Arch Therapeutics, Inc.
Form 424B3
August 06, 2014

Filed Pursuant to Rule 424(b)(3)

Registration No. 333-194745

PROSPECTUS SUPPLEMENT NO. 2 DATED AUGUST 6, 2014

TO

PROSPECTUS DATED JULY 2, 2014

(AS SUPPLEMENTED)

ARCH THERAPEUTICS, INC.

PROSPECTUS

Up to 45,600,000 Shares of Common Stock

This Prospectus Supplement No. 2 supplements the prospectus of Arch Therapeutics, Inc. ("the "Company", "we", "us", or "our") dated July 2, 2014 (as supplemented to date, the "Prospectus") with the following attached document which we filed with the Securities and Exchange Commission on August 6, 2014:

A. Our Quarterly Report on Form 10-Q for the period ended June 30, 2014

This Prospectus Supplement No. 2 should be read in conjunction with the Prospectus, which is required to be delivered with this Prospectus Supplement. This prospectus supplement updates, amends and supplements the information included in the Prospectus. If there is any inconsistency between the information in the Prospectus and this prospectus supplement, you should rely on the information in this prospectus supplement.

This prospectus supplement is not complete without, and may not be delivered or utilized except in connection with, the Prospectus, including any amendments or supplements to it.

Investing in our common stock involves a high degree of risk. Before making any investment in our common stock, you should carefully consider the risk factors for our common stock, which are described in the Prospectus, as amended or supplemented.

You should rely only on the information contained in the Prospectus, as supplemented or amended by this Prospectus Supplement No. 2 and any other prospectus supplement or amendment thereto. We have not authorized anyone to provide you with different information.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this Prospectus Supplement No. 2 is August 6, 2014

INDEX TO FILINGS

	Annex
The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2014 filed with the Securities and Exchange Commission on August 6, 2014	A

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF

THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2014

Commission File Number: **000-54986**

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

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

(617) 431-2313
Registrant's telephone number, including area code

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No £

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer £	Accelerated filer ¨
Non-accelerated filer £ (Do not check if a smaller reporting company)	Smaller reporting company x

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

As of August 5, 2014 72,076,487 shares of the registrant’s common stock were outstanding.

ARCH THERAPEUTICS, INC.

(A Development Stage Company)

Quarterly Report on Form 10-Q

For the Three Month and Nine Month Periods Ended June 30, 2014

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Arch Therapeutics, Inc.
(A Development Stage Company)
Consolidated Balance Sheets
June 30, 2014 (unaudited) and September 30, 2013

	June 30, 2014 (unaudited)	September 30, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,802,524	$ 557,319
Promissory note receivable	-	1,000,000
Prepaid expenses and other current assets	32,206	19,629
Total current assets	1,834,730	1,576,948
Long-term assets:		
Property and equipment, net	-	322
Other Assets	-	10,062
Total long-term assets	-	10,384
Total assets	$ 1,834,730	$ 1,587,332
LIABILITIES AND STOCKHOLDERS' (DEFICIT)/EQUITY		
Current liabilities:		
Accounts payable	$ 166,011	$ 314,769
Accrued expenses and other liabilities	216,110	140,840
Current derivative liabilities	3,078,000	-
Total current liabilities	3,460,121	455,609
Long-term liabilities:		
Note payable	953,002	944,707
Accrued interest, net of current portion	75,000	-
Derivative liabilities, net of current portion	5,244,000	-
Total long-term liabilities	6,272,002	944,707
Total liabilities	9,732,123	1,400,316
Commitments and contingencies		

Stockholders' (deficit) equity:		
Common stock, $0.001 par value, 300,000,000 shares authorized, 72,076,487 and 60,145,237 shares issued and outstanding as of June 30, 2014 and September 30, 2013, respectively	72,001	60,145
Additional paid in capital	5,440,314	4,758,742
Deficit accumulated during the development stage	(13,409,708)	(4,631,871)
Total stockholders' (deficit) equity	(7,897,393)	187,016
Total liabilities and stockholders' (deficit) equity	$ 1,834,730	$ 1,587,332

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

Arch Therapeutics, Inc.
(A Development Stage Company)
Consolidated Statements of Operations
For the three and nine months ended June 30, 2014 and 2013
Period from Inception (March 6, 2006) through June 30, 2014

	Three Months ended June 30, 2014	Three Months ended June 30, 2013	Nine Months ended June 30, 2014	Nine Months ended June 30, 2013	Period from Inception (March 6, 2006) through June 30, 2014
Other Revenues	$ -	$ -	$ -	$ -	$ 431,461
Operating expenses:					
General and administrative expenses	825,951	451,046	2,271,443	721,565	5,819,918
Research and development expenses	320,345	43,750	951,101	62,356	1,931,341
Total operating expenses	1,146,296	494,796	3,222,544	783,921	7,751,259
Operating loss	(1,146,296)	(494,796)	(3,222,544)	(783,921)	(7,319,798)
Other (expense) income:					
Interest expense	(27,763)	(19,596)	(83,293)	(108,384)	(671,887)
Loss on issuance of warrants	-	-	(7,541,693)	-	(7,541,693)
Adjustment to fair value of derivative	1,584,818	-	2,069,693	-	2,069,693
Other income	-	32	-	51	53,977
Total other expense	1,557,055	(19,564)	(5,555,293)	(108,333)	(6,089,910)
Net Income (Loss)	$ 410,759	$ (514,360)	$ (8,777,837)	$ (892,254)	$ (13,409,708)
Basic earnings per share					
Net Income (loss)	$ 0.01	$ (0.06)	$ (0.13)	$ (0.13)	
Weighted Common Shares – Basic	71,949,564	8,549,322	65,933,378	6,613,249	
Diluted Eanings per share					
Net Income (loss)	$ 0.01	$ (0.06)	$ (0.13)	$ (0.13)	
Weighted Common Shares – Diluted	72,084,748	8,549,322	65,933,378	6,613,249	

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

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Arch Therapeutics, Inc.
(A Development Stage Company)
Consolidated Statement of Cash Flows (Unaudited)
Nine months ended June 30, 2014 and 2013
Period from Inception (March 6, 2006) through June 30, 2014

	Nine Months ended June 30, 2014	Nine Months ended June 30, 2013	Period from Inception (March 6, 2006) through June 30, 2014
Cash flows from operating activities:			
Net loss	$ (8,777,837)	$ (892,254)	$ (13,409,708)
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation expense	322	847	18,693
Other noncash adjustments	92,500	2,859	98,252
Stock-based compensation	748,600	-	1,036,527
Noncash interest expense on notes payable	83,295	-	83,295
Noncash interest expense on convertible notes payable	-	82,147	441,253
Noncash interest expense on notes payable to related party	-	25,599	142,057
Repayment of accrued interest to related party	-	(98,288)	(98,288)
Non cash expense for issuance of warrants	5,472,000	-	5,472,000
Issuance of common stock for services	77,625	-	77,878
Changes in operating assets and liabilities:			-
(Increase) decrease in:			-
Prepaid expenses and other current assets	(2,515)	2,187	(22,144)
Other Assets	-	-	(10,062)
Increase (decrease) in:			-
Accounts payable	(148,758)	49,122	166,011
Accrued expenses and other liabilities	75,270	62,211	216,110
Net cash used in operating activities	(2,379,498)	(765,570)	(5,788,126)
Cash flows from investing activities:			
Purchases of property and equipment	-	-	(19,053)
Net cash used in investing activities	-	-	(19,053)
Cash flows from financing activities:			
Proceeds from issuance of common stock and warrants	2,624,703	1,250,000	4,624,703
Repayment of notes payable to related party	-	(275,200)	(275,200)
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 convertible notes payable	-	250,000	1,880,000
Proceeds from issuance of notes payable	1,000,000	-	1,000,000
Net cash provided by financing activities	3,624,703	1,224,800	7,609,703

Net increase in cash and cash equivalents	1,245,205	459,230	1,802,524
Cash and cash equivalents, beginning of period	557,319	17,139	-
Cash and cash equivalents, end of period	$ 1,802,524	$ 476,369	$ 1,802,524
Cash paid during the period for:			
Interest	$ -	$ 98,288	$ 98,288
Income taxes	$ -	$ -	$ -
Debt with warrants issued for promissory note receivable	$ -	$ -	$ 1,000,000
Exchange of convertible notes and related accrued interest for common stock	$ -	$ -	$ 2,470,022

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

ARCH THERAPEUTICS, 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., (together with its 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 abandoned its prior business plan and has changed its operations to the business of a life science medical device company. Subsequent to the Merger, we relocated our principal office to Wellesley, Massachusetts.

For financial reporting purposes, the Merger represents a "reverse merger" rather than a business combination and ABS is deemed to be the accounting acquirer in the transaction 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 have been replaced with the historical financial statements of ABS before the Merger in this report and will be so replaced in all future filings with the SEC that require financial statements to be included.

ABS was incorporated under the laws of 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, has generated no operating revenues to date, and is devoting substantially all of its efforts toward product research and development. The Company has incurred losses of $13,409,708 since

inception. To date, the Company has principally raised capital through borrowings and the issuance of convertible debt and units consisting of common stock and warrants.

The Company expects to incur substantial expenses for the foreseeable future relating to the research, development 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 when needed on terms acceptable to the Company, if at all. Therefore, there exists substantial doubt about the Company's ability to continue as a going concern. The unaudited interim consolidated 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.

Although we believe 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/A for the fiscal year ended September 30, 2013, filed with the SEC on May 1, 2014.

For a complete summary of our significant accounting policies, please refer to Note 2 included in Item 8 of our Form 10-K/A for the fiscal year ended September 30, 2013. There have been no material changes to our significant accounting policies during the nine months ended June 30, 2014.

Basis of Accounting

The Company is in the development stage and is devoting substantially all of its efforts to developing technologies, raising capital, establishing customer and vendor relationships, and recruiting new employees. Accordingly, the accompanying consolidated 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) 2014-10, "Development Stage Entities (Topic 915) – "Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation" was issued by the FASB in June 2014. Due to the fact that we are a development stage company, we currently include inception-to-date information, and certain disclosures required under U.S. GAAP in our financial statements. The amendments in this ASU (2014-10) remove all incremental financial reporting requirements from U.S. GAAP for development stage companies. The amendments are effective for fiscal years, and interim periods within those years, beginning after December 15, 2014 and December 15, 2015. Early adoption is permitted. We have not yet adopted the changes. The amendments when adopted will be applied retrospectively except for the clarification to Topic 275, which shall be applied prospectively to all unrecognized tax benefits that exist at the effective date.

Accounting Standards Update (ASU) 2014-09, "Revenue from Contracts with Customers (Topic 606) was issued by the FASB in May 2014. The primary purpose of the ASU is to develop a common revenue standard for revenue recognition between the FASB and the International Accounting Standards Board (IASB). The ASU removes inconsistencies and weaknesses in revenue requirements, provides a more robust framework for addressing revenue issues, improves comparability of revenue recognition practices across entities, industries, jurisdictions and capital

markets, among other items. We are a development stage company and do not currently generate revenue.

In April 2014, ASU (ASU) No. 2014-08, “Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity”, was issued. The Amendment in this update changes the criteria for reporting discontinued operations and requires additional disclosures about discontinued operations. ASU 2014-08 requires that an entity report as a discontinued operation only a disposal that represents a strategic shift in operations that has a major effect on its operations and financial results. ASU 2014-08 is effective for public business entities for annual periods, and interim periods within those annual periods, beginning on or after December 15, 2014. Early adoption is permitted, but only for a disposal (or classification as held for sale) that has not been reported in financial statements previously issued or made available for issuance. The ASU must be applied prospectively. The Company is currently assessing the impact of this guidance, but does not believe that it will have a material impact on its consolidated results of operations or financial position.

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 by the FASB in July 2013. The amendments in this ASU 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 consolidated financial statements.

Correction of an Immaterial Error

In connection with comments received from the SEC on April 18, 2014, with respect to a registration statement filed on Form S-1 on March 21, 2014, the Company identified errors in the presentation of issuances of stock and warrants in the consolidated statements of changes in stockholders' equity (deficit) and presentation matters in the consolidated statements of cash flows, as well as related footnotes.

The Company assessed the materiality of these errors for each period presented in accordance with the guidance in Accounting Standards Codification (ASC) Topic 250, *"Accounting Changes and Error Corrections,"* and ASC Topic 250-10-S99-1, *"Assessing Materiality"*, and determined that the errors were immaterial to the consolidated financial statements taken as a whole. The Company has revised its consolidated statements of changes in stockholders' equity (deficit) and cash flows, as well as related footnotes as of and for the year ended September 30, 2013, and for the period from inception (March 6, 2006) through June 30, 2014, and will reflect these corrections in all future filings that contain such consolidated financial statements.

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, during the fiscal year ended September 30, 2013, 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 with the current fiscal year, 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 a total of 10,231,197 shares.

Share-based awards

During the nine months ended June 30, 2014, the Company granted options to purchase 2,754,212 shares of the Company's common stock to employees and options to purchase 2,115,000 shares of common stock to consultants under the 2013 Plan. The options have terms ranging from 3 to 10 years, are subject to vesting terms over periods ranging from 1 year to 3 years and have exercise prices ranging from $0.19 to $0.37.

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 three and nine months ended June 30, 2014, were based on the fair market value at period end or 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 three and nine months ended June 30, 2014; expected volatility, 86% - 115%, risk-free interest rate, 0.91% - 2.77%, expected forfeiture rate, 0.00%, expected dividend yield, 0.00%, expected term, 3 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 company 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 company 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. 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, directors and non-employees. 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 is as follows:

Common Stock Options

Stock compensation activity under the 2013 Plan is as follows:

	Option Shares	Weighted Average	Weighted Average	Aggregate Intrinsic

	Outstanding	Exercise Price	Remaining Contractual Term (years)	Value
Outstanding at October 1, 2013	3,000,000			
Awarded	4,869,212	$ 0.36	-	
Exercised	(231,250)	0.40	-	
Forfeited	-	-	-	
Outstanding at June 30, 2014	7,637,962	$ 0.36	5.49	$ 29,600
Vested	2,546,470	$ 0.36	5.08	$ 6,100
Vested and expected to vest at June 30, 2014	7,637,962	$ 0.36	5.49	$ 29,600

As of June 30, 2014, 2,361,985 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 three and nine months ended June 30, 2014 resulting from stock options awarded to the Company's employees, directors and consultants was $245,245 and $748,600, respectively. Of this amount during the three and nine months ended June 30, 2014, $132,941 and $287,288, respectively was recorded in General and Administrative expenses and $112,304 and $461,312 respectively was recorded to Research and Development expenses in the Company's consolidated statement of operations.

As of June 30, 2014, there is approximately $1,368,033 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 2.06 years.

For the three and nine months ended June 30, 2013, the Company did not recognize any stock based compensation expense.

Restricted Stock

On March 24, 2014, the Company issued 300,000 restricted shares of common stock to a consultant as consideration for services to be performed, 150,000 shares vested immediately and 75,000 shares vested on June 1, 2014. The remaining shares are subject to vesting over a 5 month period. During the three and nine months ended June 30, 2014, the Company recorded the fair value of the shares of $25,875 and $77,625, respectively to General and Administrative expenses. The unvested shares of common stock are not considered outstanding shares for accounting purposes until the holders provide the requisite services and the shares vest. As of June 30, 2014, there was $25,875 of unrecognized compensation cost related to unvested restricted stock granted, which is expected to be recognized over a weighted average period of 0.42 years.

	Option Shares Outstanding	Weighted Average Grant Date Fair Value
Unvested at October 1, 2013	-	-
Awarded	300,000	$ 0.345
Vested	(225,000)	0.345
Unvested at June 30, 2014	75,000	$ 0.345

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 Loan Agreement, as defined, 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 $0.274 per share. The warrants expire on September 30, 2023. No warrants have been exercised as of June 30, 2014.

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: fair market value of common stock $.034, 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 is being 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 three and nine months ended June 30, 2014 was $2,765 and $8,294 respectively.

5. CONVERTIBLE NOTES PAYABLE

From March 2006 through September 30, 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 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 (see Note 1).

6. PRIVATE PLACEMENT FINANCING

On January 30, 2014, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with nine separate accredited 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 $2,850,000 (the "Private Placement Financing").

Upon the closing of the Private Placement Financing on February 4, 2014 (the "Closing Date"), the Company entered into a registration rights agreement (the "Registration Rights Agreement") with the Investors, pursuant to which the Company became obligated, subject to certain conditions, to file with the Securities and Exchange Commission on or before March 21, 2014 one or more registration statements to register for resale under the Securities Act of 1933, as amended, (i) the Shares and the Warrant Shares, plus (ii) an additional number of shares of common stock equal to 33% of the total number of Shares and Warrant Shares, to account for adjustments, if any, to the number of Warrant Shares issuable pursuant to the terms of the Warrants (the securities set forth in this clause (ii), the "Additional Shares").

Under the terms of the Registration Rights Agreement, the Company is permitted to reduce the number of shares covered by a registration statement if such reduction is required by the SEC as a condition for permitting such registration statement to become effective and treated as a resale registration statement (the "Cutback Provisions"). In response to comments received from the SEC and in accordance with the terms of the Registration Rights Agreement, the Company reduced the number of shares included in its draft resale registration statement by the number of Additional Shares. The Company's failure to satisfy certain other obligations and deadlines set forth in the Registration Rights Agreement may subject the Company to payment of monetary penalties as discussed below. The resale registration statement was declared effective on July 2, 2014. As described below, in the event that we fail to comply with certain requirements in the Registration Rights Agreement, we may be required to pay liquidated damages to the investors.

The Warrants are exercisable immediately upon issuance. The Series A warrants have an exercise price of $0.30 per share and expire five years from the date of their issuance. The Series B warrants have an exercise price of $0.35 per share and expire on the earlier of 12 months after their issuance date and six months after the first date on which the resale of all Registrable Securities (as defined in the Registration Rights Agreement) is covered by one or more effective registration statements. The Series C warrants have an exercise price of $0.40 per share and expire on the earlier of 18 months after their issuance date and nine months after the first date on which the resale of all Registrable Securities (as defined in the Registration Rights Agreement) is covered by one or more effective registration statements. 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, adjustment to both the exercise price of the Warrants in the event of certain subsequent issuances and sales of shares of the Company's common stock (or securities convertible or exercisable into shares of common stock) at a price per share lower than the then-effective exercise price of the Warrants, in which case the per share exercise price of the Warrants will be adjusted to equal such lower price per share and the number of shares issuable upon exercise of the Warrants will be adjusted accordingly so that the aggregate exercise price upon full exercise of the Warrants immediately before and immediately after such per share exercise price adjustment are equal. The Warrants are also subject to customary adjustments in the event of stock dividends and splits, subsequent rights offerings and pro rata distributions to the Company's common stockholders, and provide that they shall not be exercisable in the event and to the extent that the exercise thereof would result in the holder of the Warrant or any of its affiliates beneficially owning more than 4.9% of the Company's common stock.

The Company may be required to make certain payments to the investors in the Private Placement Financing under certain circumstances in the future pursuant to the terms of the Securities Purchase Agreement and the Registration Rights Agreement. These potential future payments include: (a) potential partial damages for failure to register the common stock issued or issuable upon exercise of Warrants (in a cash amount equal to 1% of the price paid to the Company by each investor in the Private Placement Financing on the date of and on each 30-day anniversary of such failure until the cure thereof); (b) amounts payable if the Company and its transfer agent fail to timely remove certain restrictive legends from certificates representing shares of common stock issued in the Private Placement Financing or issuable upon exercise of the Warrants; (c) expense reimbursement for the lead investor in the Private Placement Financing; and (d) payments in respect of claims for which the Company provides indemnification. There is no cap to the potential consideration. On July 2, 2014, we received from the SEC a Notice of Effectiveness of our Registration Statement related to the Private Placement which satisfies some of our obligation to register these securities with the SEC.

Derivative Liabilities

The Company accounted for the Warrants relating to the aforementioned Private Placement in accordance with ASC 815-10, *Derivatives and Hedging*. Because the Warrants are not indexed to the Company's stock and are not classified in stockholders' equity, they are recorded as liabilities at fair value. They are marked to market each reporting period through the consolidated statement of operations.

On the closing date, the derivative liabilities were recorded at fair value of $10,391,693. Given that the fair value of the derivative liabilities exceeded the total proceeds of the private placement of $2,850,000, no net amounts were available to be allocated to the common stock. The $7,541,693 amount by which the recorded liabilities exceeded the proceeds was charged to other expense as of the Closing Date.

The value of the derivative liability as of June 30, 2014 was $8,322,000. As of result of a change in the estimated fair market value of the derivative liability we recorded other income of $1,584,818 and $2,069,693 for the three months and nine months ended June 30, 2014, respectively. Such change in the estimated fair value was primarily due to the fluctuation in the Company's common stock price.

Fair Value Measurements Using Significant Unobservable Inputs
(Level 3)

	Warrant Derivative Liability
Beginning balance at September 30, 2013	$ —
Issuances	10,391,693

Adjustments to estimated fair value	(2,069,693)
Ending balance at June 30, 2014	$ 8,322,000

The derivative liabilities were valued as of February 4, 2014 and June 30, 2014, using Monte Carlo Simulation with the following assumptions:

	February 04, 2014	June 30, 2014
Closing price per share of common stock	$0.30	$0.23
Exercise price per share	$0.30 - 0.40	$0.30 - 0.40
Expected volatility	100 - 125%	100 - 115%
Risk-free interest rate	.12 - 1.46%	.08 - 1.47%
Dividend yield	—	—
Remaining expected term of underlying securities (years)	1-5	.60-4.60

Common Stock

At the Closing Date, the Company issued 11,400,000 shares of common stock and recorded the par value of the shares issued of $11,400 (at par value of $0.001 per share) with a corresponding reduction in additional paid-in capital, given that the fair value of the warrant liability recorded exceeded the total consideration received as of the Closing Date.

7. Coldstream Financing

In contemplation of the Merger, on April 19, 2013, the Company entered into a financing agreement (the "Financing Agreement") with Coldstream Summit Ltd. ("Coldstream") pursuant to which we agreed to issue and sell, and Coldstream agreed to purchase or assist in securing the purchase of $2,000,000 worth of units in a private offering within the 12-month period following the closing of the Merger (the "Coldstream Financing"). Each unit issued in the Coldstream Financing was to be sold at a price of $0.50 per share and was to consist of (i) one share of common stock and (ii) one warrant to purchase one share of common stock at an exercise price of $0.75 per share and with a term of 12 months. Pursuant to the Coldstream Financing, we issued and sold units consisting of 4,000,000 shares of common stock and warrants to purchase 4,000,000 shares of common stock for aggregate gross proceeds of $2,000,000.

8. Subsequent Events

The Company evaluated all events or transactions that occurred through August 6, 2014, the date which these consolidated financial statements were available to be issued. On July 2, 2014, our resale registration statement was declared effective by the SEC. This relates to the offering and resale by the selling securityholders of up to 45,600,000 shares of common stock par value $0.001 per share. These shares include 11,400,000 issued and outstanding shares, 11,400,000 shares of common stock underlying the Series A warrants, 11,400,000 shares of common stock underlying the Series B warrants and 11,400,000 shares underlying the Series C warrants.

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 unaudited interim financial statements and notes included in this report and the audited financial statements and notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K/A for the year ended September 30, 2013 filed with the Securities and Exchange Commission ("SEC").

This report contains forward looking statements. We make forward-looking statements, as defined by the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, and in some cases, you can identify these statements by forward-looking words such as "if," "shall," "may," "might," "will likely result," "should," "expect," "plan," "an "believe," "estimate," "project," "intend," "goal," "objective," "predict," "potential" or "continue," or the negative of these ter other comparable terminology. Such forward-looking statements contained in this Form 10-Q are based on various underlying assumptions and expectations and are subject to risks, uncertainties and other unknown factors, may include projections of our future financial performance based on our growth strategies and anticipated trends in our business and include risks and uncertainties relating to Arch's current cash position and its need to raise additional capital in order to be able to continue to fund its operations; the stockholder dilution that may result from future capital raising efforts and the exercise or conversion, as applicable of Arch's outstanding options and warrants; anti-dilution protection afforded investors in prior financing transactions that may restrict or prohibit Arch's ability to raise capital on terms favorable to the Company and its current stockholders; Arch's limited operating history which may make it difficult to evaluate Arch's business and future viability; Arch's ability to timely commercialize and generate revenues or profits from our anticipated products; Arch's ability to achieve the desired regulatory approvals in the United States or elsewhere; Arch's ability to retain its managerial personnel and to attract additional personnel; the strength of Arch's intellectual property, the intellectual property of others and any asserted claims of infringement; and other risk factors identified in the documents Arch has filed, or will file with the SEC. Copies of Arch's filings with the SEC may be obtained from the SEC internet site at http://www.sec.gov. We undertake no duty to update any of these forward-looking statements after the date of filing of this report to conform such forward-looking statements to actual results or revised expectations, except as otherwise required by law.

As used in this report unless otherwise indicated, the "Company", "we", "us", "our", and "Arch" refer to Arch Therapeutics, In and its consolidated subsidiary, Arch Biosurgery, Inc.

Corporate Overview

Arch Therapeutics, Inc. was incorporated under the laws of the State of Nevada on September 16, 2009 with the name "Almah, Inc." to pursue the business of distributing automobile spare parts online. Effective June 26, 2013, Arch completed a merger (the "Merger") with Arch Biosurgery, Inc. (formerly known as Arch Therapeutics, Inc.), a Massachusetts corporation ("ABS"), and Arch Acquisition Corporation ("Merger Sub"), Arch's wholly owned subsidiary formed for the purpose of the transaction, pursuant to which Merger Sub merged with and into ABS and ABS thereby became the wholly owned subsidiary of Arch. Prior to the completion of the Merger, Arch was a "shell company" under applicable rules of the SEC and had no or nominal assets or operations. Upon its acquisition of ABS, Arch abandoned its prior business plan and changed its operations to the business of a life science medical device company. For financial reporting purposes, the Merger 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 have been replaced with the historical financial statements of ABS before the Merger in this report and will be so replaced in all future filings with the SEC that require financial statements to be included.

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

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 using a novel approach to stop bleeding (referenced as “hemostasis”), control leaking (referenced as “sealant”), and provide other advantages during surgery and trauma care. Our core technology is based on a self-assembling peptide that creates a physical, mechanical barrier, which could be applied to seal organs or wounds that are leaking blood and other fluids. We believe our technology could support an innovative platform of potential products in the field of stasis and barrier applications. Our plan and business model is to develop products that apply that core technology to use with human bodily fluids and connective tissues.

Our lead product candidate, AC5 Surgical Hemostatic Device™ (which we sometimes refer to as "AC5"), relies on this technology and is designed to achieve hemostasis in minimally invasive and open surgical procedures, and we hope to develop other product candidates in the future based on our technology platform aimed at stopping bleeding and sealing other leaking fluids during surgical and other procedures. AC5 is a biocompatible synthetic peptide comprising naturally occurring amino acids. When applied to a wound, AC5 intercalates into the interstices of the connective tissue where it self-assembles into a physical, mechanical nanoscale structure that provides a barrier to leaking substances, such as blood. We believe that the results of early data from preclinical animal tests have shown quick and effective hemostasis with the use of AC5 relative to other types of hemostatic agents. AC5 is designed for either direct application as a liquid or application as a spray, which we believe will make it user-friendly and able to conform to irregular wound geometry. Additionally, AC5 is not sticky or glue-like, which we believe will enhance its utility in the setting of minimally invasive and laparoscopic surgeries. Further, AC5 is transparent, which should make it easier for a surgeons or other healthcare providers to maintain a clear field of vision during a surgical procedure and prophylactically stop bleeding as it starts, which we call Crystal Clear Surgery™.

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 European Union ("EU"), the U.S., and/or other jurisdictions as we may determine;
- developing academic scientists and institutions to collaborate on product research and development;
- developing appropriate third party relationships to manufacture, distribute, market and otherwise commercialize AC5; and
- developing additional product candidates in the hemostatic and sealant field.

With respect to our goals relating to AC5, we currently project requiring at least $6,000,000 of additional capital to complete the activities needed to obtain regulatory approval to market and sell AC5 in Europe. We expect that obtaining regulatory approval for AC5 in the U.S., including conducting additional required clinical trials, would require at least an additional $9,000,000 in capital. These estimated capital requirements could increase by potentially large amounts if any number of risks relating to conducting these activities were to occur, including without limitation those set forth under the heading "Risk Factors" in this report.

In furtherance of our long-term business goals, we expect to continue to focus on the following activities during the next twelve months:

- expand and enhance our financial and operational reporting and controls. We recently hired a full time Chief Financial Officer, a Vice President of Research and Development Engineering & Quality Systems, and engaged outside consultants, adding additional financial, operational, and quality systems expertise to meet the Company's growing needs. We expect that these actions will increase our operating expenses by approximately $400,000 per year on an annualized basis;

- expand and enhance our intellectual property portfolio by filing new patent applications, obtaining allowances on currently filed patent applications, and adding to our trade secrets in self-assembly, manufacturing, analytical methods and formulation, which activities will be ongoing as we seek to expand our product candidate portfolio. We expect these activities will increase our operating expenses by approximately $250,000 during calendar year 2014;

- work with our large scale manufacturing partners to scale up production of product compliant with current good manufacturing practices ("cGMP"). We expect these activities will increase our operating expenses by approximately $750,000 during the following twelve months;

- We recently selected a Notified Body (which is a private commercial entity designated by the national government of an EU member state as being competent to make independent judgments about whether a medical device complies with applicable regulatory requirements) for pursuit of the European regulatory pathway, confirm our plan and pathway for obtaining a CE mark (a symbol placed on a medical device that declares the product's compliance with the essential requirements of applicable EU health, safety and environmental legislation), and participate in related regulatory meetings. These activities commenced subsequent to June 30, 2014. We expect these activities will increase our operating expenses by approximately $175,000 during calendar year 2014;

- identify and select additional pipeline candidates from self-assembling peptide platform for advancement into development, which activities will be ongoing as we seek to expand our product candidate portfolio. We anticipate these activities will increase our operating expenses by approximately $200,000 during calendar year 2014, of which approximately $75,000 had been recognized as of June 30, 2014;

- conduct informal biocompatibility studies during the third calendar quarter of 2014. We expect these activities will increase our operating expenses by approximately $50,000 during calendar year 2014;

- develop initial clinical trial protocols, complete Clinical Investigational Plan with key opinion leaders and principal investigators and submit application to Ethics Committee. We anticipate these activities will occur during the second of half of calendar 2014 and will increase our operating expenses by approximately $250,000 during said period;

- commence a human clinical trial, the timeframe for which is dependent upon successful completion of certain manufacturing, regulatory, and biocompatibility activities. Based on current expectations, we estimate such a trial could be commenced as early as the fourth calendar quarter of 2014. We anticipate that the cost of conducting this clinical trial will be approximately $1,000,000 over the next twelve months; and

- seek to raise additional funding to support the milestones described above and our operations generally. Even after giving effect to recent equity and debt financing activities, we do not have sufficient cash to fund such activities and we will need to raise additional funds in the near term in order to support our business and the operational activities described above. See "Liquidity and Capital Resources" below for further information.

Liquidity

We are in the development stage and have generated no operating revenues to date and do not expect to do so in the foreseeable future due to the early stage nature of our current product candidates. We currently have no products that have obtained marketing approval in any jurisdiction. We have net income for the three months ended June 30, 2014,

of $410,759 versus net loss of $514,360 for the comparable period of 2013, which can be attributed primarily to an adjustment of the derivative liabilities to fair market value related to our outstanding warrants of $1,584,818. We have net losses for the nine months ended June 30, 2014 and 2013 of $8,777,837 and $892,254 respectively, and we have an accumulated deficit as of June 30, 2014 of $13,409,708. We are currently devoting substantially all of our 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.

Recent Developments

Not applicable

Results of Operations

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

Three Months Ended June 30, 2014 Compared to Three Months Ended June 30, 2013

	June 30, 2014 ($)	June 30, 2013 ($)	Increase (Decrease) ($)
Revenue	-	-	-
Operating Expenses			
General and Administrative	825,951	451,046	374,905
Research and Development	320,345	43,750	276,595
(Loss) from Operations	(1,146,296)	(494,796)	651,500
Other income (expense)	1,557,055	(19,564)	1,576,619
Net income (loss)	410,759	(514,360)	925,119

Revenue

We did not generate revenue in either of the three months ended June 30, 2014 and 2013.

General and Administrative Expense

General and administrative expenses during the three months ended June 30, 2014 were $825,951, an increase of $374,905 compared to $451,046 during the three months ended June 30, 2013. The increase in general and

administrative expense is primarily attributable to increased legal fees, accounting fees and investor relations expenses, personnel costs and stock-based compensation expenses incurred in connection with attracting and retaining key employees.

General and administrative expenses are generally expected to increase as a result of our plans to ramp up operations as resources permit and requirements to comply with public company reporting and control obligations.

Research and Development Expense

Research and development expenses during the three months ended June 30, 2014 were $320,345, an increase of $276,595 compared to $43,750 for the three months ended June 30, 2013. The increase in research and development expense is primarily attributed to increased pre-clinical development, additional headcount during the period including the appointment of our Vice President of Research and Development Engineering & Quality Systems as well as outside consultants. Research and development expenses are expected to increase as a result of our plans to pursue additional preclinical and clinical studies as resources permit and otherwise relating to development of our primary product candidate.

Other Income (Expense)

Other income during the three months ended June 30, 2014 was $1,557,055, an increase in other income of $1,576,619 compared to total other expense of $19,564 incurred during the three months ended June 30, 2013. Other income during the three months ended June 30, 2014 is attributed primarily to an adjustment of the derivative liabilities to fair market value related to our outstanding warrants of $1,584,818 partially offset by accrued interest on our outstanding debt. Other expense during the three months ended June 30, 2013 was primarily interest on our outstanding debt.

Nine months Ended June 30, 2014 Compared to Nine Months Ended June 30, 2013

	June 30, 2014 ($)	June 30, 2013 ($)	Increase (Decrease) ($)
Revenue	-	-	-
Operating Expenses			
General and Administrative	2,271,443	721,565	1,549,878
Research and Development	951,101	62,356	888,745
(Loss) from Operations	(3,222,544)	(783,921)	2,438,623
Other income (expense)	(5,555,293)	(108,333)	5,446,960
Net income (loss)	(8,777,837)	(892,254)	7,885,583

Revenue

We did not generate revenue in any of the nine months ended June 30, 2014 and 2013.

General and Administrative Expense

General and administrative expenses during the nine months ended June 30, 2014 were $2,271,443, an increase of $1,549,878 compared to $721,565 during the nine months ended June 30, 2013. The increase in general and administrative expenses is primarily attributable to increased legal fees, patent prosecution costs, accounting fees, investor relations expenses, personnel costs and stock-based compensation expenses incurred in increased connection attracting and retaining key employees.

General and administrative expenses are generally expected to increase as a result of our plans to ramp up operations as resources permit and requirements to comply with public company reporting and control obligations.

Research and Development Expense

Research and development expenses during the nine months ended June 30, 2014 were $951,101, an increase of $888,745 compared to $62,356 for the nine months ended June 30, 2013. The increase in research and development expense is primarily attributed to increased intellectual property legal fees, an increase in pre-clinical development and additional headcount during the period including the appointment of our aforementioned Vice President. Research and development expenses are expected to increase as a result of our plans to pursue additional pre-clinical and clinical studies as resources permit and otherwise relating to development of our primary product candidate.

Other Income (Expense)

Other expense during the nine months ended June 30, 2014 was $5,555,293, an increase of $5,446,960 compared to other expense of $108,333 incurred during the nine months ended June 30, 2013. The increase in other expense was a result of the loss on the fair value of derivatives liabilities in excess of proceeds on the issuance of warrants of $7,541,693, partially offset by a gain in the fair market value of the derivative liabilities of $2,069,693. Other expenses during the nine months ended June 30, 2013 were primarily related to interest on our outstanding debt.

Liquidity and Capital Resources

To date, we have not generated revenues from the sale of any products and have principally raised capital through borrowings and the issuance of convertible debt and units consisting of common stock and warrants to fund our operations. At June 30, 2014, we had cash and cash equivalents of $1,802,524 and negative working capital of $1,625,391.

Cash Used in Operating Activities

Cash used in operating activities increased $1,613,928 during the nine months ended June 30, 2014 to 2,379,498, compared to $765,570 during the nine months ended June 30, 2013. This increase was primarily due to an increase in general and administrative expense attributable to increased costs associated with legal and accounting fees resulting from being a public reporting entity, and research and development expenses incurred 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 nine months ended June 30, 2014 or 2013, respectively.

Cash Provided by Financing Activities

Cash provided by financing activities increased $2,399,968 to 3,624,703 for the nine months ended June 30, 2014, compared to $1,224,800 for the nine months ended June 30, 2013. This increase was the result of the receipt of net proceeds from our January 2014 private placement and borrowings under the Loan Agreement. Cash provided by financing activities during the nine months ended June 30, 2013 resulted from our receipt of $1,250,000 from the issuance of common stock and warrants and $250,000 from issuance of convertible notes to existing investors partially offset by the repayment of the notes payable to a related party totaling $275,000.

Cash Requirements

We anticipate that our operating and other expenses will increase significantly as we continue to implement our business plan and pursue our operational goals. We estimate that our cash requirements for our fiscal year ending September 30, 2014 will be approximately $3,800,000 - $4,000,000 (inclusive of the nine months ended June 30, 2014). We estimate that we will have sufficient cash to operate our 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 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 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 may not be able to obtain additional financing on commercially reasonable or acceptable terms when needed, or at all. We are bound by certain terms and obligations that may limit or otherwise impact our ability to raise additional funding in the near-term, including restrictive covenants in the Loan Agreement that limit our ability to incur certain types of additional indebtedness and certain terms of our January 2014 private placement financing that prohibit or limit us from effecting certain types of equity financings for specified periods of time or impose anti-dilution provisions that may cause dilution to the ownership interests of our current stockholders in the event of some equity financings. These restrictions and provisions could make it more challenging for us to raise capital through the incurrence of debt or through equity issuances. 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.

Since inception, we have funded our operations primarily through equity and debt financings and we expect to continue to seek to do so in the future. If we obtain additional financing by issuing equity securities, our existing stockholders' ownership will be diluted, which dilution could be increased if certain anti-dilution protections provided to the holders of our warrants are triggered by any such equity issuance. Additionally, the terms of securities we may issue in future capital-raising transactions may be more favorable for our new investors. Further, newly issued securities may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have additional dilutive effects. If we obtain additional financing by incurring debt, we may become subject to significant limitations and restrictions on our operations pursuant to the terms of any loan or credit agreement governing the debt, which would be in addition to those currently imposed by the Loan Agreement. Further, obtaining any loan, assuming a loan would be available when needed on acceptable terms, would increase our liabilities and future cash commitments. We may also seek funding from collaboration or licensing arrangements in the future, which may require that we relinquish potentially valuable rights to our product candidates or proprietary technologies or grant licenses on terms that are not favorable to us. Moreover, regardless of the manner in which we seek to raise capital, we may incur substantial costs in those pursuits, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other related costs.

Going Concern

From inception through June 30, 2014, we have not earned operating revenues from sales of products or services, and have recurring losses from operations. As of June 30, 2014, we had incurred a net loss of $13,409,708 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 June 30, 2014, there is substantial doubt about our ability to continue as a going concern. The consolidated financial statements included in this report 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:

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 changes in disclosures required by ASC 915 are that our consolidated financial statements be identified as those of a development stage company, and that the consolidated statements of operations, changes in stockholders’ (deficit) equity 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 consolidated financial statements and/or tax returns. Deferred tax assets and liabilities are based upon the differences between the consolidated financial statement carrying amounts and the tax bases of existing assets and liabilities and for loss and credit carryforwards using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

We provide reserves for potential payments of tax to various tax authorities related to uncertain tax positions when management determines that it is probable that a loss will be incurred related to these matters and the amount of the loss is reasonably determinable. We have no reserves related to uncertain tax positions as of June 30, 2014, 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 Topic 718, Compensation-Stock Compensation, which requires all stock-based payments to employees, including grants of employee stock options, to be recognized in the consolidated 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-employees 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 recognize the compensation cost of stock-based awards on a straight-line basis over the vesting period of the award.

The determination of the fair value of stock-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 uses the 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 consolidated financial statements, is based on awards that are ultimately expected to vest.

Derivative Liabilities

The Company accounts for its warrants and other derivative financial instruments as either equity or liabilities based upon the characteristics and provisions of each instrument, in accordance with ASC 815 *Derivatives and Hedging*. Warrants classified as equity are recorded at fair value as of the date of issuance on the Company's consolidated balance sheets and no further adjustments to their valuation are made. Warrants classified as derivative liabilities and other derivative financial instruments that require separate accounting as liabilities are recorded on the Company's consolidated balance sheets at their fair value on the date of issuance and will be revalued on each subsequent balance sheet date until such instruments are exercised or expire, with any changes in the fair value between reporting periods recorded as other income or expense. Management estimates the fair value of these liabilities using Monte Carlo simulation and assumptions that are based on the individual characteristics of the warrants or instruments on the valuation date, as well as assumptions for future financings, expected volatility, expected life, yield, and risk-free interest rate.

Recent Accounting Guidance

Accounting Standards Update (ASU) 2014-10, "Development Stage Entities (Topic 915) – "Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation" was issued by the FASB in June 2014. Due to the fact that we are a development stage company, we currently include inception-to-date information, and certain disclosures required under U.S. GAAP in our financial statements. The amendments in this ASU (2014-10) remove all incremental financial reporting requirements from U.S. GAAP for development stage companies. The amendments are effective for fiscal years, and interim periods within those years, beginning after December 15, 2014 and December 15, 2015. Early adoption is permitted. We have not yet adopted the changes. The amendments when adopted, will be applied retrospectively except for the clarification to Topic 275, which shall be applied prospectively to all unrecognized tax benefits that exist at the effective date.

Accounting Standards Update (ASU) 2014-09, "Revenue from Contracts with Customers (Topic 606) was issued by the FASB in May 2014. The primary purpose of the ASU is to develop a common revenue standard for revenue recognition between the FASB and the International Accounting Standards Board (IASB). The ASU removes inconsistencies and weaknesses in revenue requirements, provides a more robust framework for addressing revenue issues, improves comparability of revenue recognition practices across entities, industries, jurisdictions and capital markets, among other items. We are a development stage company and do not currently generate revenue, and as a result we do not expect the adoption of this ASU to have a material impact on the Company's consolidated financial statements.

In April 2014, ASU (ASU) No. 2014-08, "Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity", was issued. The Amendment in this update changes the criteria for reporting discontinued

operations and requires additional disclosures about discontinued operations. ASU 2014-08 requires that an entity report as a discontinued operation only a disposal that represents a strategic shift in operations that has a major effect on its operations and financial results. ASU 2014-08 is effective for public business entities for annual periods, and interim periods within those annual periods, beginning on or after December 15, 2014. Early adoption is permitted, but only for a disposal (or classification as held for sale) that has not been reported in financial statements previously issued or made available for issuance. The ASU must be applied prospectively. The Company is currently assessing the impact of this guidance, but does not believe that it will have a material impact on its consolidated results of operations or financial position

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 by the FASB in July 2013. The amendments in this ASU 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 our consolidated 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

Our management carried out an evaluation, under the supervision and with the participation of 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 our disclosure controls and procedures (as defined by Rules 13a-15(e) or 15d-15(e)) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act") as of June 30, 2014, pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were not effective as of June 30, 2014 in ensuring that information required to be disclosed by us in reports that we file or furnish under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission (the "SEC"). This conclusion is based on findings that constituted material weaknesses in our internal control over financial reporting. 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 our annual or interim financial statements will not be prevented or detected on a timely basis.

As of June 30, 2014 management has identified the following material weaknesses:

(i) We have had insufficient quantity of dedicated resources and experienced personnel involved in preparing our audited and interim consolidated financial statements and designing and implementing internal controls. As a result, a material misstatement of our interim and annual consolidated financial statements could occur and may not be prevented or detected on a timely basis. For instance, as disclosed in our Current Report on Form 8-K filed with the SEC on May 1, 2014, on April 25, 2013, we concluded that certain presentation errors existed in our consolidated financial statements as of and for the year ended September 30, 2013 and for the period from inception (March 6, 2006) through September 30, 2013, which appeared in our Annual Report on Form 10-K for the year ended September 30, 2013 filed with the SEC on December 27, 2013. Although such errors had no effect on our consolidated net loss or our consolidated stockholders' equity (deficit) and we therefore determined that such errors were immaterial, we and our independent auditor concluded that such errors required the restatement of our consolidated financial statements appearing in our Annual Report on Form 10-K for the year ended September 30, 2013. As a result, on May 1, 2014, we filed an amendment to such Annual Report on Form 10-K/A in order to include restated consolidated financial statements that correct the identified presentation errors. See such Annual Report on Form 10-K/A, including the explanatory note included therein, for a further description of the nature of the identified presentation errors.

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

(iii) We have not established an audit committee of our Board of Directors, which is an important entity-level control over the preparation of our consolidated financial statements and the engagement of our independent auditor.

(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 weaknesses in our internal control over financial reporting. Lack of an entity-level risk assessment constituted an internal control design deficiency.

Remediation Efforts

Since the completion on the Merger on June 26, 2013, we have made, and expect to continue to make efforts to expand our management team and personnel base, including personnel to support our financial and accounting reporting functions. On July 7, 2014 we announced the hiring of a full time Chief Financial Officer and Treasurer. It is expected that he will, working with the CEO and the Board of Directors, continue to rectify significant financial reporting and control deficiencies. Although we believe we currently have some personnel with experience in designing and implementing adequate internal controls and with experience and formal training in preparing our audited and interim consolidated financial statements and properly analyzing and recording complex transactions in accordance with U.S. GAAP, we continue to lack sufficient resources in these areas.

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 the preparation of our consolidated 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 new directors with the financial and accounting experience to serve on a separate standing audit committee of our Board of Directors.

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. However, 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 action and implementing enhancements and improvements to our control systems 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 three months ended June 30, 2014 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

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. 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;

- build and enhance investor relations and corporate communications capabilities;
- 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;
- advance additional candidates through our research and development pipeline;
- seek to commercialize selected product candidates for which we may obtain regulatory approval;
- hire additional regulatory, clinical, quality control, scientific, financial, 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 believe that our current cash and cash equivalents on hand 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 and debt financings, 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;

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- 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 U.S. Food and Drug Administration ("FDA") or other applicable regulatory agencies;
- the cost associated with being a public company, including obligations to regulatory agencies, investor relations, and corporate communications;

- 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, although 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. Additional funding may not be available from any of these sources when needed on acceptable terms, or at all. In addition, we are bound by certain contractual terms and obligations that may limit or otherwise impact our ability to raise additional funding in the near-term, including restrictions in our loan agreement on our ability to incur certain types of additional indebtedness and certain terms of the Private Placement Financing, including those discussed in the risk factors below. These restrictions and provisions could make it more challenging for us to raise capital through the incurrence of additional debt or through future equity issuances. Further, if we do raise capital through the sale of equity, or securities convertible into equity, the ownership of our then existing stockholders would be diluted, which dilution could be significant depending on the price at which we may be able to sell our securities. Also, if we raise additional capital through the incurrence of indebtedness, we may become subject to additional covenants restricting our business activities, and the 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.

The terms of the Private Placement Financing could impose additional challenges on our ability to raise funding in the future.

The Securities Purchase Agreement related to the Private Placement Financing imposes certain restrictions on our ability to issue equity or debt securities, including the following: until the 90-day anniversary of the first date on which all the Registrable Securities (as defined in the Registration Rights Agreement) are covered by one or more effective registration statements, we may not offer, sell or issue any securities, except for equity awards granted to service providers and securities issued in connection with certain types of strategic transactions; until the six-month anniversary of the first date on which all the Registrable Securities (as defined in the Registration Rights Agreement) are covered by one or more effective registration statements, the investors in the Private Placement Financing shall have certain notice and participation rights with respect to offers and sales of securities that we may pursue; and until the earlier of the 12-month anniversary of the first date on which all the Registrable Securities (as defined in the Registration Rights Agreement) are covered by one or more effective registration statements and the date on which the

investors in the Private Placement Financing have sold all such Registrable Securities, we may not effect or enter into an agreement for a VRT, where a "VRT" is a transaction in which we (i) issue 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 our 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 our business or the market for the common stock, other than pursuant to a customary "weighted average" anti-dilution provision or (ii) enter into any agreement whereby we or any subsidiary may sell securities at a future determined price. In addition, the Warrants contain certain anti-dilution protections that adjust downward the exercise price of the Warrants and increase the number of shares issuable under such Warrants in the event we offer, sell and issue securities at a lower price per share than the then-effective per share exercise price of the Warrants, in which case the per share exercise price of the Warrants will be adjusted to equal such lower price per share and the number of shares issuable upon exercise of the Warrants will be adjusted accordingly so that the aggregate exercise price upon full exercise of the Warrants immediately before and immediately after such per share exercise price adjustment are equal. These provisions could make our securities less attractive to investors and could limit our ability to obtain adequate financing on a timely basis or on acceptable terms in the future, which could have significant harmful effects on our financial condition and business and could include substantial limitations on our ability to continue to conduct operations. Additionally, certain of these provisions, including the anti-dilution protections in the Warrants, could further dilute the ownership interests of our other current common stockholders.

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, 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, without the prior written consent of MLSC, to incur certain types and amounts of additional indebtedness, including indebtedness senior or, in certain circumstances, equal to the MLSC Loan and any indebtedness to any of our stockholders or employees that is not expressly subordinated to the MLSC Loan. Our ability to finance our operations could be limited if, while the MLSC Loan is outstanding, the only source of capital available to us is prohibited by the restrictions set forth in the MLSC Loan Agreement, in which case we may be forced to curtail or eliminate some or all of our operations.

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 results.

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 9A of Part II of our Annual Report originally filed on December 27, 2013 and amended on May 1, 2014 and in Item 4 of Part I of our Quarterly Report filed on May 15, 2014, management has identified material weaknesses in our disclosure controls and procedures and our internal control over financial reporting as of March 31, 2014. Additional material weaknesses have been identified in our internal control over financial reporting during our current fiscal quarter, which were identified by management in connection with restating our consolidated financial statements included in our most recently filed Annual Report. A material weakness in internal control over financial reporting 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 consolidated financial statements will not be prevented or detected on a timely basis. As a result of these material weaknesses, our management concluded in our latest annual assessment that our internal control over financial reporting was not effective as of September 30, 2013, based on criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework.

Additional resources are needed to address our material weaknesses. We have developed proposed actions aimed at remediating the material weaknesses we have identified in our internal control over financial reporting. As of July 7, 2014, we have hired a new Chief Financial Officer who serves on a full-time basis. He will, working with the CEO and the Board of Directors, continue to rectify significant financial reporting and control deficiencies. If our remedial measures are insufficient to address the material weaknesses we have identified, 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. A restatement of our financial results could result in substantial costs to us for accounting and legal fees and could lead to litigation against us. In addition, even if we are successful in strengthening our controls and procedures, 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 would 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, and the market price of our stock could decline significantly. Moreover, our reputation with lenders, investors, securities analysts and others may be adversely affected.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

We maintain sensitive data pertaining to our Company on our computer networks, including information about our research and development activities, our intellectual property and other proprietary business information. Our internal computer systems and those of third parties with which we contract may be vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures, despite the implementation of security measures. System failures, accidents or security breaches could cause interruptions to our operations, including material disruption of our research and development activities, result in significant data losses or theft of our intellectual property or proprietary business information, and could require substantial expenditures to remedy. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability and our research and development programs could be delayed, any of which would harm our business and operations.

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, engineering, manufacturing, scale-up, quality systems, pre-clinical *in vitro* and *in vivo* testing, government regulation and approval, third-party reimbursement and market acceptance. Our failure to overcome any one of those challenges could harm our operations, ability to commence and/or complete a clinical trial, 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 FDA and other regulatory authorities require that we comply with standards, commonly referred to as good clinical practices ("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 planned or are conducted on our product candidates may not start or may fail.

Clinical trials are lengthy, complex and extremely expensive processes with uncertain expenditures and results and frequent failures. Any clinical trials that are planned or which commence 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 an institutional review board ("IRB") 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 current good manufacturing practices ("cGMP") or other applicable requirements;
- third-party contractors become debarred or suspended or otherwise penalized by the 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.

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 or other 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.

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. 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 s