Arch Therapeutics, Inc.
Form 424B3
April 28, 2016

Filed Pursuant to Rule 424(b)(3)

Registration No. 333-194745

PROSPECTUS SUPPLEMENT NO. 8 DATED APRIL 28, 2016

TO

PROSPECTUS DATED JANUARY 15, 2016

(AS SUPPLEMENTED)

ARCH THERAPEUTICS, INC.

PROSPECTUS

Up to 12,200,000 Shares of Common Stock

This Prospectus Supplement No. 8 supplements the prospectus of Arch Therapeutics, Inc. ("the "**Company**", "**we**", "**us**", or "**our**") dated January 15, 2016 (as supplemented to date, the "**Prospectus**") with the following attached documents which we filed with the Securities and Exchange Commission:

A. Our Current Report on Form 8-K filed with the Securities and Exchange Commission on April 25, 2016

B. Our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on April 28, 2016

This Prospectus Supplement No. 8 should be read in conjunction with the Prospectus, which is required to be delivered with this Prospectus Supplement. This Prospectus Supplement updates, amends and supplements the information included in the Prospectus. If there is any inconsistency between the information in the Prospectus and this Prospectus Supplement, you should rely on the information in this Prospectus Supplement.

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

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

You should rely only on the information contained in the Prospectus, as supplemented or amended by this Prospectus Supplement No. 1 and any other Prospectus Supplement or amendment thereto. We have not authorized anyone to provide you with different information.

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

The date of this Prospectus Supplement No. 8 is April 28, 2016

INDEX TO FILINGS

ANNEX A

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): **April 25, 2016**

ARCH THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Nevada	**000-54986**	**46-0524102**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

235 Walnut Street, Suite 6
Framingham, Massachusetts **01702**
(Address of principal executive offices) (Zip Code)

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

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

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

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

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

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

Item 8.01 Other Events.

On April 25, 2016, Arch Therapeutics, Inc. (the "**Company**") issued a press release announcing that the Company has received a notice of allowance from the U.S. Patent Office on a broad method of use patent that covers systemically administering the Company's self-assembling technology for treating damaged extracellular matrix and leaky tight junctions. The text of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibit

(d) Exhibits

Exhibit	Description
99.1	Press Release issued by Arch Therapeutics, Inc. on April 25, 2016

SIGNATURES

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

ARCH THERAPEUTICS, INC.

Dated: April 25, 2016 By:/s/ Terrence W. Norchi, M.D.
Name: Terrence W. Norchi, M.D.
Title: President, Chief Executive Officer

Exhibit List

Exhibit	Description
99.1	Press Release issued by Arch Therapeutics, Inc. on April 25, 2016

Exhibit 99.1

Arch Therapeutics Receives Notice of Allowance for Patent Covering Systemic Applications for Self-Assembling Peptides

U.S. Patent Addresses Use of the Self-Assembling Peptide Barrier Technology to Treat Disorders Involving Leaky Tight Junctions and Extracellular Matrix

FRAMINGHAM, MA – April 25, 2016 -- Arch Therapeutics, Inc. (OTCQB: ARTH) ("Arch" or the "Company"), developer of the AC5 Surgical Hemostatic Device™ (AC5™) for use in controlling bleeding and fluid loss in order to provide faster and safer surgical and interventional care, received a notice of allowance from the U.S. Patent Office for a broad method-of-use patent that covers systemically administering the Company's self-assembling technology for treating damaged extracellular matrix and leaky tight junctions.

Many disorders are associated with leakage around blood vessels and within the tight junctions between cells. Such leakage can lead to fluid invading the tissues, causing a loss in blood pressure, organ dysfunction or failure, and death. Some examples include inflammatory bowel disease, sepsis and ischemic stroke.

Dr. Terrence W. Norchi, President and CEO of Arch Therapeutics, said, "This important patent lends additional support to Arch's planned products. It is another example of Arch's inventiveness in exploring better ways to address a range of areas of unmet or poorly met medical needs with our self-assembling peptide technology."

Arch has filed its own patent applications and, in addition, has licensed worldwide exclusive rights to certain patents and patent applications assigned jointly to MIT and Versitech Limited, the technology transfer company of the University of Hong Kong, and worldwide non-exclusive rights to another portfolio of patents assigned jointly to MIT and Versitech Limited. The applications and rights cover self-assembling compositions and methods of making and using such compositions for medical applications, including stopping bleeding; preventing the movement of bodily fluids, contaminants, etc., within or on the human body; preventing adhesions; treatment of leaky or damaged tight junctions; and reinforcement of weak or damaged vessels, such as aneurysms, with patents covering this technology in the United States, Europe, Japan, Canada, Israel, Australia, Hong Kong and China. Additional patent applications are pending in multiple jurisdictions.

About Arch Therapeutics, Inc.

Arch Therapeutics, Inc. is a medical device company developing a novel approach to stop bleeding (hemostasis) and control leaking (sealant) during surgery and trauma care. Arch is developing products based on an innovative self-assembling peptide technology platform to make surgery and interventional care faster and safer for patients. Arch's flagship development stage product candidate, known as the AC5 Surgical Hemostatic Device™, is being designed to achieve hemostasis in surgical procedures.

Notice Regarding Forward-Looking Statements

This news release contains “forward-looking statements” as that term is defined in Section 27(a) of the Securities Act of 1933, as amended, and Section 21(e) of the Securities Exchange Act of 1934, as amended. Statements in this press release that are not purely historical are forward-looking statements and include any statements regarding beliefs, plans, expectations or intentions regarding the future. Such forward-looking statements include, among other things, references to novel technologies and methods, our business and product development plans and projections, or market information. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, the inherent uncertainties associated with developing new products or technologies and operating as a development stage company, our ability to retain important members of our management team and attract other qualified personnel, our ability to raise the additional funding we will need to continue to pursue our business and product development plans, our ability to obtain required regulatory approvals, our ability to develop and commercialize products based on our technology platform, and market conditions. These forward-looking statements are made as of the date of this news release, and we assume no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements. Although we believe that any beliefs, plans, expectations and intentions contained in this press release are reasonable, there can be no assurance that any such beliefs, plans, expectations or intentions will prove to be accurate. Investors should consult all of the information set forth herein and should also refer to the risk factors disclosure outlined in the reports and other documents we file with the SEC, available at www.sec.gov.

On Behalf of the Board,

Terrence W. Norchi, MD

Arch Therapeutics, Inc.

Contact:

ARTH Investor Relations

Toll Free: +1-855-340-ARTH (2784) (US and Canada)

Email: investors@archtherapeutics.com

Website: www.archtherapeutics.com

or

Richard Davis

Chief Financial Officer

Arch Therapeutics, Inc.

Phone: 617-431-2308

Email: rdavis@archtherapeutics.com

Website: www.archtherapeutics.com

ANNEX B

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

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

THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2016

Commission File Number: **000-54986**

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

Nevada	**46-0524102**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
235 Walnut Street, Suite 6 **Framingham, MA**	**01702**
(Address of principal executive offices)	(Zip Code)

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

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

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

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

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

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

As of April 27, 2016, 116,827,248 shares of the registrant’s common stock were outstanding.

ARCH THERAPEUTICS, INC.

Quarterly Report on Form 10-Q

For the Three and Six Months Ended March 31, 2016

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Arch Therapeutics, Inc.
Consolidated Balance Sheets
As of March 31, 2016 (Unaudited) and September 30, 2015

	March 31, 2016 (Unaudited)	September 30, 2015
ASSETS		
Current assets:		
Cash	$ 1,669,249	$ 3,960,100
Prepaid expenses and other current assets	90,119	42,919
Total current assets	1,759,368	4,003,019
Total assets	$ 1,759,368	$ 4,003,019
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 135,615	$ 231,761
Accrued expenses and other liabilities	163,386	245,478
Convertible notes, net of unamortized discount	100,000	473,747
Current derivative liabilities	-	335,092
Total current liabilities	399,001	1,286,078
Long-term liabilities:		
Note payable, net of unamortized discount	972,353	966,824
Accrued interest, net of current portion	270,500	210,000
Total long-term liabilities	1,242,853	1,176,824
Total liabilities	1,641,854	2,462,902
Commitments and contingencies		
Stockholders’ equity:		
Common stock, $0.001 par value, 300,000,000 shares authorized, 110,423,588 and 107,592,205 shares issued and outstanding as of March 31, 2016 and September 30, 2015, respectively	110,424	107,392
Additional paid-in capital	18,139,021	17,154,945

Accumulated deficit	(18,131,931)	(15,722,220)
Total stockholders’ equity	117,514	1,540,117
Total liabilities and stockholders' equity	$ 1,759,368	$ 4,003,019

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

Arch Therapeutics, Inc.
Consolidated Statements of Operations (Unaudited)
For the Three and Six Months Ended March 31, 2016 and 2015

	Three Months Ended March 31, 2016	Three Months Ended March 31, 2015	Six Months Ended March 31, 2016	Six Months Ended March 31, 2015
Revenues	$ -	$ -	$ -	$ -
Operating expenses:				
General and administrative expenses	868,433	853,177	1,733,946	1,723,533
Research and development expenses	386,285	402,495	800,288	802,230
Total operating expenses	1,254,718	1,255,672	2,534,234	2,525,763
Operating loss	(1,254,718)	(1,255,672)	(2,534,234)	(2,525,763)
Other income (expense):				
Interest expense	(66,823)	(50,556)	(210,569)	(78,320)
Gain on exercise of warrants and conversion of debt	13,503	-	142,964	224,000
Loss on warrant derivative modification	-	(624,016)	-	(1,924,186)
Decrease to fair value of derivative	54,982	1,096,278	192,128	3,849,448
Total other income	1,662	421,706	124,523	2,070,942
Net loss	$ (1,253,056)	$ (833,966)	$ (2,409,711)	$ (454,821)
Earnings per share - basic and diluted				
Net loss per common share - basic and diluted	$ (0.01)	$ (0.01)	$ (0.02)	$ (0.01)
Weighted common shares - basic and diluted	109,524,010	76,076,487	109,069,824	74,716,734

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

Arch Therapeutics, Inc.
Consolidated Statements of Cash Flows (Unaudited)
For the Six Months Ended March 31, 2016 and 2015

	Six Months Ended March 31, 2016	Six Months Ended March 31, 2015
Cash flows from operating activities:		
Net loss	$ (2,409,711)	$ (454,821)
Adjustments to reconcile net loss to cash used in operating activities:		
Stock-based compensation	358,330	609,272
Noncash interest expense on notes payable	210,569	78,320
Issuance of restricted stock for services	52,500	8,625
Gain on exercise of warrants and conversion of debt	(142,964)	(224,000)
Loss on warrant derivative modification	-	1,924,186
Decrease to fair value of derivative	(192,128)	(3,849,448)
Changes in operating assets and liabilities:		
(Increase) decrease in:		
Prepaid expenses and other current assets	(47,200)	11,029
Increase (decrease) in:		
Accounts payable	(96,146)	28,267
Accrued expenses and other liabilities	(64,101)	58,650
Net cash used in operating activities	(2,330,851)	(1,809,920)
Cash flows from financing activities:		
Proceeds from exercise of warrants	40,000	800,000
Proceeds from issuance of convertible notes	-	750,000
Net cash provided by financing activities	40,000	1,550,000
Net increase in cash	(2,290,851)	(259,920)
Cash, beginning of period	3,960,100	833,520
Cash and cash equivalents, end of period	$ 1,669,249	$ 573,600
Non-cash financing activities		
Conversion of 8% convertible notes and accrued interest to common stock	$ 536,278	$ -

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

ARCH THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

1. BASIS OF PRESENTATION AND DESCRIPTION OF BUSINESS

Organization and Description of Business

Arch Therapeutics, Inc., (together with its subsidiary, the "Company" or "Arch") was incorporated under the laws of the State of Nevada on September 16, 2009, under the name "Almah, Inc." to pursue the business of distributing automobile spare parts online. Effective June 26, 2013, the Company completed a merger (the "Merger") with Arch Biosurgery, Inc. (formerly known as Arch Therapeutics, Inc.), a Massachusetts corporation ("ABS"), and Arch Acquisition Corporation ("Merger Sub"), the Company's wholly owned subsidiary formed for the purpose of the transaction, pursuant to which Merger Sub merged with and into ABS and ABS thereby became the wholly owned subsidiary of the Company. As a result of the acquisition of ABS, the Company abandoned its prior business plan and changed its operations to the business of a biotechnology company. Our current principal offices are located in Framingham, Massachusetts.

For financial reporting purposes, the Merger represented a "reverse merger". ABS was deemed to be the accounting acquirer in the transaction and the predecessor of Arch. Consequently, the accumulated deficit and the historical operations that are reflected in the Company's unaudited interim consolidated financial statements prior to the Merger 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.

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

The Company has generated no operating revenues to date, and is devoting substantially all of its efforts toward product research and development. To date, the Company has principally raised capital through debt borrowings, the issuance of convertible debt, and the issuance of units consisting of common stock and warrants.

The Company expects to incur substantial expenses for the foreseeable future relating to research, development and commercialization of its potential products. The Company will be required to raise additional capital, obtain alternative means of financial support, or both, prior to or during October 2016 in order to continue to fund operations. However, there can be no assurance that the Company will be successful in securing additional resources when needed, on terms acceptable to the Company, if at all. Therefore, there exists substantial doubt about the Company's ability to continue as a going concern. The unaudited interim consolidated financial statements do not include any adjustments related to the recoverability of assets that might be necessary despite this uncertainty.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

Although we believe that the disclosures in these unaudited interim consolidated financial statements are adequate to make the information presented not misleading, certain information normally included in the footnotes prepared in accordance with US GAAP has been omitted as permitted by the rules and regulations of the Securities and Exchange Commission ("SEC"). These unaudited interim consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2015, filed with the SEC on December 11, 2015.

For a complete summary of our significant accounting policies, please refer to Note 2 included in Item 15 of our Form 10-K for the fiscal year ended September 30, 2015. There have been no material changes to our significant accounting policies during the six months ended March 31, 2016.

Basis of Accounting

The unaudited interim consolidated financial statements include the accounts of Arch Therapeutics, Inc. and its wholly owned subsidiary, Arch Biosurgery, Inc., a biotechnology company. All intercompany accounts and transactions have been eliminated in consolidation.

The Company is in the development stage and is devoting substantially all of its efforts to developing technologies, raising capital, establishing customer and vendor relationships, and recruiting new employees.

Use of Estimates

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

Recently Issued Accounting Guidance

Accounting Standards Update (ASU) 2016-09, “Compensation—Stock Compensation (Topic 718) Improvements to Employee Share-Based Payment Accounting” was issued by the Financial Accounting Standards Board (FASB) in March 2016. The purpose of this amendment is to simplify several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The amendments in this Update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2016. Early adoption is permitted. The Company does not believe that this guidance will have a material impact on its consolidated results of operations, financial position or disclosures.

ASU 2016-02, “Leases (Topic 842)” was issued by the FASB in February 2016. The purpose of this amendment requires the recognition of lease assets and lease liabilities by lessees for those leases previously classified as operating leases. The amendments in this Update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted. The Company does not believe that this guidance will have a material impact on its consolidated results of operations, financial position or disclosures.

ASU 2015-17, “Income Taxes (Topic 740) – Balance Sheet Classification of Deferred Taxes” was issued by the FASB in November 2015. The purpose of this amendment requires deferred tax assets and liabilities to be classified as noncurrent in a classified statement of financial position. The amendments in this Update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2017. Early adoption is permitted. The Company does not believe that this guidance will have a material impact on its consolidated results of operations, financial position or disclosures.

ASU 2015-03, “Interest – Imputation of Interest (Subtopic 835-30) Simplifying the Presentation of Debt Issuance Costs” was issued by the FASB in April 2015. The purpose of this amendment requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The amendments in this Update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted. The Company does not believe that this guidance will have a material impact on its consolidated results of operations, financial position or disclosures.

ASU 2015-02, “Consolidation (Topic 810) – Amendments to the Consolidation Analysis”, was issued by the FASB in February 2015. The purpose of this amendment is to change the analysis that a reporting entity must perform to determine whether it should consolidate certain types of legal entities. The amendments in this Update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted. The Company does not believe that this guidance will have a material impact on its consolidated results of operations or financial position or disclosures.

ASU 2014-16, “Derivatives and Hedging (Topic 815)” was issued by the FASB in November 2014. The primary purpose of the ASU is to determine whether the host contract in a Hybrid Financial Instrument issued in the form of a share is more akin to debt or equity. ASU 2014-16 is effective for public entities for the fiscal years and interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted. The Company does not believe that this guidance will have a material impact on its consolidated results of operations or financial position or disclosures.

ASU 2014-15, “Presentation of Financial Statements-Going Concern (Subtopic 205-40) – Disclosure of Uncertainties about an Entity’s Ability to ‘Continue as a Going Concern” was issued by the FASB in August 2014. The primary purpose of the ASU is to provide guidance in GAAP about management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and to provide related footnote disclosures. The amendments should reduce diversity in the timing and content of footnote disclosure. ASU 2014-15 is effective for the annual period ending after December 15, 2016, and for the annual periods and interim periods thereafter. Early adoption is permitted. 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, financial position or disclosures.

ASU 2014-12, “Compensation-Stock Compensation (Topic 718) – Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period” was issued by the FASB in June 2014. ASU 2014-12 requires that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. ASU 2014-12 is effective for public business entities for annual periods and interim periods within the annual periods beginning after December 15, 2015. Early adoption is permitted. 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, financial position or disclosures.

ASU 2014-09, “Revenue from Contracts with Customers (Topic 606) was issued by the FASB in May 2014. The primary purpose of the ASU is to develop a common revenue standard for revenue recognition between the FASB and the International Accounting Standards Board (IASB). The ASU removes inconsistencies and weaknesses in revenue requirements, provides a more robust framework for addressing revenue issues, and improves comparability of revenue recognition practices across entities, industries, jurisdictions and capital markets, among other items. We are a development stage company and do not currently generate revenue. ASU 2014-09 is effective for public business entities for annual periods beginning after December 15, 2017. While we are a development stage company and do not currently generate revenue, we currently anticipate generating revenue by the effective date of this ASU and therefore will be subject to this guidance. 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, financial position or disclosures.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. The Company had no cash equivalents as of March 31, 2016 and September 30, 2015.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist primarily of cash. The Company maintains its cash in bank deposit accounts, which, at times, may exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk on cash.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful life of the related asset. Upon sale or retirement, the cost and accumulated depreciation are eliminated from their respective accounts, and the resulting gain or loss is included in income or loss for the period. Repair and maintenance expenditures are charged to expense as incurred.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment when circumstances indicate the carrying value of an asset may not be recoverable in accordance with ASC 360, *Property, Plant and Equipment*. For assets that are to be held and used, impairment is recognized when the estimated undiscounted future cash flows associated with the asset or group of assets is less than their carrying value. If impairment exists, an adjustment is made to write the asset down to its fair value, and a loss is recorded as the difference between the carrying value and fair value. Fair values are determined based on quoted market values, discounted cash flows or internal and external appraisals, as applicable. Assets to be disposed of are carried at the lower of carrying value or estimated net realizable value. For the three and six month periods ended March 31, 2016 and 2015 there were no impairments of long-lived assets.

Convertible Debt

The Company records a discount to convertible notes for the intrinsic value of conversion options embedded in debt instruments based upon the differences between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the note. Debt discounts under these arrangements are amortized to noncash interest expense using the effective interest rate method over the term of the related debt through their date of maturity. If a security or instrument becomes convertible only upon the occurrence of a future event outside the control of the Company, or, is convertible from inception, but contains conversion terms that change upon the occurrence of a future event, then any contingent beneficial conversion feature is measured and recognized when the triggering event occurs and the contingency has been resolved.

Income Taxes

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

The Company provides 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. The Company has no reserves related to uncertain tax positions as of March 31, 2016 and September 30, 2015.

Research and Development

The Company expenses internal and external research and development costs, including costs of funded research and development arrangements, in the period incurred.

Accounting for Stock-Based Compensation

The Company accounts for employee stock-based compensation in accordance with the guidance of ASC 718, *Compensation-Stock Compensation*, which requires all share-based payments to employees, including grants of employee stock options, to be recognized in the consolidated financial statements based on their fair values. The Company accounts for non-employee stock-based compensation in accordance with the guidance of ASC 505, *Equity,* 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. ASC 505 requires the Company to re-measure the fair value of stock options issued to non-employees at each reporting period during the vesting period or until services are complete.

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

The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by the fair value of the common stock and a number of other assumptions, including expected volatility, expected life, risk-free interest rate, and expected dividends. The Company has a limited history of market prices of its common stock, and as such volatility is estimated in accordance with ASC 718-10-S99 Staff Accounting Bulletin ("SAB") No. 107, *Share-Based Payment* ("SAB No. 107"), using historical volatilities of similar public entities. The Company uses a simplified method for all "plain vanilla" options, as defined in SAB No. 107 and the contractual term for all other employee and non-employee awards to estimate the expected life. 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.

Fair Value Measurements

The Company measures both financial and nonfinancial assets and liabilities in accordance with ASC 820, *Fair Value Measurements and Disclosures*. The standard created a fair value hierarchy which prioritizes the inputs to valuation techniques used to measure fair value into three broad levels as follows: Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities; Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and Level 3 inputs are unobservable inputs that reflect the Company's expectations about the assumptions market participants would use in pricing the asset or liability.

At March 31, 2016 and September 30, 2015, the carrying amounts of cash, accounts payable, accrued liabilities, and convertible notes approximate fair value because of their short-term nature. The fair value of note payable, which is influenced by interest rates and the company's liquidity, approximates carrying value.

Subsequent Events

The Company evaluated all events or transactions that occurred through April 27, 2016 the date which these unaudited interim consolidated financial statements were available to be issued. The Company disclosed material subsequent events in Note 9 of these unaudited interim consolidated financial statements.

Going Concern Basis of Accounting

The Company does not currently believe its existing cash resources are sufficient to meet its anticipated needs during the next twelve months. As reflected in the unaudited interim consolidated financial statements, the Company has an accumulated deficit, has suffered significant net losses and negative cash flows from operations, and has limited working capital. The 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, 2016, there is substantial doubt about our ability to continue as a going concern. The unaudited interim consolidated financial statements included in this report do not include any adjustments that might be necessary should operations discontinue. The Company expects to incur substantial expenses for the foreseeable future for the research, development and commercialization of its potential products. In addition, the Company will require additional financing in order to seek to license or acquire new assets, research and develop any potential patents and the related compounds, and obtain any further intellectual property that the Company may seek to acquire. The Company does not have sufficient cash to support its current operating plan. The Company will be required to raise additional capital, obtain alternative means of financial support, or both, in order to continue to fund operations. Therefore, there exists substantial doubt about the Company's ability to continue as a going concern. Historically, the Company has funded its operations primarily through equity and debt financings.

3.STOCK-BASED COMPENSATION

2013 Stock Incentive Plan

On June 18, 2013, the Company established the 2013 Stock Incentive Plan (the "2013 Plan"). Under the 2013 Plan, during the fiscal year ended September 30, 2015, a maximum number of 13,114,256 shares of the Company's authorized and available common stock could be issued in the form of: options, stock appreciation rights, sales or bonuses of restricted stock, restricted stock units or dividend equivalent rights, and an award may consist of one such security or benefit, or two or more of them in any combination or alternative. The 2013 Plan provides that on the first business day of each fiscal year commencing with fiscal year 2014, the number of shares of our common stock reserved for issuance under the 2013 Plan for all awards except for incentive stock option awards will be subject to increase by an amount equal to the lesser of (A) 3,000,000 Shares, (B) four (4) percent of the number of shares outstanding on the last day of the immediately preceding fiscal year of the Company, or (C) such lesser number of shares as determined by the Company's Board of Directors (the "Board"). The exercise price of each option shall be the fair market value as determined in good faith by the Board at the time each option is granted. On October 1, 2015, the aggregate number of authorized shares under the Plan was further increased by 3,000,000 shares to a total of 16,114,256 shares.

As of March 31, 2016, a total of 8,479,212 options had been issued to employees and directors and 4,652,500 options had been issued to consultants. The exercise price of each option has either been equal to the closing price of a share of our common stock on the date of grant or has been determined to be in compliance with Internal Revenue Section 409A.

Share-based awards

During the three and six months ended March 31, 2016, the Company did not grant options to employees and directors or to consultants to purchase shares of common stock under the 2013 Plan.

The Company recognizes compensation expense for stock option awards on a straight-line basis over the applicable service period of the award. The service period is generally the vesting period, with the exception of options granted subject to a consulting agreement, whereby the option vesting period and the service period are defined pursuant to the terms of the consulting agreement. Share-based compensation expense for awards outstanding during the three and six months ended March 31, 2016 was based on the fair market value at period end or grant date fair value estimated using the Black-Scholes option pricing model. The following assumptions were used to calculate the fair value of share based compensation for the three and six months ended March 31, 2016; expected volatility, 76.57% - 119.44%, risk-free interest rate, 0.58% - 2.40%, expected dividend yield, 0.00%, expected term, 1 to 10 years.

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

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

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

Stock compensation plan activity is as follows:

Common Stock Options

Stock compensation activity under the 2013 Plan for the six months ended March 31, 2016 follows:

	Option Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at September 30, 2015	10,776,500	$ 0.30	-	$ -
Awarded	-	-	-	-
Exercised	-	-	-	-
Forfeited	(37,500)	$ 0.22	-	-
Outstanding at March 31, 2016	10,739,000	$ 0.31	5.67	593,828
Vested	9,816,751	$ 0.31	4.87	434,330
Vested and expected to vest at March 31, 2016	10,739,000	$ 0.31	5.67	593,828

As of March 31, 2016, 4,381,704 shares are available for future grants under the 2013 Plan. Share-based compensation expense recorded in the Company’s unaudited interim consolidated statements of operations for the three months ended March 31, 2016 and 2015 resulting from outstanding stock option awards to the Company’s employees, directors and consultants was approximately $210,000 and $331,000, respectively. Of this amount during the three months ended March 31, 2016 and 2015, approximately $114,000 and $153,000 respectively was recorded to research and development expenses, and approximately $96,000 and $178,000, respectively was recorded in general and administrative expenses in the Company’s unaudited interim consolidated statements of operations. Share-based compensation expense recorded in the Company’s unaudited interim consolidated statements of operations for the six months ended March 31, 2016 and 2015 resulting from outstanding stock option awards to the Company’s employees, directors and consultants was approximately $358,000 and $609,000, respectively. Of this amount during the six months ended March 31, 2016 and 2015, approximately $168,000 and $274,000 respectively was recorded to research and development expenses, and approximately $190,000 and $335,000, respectively was recorded in general and administrative expenses in the Company’s unaudited interim consolidated statements of operations.

As of March 31, 2016, there is approximately $219,000 of unrecognized compensation expense related to unvested stock-based compensation arrangements granted under the 2013 Plan. That cost is expected to be recognized over a weighted average period of 1.18 years.

4. 2015 RESTRICTED STOCK

On August 6, 2015, we entered into separate consulting agreements with two investor relations firms, Excelsior Global Advisors LLC ("**Excelsior**") and Acorn Management Partners, LLC ("**Acorn**"). In consideration of the services to be provided under and in accordance with the terms of each consulting agreement, we issued 300,000 shares of Common Stock subject to time-based vesting restrictions to each of Excelsior and John R. Exley, Acorn's Chief Executive Officer and the party designated by Acorn to receive its shares, at an agreed upon value of $0.35 per share, which was the closing price of our common stock on August 6, 2015. 150,000 of the shares of common stock granted to each of Excelsior and Mr. Exley vested immediately upon issuance, and the remaining 150,000 shares were scheduled to vest in 75,000, 50,000 and 25,000 share increments on September 4, 2015, October 2, 2015, and November 4, 2015, respectively. The issuance and sale of the shares of Common Stock to Excelsior and Acorn has not been registered under the Securities Act, and such securities may not be offered or sold in the United States absent registration under or exemption from the Securities Act and any applicable state securities laws. The securities were issued and sold in reliance upon an exemption from registration afforded by Section 4(a)(2) of the Securities Act based on the following facts: each of Excelsior and Acorn has represented that it is an accredited investor as defined in Regulation D promulgated under the Securities Act; that it is acquiring the securities for investment only and not with a view towards, or for resale in connection with, a distribution thereof in violation of applicable securities laws; that it understood that the securities would be issued as restricted securities and as a result, it must bear the economic risk of its investment in the securities for an indefinite period of time.

Restricted stock activity for the six months ended March 31, 2016 is as follows:

	Restricted Stock
Non Vested at September 30, 2015	150,000
Awarded	-
Vested	(150,000)
Forfeited	-
Non Vested at March 31, 2016	-

The weighted average restricted stock award date fair value information for the six months ended March 31, 2016 is as follows:

Non Vested at September 30, 2015	$0.35
Awarded	-
Vested	0.35
Forfeited	-
Non Vested at March 31, 2016	$-

For the three and six months ended March 31, 2016, compensation expense recorded for the restricted stock awards was $0 and $52,500, respectively.

5.8% CONVERTIBLE NOTES

Beginning March 11, 2015 and through March 13, 2015, the Company entered into a series of substantially similar subscription agreements (each a “Subscription Agreement”) with each of Anson Investments Master Fund, Ltd., Equitec Specialists, LLC and Capital Ventures International (collectively, the “Note Investors”) pursuant to which the Company issued unsecured 8% Convertible Notes (the “Notes”, and such transaction, the “Notes Offering”) to the Note Investors in the aggregate principal amount of $750,000. On the closing of the Notes Offering on March 13, 2015 (the “Closing Date”), each Note Investor was issued a Note in the principal amount of $250,000. The Company did not engage any underwriter or placement agent in connection with the Notes Offering.

During the three months ended March 31, 2016, $195,000 of Notes and $15,381 of accrued interest were converted into 1,051,904 shares of the Company’s Common Stock. During the six months ended March 31, 2016, $505,000 of Notes and $31,278 of accrued interest were converted into 2,681,383 shares of the Company’s Common Stock. As of March 31, 2016 and September 30, 2015 principal amounts outstanding under the Notes amounted to $100,000 and $605,000, respectively. On April 4, 2016, the remaining $100,000 of Notes and $8,622 of accrued interest were

converted into 543,111 shares of the Company's Common Stock.

The issuance and sale of the Notes and Conversion Shares (collectively, the "Securities") has not been, and will not upon issuance be, registered under the Securities Act of 1933, as amended (the "Securities Act"), and the Securities may not be offered or sold in the United States absent registration under or exemption from the Securities Act and any applicable state securities laws. The Securities were issued and sold in reliance upon an exemption from registration afforded by Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated under the Securities Act, based on the following facts: each of the Note Investors has represented that it is (and on the date of any conversion or sale of the Notes and/or Conversion Shares will be) an accredited investor as defined in Rule 501(a) promulgated under the Securities Act, that it is acquiring the Securities for investment only and not with a view towards, or for resale in connection with, the public sale or distribution thereof in violation of applicable securities laws and that it has sufficient investment experience to evaluate the risks of the investment. The Company used no advertising or general solicitation in connection with the issuance and sale of the Securities to the Note Investors; the Securities were issued as restricted securities.

Derivative Liabilities

The Company accounted for the conversion feature embedded within the Notes in accordance with ASC 815-10, *Derivatives and Hedging*. Because the options to convert into Common Stock are not indexed to the Company's stock and are not classified within stockholders' equity, the options to convert are recorded as liabilities at fair value. They are marked to fair value each reporting period through the consolidated statement of operations.

On the Closing Date, the derivative liability was recorded at fair value of $354,988 with the remaining proceeds of $395,012 allocated to the Notes. The allocation of funds to the derivative liability resulted in a discount on the Notes, which is being accreted to interest expense over the life of the loan. For the three and six months ended March 31, 2016, $29,101 and $131,252, respectively of the loan discount has been accreted to interest expense. As of March 31, 2016 the accreted balance of the outstanding Notes was $100,000. On April 4, 2016, the remaining $100,000 of Notes and $8,622 of interest were converted into 543,111 shares of the Company's Common Stock.

As a result of the conversion of notes we recorded other income of $13,503 and $142,964 for the three and six months ended March 31, 2016, respectively and due to the change in the estimated fair value of the derivative liability we recorded other income of $54,982 and $192,128 for the three and six months ended March 31, 2016, respectively. As of March 31, 2016, the remaining derivative liability balance was deemed to be immaterial to the accompanying unaudited interim consolidated financial statements.

Fair Value Measurements Using Significant Unobservable Inputs
(Level 3)

	Convertible Debt Derivative Liability
Beginning balance at September 30, 2015	$ 335,092
Conversion of notes	(142,964)
Adjustments to estimated fair value	(192,128)
Ending balance at March 31, 2016	$ -

The derivative liability was valued as of September 30, 2015, October 29, 2015 (weighted average conversion date) and December 31, 2015 using Monte Carlo Simulations with the following assumptions:

	September 30, 2015	October 29, 2015	December 31, 2015
Stated interest rate	8.0 %	8.0 %	8.0 %
Exercise price per share	$ 0.20	$ 0.20	$ 0.20
Expected volatility	80.0 %	85.0 %	110.0 %
Risk-free interest rate	0.07 %	0.14 %	0.16 %
Credit adjusted discount rate	22.0 %	22.0 %	25.0 %
Remaining expected term of underlying securities (years)	0.46	0.38	0.21

6. NOTE PAYABLE

On September 30, 2013, the Company entered into the Life Sciences Accelerator Funding Agreement (the "MLSC Loan Agreement") with the Massachusetts Life Sciences Center ("MLSC"), pursuant to which MLSC provided an unsecured subordinated loan in the principal amount of $1,000,000. The loan bears interest at a rate of 10% per annum, and will become fully due and payable on the earlier of (i) September 30, 2018, (ii) the occurrence of an event of default under the MLSC Loan Agreement, or (iii) the completion of a sale of substantially all of our assets, a change-of-control transaction or one or more financing transactions in which we receive from third parties other than our then-existing shareholders net proceeds of $5,000,000 or more in a 12-month period. The MLSC Loan Agreement includes warrants to purchase 145,985 shares of the Company's Common Stock at an exercise price of $0.27 per share. None of the warrants, which expire on September 30, 2023, have been exercised as of March 31, 2016.

Of the $1,000,000, the Company allocated $944,707 to the loan and $55,293 to the warrants. The warrant valuation was derived at the date of grant 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 warrants was recorded as an increase to additional paid-in capital. The allocation of funds to the warrants resulted in a discount on the loan, which is being accreted to interest expense over the life of the loan. For both the three months ended March 31, 2016 and 2015, $2,764 of the loan discount has been accreted to interest expense. For both the six months ended March 31, 2016 and 2015, $5,529 of the loan discount has been accreted to interest expense. As of March 31, 2016 and September 30, 2015 the accreted balance of the MLSC Loan was $972,353 and $966,824, respectively.

7. 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 ("2014 Investors") providing for the issuance and sale by the Company to the

2014 Investors, in a private placement, of an aggregate of 11,400,000 shares of Common Stock (collectively, the "2014 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 "2014 Warrants," and the shares issuable upon exercise of the 2014 Warrants, collectively, the "2014 Warrant Shares"), for aggregate gross proceeds to the Company of approximately $2,850,000 (the "2014 Private Placement Financing").

Upon the closing of the 2014 Private Placement Financing on February 4, 2014 (the "Closing Date"), the Company entered into a registration rights agreement (the "2014 Registration Rights Agreement") with the 2014 Investors, pursuant to which the Company became obligated, subject to certain conditions, to file with the SEC 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 2014 Shares and the 2014 Warrant Shares, plus (ii) an additional number of shares of Common Stock equal to 33% of the total number of 2014 Shares and 2014 Warrant Shares, to account for adjustments, if any, to the number of 2014 Warrant Shares issuable pursuant to the terms of the 2014 Warrants (the securities set forth in this clause (ii), the "Additional Shares"). Under the terms of the 2014 Registration Rights Agreement, the Company is permitted to reduce the number of shares covered by a registration statement if such reduction is required by the SEC as a condition for permitting such registration statement to become effective and treated as a resale registration statement (the "Cutback Provisions"). In response to comments received from the SEC and in accordance with the terms of the 2014 Registration Rights Agreement, the Company reduced the number of shares included in its draft resale registration statement by the number of Additional Shares. The Company's failure to satisfy certain other obligations and deadlines set forth in the 2014 Registration Rights Agreement may subject the Company to payment of monetary penalties as discussed below. The resale registration statement was declared effective on July 2, 2014. As described below, in the event that we fail to comply with certain requirements in the 2014 Registration Rights Agreement, we may be required to pay liquidated damages to the investors.

The 2014 Warrants were exercisable immediately upon issuance. The Series A warrants had an initial exercise price of $0.30 per share and expire five years from the date of their issuance. The Series B warrants had an initial exercise price of $0.35 per share and expired on the earlier of 12 months after their issuance date or six months after the first date on which the resale of all Registrable Securities (as defined in the 2014 Registration Rights Agreement) is covered by one or more effective registration statements. The Series B warrants expired on January 2, 2015. The Series C warrants had an initial exercise price of $0.40 per share and an initial expiration on the earlier of 18 months after their issuance date or nine months after the first date on which the resale of all Registrable Securities (as defined in the 2014 Registration Rights Agreement) is covered by one or more effective registration statements. The Series C warrants were set to expire on April 2, 2015 and, as described below, were amended to expire on July 2, 2016. The number of shares of the Company's Common Stock into which each of the 2014 Warrants is exercisable and the exercise price therefore were subject to adjustment as set forth in the 2014 Warrants, including, without limitation, adjustment to both the exercise price of the 2014 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 2014 Warrants, in which case the per share exercise price of the 2014 Warrants would be adjusted to equal such lower price per share and the number of shares issuable upon exercise of the 2014 Warrants would be adjusted accordingly so that the aggregate exercise price upon full exercise of the 2014 Warrants immediately before and immediately after such per share exercise price adjustment were equal. The 2014 Warrants are also subject to customary adjustments in the event of stock dividends and splits, subsequent rights offerings and pro rata distributions to the Company's common stockholders, and provide that they shall not be exercisable in the event and to the extent that the exercise thereof would result in the holder of the Warrant or any of its affiliates beneficially would then own more than 4.9% of the Company's Common Stock. The 2014 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 our Common Stock.

The Company may be required to make certain payments to the 2014 Investors under certain circumstances in the future pursuant to the terms of the Securities Purchase Agreement and the 2014 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 2014 Warrants (in a cash amount equal to 1% of the price paid to the Company by each investor in the 2014 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 2014 Private Placement Financing or issuable upon exercise of the 2014 Warrants; (c) expense reimbursement for the lead investor in the 2014 Private Placement Financing; and (d) payments in respect of claims for which the Company provides indemnification. There is no cap to the potential consideration. On July 2, 2014, we received from the SEC a Notice of Effectiveness of our Registration Statement related to the 2014 Private Placement Financing which satisfied some of our obligation to register these securities with the SEC.

On December 1, 2014, the Company agreed to amend certain provisions of the 2014 Warrants (the "December 2014 Amendment"). Under the terms of the December 2014 Amendment, the affected 2014 Warrants were amended to (i) reduce the exercise price of the Series B Warrants from $0.35 to $0.20, (ii) reduce the exercise price of the Series C Warrants from $0.40 to $0.20, and (iii) clarify that each series of 2014 Warrants may be amended individually, without having to amend all three series of 2014 Warrants. The number of shares of the Company's Common Stock,

which may be purchased from the Company upon exercise of each 2014 Warrant, remained unchanged. In conjunction with the December 2014 Amendment, the Company recognized a loss on the modification of 2014 Warrants in the amount of $1,300,170, which was determined using Monte Carlo Simulation valuation model.

As of December 2, 2014, Series B Warrants had been exercised for an aggregate issuance of 4,000,000 shares of the Company's Common Stock resulting in gross proceeds to the Company of $800,000. In conjunction with the exercise of the Series B Warrants, their corresponding fair value at the exercise dates of $224,000 were extinguished from the derivative liabilities balance.

On March 13, 2015, the Company issued unsecured 8% Convertible Notes in the aggregate principal amount of $750,000. The Company's issuance of the Notes triggered the anti-dilution provisions of the Series A Warrants and, as a result, the exercise price of the Series A Warrants was reduced to $0.20 per share and the aggregate number of shares issuable under the Series A Warrants increased by 5,700,000 shares from 11,400,000 shares to 17,100,000 shares. In addition, on March 13, 2015 and May 30, 2015, respectively the expiration date of the Series C Warrants was extended to June 2, 2015 and July 2, 2015, respectively. In conjunction with the March 13, 2015 amendment, the Company recognized a loss on the modification of warrants in the amount of $624,016, which was determined using Monte Carlo Simulation.

On June 22, 2015 the Company entered into an amendment to the Series A Warrants and Series C Warrants to purchase Common Stock (the "June 2015 Amendment"), with Cranshire Capital Master Fund, Ltd. ("Cranshire"), to (i) delete the full ratchet anti-dilution provisions set forth in the Series A Warrants and Series C Warrants; and (ii) extend the expiration date of the Series C Warrants from to 5:00 p.m., New York time, on July 2, 2015 to 5:00 p.m., New York time, on July 2, 2016. In consideration of Cranshire's entrance into the June 2015 Amendment (and for no additional consideration), the Company agreed to issue to the holders of the 2014 Warrants up to 570,000 shares of Company's Common Stock subject to the delivery by each such holder of an investor certificate to the Company (such shares of Common Stock, the "Inducement Shares"). All 570,000 Inducement Shares have been issued. As of June 22, 2015, the Company determined that its Series A and C Warrants were eligible for equity classification due to the elimination of the full ratchet anti-dilution provision. As a result, as of June 22, 2015, the derivative liabilities were reclassified as equity within the Company's consolidated financial statements.

During the three and six months ended March 31, 2016, Series C Warrants had been exercised on a cash basis for an aggregate issuance of 200,000 shares of the Company's Common stock resulting in gross proceeds to the Company of $40,000. During the three and six months ended March 31, 2015, Series B Warrants had been exercised on a cash basis for an aggregate issuance of 4,000,000 shares of the Company's Common Stock resulting in gross proceeds to the Company of $800,000.

8. 2015 PRIVATE PLACEMENT FINANCING

Beginning June 22, 2015 and through June 30, 2015, the Company entered into a series of substantially similar subscription agreements (each a "Subscription Agreement") with 20 accredited investors (collectively, the "2015 Investors") providing for the issuance and sale by the Company to the 2015 Investors, in a private placement, of an aggregate of 14,390,754 Units ("Unit") at a purchase price of $0.22 per Unit (the "2015 Private Placement Financing").

Each Unit consisted of a share of Common Stock (the "2015 Shares") and a Series D Warrant to purchase a share of Common Stock at an exercise price of $0.25 per share at any time prior to the fifth anniversary of the issuance date of the Series D Warrant (the "Series D Warrants," and the shares issuable upon exercise of the Series D Warrants, collectively, the "2015 Warrant Shares"). The Company did not engage any underwriter or placement agent in connection with the 2015 Private Placement Financing, and the aggregate gross proceeds raised by the Company in the 2015 Private Placement Financing totaled approximately $3,100,000.

The Company's obligation to issue and sell the 2015 Shares and the Series D Warrants and the corresponding obligation of the 2015 Investors to purchase such 2015 Shares and Series D Warrants were subject to a number of conditions precedent including, but not limited to, the amendment of the Company's Series A Warrants and Series C Warrants to delete certain of the anti-dilution provisions contained therein, as described in Note 7, 2014 Private Placement Financing, and other customary closing conditions. The conditions precedent were satisfied June 30, 2015 (the "Initial Closing Date"), and the Company conducted an initial closing (the "Initial Closing") pursuant to which it sold and 19 of the 2015 Investors (the "Initial Investors") purchased 13,936,367 Units at an aggregate purchase price of $3,066,000. On July 2, 2015, the Company conducted a second closing (the "Second Closing" and together with the Initial Closing, the "Closings") pursuant to which it sold and one of the 2015 Investors purchased 454,387 Units at an aggregate purchase price of $100,000.

On the Initial Closing Date, the Company entered into a registration rights agreement with the Initial Investors (the " 2015 Registration Rights Agreement"), pursuant to which the Company was obligated, subject to certain conditions, to file with the Securities and Exchange Commission within 90 days after the closing of the 2015 Private Placement Financing one or more registration statements (any such registration statement, a "Resale Registration Statement") to register the 2015 Shares and the 2015 Warrant Shares for resale under the Securities Act of 1933, as amended (the "Securities Act"). The remaining 2015 Investor became a party to the 2015 Registration Rights Agreement upon the consummation of the Second Closing. The Company's failure to satisfy certain filing and effectiveness deadlines with respect to a Resale Registration Statement and certain other requirements set forth in the 2015 Registration Rights Agreement may subject the Company to payment of monetary penalties. On October 27, 2015, we received from the SEC a Notice of Effectiveness of our Registration Statement related to the 2015 Private Placement Financing which satisfied some of our obligation to register these securities with the SEC.

Following each Closing, each 2015 Investor was also issued Series D Warrants to purchase shares of the Company's Common Stock up to 100% of the 2015 Shares purchased by such 2015 Investor under such 2015 Investor's Subscription Agreement. The Series D Warrants have an exercise price of $0.25 per share, are exercisable immediately after their issuance and have a term of exercise equal to five years after their issuance date. The number of shares of the Company's Common Stock into which each of the Series D Warrants is exercisable and the exercise price therefore are subject to adjustment, as set forth in the Series D Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise). In addition, at anytime during the term of the Series D Warrants, the Company may reduce the then-current exercise price to any amount and for any period of time deemed appropriate by the Board of the Company.

Common Stock

At the June 30, 2015 Initial Closing Date of the 2015 Private Placement Financing, the Company issued 13,936,367 shares of Common Stock. On July 2, 2015, the Company conducted the Second Closing pursuant to which it sold and one of the 2015 Investors purchased 454,387 shares of Common Stock.

Equity Value of Warrants

The Company accounted for the Series D Warrants relating to the aforementioned 2015 Private Placement Financing in accordance with ASC 815-40, *Derivatives and Hedging*. Because the Series D Warrants are indexed to the Company's stock, they are classified within stockholders' equity in the accompanying unaudited interim consolidated financial statements.

9.SUBSEQUENT EVENTS

During the period commencing April 1, 2016 and ending on April 27, 2016, additional Series A and Series C Warrants have been exercised for an aggregate issuance of 2,699,725 shares of the Company's Common Stock at an exercise price of $0.20 per share, resulting in gross proceeds to the Company of $539,945. In addition, 1,400,000 Series A Warrants were exercised on a cashless basis, resulting in the issuance of 727,084 shares of the Company's Common Stock. Also during this period additional Series D Warrants have been exercised for an aggregate issuance of 2,404,227 shares at an exercise price of $0.25 per shares, resulting in gross proceeds to the Company of $601,057. During April 2016, the remaining $100,000 of Notes and $8,622 of accrued interest were converted into 543,111 shares of the Company's Common Stock.

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

The following discussion and analysis should be read in conjunction with our unaudited interim financial statements and notes included in this report and the audited financial statements and notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended September 30, 2015 filed with the Securities and Exchange Commission ("**SEC**").

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

As used in this report on Form 10-Q unless otherwise indicated, the "**Company**", "**we**", "**us**", "**our**", and "**Arch**" refer to Arch Therapeutics, Inc. and its consolidated subsidiary, Arch Biosurgery, Inc.

Corporate Overview

Arch Therapeutics, Inc. was incorporated under the laws of the State of Nevada on September 16, 2009 with the name "Almah, Inc." to pursue the business of distributing automobile spare parts online. Effective June 26, 2013, Arch completed a merger (the " **Merger**") with Arch Biosurgery, Inc. (formerly known as Arch Therapeutics, Inc.), a Massachusetts corporation ("**ABS**"), and Arch Acquisition Corporation ("**Merger Sub**"), Arch's wholly owned subsidiary formed for the purpose of the transaction, pursuant to which Merger Sub merged with and into ABS and ABS thereby became the wholly owned subsidiary of Arch. Prior to the completion of the Merger, Arch was a "shell company" under applicable rules of the SEC and had no or nominal assets or operations. As part of the acquisition, Almah management resigned and was replaced with ABS management. Upon its acquisition of ABS, Arch abandoned its prior business plan and changed its operations to the business of a biotechnology company.

For financial reporting purposes, the Merger represented a "reverse merger". ABS was deemed to be the accounting acquirer in the transaction and the predecessor of Arch. Consequently, the assets, liabilities, accumulated deficit and

the historical operations that are reflected in the Company's unaudited interim 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 was 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 on Form 10-Q and will be so replaced in all future filings with the SEC that require financial statements to be included.

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

Business Overview

We are a biotechnology 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 "hemostatic" or "hemostasis"), control leaking (referenced as "sealant" or "sealing"), 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, the 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 hemostatic or sealant product candidates in the future based on our self-assembling peptide technology platform. Our plan and business model is to develop products that apply that core technology to use with human bodily fluids and connective tissues.

AC5 is designed to be 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 structure that provides a barrier to leaking substances, such as blood. AC5 is designed for direct application as a liquid, 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 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 ability to conduct clinical trials and our subsequent commercialization timeline.

Our long-term business plan includes the following goals:

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

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

- seek additional funding to support the milestones described above and our operations generally;

- work with our large scale manufacturing partners to continue to scale up production of product compliant with current good manufacturing practices ("**cGMP**"), which activities will be ongoing as we seek to advance toward, enter into, and, if successful, subsequently increase commercialization activities;

- complete clinical trial protocols and Clinical Investigational Plans with principal investigators for AC5 and submit applications to Ethics Committee and required authoritative agencies for initiation of additional initial clinical trials;

- commence additional and complete our current human clinical trial(s) for AC5, the timeframe for which is dependent upon successful completion of certain manufacturing, regulatory, and biocompatibility activities;

- continue to expand and enhance our financial and operational reporting and controls;

- 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

- assess our self-assembling peptide platform in order to identify and select product candidates for advancement into development.

With respect to our goals relating to AC5, we currently project requiring at least $3,000,000 - $5,000,000 of additional expenditures to complete the clinical and regulatory milestones to obtain necessary and expanded regulatory approvals in Europe. We further expect that obtaining regulatory approvals in the U.S., including conducting additional required clinical trials, would require at least an additional $7,000,000 - $9,000,000 in capital. In addition, we further expect to require additional funds for corporate and development programs. These estimated capital requirements potentially could increase significantly if a number of risks relating to conducting these activities were to occur, including without limitation those set forth under the heading "**Risk Factors**" in this filing.

Merger with ABS and Related Activities

As noted earlier in this document, on June 26, 2013, the Company completed the Merger with ABS, pursuant to which ABS became a wholly owned subsidiary of the Company. In contemplation of the Merger, effective May 24, 2013, the Company increased its authorized common stock, par value $0.001 per share ("**Common Stock**"), from 75,000,000 shares to 300,000,000 shares and effected a forward stock split, by way of a stock dividend, of its issued and outstanding shares of Common Stock at a ratio of 11 shares to each one issued and outstanding share. Also in contemplation of the Merger, effective June 5, 2013, the Company changed its name from Almah, Inc. to Arch Therapeutics, Inc. and changed the ticker symbol under which its Common Stock trades on the OTC Bulletin Board from "AACH" to "ARTH".

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 do not have any products that have obtained marketing approval in any jurisdiction. We have net losses for the three months ended March 31, 2016 and 2015 of $1,253,056 and $833,966, respectively. The net losses for the three months ended March 31, 2016 and 2015 can be attributed to general and administrative costs and increased research and development expenses associated with pre-clinical development expenses, manufacturing and quality management system

consulting and advisory related expenses. For the six months ended March 31, 2016 and 2015, we have net losses of $2,409,711 and $454,821, respectively. We devote a significant amount of our efforts towards fundraising and product research.

Recent Developments

During the three months ended March 31, 2016, the Company announced that (i) it had initiated patient enrollment and treatment in its first clinical trial in Western Europe, (ii) it had received an internationally recognized ISO quality certification, and (iii) it had obtained favorable results from a broad panel of preclinical biocompatibility tests that were performed on AC5 in support of Arch's planned filing of a CE Mark application that indicate that AC5's peptide structure and mechanism of action, which is based on the formation of a local physical-mechanical barrier at the wound site, does not promote toxicity to the overall biological system following exposure to AC5. In addition, on April 5, 2016 and April 11, 2016, respectively, the Company announced that notices of allowance from the U.S. Patent Office had been received on a broad composition-of-matter patent and a broad method of use patent that are assigned to the Massachusetts Institute of Technology (MIT) and Versitech Limited and are exclusively licensed worldwide to Arch. The broad composition claims of the composition-of-matter patent cover Arch's present and proposed products, which contain peptides that self-assemble into barrier structures on tissue that inhibit or prevent the passage of bodily fluids, and the broad method claims of the method of use patent cover techniques for preventing the loss or unwanted movement of body fluids. In addition, the Company has initiated the FDA regulatory process.

During the six months ended March 31, 2016, $505,000 of principal on the Company's outstanding convertible notes and $31,278 of associated accrued interest were converted into an aggregate of 2,681,383 shares of common stock. In addition, during six months ended March 31, 2016, Series C Warrants had been exercised on a cash basis for an aggregate issuance of 200,000 shares of the Company's Common stock resulting in gross proceeds to the Company of $40,000.

Results of Operations

The following discussion of our results of operations should be read together with the unaudited interim consolidated financial statements included in this report on Form 10-Q. 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, 2016 Compared to Three Months Ended March 31, 2015

	March 31, 2016 ($)	March 31, 2015 ($)	Increase (Decrease) ($)
Revenue	-	-	-
Operating Expenses			
General and administrative	868,433	853,177	15,256
Research and development	386,285	402,495	(16,210)
Loss from operations	(1,254,718)	(1,255,672)	(954)
Other income	1,662	421,706	(420,044)
Net loss	(1,253,056)	(833,966)	419,090)

Revenue

We did not generate revenue in either of the three months ended March 31, 2016 and 2015.

General and Administrative Expense

General and administrative expenses during the three months ended March 31, 2016 were $868,433, an increase of $15,256 compared to $853,177 for the three months ended March 31, 2015. The increase in general and administrative expense is primarily attributable to an increase in patent-related expenses partially offset by a decrease in stock based compensation and payroll expenses.

Research and Development Expense

Research and development expenses during the three months ended March 31, 2016 were $386,285, a decrease of $16,210 compared to $402,495 for the three months ended March 31, 2015. The decrease in research and development expense is primarily attributable to an increase in expenses associated with pre-clinical development expenses and manufacturing and quality management system consulting and advisory related expenses offset primarily by a decrease in stock based compensation expenses. Research and development expenses are expected to increase as a result of our plans to expand clinical programs and clinical studies as resources permit. The Company has initiated patient enrollment and treatment in its first clinical trial in Western Europe.

Other Income (Expense)

Other income during the three months ended March 31, 2016 was $1,662 a decrease of $420,044 compared to other income of $421,706 for the three months ended March 31, 2015. This decrease resulted from a change in adjustments to derivative liabilities of $403,777 during fiscal 2016 as compared to fiscal 2015. Other income during the three months ended March 31, 2016 was attributed primarily to a net gain on adjustments of derivative liabilities related to our outstanding warrants of $68,485, partially offset by interest expense of $66,823.

Six Months Ended March 31, 2016 Compared to Six Months Ended March 31, 2015

	March 31, 2016 ($)	March 31, 2015 ($)	Increase (Decrease) ($)
Revenue	-	-	-
Operating Expenses			
General and administrative	1,733,946	1,723,533	10,413
Research and development	800,288	802,230	(1,942)
Loss from operations	(2,534,234)	(2,525,763)	8,471
Other income	124,523	2,070,942	(1,946,419)
Net loss	(2,409,711)	(454,821)	1,954,890)

Revenue

We did not generate revenue in either of the six months ended March 31, 2016 and 2015.

General and Administrative Expense

General and administrative expenses during the six months ended March 31, 2016 were $1,733,946, an increase of $10,413 compared to $1,723,533 for the six months ended March 31, 2015. The increase in general and administrative expense is primarily attributable to an increase in patent-related expenses partially offset by a decrease in stock based compensation.

Research and Development Expense

Research and development expenses during the six months ended March 31, 2016 were $800,288, a decrease of $1,942 compared to $802,230 for the six months ended March 31, 2015. The decrease in research and development expense is primarily attributable to an increase in expenses associated with pre-clinical development expenses and manufacturing and quality management system consulting and advisory related expenses offset primarily by a decrease in stock based compensation expenses. Research and development expenses are expected to increase as a result of our plans to expand clinical programs and clinical studies as resources permit. The Company has initiated patient enrollment and treatment in its first clinical trial in Western Europe.

Other Income (Expense)

Other income during the six months ended March 31, 2016 was $124,523 a decrease of $1,946,419 compared to other income of $2,070,942 for the six months ended March 31, 2015. This decrease resulted from a change in adjustments to derivative liabilities of $1,814,170 during fiscal 2016 as compared to fiscal 2015. Other income during the six months ended March 31, 2016 was attributed primarily to a net gain on adjustments of derivative liabilities related to our outstanding notes of $335,092 partially offset by interest expense of $210,569.

Liquidity and Capital Resources

To date, we have not generated revenues from the sale of any products and have principally raised capital through borrowings and the issuance of convertible debt and units consisting of Common Stock and warrants to fund our operations. At March 31, 2016, we had cash of $1,669,249 and positive working capital of $1,360,367.

Cash Used in Operating Activities

Working Capital

At March 31, 2016, we had total current assets of $1,759,368 (including cash of $1,669,249) and working capital of $1,360,367. Our working capital as of March 31, 2016 and September 30, 2015 is summarized as follows:

	March 31, 2016	September 30, 2015
Total Current Assets	$1,759,368	$ 4,003,019
Total Current Liabilities	399,001	1,286,078
Working Capital	$1,360,367	$ 2,716,941

Total current assets as of March 31, 2016 were $1,759,368, a decrease of $2,243,651 compared to $4,003,019 as of September 30, 2015. The decrease in current assets is primarily attributable to general and administrative expenses resulting from intellectual property costs and research and development expenses incurred in connection with activities to develop our primary product candidate. Our total current assets as of March 31, 2016 and September 30, 2015 were comprised primarily of cash, prepaid expenses and other current assets.

Total current liabilities as of March 31, 2016 were $399,001, a decrease of $887,077 compared to $1,286,078 as of September 30, 2015. The decrease is primarily due to the conversion of $505,000 of convertible notes into equity and an adjustment to the fair value of the derivative liabilities associated with these Notes, partially offset by the timing of payments in accounts payable. Our total current liabilities as of March 31, 2016 and September 30, 2015 were comprised primarily of the current portion of the derivative liability, the convertible notes, accounts payable and accrued expenses.

Cash Flow for the Six Months Ended

	March 31, 2016	March 31, 2015
Cash Used in Operating Activities	$(2,330,851)	$(1,809,920)
Cash Used in Investing Activities	-	-
Cash Provided by Financing Activities	40,000	1,550,000
Net decrease in cash	$(2,290,851)	$(259,920)

Cash Used in Operating Activities

Cash used in operating activities increased $520,931 during the six months ended March 31, 2016 to $2,330,851 compared to $1,809,920 during the six months ended March 31, 2015. The increase was primarily due to an increase in general and administrative expense primarily attributable to increased intellectual property costs and research and development expenses incurred in connection with activities to develop our primary product candidate.

Cash Used in Investing Activities

There was no cash used in investing activities during the six months ended March 31, 2016 and 2015, respectively.

Cash Provided by Financing Activities

Cash provided by financing activities decreased $1,510,000 to $40,000 during the six months ended March 31, 2016, compared to $1,550,000 during the six months ended March 31, 2015. For the six months ended March 31, 2016, the cash provided by financing resulted from the exercise of the Series C Warrants to purchase 200,000 shares of our Common Stock. For the six months ended March 31, 2015, the cash provided by financing resulted from the $800,000 in proceeds received by us from the exercise of Series B Warrants to purchase 4,000,000 shares of our Common Stock and proceeds received of $750,000 from the issuance of the 8% Convertible Note.

Cash Requirements

We anticipate that our operating and other expenses will increase significantly as we continue to implement our business plan and pursue our operational goals. We estimate that our cash requirements for our fiscal year ending September 30, 2016 will be approximately $5,500,000. We estimate that we currently have sufficient cash to operate our business into October 2016. 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 or other issues arise, in which case our current funds may not be sufficient to operate our business for the period we expect.

We do not presently have, nor do we expect in the near future to have, revenue to fund our business from our operations, and will need to obtain all of our necessary funding from external sources for the foreseeable future. We do not have any commitments for future capital. Significant additional financing will be required to fund our planned operations in the near term and in future periods, including research and development activities relating to our principal product candidate, seeking regulatory approval of that or any other product candidate we may choose to develop, commercializing any product candidate for which we are able to obtain regulatory approval or certification, seeking to license or acquire new assets or businesses, and maintaining our intellectual property rights and pursuing rights to new technologies. We may not be able to obtain additional financing on commercially reasonable or acceptable terms when needed, or at all. We are bound by certain contractual terms and obligations that may limit or otherwise impact our ability to raise additional funding in the near-term including, but not limited to, provisions in the MLSC Loan Agreement (i) restricting our ability to incur certain types of additional indebtedness, and (ii) that would cause all amounts under the MLSC Loan Agreement to become immediately due and payable if we receive net proceeds of $5,000,000 or more in one or more financing transactions in any 12-month period from third parties other than our then existing shareholders. 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.

As previously noted, 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. Additionally, the terms of securities we may issue in future capital-raising transactions may be more favorable for our new investors, and in particular 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, 2016 we have not earned operating revenues from sales of products or services, and have recurring losses from operations. 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, 2016, there is substantial doubt about the Company’s ability to continue as a going concern. The unaudited interim consolidated financial statements included in this Quarterly Report on Form 10-Q do not include any adjustments that might be necessary should operations discontinue.

Critical Accounting Policies and Significant Judgments and Estimates

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

Basis of Presentation

The unaudited interim consolidated financial statements include the accounts of Arch Therapeutics, Inc. and its wholly owned subsidiary, Arch Biosurgery, Inc. a biotechnology company. All intercompany accounts and transactions have been eliminated in consolidation.

The Company is in the development stage and is devoting substantially all of its efforts to developing technologies, raising capital, establishing customer and vendor relationships, and recruiting new employees.

Income Taxes

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

We provide reserves for potential payments of tax to various tax authorities related to uncertain tax positions when management determines that it is probable that a loss will be incurred related to these matters and the amount of the loss is reasonably determinable. We have no reserves related to uncertain tax positions as of March 31, 2016 and September 30, 2015.

Accounting for Stock-Based Compensation

The Company accounts for employee stock-based compensation in accordance with ASC 718, *Compensation-Stock Compensation* ("**ASC 718**") which requires all share-based payments to employees, including grants of employee stock options, to be recognized in the consolidated financial statements based on their fair values. The Company accounts for non-employee stock-based compensation in accordance with the guidance of ASC 505, *Equity* ("**ASC 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. ASC 505 requires the Company to re-measure the fair value of stock options issued to non-employees at each reporting period during the vesting period or until services are complete.

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

The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by the fair value of the Common Stock and a number of other assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. The Company does not have a history of market prices of its Common Stock, and as such volatility is estimated in accordance with ASC 718-10-S99 and Staff Accounting Bulletin ("**SAB**") No. 107, *Share-Based Payment* ("**SAB No. 107**"), using historical volatilities of similar public entities. For the life term for awards, the Company uses the simplified method for all "plain vanilla" options, as defined in SAB No. 107 and the contractual term for all other employee and non-employee awards. The risk-free interest rate assumption is based on observed interest rates appropriate for the terms of our awards. The dividend yield assumption is based on history and the expectation of paying no dividends. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Stock-based compensation expense, when recognized in the consolidated financial statements, is based on awards that are ultimately expected to vest.

Derivative Liabilities

The Company accounts for its warrants and other derivative financial instruments as either equity or liabilities based upon the characteristics and provisions of each instrument, in accordance with ASC 815, *Derivatives and Hedging*. Warrants classified as equity are recorded at fair value as of the date of issuance on the Company's consolidated balance sheets and no further adjustments to their valuation are made. Warrants classified as derivative liabilities and other derivative financial instruments that require separate accounting as liabilities are recorded on the Company's consolidated balance sheets at their fair value on the date of issuance and will be revalued on each subsequent balance sheet date until such instruments are exercised or expire, with any changes in the fair value between reporting periods recorded as other income or expense. Management estimates the fair value of these liabilities using 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) 2016-09, "Compensation—Stock Compensation (Topic 718) Improvements to Employee Share-Based Payment Accounting" was issued by the Financial Accounting Standards Board (FASB) in March 2016. The purpose of this amendment is to simplify several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The amendments in this Update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2016. Early adoption is permitted. The Company does not believe that this guidance will have a material impact on its consolidated results of operations, financial position or disclosures.

ASU 2016-02, "Leases (Topic 842)" was issued by the FASB in February 2016. The purpose of this amendment requires the recognition of lease assets and lease liabilities by lessees for those leases previously classified as operating leases. The amendments in this Update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted. The Company does not believe that this guidance will have a material impact on its consolidated results of operations, financial position or disclosures.

ASU 2015-17, "Income Taxes (Topic 740) – Balance Sheet Classification of Deferred Taxes" was issued by the FASB in November 2015. The purpose of this amendment requires deferred tax assets and liabilities to be classified as noncurrent in a classified statement of financial position. The amendments in this Update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2017. Early adoption is permitted. The Company does not believe that this guidance will have a material impact on its consolidated results of operations, financial position or disclosures.

ASU 2015-03, “Interest – Imputation of Interest (Subtopic 835-30) Simplifying the Presentation of Debt Issuance Costs” was issued by the FASB in April 2015. The purpose of this amendment requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The amendments in this Update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted. The Company does not believe that this guidance will have a material impact on its consolidated results of operations, financial position or disclosures.

ASU 2015-02, “Consolidation (Topic 810) – Amendments to the Consolidation Analysis”, was issued by the FASB in February 2015. The purpose of this amendment is to change the analysis that a reporting entity must perform to determine whether it should consolidate certain types of legal entities. The amendments in this Update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted. The Company does not believe that this guidance will have a material impact on its consolidated results of operations or financial position or disclosures.

ASU 2014-16, “Derivatives and Hedging (Topic 815)” was issued by the FASB in November 2014. The primary purpose of the ASU is to determine whether the host contract in a Hybrid Financial Instrument issued in the form of a share is more akin to debt or equity. ASU 2014-16 is effective for public entities for the fiscal years and interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted. The Company does not believe that this guidance will have a material impact on its consolidated results of operations or financial position or disclosures.

ASU 2014-15, “Presentation of Financial Statements-Going Concern (Subtopic 205-40) – Disclosure of Uncertainties about an Entity’s Ability to ‘Continue as a Going Concern” was issued by the FASB in August 2014. The primary purpose of the ASU is to provide guidance in GAAP about management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and to provide related footnote disclosures. The amendments should reduce diversity in the timing and content of footnote disclosure. ASU 2014-15 is effective for the annual period ending after December 15, 2016, and for the annual periods and interim periods thereafter. Early adoption is permitted. 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, financial position or disclosures.

ASU 2014-12, “Compensation-Stock Compensation (Topic 718) – Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period” was issued by the FASB in June 2014. ASU 2014-12 requires that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. ASU 2014-12 is effective for public business entities for annual periods and interim periods within the annual periods beginning after December 15, 2015. Early adoption is permitted. 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, financial position or disclosures.

ASU 2014-09, “Revenue from Contracts with Customers (Topic 606) was issued by the FASB in May 2014. The primary purpose of the ASU is to develop a common revenue standard for revenue recognition between the FASB and the International Accounting Standards Board (IASB). The ASU removes inconsistencies and weaknesses in revenue requirements, provides a more robust framework for addressing revenue issues, and improves comparability of revenue recognition practices across entities, industries, jurisdictions and capital markets, among other items. We are a development stage company and do not currently generate revenue. ASU 2014-09 is effective for public business entities for annual periods beginning after December 15, 2017. While we are a development stage company and do not currently generate revenue, we currently anticipate generating revenue by the effective date of this ASU and therefore will be subject to this guidance. 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, financial position or disclosures.

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, 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 the design of our disclosure controls and procedures (as defined by Exchange Act Rules 13a-15(e) or 15d-15(e)) as of March 31, 2016, 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, 2016 in ensuring that information required to be disclosed by us in reports that we file or furnish under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. This conclusion is based on findings that constituted material weaknesses in our internal control over financial reporting.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal controls over financial reporting that occurred during the quarter ended March 31, 2016 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

Risks Related to our Business

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

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 investment before it could potentially be commercialized. As a result, we have not generated any revenue from operations since inception, and we have incurred substantial net losses to date. 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. In particular and as discussed in greater detail below under the risk factor entitled "***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 believe that our current cash and cash equivalents on hand will only be sufficient to meet our anticipated cash requirements into October 2016.

We have incurred significant losses since inception. We expect to continue to incur losses for the foreseeable future, and we may never generate revenue or achieve or maintain profitability.

As noted above under the risk factor entitled "***There is substantial doubt about our ability to continue as a going concern***," we are a development stage company with no commercial products. Consequently, 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 incurred in connection with both the closing of the Merger and complying with public company reporting and control obligations, 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; and
- hire additional regulatory, clinical, quality control, scientific, financial, and management, consultants and advisors.

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 many 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 further decline or lack of increase in the prices of our Common Stock could cause our stockholders to lose all or a part of their investment in the Company.

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.

Based on our current operating expenses and working capital requirements, we believe that our current cash and cash equivalents on hand will only be sufficient to meet our anticipated cash requirements into October 2016. In addition to the funds raised from our previous equity and convertible debt financings and borrowings under the Life Sciences Accelerator Funding Agreement (the "**MLSC Loan Agreement**") that we entered into with Massachusetts Life Sciences Center ("**MLSC**"), we will need to obtain additional financing on or prior to October 2016 to continue operations and fund our planned future operations, including the continuation of our ongoing research and development efforts, the licensing or acquisition of 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. In particular, we currently estimate that we will require up to $10,000,000 to $14,000,000 and potentially more in additional capital to obtain regulatory approval of AC5 in the U.S. and Europe. Our future capital requirements will depend on many factors, including:

- the scope, progress and results of our research, preclinical, and clinical development activities;
- the scope, progress and results of our research and development collaborations;
- the extent of potential direct or indirect grant funding for our research and development activities;
- the scope, progress, results, costs, timing and outcomes of any regulatory process and 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, and increased investor relations and corporate communications expenses; and

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

We intend to obtain additional financing for our business through public or private securities offerings, the incurrence of additional indebtedness, or some combination of those sources. We have sought funding through collaborative arrangements, such as the Project Agreement that we entered into with the National University of Ireland Galway ("**NUIG**") on May 28, 2015, and we may continue to seek funding through additional collaborative arrangements with strategic partners 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. We cannot provide any assurance that additional financing from these sources will be available on favorable terms, if at all. In addition, we are bound by certain contractual terms and obligations that may limit or otherwise impact our ability to raise additional funding in the near-term including, but not limited to, provisions in the MLSC Loan Agreement (i) restricting our ability to incur certain types of additional indebtedness, and (ii) that would cause all amounts under the MLSC Loan Agreement to become immediately due and payable if we receive net proceeds of $5,000,000 or more in one or more financing transactions in any 12-month period from third parties other than our then existing shareholders. These restrictions and provisions, which are discussed in greater detail below under the risk factor entitled "***Our current and any future debt facilities or instruments may 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***," 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. Finally, servicing the interest and principal repayment obligations under our debt facilities could divert funds that would otherwise be available to support research and development, clinical or commercialization activities.

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

Our current and any future debt facilities or instruments may 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 MLSC Loan Agreement with 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 from third parties other than our then existing shareholders 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 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 subject to a security interest and 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 Terrence Norchi, MD, our President and Chief Executive Officer. The loss of Dr. Norchi or any of our other key personnel could harm our business and might significantly delay or prevent the achievement of research, development or business objectives. Further, our operation as a public company will require that we attract additional personnel to support the establishment of appropriate financial reporting and internal controls systems. Competition for personnel is intense. We may not be able to attract, retain and/or successfully integrate qualified scientific, financial and other management personnel, which could materially harm our business.

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

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

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

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"). As disclosed in Item 9A of Part II of our Annual Report on Form 10-K and Item 4 of Part I of our Quarterly Reports on Form 10-Q filed with the SEC, management has identified material weaknesses in our disclosure controls and procedures and our internal control over financial reporting as of September 30, 2015. A material weakness in internal control over financial reporting is defined as a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our consolidated financial statements will not be prevented or detected on a timely basis. As a result of these material weaknesses, our management concluded in our latest annual assessment that our internal control over financial reporting was not effective as of September 30, 2015, based on criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework.

We have taken steps to remediate certain material weaknesses we had identified in our internal control over financial reporting. If our remedial measures are insufficient to address the material weaknesses we have identified, or if additional material weaknesses or significant deficiencies in our internal control are discovered or occur in the future, there may be an increased likelihood that our consolidated financial statements contain material misstatements. A restatement of our financial results could result in substantial costs to us for accounting and legal fees and could lead to litigation against us. In addition, even if we are successful in strengthening our controls and procedures, those controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our consolidated financial statements. If we fail to achieve and maintain the adequacy of our internal controls in accordance with applicable standards, we would be unable to conclude that we have effective internal controls over financial reporting. If we cannot produce reliable financial reports, our business and financial condition could be harmed, investors could lose confidence in our reported financial information, and the market price of our stock could decline significantly. Moreover, our reputation with lenders, investors, securities analysts and others may be adversely affected.

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

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

Risks Related to the Development and Commercialization of our Product Candidates

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

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

The Chemistry, Manufacturing and Control ("CMC") process may be challenging.

Because of the complexity of our lead product candidate, the CMC process, including product scale-up activities, 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 ability to conduct clinical trials and our subsequent commercialization timeline. Furthermore, we have, and the third parties with whom 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 complete a clinical trial, and overall chances for success.

The manufacturing, production, and sterilization methods that we intend to be utilized are detailed and complex and are a difficult process to manage.

We intend to utilize third party manufacturers to manufacture and sterilize our products. We believe that our proposed manufacturing methods make our choice of manufacturer and sterilizer critical, as they must possess sufficient expertise in synthetic organic chemistry and device manufacturing. If such manufacturers are unable to properly manufacture to product specifications or sterilize our products adequately, that could severely limit our ability to market our products.

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, and in February 2015 we received confirmation from The British Standards Institution ("**BSI**"), a Notified Body (which is a private commercial entity designated by the national government of an European Union ("**EU**") member state as being competent to make independent judgments about whether a medical device complies with applicable regulatory requirements) in the EU, that AC5 fulfills the definition of a medical device within the EU and will be classified as such in consideration for CE mark designation. However, the FDA and other applicable foreign agencies, including European Competent Authorities, 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 and support our regulatory submissions, our product development efforts, and subsequent regulatory approvals 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 third party research institutions, organizations and clinical investigators to conduct our preclinical and clinical trials and support our regulatory submissions. If we are unable to reach agreement with qualified research institutions, organizations 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 and support our regulatory submissions will provide us with less control over the timing and cost of those trials, the ability to recruit suitable subjects to participate in the trials, and the timing, cost, and probability of success for the regulatory submissions. 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, both 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. While the Company has initiated patient enrollment and treatment in its first clinical trial in Western Europe, clinical trials that are planned or which have or shall 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, or other relevant decision making bodies 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 the anticipated schedule or consistent with the clinical trial protocol, GCP or regulatory requirements, or other third parties do not perform data collection and analysis in a timely or accurate manner;
- inspections of clinical trial sites by the FDA or an institutional review board ("**IRB**") or other applicable regulatory authorities find violations that require us to undertake corrective action, suspend or terminate one or more testing sites, or prohibit us from using some or all of the resulting data in support of our marketing applications with the FDA or other applicable agencies;
- manufacturing facilities of our third party manufacturers are ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of current good manufacturing practices ("**cGMP**") or other applicable requirements;
- third-party contractors become debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements;
- the FDA or other regulatory authorities impose requirements on the design, structure or other features of the clinical trials for our product candidates that we and/or our third party contractors are unable to satisfy;
- one or more IRBs refuses to approve, suspends or terminates a trial at an investigational site, precludes enrollment of additional subjects, or withdraws its approval of the trial;
- the FDA or other regulatory authorities seek the advice of an advisory committee of physician and patient representatives that may view the risks of our product candidates as outweighing the benefits;
- the FDA or other regulatory authorities require us to expand the size and scope of the clinical trials, which we may not be able to do; or
- the FDA or other regulatory authorities impose prohibitive post-marketing restrictions on any of our product candidates that 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 believe that 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.

We cannot guarantee that we will be able to effectively market our product candidates.

A significant part of our success depends on the various marketing strategies we plan to implement. Our business model has historically focused solely on product development, and we have never attempted to commercialize any product. There can be no assurance as to the success of any such marketing strategy that we develop or that we will be able to build a successful sales and marketing organization. If we cannot effectively market those products we seek to commercialize directly, such products' prospects will be harmed.

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;
- 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 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.

As demonstrated by the Project Agreement that we entered into with NUIG on May 28, 2015, 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 additional 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 expand our current relationship with NUIG and/or seek additional collaborators in the future but are unable to reach agreements with NUIG and/or such other collaborators, as applicable, 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 additional collaborations or other alternative arrangements. The terms of any collaboration or other arrangements that we establish may not be favorable to us, and the success of any such collaboration will depend heavily on the efforts and activities of our collaborators. Any failure to engage successful collaborators could cause delays in our product development and/or commercialization efforts, which could harm our financial condition and operational results.

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

The medical device, pharmaceutical and biotechnology industries are highly competitive. If our product candidates become available for commercial sale, we will compete in that competitive marketplace. There are several products on the market or in development that could be competitors with our lead product candidate. Further, most of our competitors have greater resources or capabilities and greater experience in the development, approval and commercialization of medical devices or other products than we do. We may not be able to compete successfully against them. We also compete for funding with other companies in our industry that are focused on discovering and developing novel improvements in 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 payers 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 payer 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 payers 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 currently have clinical trial liability coverage. We will need to obtain additional product liability insurance coverage if and when we begin commercialization of any of our product candidates. 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. One of our licensed MIT European patents has been opposed in an administrative hearing. 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 our intellectual property 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.

We do not have exclusive rights to certain intellectual property as our patent portfolio includes certain patents that are jointly owned with our collaborators and others that have been in-licensed on a non-exclusive basis.

As of March 31, 2016, we jointly owned a small number of U.S. patents, U.S. patent applications and international (PCT) patent applications with certain of our collaborators. The rights of our collaborators to these patents, patent applications and other compounds under the collaborations may in the future restrict our ability to further develop or generate revenues from those compounds except through the collaborations.

Our patent portfolio, which covers self-assembling peptides and methods of use thereof, includes four patents that have been either allowed, issued or granted, and seventeen pending applications in eight jurisdictions. We have also entered into a license agreement with MIT pursuant to which we have been granted exclusive rights under one portfolio of patents and non-exclusive rights under another portfolio of patents. The portfolio exclusively licensed from MIT includes twelve patents that have been either allowed, issued or granted and ten applications that are pending in a total of eight jurisdictions. The portfolio non-exclusively licensed from MIT includes a number of PCT applications which have now entered the national and regional phases outside of the US, including 7 issued patents in three jurisdictions that expire between 2016 and 2027 (absent patent term extension), and three pending patent applications in four jurisdictions.

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, and 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 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 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, including issuances of shares upon exercise of the Series D Warrants, or the 2014 Warrants, our existing stockholders will be diluted.

Our articles of incorporation authorize the issuance of up to 300,000,000 shares of Common Stock. In connection with the 2015 Private Placement Financing that concluded on July 2, 2015, we issued an aggregate of 14,390,754 shares of our Common Stock, which equaled approximately 18% of the 78,766,487 shares of our Common Stock that were issued and outstanding immediately prior to the commencement of the 2015 Private Placement Financing. Upon the closing of the 2015 Private Placement Financing, we also issued Series D Warrants to acquire up to an additional 14,390,754 shares of our Common Stock at an initial exercise price of $0.25 per share.

Similarly, between March 11, 2015 and through March 13, 2015, we entered into substantially similar Convertible Notes Subscription Agreements with three of our existing investors (the "Convertible Notes Investors") pursuant to which we issued unsecured 8% Convertible Notes to the Convertible Notes Investors in the aggregate principal amount of $750,000. The remaining $100,000 in outstanding principal on our Convertible Notes, which bore interest on the unpaid principal balance at a rate equal to eight percent (8.0%) (computed on the basis of the actual number of days elapsed in a 360-day year) per annum and were convertible into shares of our Common Stock at a conversion price of $0.20 per share, was converted into shares of our Common Stock on April 4, 2016. After giving effect to approximately $46,073 of interest that was accrued under the Convertible Notes, a total of 3,980,359 shares of Common Stock were issued upon the conversion of the Convertible Notes at an average price of approximately $0.1884 per share.

Upon the closing of the 2014 Private Placement Financing on February 4, 2014, we issued an aggregate of 11,400,000 shares of our Common Stock, which equaled approximately 16% of our currently issued and outstanding Common Stock on the date the 2014 Private Placement Financing closed. Upon the closing of the 2014 Private Placement Financing, we also issued three series of Warrants to acquire up to an additional 34,200,000 shares of our Common Stock at initial exercise prices ranging from $0.30 per share (the Series A Warrants), $0.35 per share (the Series B Warrants), and $0.40 per share (the Series C Warrants). On December 1, 2014, the Company entered into that certain Amendment to Series A Warrants, Series B Warrants and Series C Warrants to Purchase Common Stock, dated as of December 1, 2014, with Cranshire pursuant to which, among other things, the exercise prices of the Series B Warrants and Series C Warrants were lowered to $0.20 per share. Following the December 1, 2014 amendment, 4,000,000 shares underlying the Series B Warrants were exercised, and the remaining 7,400,000 expired unexercised on January 3, 2015 when the term of the Series B Warrants expired. As a result of the conversion price of our Convertible Notes, the closing of the Notes Offering and the subsequent issuance of the Convertible Notes triggered the Anti-Dilution Provisions of the Series A Warrants, which in turn reduced the exercise price of the Series A Warrants to $0.20 per share and increased the aggregate number of shares issuable under the Series A Warrants by 5,700,000 shares (or fifty-percent (50%)) from 11,400,000 shares to 17,100,000 shares. As of April 27, 2016, up to 2,500,275 shares may be acquired upon the exercise of the Series C Warrants and up to 5,950,000 shares may be acquired upon the exercise of the Series A Warrants.

Additionally, pursuant to the 2013 Plan, as of April 27, 2016, we were authorized to grant equity awards to our employees, directors and consultants for up to an aggregate of 15,091,195 shares (net of 1,318,750 options already exercised and 300,000 shares of restricted stock awarded) of our Common Stock (and such authorized amount may increase by up to 3 million shares on the first business day of each following fiscal year as set forth in the 2013 Plan), and in addition to the Series D Warrants granted in connection with the 2015 Private Placement Financing, the 2014 Warrants granted in connection with the 2014 Private Placement Financing and the Convertible Notes issued in the Notes Offering, there are currently outstanding warrants to acquire up to 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.

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, compensating consultants by issuing shares or options to purchase shares of our Common Stock, or other transactions and corporate purposes that our Board of Directors deems are in the Company's best interest. By way of example, on August 6, 2015, we issued an aggregate of 600,000 shares of restricted stock in connection with our entrance into separate consulting agreements with two investor relations firms, Excelsior Global Advisors LLC and Acorn Management Partners, LLC, in each case in consideration of the services to be provided under and in accordance with the terms of each consulting agreement. 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.

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.

As noted above under the risk factor entitled, "***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 will need to obtain additional financing prior to or during October 2016 to continue operations and fund our planned future 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 resale of our Common Stock by our existing stockholders could cause the market price of our Common Stock to decline.

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 completed a reverse merger transaction in June 2013.

Additional risks may exist because we completed a "reverse merger" transaction in June 2013. Securities analysts of major brokerage firms may not provide coverage of the Company 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 that 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 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. As of April 27, 2016, Dr. Terrence W. Norchi, our President, Chief Executive Officer and a director, Dr. Avtar Dhillon, the Chairman of our Board of Directors, and James R. Sulat, a director, beneficially own (as determined under Section 13(d) of the Exchange Act and the rules and regulations thereunder) approximately 19% of our 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, has caused, and could continue to cause, our operational expenses to remain at higher levels or continue to increase.

Our present management team has limited experience in 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 additional 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 as well as additional IT systems 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. 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.

Rule 144 imposes 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. We were a shell company prior to the closing of the Merger, and such status 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. In addition, under the terms of the MLSC Loan Agreement, we must obtain MLSC's prior consent before declaring or paying any dividends during the term of the MLSC Loan Agreement. As a result, 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.

FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements that involve risks, uncertainties and assumptions. In some cases, you can identify forward-looking statements by terminology such as "if," "shall," "may," "might," "will likely result," "should," "e "plan," "anticipate," "believe," "estimate," "project," "intend," "goal," "objective," "predict," "potential" or "continue," or the these terms or other comparable terminology. All statements made in this report on Form 10-Q other than statements of historical fact are statements that could be deemed forward-looking statements, including without limitation statements about our business plan, our plan of operations and our need to obtain future financing. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks in the section entitled "**Risk Factors**" and the risks set out below, any of which may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. These risks include, by way of example and not in limitation, risks related to:

- Our ability to continue as a going concern;
- Our ability to obtain financing necessary to operate our business;

- Our limited operating history;
- The results of our research and development activities, including uncertainties relating to the preclinical and clinical testing of our product candidates;
- The early stage of our primary product candidate presently under development;
- Our ability to develop, obtain required approvals for and commercialize our product candidates;
- Our ability to recruit and retain qualified personnel;
- Our ability to manage any future growth we may experience;
- Our ability to obtain and maintain protection of our intellectual property;
- Our dependence on third party manufacturers, suppliers, research organizations, academic institutions, testing laboratories and other potential collaborators;
- The size and growth of the potential markets for any of our approved product candidates, and the rate and degree of market acceptance of any of our approved product candidates;
- Our ability to successfully complete potential acquisitions and collaborative arrangements;
- Competition in our industry;

•General economic and business conditions; and

•Other factors discussed under the section entitled "**Risk Factors**".

New risks emerge in our rapidly-changing industry from time to time. As a result, it is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business. If any such risks or uncertainties materialize or such assumptions prove incorrect, our results could differ materially from those expressed or implied by such forward-looking statements and assumptions. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity or performance. These forward-looking statements speak only as of the date of this report on Form 10-Q. Except as required by applicable law, we do not intend to update any of these forward-looking statements.

Item 6. Exhibits

Exhibit	Description
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 Richard E. Davis, 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

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: April 28, 2016 By: /s/ TERRENCE W. NORCHI, MD
Terrence W. Norchi, MD
President and Chief Executive Officer
(Principal Executive Officer)

Date: April 28, 2016 By: /s/ RICHARD E. DAVIS
Richard E. Davis
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 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

I, Terrence W. Norchi, certify that:

1. I have reviewed this Form 10-Q of Arch Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted

accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 28, 2016

/s/ TERRENCE W. NORCHI, MD
Terrence W. Norchi, MD
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 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

I, Richard E. Davis, certify that:

1. I have reviewed this Form 10-Q of Arch Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: April 28, 2016

/s/ RICHARD E. DAVIS
Name: Richard E. Davis
Title: *Chief Financial Officer*
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION REQUIRED BY

SECTION 1350 OF TITLE 18 OF THE UNITED STATES CODE

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned officers of Arch Therapeutics, Inc. (the "Company") that the quarterly report of the Company on Form 10-Q for the fiscal quarter ended March 31, 2016 fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: April 28, 2016

/s/ TERRENCE W. NORCHI, MD
Name: Terrence W. Norchi, MD
Title: *President and Chief Executive Officer*
(Principal Executive Officer)

Dated: April 28, 2016

/s/ RICHARD E. DAVIS
Name: Richard E. Davis
Title: *Chief Financial Officer*
(Principal Financial and Accounting Officer)

This certification accompanies this Report on Form 10-Q pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.