and pursue our operational goals. We estimate that our aggregate operating expenses and working capital requirements for our fiscal year ending September 30, 2014 will be $3,600,000 (inclusive of the three months ended December 31, 2013). After giving effect to the funds received in our recent equity financings, including the Private Placement Financing entered into on January 30, 2014, and debt financings, including the MLSC Loan entered into on September 30, 2013, we estimate we have sufficient funds to operate the business through October 2014. 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 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. Further, our estimates regarding our use of cash could change if we encounter unanticipated difficulties, in which case our current funds may not be sufficient to operate our business for the period we expect.

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

The MLSC Loan Agreement and Private Placement Financing significantly restrict our ability to raise capital in the future. In particular, the MLSC Loan Agreement restricts our ability to enter into debt financing transactions under certain circumstances which may prevent us from executing our business plan. The provision of full ratchet anti-dilution protection as set for in the Warrants in connection with the Private Placement Financing also adversely impacts our ability to issue our stock. Both restrictions imposed by the MLSC Loan Agreement and the Private Placement Financing are discussed in greater deal under the caption “Risk Factors” in this report.

Going Concern

From inception through December 31, 2013, we have not earned operating revenues from sales of products or services, and have recurring losses from operations. As of December 31, 2013, we had incurred a net loss of $5,440,312 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. As of December 31, 2013, there is substantial doubt about the Company’s ability to continue as a going concern. The financial statements included in this report on Form 10-Q do not include any adjustments that might be necessary should operations discontinue.

Critical Accounting Policies and Significant Judgments and Estimates

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

judgments are as follows:

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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") Accounting Standards Codification ("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 December 31, 2013 and September 30, 2013.

Accounting for Stock-Based Compensation

The Company accounts for employee stock-based compensation in accordance with the guidance of FASB ASC Topic718, Compensation-Stock Compensation, which requires all share- based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. We account for non-employee stock-based compensation in accordance with the guidance of FASB ASC Topic 505, Equity ("FASB ASC Topic 505"), which requires that companies recognize compensation expense based on the estimated fair value of options granted to non-employees over their vesting period, which is generally the period during which services are rendered by such non-employees. FASB ASC Topic 505 requires us to re-measure the fair value of stock options issued to non- employee at each reporting period during the vesting period or until services are complete.

In accordance with FASB ASC Topic 718, Compensation-Stock Compensation, we have elected to use the Black-Scholes option pricing model to determine the fair value of options granted and recognizes the compensation cost of share-based awards on a straight-line basis over the vesting period of the award.

The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by the fair value of the common stock and a number of other assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. We do not have a history of market prices of the common stock, and as such volatility is estimated in accordance with ASC 718-10-S99 Compensation-Stock Compensation ("ASC 718-10-S99"), using historical volatilities of similar public entities. The life term for awards and, therefore, uses simplified method for all "plain vanilla" options, as defined in ASC 718-10-S99 and the contractual term for all other employee and non-employee awards. The risk-free interest rate assumption is based on observed interest rates appropriate for the terms of our awards. The dividend yield assumption is based on history and the expectation of paying no dividends. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Stock-based compensation expense, when recognized in the financial statements, is based on awards that are ultimately expected to vest.

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 adoption of this ASU has not had a material impact on the Company’s 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 December 31, 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 December 31, 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 December 31, 2013 management has identified the following material weaknesses:

(i) We have had insufficient quantity of dedicated resources and experienced personnel involved in reviewing and 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 achieved the optimal level of segregation of duties relative to key financial reporting functions.

(iii) 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.

(iv) 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 any, as a result of the material weakness on our internal control over financial reporting. Lack of an entity-level risk assessment constituted an internal control design deficiency.

Remediation

On June 26, 2013, the Company completed the Merger with ABS. With the closing of the Merger and the addition of certain members to our management team, we believe that we now have some personnel with sufficient experience to review and design adequate internal control over financial reporting and the experience and formal training to properly analyze and record complex transactions in accordance with U.S. GAAP; however, we continue to lack a sufficient

team of resources with such experience and knowledge.

We expect to implement additional changes to our disclosure controls and procedures and internal control over financial reporting in the near term as resources permit, including identifying specific changes to be made within our governance, accounting and financial reporting processes to address our material weaknesses and adding personnel to our finance and accounting staff to achieve adequate segregation of duties to key financial reporting functions. In lieu of an audit committee comprised of independent directors, we currently rely on our full 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 to serve on our Board of Directors, as well as other persons to serve as independent directors.

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

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 quarter ended December 31, 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 business. To date, we have financed our operations entirely through equity

and debt investments by founders, other investors and third parties, and we expect to continue to rely on these sources of funding, to the extent available in the foreseeable future. Losses from operations have resulted principally from costs incurred in research and development programs and from general and administrative expenses, including significant costs associated with establishing and maintaining intellectual property rights, significant legal and accounting costs pertaining to the closing of the Merger and related regulatory filings, and personnel expenses. We have devoted substantially all of our time, money and efforts to date to the advancement of our technology and raising capital to support our business, 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 , including further development of the product's composition and conducting preclinical biocompatibility studies;
- raise capital needed to fund our operations;
- 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;
- establish relationships with contract manufacturing partners, and invest in product and process development through such 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 number of challenging activities, including successfully completing preclinical testing and clinical trials of product candidates, obtaining regulatory approval for our product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of the earliest 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 will be commercially available for several years, if at all.

We believe that our current cash and cash equivalents on hand, including the proceeds of the Private Placement Financing entered into on January 30, 2014, as well as of the MLSC Loan Agreement entered into September 30, 2013, will be sufficient to meet our anticipated cash requirements through October 2014; 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 for the next twelve months. In addition to the funds raised from our equity financings, including the proceeds of the Private Placement Financing entered into on January 30, 2014, and debt financing, including the proceeds of the MLSC Loan Agreement, 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;
- the costs associated with maintaining and expanding our product pipeline;
- the costs associated with expanding our geographic focus;
- operating revenues, if any, received from sales of our product candidates, if any are approved by the FDA or other applicable regulatory agencies;
- the cost associated with being a public company, including obligations to regulatory agencies and investor relations;
- the costs of additional general and administrative personnel, including accounting and finance, legal and human resources employees; and
- operating revenues, if any, received from sales of our product candidates, if any are approved by the FDA or other applicable regulatory agencies.

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 of those sources. 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. The number of shares of the Company's common stock into which each of the Warrants issued in connection with the Private Placement Financing is exercisable and the exercise price therefor are subject to adjustment as set forth in the Warrants, including, without limitation, full ratchet anti-dilution protection in the event of certain dilutive issuances of the Company's equity securities following the issuance date of the Warrants. The existence of full ratchet anti-dilution protection could result in additional funding not being available when needed on acceptable terms, or at all. The MLSC Loan Agreement also provides that, for so long as any of the MLSC Loan remains outstanding, the Company's headquarters and at least a majority of its employees must be located in Massachusetts and the Company must not take certain actions without obtaining MLSC's prior consent, including incurring certain types and amounts of additional indebtedness. The existence of these restrictive covenants under the MLSC Loan Agreement could result in additional funding not being 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 any 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 may 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.

There could be additional risks due to certain covenants in the Securities Purchase Agreement related to our Private Placement Financing.

The Securities Purchase Agreement related to the Private Placement Financing entered into on January 30, 2014 places certain restrictions on the Company's ability to issue certain equity or debt securities for a limited period of time. Additionally, the Company is restricted from issuing securities in a Variable Rate Transaction ("VRT") for a certain period of time. As defined in the Securities Purchase Agreement, a VRT is a transaction in which the Company (i) issues convertible securities at (A) a conversion, exercise or exchange rate or other price that is based upon and/or varies with the trading prices of, or quotations for, the shares of Company's common stock at any time after the initial issuance of such Convertible Securities, or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such convertible securities or upon the occurrence of specified or contingent events directly or indirectly related to the business of the Company or the market for the common stock, other than pursuant to a customary "weighted average" anti-dilution provision or (ii) enters into any agreement whereby the Company or any subsidiary may sell securities at a future determined price. Such restriction could limit the company's ability to obtain adequate financing on a timely basis or on acceptable terms in the future.

Our current and any future debt facilities will require us to use our limited capital to repay amounts owed and may impose limitations on our operations, which could negatively affect our business plans.

On September 30, 2013, we entered into the Life Sciences Accelerator Funding Agreement (the "MLSC Loan Agreement") with the Massachusetts Life Sciences Center ("MLSC"), pursuant to which MLSC has provided us an unsecured subordinated loan in principal amount of $1,000,000 (such loan, the "MLSC Loan"). The MLSC Loan bears interest at a rate of 10% per annum, and will become fully due and payable on the earlier of (i) September 30, 2018, (ii) the occurrence of an event of default under the MLSC Loan Agreement, or (iii) the completion of a sale of substantially all of our assets, a change-of-control transaction or one or more financing transactions in which we receive net proceeds of $5,000,000 or more in a 12-month period. We will need substantial amounts of cash in order to repay the principal and interest owed under the MLSC Loan as it becomes due, which we may not have or be able to obtain. Any failure to make payments as required under the MLSC Loan Agreement would constitute an event of default, and could result in, among other things, MLSC's acceleration of all amounts due thereunder.

Further, the MLSC Loan Agreement restricts our use of the proceeds of the MLSC Loan to funding working capital requirements and/or the purchase of capital assets in the life sciences field, and we are expressly prohibited from using any such proceeds for any severance payment, investment in certain securities or payment for goods or services to a related party of the Company. Additionally, the MLSC Loan Agreement provides that, for so long as any of the MLSC Loan remains outstanding, our headquarters and at least a majority of our employees must be located in Massachusetts and we must not take certain actions without obtaining MLSC's prior consent, including without limitation paying dividends on our capital stock, redeeming any of our outstanding securities, incurring certain types and amounts of additional indebtedness, and completing a sale of substantially all of our assets or a change-of-control transaction. Further, our failure to remain a "certified life sciences company" under the Massachusetts General Law would constitute an event of default under the MLSC Loan Agreement. Our ability to pursue our business plans during the term of the MLSC Loan may be severely limited as a result of those restrictions, which could cause our operations and financial condition to suffer.

In addition, the MLSC Loan agreement restricts our ability to do the following without the prior written consent of MLSC:

- create, incur, assume or permit to exist any indebtedness that is (i) senior to, or (ii) in the case of affiliated third parties (including without limitation owners of ten percent (10%) or more of the issued and outstanding equity securities of Recipient), pari passu with, the rights or privileges granted to MLSC pursuant to the Transaction Documents and the Uniform Commercial Code in effect from time to time in the Commonwealth of Massachusetts, other than indebtedness for the benefit of a Senior Lender; or

- create, incur, assume, guarantee, be liable for or remain liable with respect to, or grant a security interest in connection with, indebtedness to Recipient's officers, directors, shareholders or employees unless such indebtedness is fully subordinated to the Loan pursuant to a subordination agreement or intercreditor agreement in a form reasonably satisfactory to MLSC.

These restrictive covenants could limit our ability to finance our operations and execute our business plan if, at any point in the future, the only source of capital available to the Company is debt covered by the aforementioned restrictive covenants. Our inability to create indebtedness senior to or, in certain cases, pari passu with, MLSC, as well as our inability to grant MLSC-superior security interests to our officers, directors, shareholders or employees, may make the execution of our business plan impossible in the future if those sources of debt are our only options.

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

We are a development stage company subject to the risks, uncertainties and difficulties frequently encountered by early-stage companies in evolving markets. Our operations to date have been primarily limited to organizing and staffing, developing and securing our technology and undertaking or funding preclinical studies of our 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 our behalf, or conduct sales and marketing activities necessary for successful product commercialization.

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

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

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

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

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

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 Securities Exchange Act of 1934, as amended (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 December 31, 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 proposed actions aimed at remediating some of 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, there may be an increased likelihood that our consolidated financial statements contain material misstatements. If that were to occur, 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 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 our lead product candidate, the CMC process may be difficult to complete successfully within the parameters required by the FDA or its foreign counterparts. Peptide formulation optimization is particularly

challenging, and any delays could negatively impact our anticipated clinical trial and subsequent commercialization timeline. Furthermore, we have, and the third parties with which we may establish relationships may also have, limited experience with attempting to commercialize a self-assembling peptide as a medical device, which increases the risks associated with completing the CMC process successfully, on time, or within the projected budget. Failure to complete the CMC process successfully would impact our ability to start a clinical trial and could severely limit the long-term viability of our business.

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 our technology.

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

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

The development plan for our lead product 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 than we presently anticipate, financing needs would increase, the timeline for product approval would lengthen, the program complexity and resource requirements world increase, and the probability of successfully commercializing a product would decrease. Any or all of those circumstances would materially adversely affect our business.

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 have relied and will need to continue 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 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 any 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 place 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 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 resulting data in support of our marketing applications with the FDA or other applicable agencies;
- manufacturing facilities of our third party manufacturers are ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of 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 our 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 process of FDA Premarket Approval (“PMA”) for the product, which is based on novel technologies and likely will be classified as a Class III medical device. This approval pathway can be lengthy and expensive, and is estimated to take from one to three years or longer from the time the PMA application is submitted to the FDA until approval is obtained, if approval can be obtained at all.

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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, including completion of one or more successful clinical trials.

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

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

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

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

- restrictions on the marketing or distribution of a product, including refusals to permit the import or export of the product;
- warning letters from governmental agencies;
- the requirement to include warning labels on the products;
- withdrawal or recall of the products from the market;
- refusal by the FDA or other regulatory agencies to approve pending applications or supplements to approved applications that we may submit;
- suspension of any ongoing clinical trials;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals or certifications; or
- civil or criminal penalties.

If any of our product candidates achieves required regulatory marketing approvals or certifications in the future, the subsequent occurrence of any such post-approval consequences would materially adversely affect our business and operations.

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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 health care settings, or only in conjunction with special patient testing and monitoring. The legislation also includes requirements for disclosing clinical study results to the public through a clinical study registry, and renewed requirements for conducting clinical studies to generate information on the use of products in pediatric patients. Under the FDAAA, companies that violate these laws are subject to substantial civil monetary penalties. The requirements and changes imposed by the FDAAA, or any other new legislation, regulations or policies that grant the FDA or other regulatory agencies additional authority that further complicates the process for obtaining marketing approval and/or further restricts or regulates post-marketing approval activities, could make it more difficult and more costly for us to obtain and maintain approval of any of our product candidates.

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

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

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

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

Reliance on third party manufacturers entails risks to our business, including without limitation:

- the failure of the third party to maintain regulatory compliance, quality assurance, and general expertise in advanced manufacturing techniques and processes that may be necessary for the manufacture of our product candidates;
- limitations on supply availability resulting from capacity and scheduling constraints of the third parties;
-

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

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

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

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

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

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

We intend to collaborate with physicians, patient advocacy groups, foundations, government agencies, and/or other third parties to assist with the development of our product candidates. If required regulatory approvals are obtained for any of our product candidates, then we may consider entering into selective collaboration arrangements with medical technology, pharmaceutical or biotechnology companies and/or seek to establish strategic relationships with marketing partners for the development, sale, marketing and/or distribution of our products within or outside of the U.S. If we elect to 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 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 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 candidate we may seek to develop non-competitive or otherwise obsolete. Any such circumstances could cause our operations to suffer.

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

Acceptance in the marketplace of our lead product 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 and develop programs to effectively train them to use those products. If we fail to do so, we will not be able to generate revenue from product sales and our business, financial condition and results of operations will be adversely affected.

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

If our product candidates are approved for commercialization, any sales will depend in part on the availability of 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 obtain marketing approval, pricing and reimbursement may be uncertain. Both the federal and state governments in the U.S. and foreign governments continue to propose and pass new legislation affecting coverage and reimbursement policies, which are designed to contain or reduce the cost of healthcare. Further, federal, state and foreign healthcare proposals and reforms could limit the prices that can be charged for the product candidates that we may develop, which may limit our commercial opportunity. Adoption of our product candidates by the medical community may be limited if doctors and hospitals do not receive adequate partial or full reimbursement for use of our products, 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 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 ability to obtain patents covering technology in the field of medical devices generally is highly uncertain and involves complex legal, technical, scientific and factual questions. We may not be able to obtain and maintain patent protection relating to our technology or products. 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 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 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 MIT to terminate the agreement. Further, we are responsible for all patent prosecution and maintenance fees under that agreement, and a failure to pay such fees on a timely basis could also entitle MIT to terminate the agreement. Any failure by us to satisfy our obligations under our license agreement with MIT or any other dispute or other issue relating to that agreement could cause us to lose some or all of our rights to use certain intellectual property that is material to our business and our lead product candidate, which would materially harm our product development efforts and could cause our business to fail.

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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 or them could be non-exclusive, which could result in our competitors gaining access to the same intellectual property rights and materially negatively affecting the commercialization potential of our planned products. Ultimately, we could be prevented from commercializing one or more product candidates, or be forced to cease some aspects of our business operations, if, as a result of actual or threatened infringement claims, we are unable to enter into licenses on acceptable terms or at all or otherwise settle such claims. Further, if any such claims were successful against us, we could be forced to pay substantial damages. Any of those results could significantly harm our business, prospects and operations.

Risks Related to the Merger and our Common Stock

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

There currently is a limited market for our common stock. Although our common stock is quoted on the 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.

Issued warrants with full ratchet anti-dilution protection could result in additional dilution to our existing shareholders.

The number of shares of the Company's common stock into which each of the Warrants issued in connection with the Private Placement Financing entered into on January 30, 2014, is exercisable and the exercise price therefore are subject to adjustment as set forth in the Warrants, including, without limitation, full ratchet anti-dilution protection in the event of certain dilutive issuances of the Company's equity securities following the issuance date of the Warrants. The existence of such anti-dilution protection could lead to further dilution of our existing shareholders.

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

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

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

Certain of our directors and executive officers own a significant percentage of our outstanding capital stock. 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 approximately 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, and have significant influence over our affairs. This concentration of ownership could have the effect of delaying or preventing a change in control of our Company, even if such a change in control would be beneficial to our stockholders.

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

Our articles of incorporation 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 Nevada law and, subject to certain conditions, advance the expenses incurred by any director or officer in defending any action, suit or proceeding prior to its final disposition. Those indemnification obligations could result in our Company incurring substantial expenditures to cover the cost of settlement or damage awards against our directors or officers, which we may be unable to recoup. These provisions and resultant costs may also discourage us from bringing a lawsuit against any of our current or former directors or officers for breaches of their fiduciary duties, and may similarly discourage the filing of derivative litigation by our stockholders against our directors and officers even if such actions, if successful, might otherwise benefit us or our stockholders.

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

We are a public reporting company in the U.S., and, accordingly, are subject to the information and reporting requirements of the Exchange Act and other federal securities laws, including the obligations imposed by the Sarbanes-Oxley Act. The costs associated with preparing and filing annual, quarterly and current reports, proxy statements and other information with the SEC in the ordinary course, as well as preparing and filing audited financial statements, have caused, and could continue to cause, our operational expenses to remain at higher levels or continue to increase.

Our present management team has only limited experience managing public companies. It will be time consuming, difficult and costly for our management team to acquire additional expertise and experience in operating a public company, and to develop and implement the internal controls and reporting procedures required by Sarbanes-Oxley and other applicable securities laws. We will need to hire additional financial reporting, internal controls, accounting and other finance staff in order to 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 are subject to resale restrictions imposed by Rule 144, including those set forth in Rule 144(i) which apply to a former "shell company." In addition, any shares of our common stock that are held by affiliates, including any that are registered, will be subject to the resale restrictions of Rule 144.

Pursuant to Rule 144 ("Rule 144") under 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. We were a shell company prior to the closing of the Merger, and as such, sales of our securities pursuant to Rule 144 are not permitted until at least 12 months have elapsed since 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 outstanding restricted securities or any restricted securities we may sell in the future or issue to consultants or employees in consideration for services rendered or for any other purpose will have limited liquidity unless and until such securities are registered under the Securities Act and/or until at least June 26, 2014. Rule 144 also imposes other requirements on us and our stockholders that must be met in order to effect a sale thereunder. As a result, it will be more difficult for us to raise funding to support our operations through the sale of debt or equity securities unless we agree to register such securities under the Securities Act, which could cause us to expend significant additional time and cash resources and which we presently have no intention to pursue. Further, it may be more difficult for us to compensate our employees and consultants with our securities instead of cash. 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), and could cause the value of our securities to decline. In addition, any shares held by affiliates, including shares received in any registered offering, will be subject to certain additional requirements in order to effect a sale of such shares under Rule 144.

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

We have never declared or paid any dividends on our shares and do not anticipate paying any such dividends in the foreseeable future. Any future payment of cash dividends would depend on our financial condition, contractual restrictions, solvency tests imposed by applicable corporate laws, results of operations, anticipated cash requirements and other factors and will be at the discretion of our Board of Directors. 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 marketplace, particularly following a company's initial public offering. Due to the volatility of our stock price, we could be the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources.

Item 6. Exhibits

Exhibit	Description
4.1	Form of Series A Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed by the Company with the SEC on January 31, 2014)
4.2	Form of Series B Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed by the Company with the SEC on January 31, 2014)
4.3	Form of Series C Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K filed by the Company with the SEC on January 31, 2014)
10.1	

	Life Sciences Accelerator Funding Agreement dated September 30, 2013 between Arch Therapeutics, Inc. and the Massachusetts Life Sciences Center (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Company with the SEC on October 4, 2013)
10.2	Form of Warrant to Purchase Shares of Common Stock dated September 30, 2013 issued by Arch Therapeutics, Inc. to the Massachusetts Life Sciences Center (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed by the Company with the SEC on October 4, 2013)
10.3	Sublease dated August 30, 2013 and effective October 1, 2013, between Arch Therapeutics, Inc. and Stream Global Services, Inc. (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed by the Company with the SEC on October 4, 2013)
10.4	Securities Purchase Agreement dated January 30, 2014, by and among Arch Therapeutics, Inc. and the investors listed on the Schedule of Buyers attached thereto (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Company with the SEC on January 31, 2014)
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

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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: February 14, 2014	By:	/s/ TERRENCE W. NORCHI Terrence W. Norchi *President and Chief Executive Officer* *(Principal Executive Officer)*
Date: February 14, 2014	By:	/s/ ALAN T. BARBER Alan T. Barber *Chief Financial Officer* *(Principal Financial and Accounting Officer)*