VISTEON CORP
Form 10-Q
October 29, 2009

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2009, or

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

For the transition period from – – to – –

Commission File Number 1-15827

VISTEON CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	**38-3519512**
(State of incorporation)	(I.R.S. employer Identification number)
One Village Center Drive, Van Buren Township, Michigan	**48111**
(Address of principal executive offices)	(Zip code)

Registrant s telephone number, including area code: (800)-VISTEON

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 ü 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 (Section 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 ___ 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. (Check one):

Large Accelerated Filer ___ Accelerated Filer ___ Non-Accelerated Filer ___ Smaller Reporting Company _ü_
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes___ No_ü_

As of October 23, 2009, the Registrant had outstanding 130,334,131 shares of common stock, par value $1.00 per share.

Exhibit index located on page number 63.

VISTEON CORPORATION AND SUBSIDIARIES
FORM 10-Q FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2009

INDEX

Table of Contents

PART I

FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

VISTEON CORPORATION AND SUBSIDIARIES
(DEBTOR-IN-POSSESSION)
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30		Nine Months Ended September 30	
	2009	2008	2009	2008
	(Dollars in Millions, Except Per Share Data)			
Net sales				
Products	$ 1,672	$ 2,010	$ 4,449	$ 7,530
Services	61	110	205	361
	1,733	2,120	4,654	7,891
Cost of sales				
Products	1,557	1,968	4,211	7,064
Services	60	109	202	358
	1,617	2,077	4,413	7,422
Gross margin	116	43	241	469
Selling, general and administrative expenses	95	138	300	442
Restructuring expenses	27	42	72	117
Reimbursement from escrow and accommodation agreements	4	39	66	81
Reorganization items	23		30	
Deconsolidation gain			95	
Asset impairments and loss on divestitures		19		70
Operating loss	(25)	(117)		(79)
Interest expense	8	48	110	160
Interest income	2	10	8	38
Equity in net income of non-consolidated affiliates	26	5	52	35
Loss before income taxes	(5)	(150)	(50)	(166)
Provision for income taxes	18	31	63	131

Net loss	(23)	(181)	(113)	(297)
Net income attributable to noncontrolling interests	15	7	35	38
Net loss attributable to Visteon Corporation	$ (38)	$ (188)	$ (148)	$ (335)
Per Share Data:				
Net loss per share attributable to Visteon Corporation	$ (0.29)	$ (1.45)	$ (1.14)	$ (2.59)

See accompanying notes to the consolidated financial statements.

Table of Contents

VISTEON CORPORATION AND SUBSIDIARIES
(DEBTOR-IN-POSSESSION)
CONSOLIDATED BALANCE SHEETS

	(Unaudited) September 30 2009	December 31 2008
	(Dollars in Millions)	
ASSETS		
Cash and equivalents	$ 712	$ 1,180
Restricted cash	102	
Accounts receivable, net	1,126	989
Inventories, net	360	354
Other current assets	224	249
Total current assets	2,524	2,772
Property and equipment, net	2,039	2,162
Equity in net assets of non-consolidated affiliates	266	220
Other non-current assets	78	94
Total assets	$ 4,907	$ 5,248
LIABILITIES AND SHAREHOLDERS DEFICIT		
Short-term debt, including current portion of long-term debt and debt in default	$ 136	$ 2,697
Accounts payable	952	1,058
Accrued employee liabilities	159	228
Other current liabilities	262	288
Total current liabilities	1,509	4,271
Long-term debt	66	65
Employee benefits	416	1,031
Deferred income taxes	149	139
Other non-current liabilities	340	365
Liabilities subject to compromise	3,126	
Shareholders deficit:		
Preferred stock (par value $1.00, 50 million shares authorized, none outstanding)		
Common stock (par value $1.00, 500 million shares authorized, 131 million shares issued, 130 million and 131 million shares outstanding, respectively)	131	131
Stock warrants	127	127
Additional paid-in capital	3,407	3,407
Accumulated deficit	(4,852)	(4,704)
Accumulated other comprehensive income	201	157
Other	(5)	(5)
Total Visteon Corporation shareholders deficit	(991)	(887)
Noncontrolling interests	292	264

Total shareholders deficit	(699)	(623)
Total liabilities and shareholders deficit	$ 4,907	$ 5,248

See accompanying notes to the consolidated financial statements.

Table of Contents

VISTEON CORPORATION AND SUBSIDIARIES
(DEBTOR-IN-POSSESSION)
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30	
	2009	2008
	(Dollars in Millions)	
Operating activities		
Net loss	$ (113)	$ (297)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization	255	327
Deconsolidation gain	(95)	
Asset impairments and loss on divestitures		70
Gain (loss) on asset sales	1	(15)
Equity in net income of non-consolidated affiliates, net of dividends remitted	(46)	(30)
Reorganization items	30	
Other non-cash items	(18)	(43)
Changes in assets and liabilities:		
Accounts receivable	(142)	204
Inventories	6	(16)
Accounts payable	50	(259)
Other assets and liabilities	(79)	(94)
Net cash used by operating activities	(151)	(153)
Investing activities		
Capital expenditures	(87)	(230)
Cash associated with deconsolidation	(11)	
Proceeds from divestitures and asset sales	5	65
Other		5
Net cash used by investing activities	(93)	(160)
Financing activities		
Short-term debt, net	(24)	24
Cash restriction	(102)	
Proceeds from issuance of debt, net of issuance costs	56	185
Principal payments on debt	(119)	(78)
Repurchase of unsecured debt securities		(337)
Other, including overdrafts	(56)	(62)
Net cash used by financing activities	(245)	(268)
Effect of exchange rate changes on cash	21	(44)
Net decrease in cash and equivalents	(468)	(625)
Cash and equivalents at beginning of year	1,180	1,758

Cash and equivalents at end of period	$ 712	$ 1,133

See accompanying notes to the consolidated financial statements.

Table of Contents

VISTEON CORPORATION AND SUBSIDIARIES
(DEBTOR-IN-POSSESSION)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

NOTE 1. Description of Business and Company Background

Visteon Corporation (the Company or Visteon) is a leading global supplier of climate, interiors and electronics systems, modules and components to global automotive original equipment manufacturers (OEMs). Headquartered in Van Buren Township, Michigan, Visteon has a workforce of approximately 30,000 employees and a network of manufacturing operations, technical centers, sales offices and joint ventures in every major geographic region of the world.

Reorganization under Chapter 11 of the U.S. Bankruptcy Code

On May 28, 2009 (the Petition Date), Visteon and certain of its U.S. subsidiaries (the Debtors) filed voluntary petitions for reorganization relief under chapter 11 of the United States Bankruptcy Code (the Bankruptcy Code) in the United States Bankruptcy Court for the District of Delaware (the Court). The reorganization cases are being jointly administered as Case No. 09-11786 under the caption In re Visteon Corporation, et al (hereinafter referred to as the Chapter 11 Proceedings). The Debtors continue to operate their businesses as debtors-in-possession (DIP) under the jurisdiction of the Court and in accordance with the applicable provisions of the Bankruptcy Code and orders of the Court. The Company s other subsidiaries, primarily non-U.S. subsidiaries, have been excluded from the Chapter 11 Proceedings and continue to operate their businesses without supervision from the Court and are not subject to the requirements of the Bankruptcy Code.

The Chapter 11 Proceedings were initiated in response to sudden and severe declines in global automotive production during the latter part of 2008 and early 2009 and the adverse impact on the Company s cash flows and liquidity. Under the Chapter 11 Proceedings, the Debtors expect to develop and implement a plan to restructure their capital structure to reflect the current automotive industry demand. Additional details regarding the status of the Company s Chapter 11 Proceedings are included herein under Note 4, Voluntary Reorganization under Chapter 11 of the United States Bankruptcy Code, to the consolidated financial statements.

Visteon UK Limited Administration

On March 31, 2009, in accordance with the provisions of the United Kingdom Insolvency Act of 1986 and pursuant to a resolution of the board of directors of Visteon UK Limited, a company organized under the laws of England and Wales (the UK Debtor) and an indirect, wholly-owned subsidiary of the Company, representatives from KPMG (the Administrators) were appointed as administrators in respect of the UK Debtor (the UK Administration). The UK Administration was initiated in response to continuing operating losses of the UK Debtor and mounting labor costs and their related demand on the Company s cash flows, and does not include the Company or any of the Company s other subsidiaries. The effect of the UK Debtor s entry into administration was to place the management, affairs, business and property of the UK Debtor under the direct control of the Administrators. Since their appointment, the Administrators have wound down the business of UK Debtor and closed its operations in Enfield, UK, Basildon, UK and Belfast, UK, and made the employees redundant. The Administrators continue to realize the UK Debtor s assets, comprised mainly of receivables.

Table of Contents

VISTEON CORPORATION AND SUBSIDIARIES
(DEBTOR-IN-POSSESSION)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 1. Description of Business and Company Background (Continued)

The UK Debtor recorded sales, negative gross margin and net loss of $32 million, $7 million and $10 million, respectively, for the three months ended March 31, 2009. As of March 31, 2009 total assets of $64 million, total liabilities of $132 million and related amounts deferred as Accumulated other comprehensive income of $84 million, were deconsolidated from the Company s balance sheet resulting in a deconsolidation gain of $152 million. The Company also recorded $57 million for contingent liabilities related to the UK Administration, including $45 million of costs associated with former employees of the UK Debtor, for which the Company was reimbursed from the escrow account on a 100% basis.

Additional amounts related to these items or other contingent liabilities for potential claims under the UK Administration, which may result from (i) negotiations; (ii) actions of the Administrators; (iii) resolution of contractual arrangements, including unexpired leases; (iv) material adverse developments; or other events, may be recorded in future periods. No assurance can be provided that the Company will not be subject to future litigation and/or liabilities related to the UK Administration. Additional liabilities, if any, will be recorded when they become probable and estimable and could materially affect the Company s results of operations and financial condition in future periods.

Transactions with Ford Motor Company

The Company transacts a significant amount of commercial activity with Ford Motor Company (Ford). The financial statement impact of these commercial activities is summarized in the table below.

	Three Months Ended September 30		Nine Months Ended September 30	
	2009	2008	2009	2008
	(Dollars in Millions)			
Net Sales				
Products	$ 443	$ 643	$ 1,269	$ 2,631
Services	$ 61	$ 106	$ 205	$ 347

	September 30 2009	December 31 2008
	(Dollars in Millions)	
Accounts receivable, net	$ 233	$ 174
Postretirement employee benefits	$	$ 113
Liabilities subject to compromise	$ 229	$

On May 13, 2009, the Company entered into certain transactions whereby Ford purchased, assumed and took an assignment of all of the outstanding loans, obligations and other interests of the lenders under the ABL Credit

Agreement. As of September 30, 2009, the balance owed to Ford under the ABL Credit Agreement was approximately $110 million, including $21 million related to unreimbursed draws on letters of credit. Additionally, as of September 30, 2009 there was approximately $35 million outstanding on undrawn letters of credit.

NOTE 2. Basis of Presentation

Interim Financial Statements: The unaudited consolidated financial statements of the Company have been prepared in accordance with the rules and regulations of the U.S. Securities and Exchange Commission (SEC). Certain information and footnote disclosures normally included in
financed 4,869,212 $0.35 - Exercised (231,250) 0.40 - Forfeited - - - Outstanding at March 31, 2014 7,637,962 $0.36 5.67 $29,600 Vested 2,119,803 $0.37 4.98 $6,100 Vested and expected to vest at March 31, 2014 7,637,962 $0.36 5.67 $29,600

As of March 31, 2014, 2,361,895 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 six months ended March 31, 2014 resulting from stock options awarded to the Company's employees, directors and consultants was $371,792 and $503,355, respectively. Of this amount during the three and six months ended March 31, 2014, $263,009 and $349,008, respectively was recorded to Research and Development expenses, and $108,783 and $154,347, respectively was recorded in General and Administrative expenses in the Company's consolidated statement of operations.

As of March 31, 2014, there is approximately $1,576,053 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 2.31 years.

For the three and six months ended March 31, 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 of which vested immediately. The remaining shares are subject to vesting over an 8 month period. During the three months ended March 31, 2014, the Company recorded the fair value of the shares of $51,750 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 March 31, 2014, there was $51,750 of unrecognized compensation cost related to non vested restricted stock granted, which is expected to be recognized over a weighted average period of 0.67 years.

	Option Shares Outstanding	Weighted Average Grant Date Fair Value
Nonvested at October 1, 2013	-	-
Awarded	300,000	$ 0.345
Vested	(150,000)	0.345
Nonvested at March 31, 2014	150,000	$ 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 MLSC 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 $0.27 per share. The warrants expire on September 30, 2023. No warrants have been exercised as of March 31, 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: 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 six months ended March 31, 2014 was $2,765 and $5,530 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 warrants had various expiration dates through January 2015 as identified in Footnote 1 in this Form 10-Q.

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

On April 20, 2013, the convertible noteholders and the Company entered into an agreement to cancel the warrants and exchange the notes (with a total aggregate principal balance of $1,880,000) and the interest accrued through April 30, 2013 for the Company's common stock upon the completion of the Merger completed on June 26, 2013. 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 $2.85 million (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. As of the date of this report, the Company is in compliance with such filing obligations under the Registration Rights Agreement. 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.

The Warrants are exercisable immediately upon issuance. The Series A warrants have an exercise price of $0.30 per share and have a term of exercise equal to five years from their issuance. The Series B warrants have an exercise price of $0.35 per share and have a term of exercise equal to the shorter of 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 Securities Purchase Agreement) is covered by one or more effective registration statements. The Series C warrants have an exercise price of $0.40 per share and have a term of exercise equal to the shorter of 18 months after their issuance date and nine months after the first date on which the resale of all Registrable Securities (as defined in the Securities Purchase 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 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 exercise price of the Warrants will be adjusted to equal such lower price per share, as well as customary adjustments in the event of stock dividends and splits, subsequent rights offerings and pro rata distributions to the Company's common stockholders. The Warrants also 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. In addition, if there is no effective registration statement registering the resale of the shares of common stock underlying the Warrants as of certain time periods (as provided in the Warrants), the Warrant holders may choose to exercise their Warrants on a "cashless exercise" or "net exercise" basis.

Derivative Liabilities

The Company accounted for the Warrants 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 with continuous adjustment to fair value 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 Company revalued the derivative liability as of March 31, 2014. The change in the estimated fair value resulted in other income of $484,875 for the three months and six months ended March 31, 2014. 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 December 31, 2013	$ —
Issuances	10,391,693
Adjustments to estimated fair value	(484,875)
Ending balance at March 31, 2014	$ 9,906,818

The derivative liabilities were valued as of February 4, 2014 and March 31, 2014, using Monte Carlo Simulation with the following assumptions:

	February 04, 2014	March 31, 2014
Closing price per share of common stock	$0.30	$0.33
Exercise price per share	$0.30 - 0.40	$0.30 - 0.40
Expected volatility	100 - 125%	100 - 125%
Risk-free interest rate	.12 - 1.46%	.11 - 1.67%
Dividend yield	—	—
Remaining expected term of underlying securities (years)	1-5	.85-4.85

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.

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. This section and other sections of this report contain forward looking statements. We make forward-looking statements, as defined by the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, and in some cases, you can identify these statements by forward-looking words such as "if," "shall," "may," "might," "will likely result," "should," "expect," "plan," "anticipate," "believe," "estimate," "project," "intend," "goal," "objec "potential" or "continue," or the negative of these terms and other comparable terminology. These forward-looking statements, which are based on various underlying assumptions and expectations and are subject to risks, uncertainties and other unknown factors, may include projections of our future financial performance based on our growth strategies and anticipated trends in our business. These statements are only predictions based on our current expectations and projections about future events that we believe to be reasonable. There are important factors that could cause our actual results, level of activity, performance or achievements to differ materially from the historical or future results, level of activity, performance or achievements expressed or implied by such forward-looking statements. These factors include, but are not limited to, those discussed under the caption "Risk Factors" in this report. We undertake no duty to update any of these forward-looking statements after the date of filing of this report to conform such forward-looking statements to actual results or revised expectations, except as otherwise required by law.

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 Securities and Exchange Commission (the "SEC") and had no or nominal assets or operations. Upon its acquisition of ABS, Arch abandoned its prior business plan and changed its operations to the business of a life science medical device company. For financial reporting purposes, the Merger represents a "reverse merger" rather than a business combination and ABS is deemed to be the accounting acquirer in the transaction and the predecessor of Arch. Consequently, the assets, liabilities, deficit accumulated during the development stage and the historical operations that are reflected in the Company's consolidated financial statements are those of ABS. All share information has been restated to reflect the effects of the Merger. The Company's financial information has been consolidated with that of ABS after consummation of the Merger on June 26, 2013, and the historical financial statements of the Company before the Merger 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.

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 not generated revenues since inception, we had net losses for the year ended September 30, 2013 and for the six months ended March 31, 2014 of $1,853,791 and $9,188,596 respectively, and we had an accumulated deficit as of March 31, 2014 of $13,820,467. We are currently devoting substantially all of its efforts toward product research and development. As further discussed in “Liquidity and Capital Resources” below, we will need to raise substantial additional funds in order to continue operating our business.

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 lead product candidate, AC5 Surgical Hemostatic Device™ (which we sometimes refer to as “AC5”), is designed to achieve hemostasis in minimally invasive and open surgical procedures, and we hope to develop other product candidates in the future based on our technology platform aimed at stopping bleeding and sealing other leaking fluids during surgical and other procedures. Our plan and business model is to develop products that apply that core technology to use with human bodily fluids and connective tissues.

Our primary product candidate, AC5, relies on this technology and is designed to achieve hemostasis during surgical procedures. AC5 is a biocompatible synthetic peptide comprising naturally occurring amino acids. When applied to a wound, AC5 intercalates into the interstices of the connective tissue where it self-assembles into a physical, mechanical nanoscale structure that provides a barrier to leaking substances, such as blood. We believe that the results of early data from preclinical animal tests have shown quick and effective hemostasis with the use of AC5 relative to other types of hemostatic agents. AC5 is designed for either direct application as a liquid or application as a spray, which we believe will make it user-friendly and able to conform to irregular wound geometry. Additionally, AC5 is not sticky or glue-like, which we believe will enhance its utility in the setting of minimally invasive and laparoscopic surgeries. Further, AC5 is transparent, which should make it easier for a 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;

- expanding our intellectual property portfolio;
- developing appropriate third party relationships to manufacture, distribute, market and otherwise commercialize AC5; and
- developing additional product candidates in the hemostatic and sealant field.

With respect to our goals relating to AC5, we currently project requiring 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 focus on the following activities during the next twelve months:

- expand our team during the second calendar quarter by hiring a Vice President of Research and Development Engineering, adding additional quality systems expertise, and hiring a full time Chief Financial Officer in order to meet the Company’s growing needs, which we anticipate will require approximately $400,000 for salary and related expenses during calendar year 2014;

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

- select a large scale manufacturing partner for scale-up and initiate production of product compliant with current good manufacturing practices (“cGMP”), which we anticipate will start in the third calendar quarter of 2014 and will require approximately $750,000 during the next twelve months;

- select 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, which activities we anticipate will start during the second calendar quarter of 2014, continue throughout the balance of the year, and require approximately $200,000 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 and which we

anticipate will require approximately $200,000 during calendar year 2014;

- conduct both informal and formal biocompatibility studies during the second and third calendar quarters of 2014, which we anticipate will require approximately $250,000 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, which activities we anticipate will occur during the second half of 2014 and require approximately $300,000 during calendar year 2014;

- 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 activities related to the clinical trial will require approximately $1,000,000 over the next twelve months; and

- seek to raise additional funding when and as needed to support the milestones described above and our operations generally. The anticipated costs of our activities described above totals approximately $3.35 million over the next 12 months. 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.

Recent Developments

MLSC Loan Agreement and Warrant

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

In connection with and as a condition of the MLSC Loan Agreement, on September 30, 2013, we issued to MLSC a warrant (the "MLSC Warrant") to purchase 145,985 shares of our common stock at an exercise price of $0.274 per share. The MLSC Warrant has been issued as partial consideration for the funding provided under the MLSC Loan Agreement and for no separate consideration. The MLSC Warrant is exercisable immediately upon its issuance and expires on the earlier of September 30, 2023 and the completion of a sale of substantially all of our assets or a change-of-control transaction. No warrants have been exercised as of March 31, 2014.

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 $2.85 million (the "Private Placement Financing").

Upon the closing of the Private Placement Financing on February 4, 2014, the Company entered into a registration rights agreement (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. As of the date of this report, the Company is in compliance with such filing obligations under the Registration Rights Agreement. 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.

The Warrants are exercisable immediately upon issuance. The Series A warrants have an exercise price of $0.30 per share and have a term of exercise equal to five years from their issuance. The Series B warrants have an exercise price of $0.35 per share and have a term of exercise equal to the shorter of 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 Securities Purchase Agreement) is covered by one or more effective registration statements. The Series C warrants have an exercise price of $0.40 per share and have a term of exercise equal to the shorter of 18 months after their issuance date and nine months after the first date on which the resale of all Registrable Securities (as defined in the Securities Purchase 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 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 exercise price of the Warrants will be adjusted to equal such lower price per share, as well as customary adjustments in the event of stock dividends and splits, subsequent rights offerings and pro rata distributions to the Company's common stockholders. The Warrants also 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. In addition, if there is no effective registration statement registering the resale of the shares of common stock underlying the Warrants as of certain time periods (as provided in the Warrants), the Warrant holders may choose to exercise their Warrants on a “cashless exercise” or “net exercise” basis.

Merger with ABS and Related Activities

On June 26, 2013, the Company completed the Merger with ABS, pursuant to which ABS became a wholly-owned subsidiary of the Company. As a result of the acquisition of ABS, the Company has abandoned its prior business plan and has changed its operations to that of a life science medical device company. We are in the development stage and have generated no operating revenues to date. We are currently devoting substantially all of efforts toward product research and development.

In contemplation of the Merger, (a) effective May 24, 2013, the Company increased its authorized common stock from 75,000,000 shares to 300,000,000 shares and effected a forward stock split, by way of a stock dividend, of its issued and outstanding shares of common stock at a ratio of 11 shares to each one issued and outstanding share, (b) effective June 18, 2013, the Company adopted a new stock incentive plan that currently authorizes the issuance of up to 10,231,197 shares of our common stock as incentives to employees, consultants and directors and adopted amended and restated bylaws to govern our corporate affairs, (c) effective June 5, 2013, the Company changed its name form Almah, inc. to Arch Therapeutics, Inc. and changed the ticker symbol under which its common stock trades from “AACH “ to “ARTH”.

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

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 is to be sold at a price of $0.50 per share and is to consist of (i) one share of common stock and (ii) one warrant to purchase one share of common stock at an exercise price of $0.75 per share and with a term of 12 months. On June 26, 2013, the Company issued and sold units consisting of 2,500,000 shares of common stock and warrants to purchase 2,500,000 shares of common stock in the Coldstream Financing to a foreign accredited investor identified by Coldstream, for aggregate gross proceeds of $1,250,000. On July 3, 2013, pursuant to the Coldstream Financing, the Company issued and sold additional units consisting of 500,000 shares of common stock and warrants to purchase 500,000 shares of common stock to a foreign accredited investor identified by Coldstream for gross proceeds of $250,000. On August 30, 2013, pursuant to the Coldstream Financing the Company issued and sold additional units consisting of 1,000,000 shares of common stock and warrants to purchase 1,000,000 shares of common stock to a foreign accredited investor identified by Coldstream for gross proceeds of $500,000. Following such issuance and sale on August 30, 2013, Coldstream has satisfied its obligations under the Financing Agreement and we have received all aggregate gross proceeds thereunder, totaling $2,000,000.

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 March 31, 2014 Compared to Three Months Ended March 31, 2013

	March 31, 2014 ($)	March 31, 2013 ($)	Increase (Decrease) ($)
Revenue	$-	$-	$-
Operating Expenses			
General and Administrative	808,483	117,649	690,834
Research and Development	487,090	9,240	477,850
(Loss) from Operations	(1,295,573)	(126,889)	1,168,684
Other income (expense)	(7,084,583)	(45,787)	7,038,796
Net income (loss)	$(8,380,156)	$(172,676)	$8,207,480

Revenue

We did not generate revenue in either of the three months ended March 31, 2014 or 2013.

General and Administrative Expense

We incurred general and administrative expenses during the three months ended March 31, 2014 in the amount of $808,483, compared to general and administrative expenses incurred during the three months ended March 31, 2013 in the amount of $117,649 (an increase of $690,834). General and administrative expenses during the three months ended March 31, 2014 primarily included legal and accounting fees, patent prosecution costs, payroll related expenses, stock-based compensation, director fees, compensation paid to investor relations consultants and office overhead. General and administrative expenses during the three months ended March 31, 2013 primarily included legal fees, patent prosecution costs, and office overhead. The increase in general and administrative expense period over period is primarily attributable to increased costs associated with legal fees, accounting fees and investor relations expenses, personnel costs and stock-based compensation expenses incurred in connection attracting and retaining key employees.

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

Research and Development Expense

We incurred research and development expenses during the three months ended March 31, 2014 in the amount of $487,090 compared to research and development expenses incurred during the three months ended March 31, 2013 in the amount of $9,240 (an increase of $477,850). Research and development expenses primarily relate to our activities to develop our primary product candidate, and consist mostly of payroll related expenses, stock-based compensation and independent contractors expenses.

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

Other Income (Expense)

We incurred total other expenses during the three months ended March 31, 2014 in the amount of $7,084,583, compared to total other expenses incurred during the three months ended March 31, 2013 in the amount of $45,787 (an increase of $7,038,796). Other expenses incurred during the three months ended March 31, 2014 were primarily interest accrued on debt and loss on the fair value of derivative liabilities in excess of proceeds as well as the adjustment to fair market value for said derivatives. Other expenses incurred during the three months ended March 31, 2013 were primarily interest accrued on debt. The increase in other expense between periods is attributable to the issuance of warrants partially offset by repayment of related party notes and cancellation of convertible notes in exchange for equity in connection with the Merger.

Six Months Ended March 31, 2014 Compared to Six Months Ended March 31, 2013

	March 31, 2014 ($)	March 31, 2013 ($)	Increase (Decrease) ($)
Revenue	$-	$-	$-
Operating Expenses			
General and Administrative	1,445,492	278,411	1,167,081
Research and Development	630,756	11,290	619,466
(Loss) from Operations	(2,076,248)	(289,701)	1,786,547
Other income (expense)	(7,112,348)	(88,192)	7,024,156
Net income (loss)	$(9,188,596)	$(377,893)	$8,810,703

Revenue

We did not generate revenue in any of the six months ended March 31, 2014 or 2013.

General and Administrative Expense

We incurred general and administrative expenses during the six months ended March 31, 2014 in the amount of $1,445,492, compared to general and administrative expenses incurred during the six months ended March 31, 2013 in the amount of $278,411 (an increase of $1,167,081). General and administrative expenses during the six months ended March 31, 2014 primarily included legal and accounting fees, payroll related expenses, stock based compensation, director fees, compensation paid to investor relations consultants and office overhead. General and administrative expenses during the six months ended March 31, 2013 primarily included legal fees, patent prosecution costs, and office overhead. The increase in general and administrative expense period over period is primarily attributable to increased costs associated with legal fees, accounting fees, stock-based compensation expenses, personnel additions, and investor relations expenses incurred in connection with being a public company.

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

Research and Development Expense

We incurred research and development expenses during the six months ended March 31, 2014 in the amount of $630,756 compared to research and development expenses incurred during the six month period ended March 31, 2013 of $11,290 (an increase of $619,466). Research and development expenses primarily relate to our activities to develop our primary product candidate, and consist mostly of payroll related expenses, stock based compensation and fees paid to independent contractors.

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

Other Income (Expense)

We incurred total other expenses during the six months ended March 31, 2014 in the amount of $7,112,348, compared to total other expenses incurred during the six months ended March 31, 2013 in the amount of $88,192 (an increase of $7,024,156). Other expenses incurred during the six months ended March 31, 2014 were primarily interest accrued on debt and loss on the fair value of derivative liabilities in excess of proceeds as well as the adjustment to fair market value for said derivatives. Other expenses incurred during the six months ended March 31, 2013 were primarily interest accrued on debt. The increase in other expense between periods is primarily attributable to the issuance of warrants partially offset by repayment of related party notes and cancellation of convertible notes in exchange for equity in connection with the Merger.

Liquidity and Capital Resources

Working Capital

As of March 31, 2014, total current assets were $2,662,202, compared to total current assets of $1,576,948 as of September 30, 2013 (an increase of $1,085,254). The increase was primarily due to our receipt of funding under the MLSC Loan totaling $1,000,000 and our receipt of Private Placement Financing totaling $2,850,000 less transaction costs incurred through March 31, 2014 of $134,597, partially offset by our payment of operating expenditures incurred during the period. Our total current assets as of March 31, 2014 were comprised of cash and prepaid expenses.

As of March 31, 2014, total current liabilities were $4,368,876, compared to total current liabilities of $455,609 as of September 30, 2013 (an increase of $3,913,267). The increase was primarily due to the establishment of the derivative liabilities resulting from the private placement financing. Our total current liabilities as of March 31, 2014 were comprised primarily of the aforementioned derivative liabilities, accounts payable and accrued expenses.

As a result, on March 31, 2014, we had negative working capital of $1,706,674, compared with positive working capital as of September 30, 2013 of $1,121,339.

Cash Flow

Our cash on-hand as of March 31, 2014 was $2,631,285, compared to cash on-hand as of September 30, 2013 of $557,319 (an increase of $2,073,966). The increase was primarily due to our receipt of funding under the MLSC Loan of $1,000,000 and our receipt of the proceeds from the Private Placement Financing of $2,850,000 less transaction costs incurred through March 31, 2014 of $134,597, partially offset by payment of operating expenditures during the period.

Cash Used in Operating Activities

Cash used in operating activities during the six months ended March 31, 2014 was $1,641,437, compared to cash used in operating activities during the six months ended March 31, 2013 of $266,258 (an increase of $1,375,179). The increase was primarily due to an increase in general and administrative expense attributable to increased costs associated with legal and accounting fees incurred in connection with being a public reporting entity and research and development expenses incurred in connection with activities to develop our primary product candidate partially offset by certain non-cash expenses and fair value adjustments.

Cash Used in Investing Activities

There was no cash used in investing activities during the six months ended March 31, 2014 or 2013, respectively.

Cash Provided by Financing Activities

Cash provided by financing activities during the six months ended March 31, 2014 was $3,715,403 compared to cash provided by financing activities during the six months ended March 31, 2013 of $250,000 (an increase of $3,465,403). The increase in cash provided by financing activities during the six months ended March 31, 2014 was the result of our receipt of funding under the MLSC Loan, totaling $1,000,000 and our receipt of the proceeds of the Private Placement Financing, totaling $2,850,000 less transaction costs incurred though March 31, 2014 of $134,597 as compared to our receipt of $250,000 from issuance of convertible notes to existing investors during the six months ended March 31, 2013.

Sources of Capital

Prior to the closing of the Merger, we had primarily funded our operations through the issuance of convertible debt and other promissory notes and related warrants, from which we received an aggregate of $1,985,000 in exchange for such issuances from inception through the closing of the Merger on June 26, 2013. All of such convertible notes and related warrants were cancelled in exchange for shares of our common stock in connection with the closing of the Merger. Subsequent to the Merger, we have funded our operations through equity financings for aggregate gross proceeds during such period totaling $4,850,000, including the Private Placement Financing entered into on January 30, 2014 in the aggregate amount of $2,850,000, the Coldstream financing in the aggregate amount of $2,000,000, and the incurrence of indebtedness under the MLSC Loan Agreement, for aggregate gross funding of $1,000,000. We have no contractual commitments for any additional funding.

Cash Requirements

As described above, we anticipate that our operating and other expenses will increase as we continue to implement our business plan and pursue our operational goals. We estimate that our aggregate operating expenses and working capital requirements for our fiscal year ending September 30, 2014 will be approximately $3,600,000 - $3,800,000 (inclusive of the six months ended March 31, 2014). After giving effect to the funds received in our recent equity financings, including the Private Placement Financing, and debt financings, including the MLSC Loan, we estimate we have sufficient funds to operate the business through October 2014. We will require additional financing to fund our planned future operations, including the continuation of our ongoing research and development efforts, seeking to license or acquire new assets, and researching and developing any potential patents, the related compounds and any further intellectual property that we may acquire. In addition, our estimates of the amount of cash necessary to operate our business may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. Further, our estimates regarding our use of cash could change if we encounter unanticipated difficulties, in which case our current funds may not be sufficient to operate our business for the period we expect.

We do not have any commitments for future capital. Significant additional financing will be required to fund our planned operations in the near term and in future periods, including research and development activities relating to our principal product candidate, seeking regulatory approval of that or any other product candidate we may choose to develop, commercializing any product candidate for which we are able to obtain regulatory approval or certification, seeking to license or acquire new assets or businesses, and maintaining our intellectual property rights and pursuing rights to new technologies. We do not presently have, nor do we expect in the near future to have, revenue to fund our business from our operations, and will need to obtain all of our necessary funding from external sources for the foreseeable future. We may not be able to obtain additional financing on commercially reasonable or acceptable terms when needed, or at all. 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 MLSC Loan Agreement that limit our ability to incur certain types of additional indebtedness and certain terms of the 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 the 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 MLSC 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 March 31, 2014, we have not earned operating revenues from sales of products or services, and have recurring losses from operations. As of March 31, 2014, we had incurred a net loss of $13,820,467 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 March 31, 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 March 31, 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- employee at each reporting period during the vesting period or until services are complete.

In accordance with FASB ASC Topic 718, Compensation-Stock Compensation, we have elected to use the Black-Scholes option pricing model to determine the fair value of options granted and recognizes the compensation cost of 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 and, therefore, uses simplified method for all "plain vanilla" options, as defined in ASC 718-10-S99 and the contractual term for all other employee and non-employee awards. The risk-free interest rate assumption is based on observed interest rates appropriate for the terms of our awards. The dividend yield assumption is based on history and the expectation of paying no dividends. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Stock-based compensation expense, when recognized in the 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 *Dervivatives 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 option pricing models 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) 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.

In April, 2014, the FASB issued ASU 2014-08, “Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity”, which in April 2014. 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.

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 March 31, 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 March 31, 2014 in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rule and forms of the Securities and Exchange Commission's (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 March 31, 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 discovered certain presentation errors 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. 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. In light of our discovery of errors in, and our resulting conclusion to restate, our consolidated financial statements that appeared in our originally filed Annual Report on Form 10-K for the year ended September 30, 2013, we expect to increase our efforts in the near term to strengthen our financial reporting functions. Such efforts include our intention to hire a new Chief Financial Officer that is able to serve our Company on a full-time basis, which we have been pursuing during the quarter ended March 31, 2014 by actively seeking candidates for such position.

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 March 31, 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

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 anticipate that none of our product candidates will be commercially available for several years, if at all.

We believe that our current cash and cash equivalents on -hand 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 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 our recent equity financings, each discussed in further detail 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.

On January 30, 2014, we entered into a securities purchase agreement (the “Securities Purchase Agreement”) with nine separate accredited investors providing for our issuance and sale, in a private placement, of an aggregate of 11,400,000 shares of our common stock 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 our common stock (collectively, the “Warrants”), for aggregate gross proceeds to us of approximately $2.85 million (the “Private Placement Financing”).

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: during the period commencing on January 30, 2014 and ending on the 90-day anniversary of the first date on which all the Registrable Securities (as defined in the Securities Purchase 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; during the period commencing on January 30, 2014 and ending on the six-month anniversary of the first date on which all the Registrable Securities (as defined in the Securities Purchase Agreement) are covered by one or more effective registration statements, such investors 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 Securities Purchase Agreement) are covered by one or more effective registration statements and the date on which all such Registrable Securities have sold, 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. If we experience delays in the registration of the Registrable Securities, these terms of the Securities Purchase Agreement and certain applicable securities laws could prohibit or restrict us from pursuing equity financing transactions for what could be an extended period of time. In addition, the Warrants contain certain anti-dilution protections that adjust downward the exercise price of the Warrants in the event we offer, sell and issue securities at a lower consideration price per share than the then-effective exercise price of the Warrants. All of 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 harmful effects on our financial condition and operations. Additionally, certain of those provisions could 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, and we have been required to restate our audited consolidated financial statements as of and for the year ended September 30, 2013. The continuing material weaknesses in our internal control over financial reporting could, if not remediated, result in future restatements of and/or 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 Exchange Act. As disclosed in Item 4 of Part I of this report, management has identified material weaknesses in our disclosure controls and procedures and our internal control over financial reporting. A material weakness is defined as a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our consolidated financial statements will not be prevented or detected on a timely basis. As a result of these material weaknesses, our management concluded that our internal control over financial reporting was not effective as of September 30, 2013, and that our disclosure controls and procedures were not effective as of March 31, 2014.

Additionally, as described in Item 4 of Part I of this report and as disclosed in our Current Report on Form 8-K filed with the SEC on May 1, 2014, on April 25, 2013, we discovered certain presentation errors 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.

We have developed proposed actions aimed at remediating some of the material weaknesses we have identified in our internal control over financial reporting. In light of our discovery of errors in, and our resulting conclusion to restate, our consolidated financial statements that appeared in our originally filed Annual Report on Form 10-K for the year ended September 30, 2013, we expect to increase our efforts in the near term to strengthen our financial reporting functions, including our intention to hire a new Chief Financial Officer that is able to serve our Company on a full-time basis, which we have been pursuing during the quarter ended March 31, 2014 by actively seeking candidates for such position. 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 require further restatements and/or contain material misstatements. Any restatement of our financial results, including without limitation the restatement described above, 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 may become involved in litigation and administrative proceedings that may materially affect us.

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

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 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.

32

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. While our management, which is familiar with these other products, believes that our lead product candidate could be safer and possibly more effective than those competitors, those beliefs may be wrong. Further, most of our competitors have greater resources or capabilities and greater experience in the development, approval and commercialization of medical devices or other products than we do. We may not be able to compete successfully against them. We also compete for funding with other companies in our industry that are focused on discovering and developing novel improvements in surgical bleeding prevention.

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

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

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

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

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

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

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

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

Risks Related to our Intellectual Property

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

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

intellectual property rights we use would materially harm our business, product development programs and prospects.

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

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

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

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

Our research, development and commercialization activities, as well as any product candidates or products resulting from those activities, may infringe or be accused of infringing a patent or other intellectual property under which we do not hold a license or other rights. Third parties may own or control those patents or other rights in the U.S. or abroad. The third parties that own or control those intellectual property rights could bring claims against us that would cause us to incur substantial time, expense, and diversion of management attention. If a patent or other intellectual property infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales, if any, of the applicable product or product candidate that is the subject of the suit. In order to avoid or settle potential claims with respect to any of the patent or other intellectual property rights of third parties, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both. Any such license may not be available on acceptable terms, or at all. Even if we or our future collaborators were able to obtain a license, the rights granted to us or them could be non-exclusive, which could result in our competitors gaining access to the same intellectual property rights and materially negatively affecting the commercialization potential of our planned products. Ultimately, we could be prevented from commercializing one or more product candidates, or be forced to cease some aspects of our business operations, if, as a result of actual or threatened infringement claims, we are unable to enter into licenses on acceptable terms or at all or otherwise settle such claims. Further, if any such claims were successful against us, we could be forced to pay substantial damages. Any of those results could significantly harm our business, prospects and operations.

Risks Related to the Merger and Ownership of our Common Stock

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

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

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

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

Our common stock is a "penny stock."

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

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

Our articles of incorporation authorize the issuance of up to 300,000,000 shares of common stock. Since the closing of the merger on June 26, 2013, we have issued an aggregate of 15,400,000 shares of our common stock in capital-raising transactions, which equals approximately 21.4% of our currently issued and outstanding common stock, and have also issued warrants to acquire up to an additional 38,345,985 shares of our common stock in connection with such capital raising transactions, which, assuming no adjustments to and the full exercise of all such warrants and no other issuances of our common stock, would equal approximately 34.7% of our then-issued and outstanding common stock. In addition to capital -raising activities, other possible business and financial uses for our authorized common stock include, without limitation, future stock splits, acquiring other companies, businesses or products in exchange for shares of common stock, issuing shares of our common stock to partners in connection with strategic alliances, attracting and retaining employees by the issuance of additional securities under our various equity compensation plans, or other transactions and corporate purposes that our Board of Directors deems are in the Company's best interest. Additionally, shares of common stock could be used for anti-takeover purposes or to delay or prevent changes in control or management of the Company. We cannot provide assurances that any issuances of common stock will be consummated on favorable terms or at all, that they will enhance stockholder value, or that shares will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our common stock. If we issue any such additional shares, such issuance will reduce the proportionate ownership and voting power of all current shareholders. Further, such issuance may result in a change of control of our corporation.

Certain terms of our outstanding warrants could result in additional dilution to our existing stockholders.

The number of shares of our common stock into which each of our outstanding warrants is exercisable and the exercise price therefor are subject to adjustment in certain circumstances as set forth in the terms of the warrants, including, without limitation, adjustment to the exercise price of the Warrants issued in the Private Placement Financing in the event of certain subsequent issuances and sales of shares of our common stock (or securities convertible or exercisable into shares of our common stock) at a price per share lower than the then-effective exercise price of the Warrants, in which case the exercise price of the Warrants will be adjusted to equal such lower price per share. In the event any such adjustment is triggered, all or some of our outstanding warrants could become exercisable for a greater number of shares of our common stock and thereby dilute the ownership of our other stockholders upon an exercise thereof. Depending on the terms of any subsequent issuance of securities or other circumstance that might trigger such an adjustment and the number of warrants that are exercised, the amount of any such dilution could be significant.

Future sales of our common stock or rights to purchase common stock, or the perception that such sales could occur, could cause our stock price to fall.

Even after giving effect to the funds raised in recent equity and debt financings, we expect that significant additional capital will be needed in the near-term to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. Any such sales of our common stock by us or resales of our common stock by our existing stockholders could cause the market price of our common stock to decline.

We have filed a registration statement seeking to register for resale the 11,400,000 shares of our common stock issued in the Private Placement Financing, equal to approximately 15.8% of our currently issued and outstanding common stock, and the 34,200,000 shares of our common stock that are currently issuable upon exercise of the Warrants issued in the Private Placement Financing, which, assuming no adjustments to and the full exercise of the Warrants and no other issuances of our common stock, equal approximately 32.2% of our then-issued and outstanding common stock. All such shares would become registered and freely tradable upon the effectiveness of such a registration statement, and, even in the absence of such an effective registration statement, such shares will become eligible for resale in the public market in accordance with Rule 144, as defined and described further in these risk factors below, after specified periods of time have elapsed from their initial issuance. Additionally, we have issued warrants in transactions unrelated to the Private Placement Financing to acquire up to an additional 4,145,985 shares of our common stock, and we are authorized to grant equity awards under the our stock incentive plan to our employees, directors and consultants for up to an aggregate of 10,231,197 shares of our common stock. Any future grants of warrants, options or other securities exercisable or convertible into our common stock, or the exercise or conversion of such shares, and any sales of such shares in the market, or the perception that such sales could occur, could cause our stock price to fall.

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

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

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

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

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

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

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

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

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

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

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

We are a public reporting company in the U.S., and, accordingly, are subject to the information and reporting requirements of the Exchange Act and other federal securities laws, including the obligations imposed by the Sarbanes-Oxley Act of 2002 (the “Sarbanes-Oxley Act”). The costs associated with preparing and filing annual, quarterly and current reports, proxy statements and other information with the SEC in the ordinary course, as well as preparing and filing annual audited and interim unaudited consolidated financial statements, have caused, and could continue to cause, our operational expenses to remain at higher levels or continue to increase.

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

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

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

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

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

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

In the past, securities class action litigation has been brought against companies following periods of volatility of its securities in the marketplace, particularly following a company's initial public offering. Due to the volatility of our stock price, we could be the target of securities litigation in the future. Securities litigation could result in substantial

costs and divert management's attention and resources.

Investment in our common stock involves a high degree of risk. The risk factors described below summarize some of the material risks inherent in and affecting our business. You should carefully consider the following risk factors before making an investment decision. If any of the following risks and uncertainties actually occurs, our business, financial condition, and results of operations could be negatively impacted and you could lose all or part of your investment.

Risks Related to our Business

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

We have incurred losses in each year since our inception and we expect that losses will continue to be incurred in the foreseeable future in the operation of our business. To date, we have financed our operations entirely through equity and debt investments by founders, other investors and third parties, and we expect to continue to rely on these sources of funding, to the extent available in the foreseeable future. Losses from operations have resulted principally from costs incurred in research and development programs and from general and administrative expenses, including significant costs associated with establishing and maintaining intellectual property rights, significant legal and accounting costs pertaining to the closing of the Merger and related regulatory filings, and personnel expenses. We have devoted substantially all of our time, money and efforts to date to the advancement of our technology and raising capital to support our business, and expect to continue to devote significant time, money and efforts to such activities going forward.

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

- develop our principal product candidate, AC5, including further development of the product's composition and conducting preclinical biocompatibility studies;
- raise capital needed to fund our operations;
- 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 anticipate that none of our product candidates will be commercially available for several years, if at all.

We believe that our current cash and cash equivalents on hand 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;
- 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 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, discussed in further detail in these Risk Factors below, and certain terms of the Private Placement Financing, including those discussed in these 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: during the period commencing on January 30, 2014 and ending on the 90-day anniversary of the first date on which all the Registrable Securities (as defined in the Securities Purchase 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; during the period commencing on January 30, 2014 and ending on the six-month anniversary of the first date on which all the Registrable Securities (as defined in the Securities Purchase Agreement) are covered by one or more effective registration statements, such investors 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 Securities Purchase Agreement) are covered by one or more effective registration statements and the date on which all such investors have sold all of the shares of common stock to be registered hereunder, we may not effect or enter into an agreement for and 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 in the event we offer, sell and issue securities at a lower consideration price per share than the then-effective exercise price of the Warrants. Those 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 harmful effects on our financial condition and operations. Additionally, certain of those provisions could 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 there under.

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 statements.

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Management has identified material weaknesses in our internal control over financial reporting as of December 31, 2013. A material weakness is defined as a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our consolidated financial statements will not be prevented or detected on a timely basis. As a result of these material weaknesses, our management concluded that our internal control over financial reporting was not effective based on criteria set forth by the Committee of Sponsoring Organization of the Treadway Commission in 2013 Internal Control—Integrated Framework. We have developed proposed actions aimed at remediating some of these material weaknesses. If our remedial measures are insufficient to address the material weaknesses, or if additional material weaknesses or significant deficiencies in our internal control are discovered or occur in the future, there may be an increased likelihood that our consolidated financial statements contain material misstatements. If that were to occur, we could be required to restate our financial results, which could lead to substantial additional costs for accounting and legal fees and litigation. In addition, even if we are successful in strengthening our controls and procedures, in the future those controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our consolidated financial statements. If we fail to achieve and maintain the adequacy of our internal controls in accordance with applicable standards, we may be unable to conclude that we have effective internal controls over financial reporting. If we cannot produce reliable financial reports, our business and financial condition could be harmed, investors could lose confidence in our reported financial information, or the market price of our stock could decline significantly. Moreover, our reputation with lenders, investors, securities analysts and others may be adversely affected.

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

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

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security 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 our contractors or we 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 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 attain 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 Europe, 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. While our management, which is familiar with these other products, believes that our lead product candidate could be safer and possibly more effective than those competitors, those beliefs may be wrong. Further, most of our competitors have greater resources or capabilities and greater experience in the development, approval and commercialization of medical devices or other products than we do. We may not be able to compete successfully against them. We also compete for funding with other companies in our industry that are focused on discovering and developing novel improvements in surgical bleeding prevention.

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

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

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

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

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

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

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

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

Risks Related to our Intellectual Property

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

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

In addition, our proprietary information, trade secrets and know-how are important components of our intellectual property rights. We seek to protect our proprietary information, trade secrets, know-how and confidential information, in part, with confidentiality agreements with our employees, corporate partners, outside scientific collaborators, sponsored researchers, consultants and other advisors. We also have invention or patent assignment agreements with our employees and certain consultants and advisors. If our employees or consultants breach those agreements, we may not have adequate remedies for any of those breaches. In addition, our proprietary information, trade secrets and know-how may otherwise become known to or be independently developed by others. Enforcing a claim that a party

illegally obtained and is using our proprietary information, trade secrets and know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect trade secrets. Costly and time consuming litigation could be necessary to seek to enforce and determine the scope of our intellectual property rights, and failure to obtain or maintain protection thereof could adversely affect our competitive business position and results of operations.

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

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

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

Our research, development and commercialization activities, as well as any product candidates or products resulting from those activities, may infringe or be accused of infringing a patent or other intellectual property under which we do not hold a license or other rights. Third parties may own or control those patents or other rights in the U.S. or abroad. The third parties that own or control those intellectual property rights could bring claims against us that would cause us to incur substantial time, expense, and diversion of management attention. If a patent or other intellectual property infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales, if any, of the applicable product or product candidate that is the subject of the suit. In order to avoid or settle potential claims with respect to any of the patent or other intellectual property rights of third parties, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both. Any such license may not be available on acceptable terms, or at all. Even if we or our future collaborators were able to obtain a license, the rights granted to us or them could be non-exclusive, which could result in our competitors gaining access to the same intellectual property rights and materially negatively affecting the commercialization potential of our planned products. Ultimately, we could be prevented from commercializing one or more product candidates, or be forced to cease some aspects of our business operations, if, as a result of actual or threatened infringement claims, we are unable to enter into licenses on acceptable terms or at all or otherwise settle such claims. Further, if any such claims were successful against us, we could be forced to pay substantial damages. Any of those results could significantly harm our business, prospects and operations.

Risks Related to the Merger and Ownership of our Common Stock

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

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

We do not now, and are not expected to in the foreseeable future, meet the initial listing standards of the Nasdaq Stock Market or any other national securities exchange. We presently anticipate that our common stock will continue to be

quoted on the OTCQB or another over-the-counter quotation system. In those venues, our stockholders may find it difficult to obtain accurate quotations as to the market value of their shares of our common stock, and may find few buyers to purchase their stock and few market makers to support its price.

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

Our common stock is a "penny stock."

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

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

Our articles of incorporation authorize the issuance of up to 300,000,000 shares of common stock. Upon the closing of the Private Placement Financing, we issued an aggregate of 11,400,000 shares of our common stock, which equals approximately 16% of our currently issued and outstanding common stock. Upon the closing of the Private Placement Financing, we also issued Warrants to acquire up to an additional 34,200,000 shares of our common stock, which, assuming no adjustments to and the full exercise of the Warrants and no other issuances of our common stock, would equal approximately 32% of our then-issued and outstanding common stock. In addition to capital raising activities, other possible business and financial uses for our authorized common stock include, without limitation, future stock splits, acquiring other companies, businesses or products in exchange for shares of common stock, issuing shares of our common stock to partners in connection with strategic alliances, attracting and retaining employees by the issuance of additional securities under our various equity compensation plans, or other transactions and corporate purposes that our Board of Directors deems are in the Company's best interest. Additionally, shares of common stock could be used for anti-takeover purposes or to delay or prevent changes in control or management of the Company. We cannot provide assurances that any issuances of common stock will be consummated on favorable terms or at all, that they will enhance stockholder value, or that they will not adversely affect our business or the trading price of our common stock. The issuance of any such shares will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our common stock. If we issue any such additional shares, such issuance will reduce the proportionate ownership and voting power of all current shareholders. Further, such issuance may result in a change of control of our corporation.

Certain terms of the Warrants could result in additional dilution to our existing stockholders.

The number of shares of our common stock into which each of the Warrants issued in connection with the Private Placement Financing is exercisable and the exercise price therefore are subject to adjustment as set forth in the Warrants, including, without limitation, adjustment to the exercise price of the Warrants in the event of certain

subsequent issuances and sales of shares of our common stock (or securities convertible or exercisable into shares of our common stock) at a price per share lower than the then-effective exercise price of the Warrants, in which case the exercise price of the Warrants shall be adjusted to equal such lower price per share, as well as customary adjustments in the event of stock dividends and splits, subsequent rights offerings and pro rata distributions to our common stockholders. In the event any such adjustment is triggered, the Warrants could become exercisable for a greater number of shares of our common stock and thereby dilute the ownership of our other stockholders if those Warrants are exercised. Depending on the terms of any subsequent issuance of securities or other circumstance that might trigger such an adjustment and the number of Warrants that are exercised, the amount of any such dilution could be significant.

Future sales of our common stock or rights to purchase common stock, or the perception that such sales could occur, could cause our stock price to fall.

After giving effect to the funds raised in the Private Placement Financing, we expect that significant additional capital will be needed in the near-term to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. Any such sales of our common stock by us or re-sales of our common stock by our existing stockholders could cause the market price of our common stock to decline.

Upon the effectiveness of the registration statement of which this prospectus forms a part, approximately 16% of our currently issued and outstanding common stock will become registered and freely tradable, and, assuming no adjustments to and the full exercise of the Warrants and no other issuances of our common stock, up to 32% of our then-issued and outstanding common stock would become registered and freely tradable. The sales of such shares in the market, or the perception that such sales could occur following the effectiveness of the registration statement of which this prospectus forms a part, could cause our stock price to fall. Additionally, pursuant to the 2013 Plan, we are authorized to grant equity awards to our employees, directors and consultants for up to an aggregate of 10,231,197 shares of our common stock, and there are additional currently outstanding warrants to acquire up to 4,145,985 shares of our common stock. Any future grants of options, warrants or other securities exercisable or convertible into our common stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our common stock.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Item 6. Exhibits

Exhibit	Description
4.1	Form of Series A Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed by the Company with the SEC on January 31, 2014)
4.2	Form of Series B Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed by the Company with the SEC on January 31, 2014)
4.3	Form of Series C Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K filed by the Company with the SEC on January 31, 2014)
10.1	Securities Purchase Agreement dated January 30, 2014, by and among Arch Therapeutics, Inc. and the investors listed on the Schedule of Buyers attached thereto (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Company with the SEC on January 31, 2014)
10.2	Form of Registration Rights Agreement, entered into on February 4, 2014 by and among Arch Therapeutics, Inc. and each of the buyers named therein (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed by the Company with the SEC on January 31, 2014)
10.3	Securities Transfer Agreement dated February 28, 2014 by and among Arch Therapeutics, Inc., Punit Dhillon and 0903746 B.C. Ltd. (incorporated by reference to Exhibit 10.20 to the Registration Statement on Form S-1/A filed by the Company with the SEC on May 5, 2014)
10.4#	First Amendment to Executive Employment Agreement, dated March 23, 2014, by and between Arch Therapeutics, Inc. and Terrence W. Norchi (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Company with the SEC on March 26, 2014)
10.5#	

	First Amendment to Executive Employment Agreement, dated March 23, 2014, by and between Arch Therapeutics, Inc. and William M. Cotter (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed by the Company with the SEC on March 26, 2014)
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities and Exchange Act of 1934
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities and Exchange Act of 1934
32.1*	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, executed by Terrence W. Norchi, President and Chief Executive Officer, and Alan T. Barber, Chief Financial Officer
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

Management contract or compensatory plan or arrangement.

SIGNATURE

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

ARCH THERAPEUTICS, INC.

Date: May 15, 2014 By: /s/ TERRENCE W. NORCHI
Terrence W. Norchi
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 15, 2014 By: /s/ ALAN T. BARBER
Alan T. Barber
Chief Financial Officer
(Principal Financial and Accounting Officer)