

Arch Therapeutics, Inc.
Form 424B3
February 16, 2016

Filed Pursuant to Rule 424(b)(3)

Registration No. 333-206873

PROSPECTUS SUPPLEMENT NO. 1 DATED FEBRUARY 16, 2016

TO

PROSPECTUS DATED JANUARY 15, 2016

(AS SUPPLEMENTED)

ARCH THERAPEUTICS, INC.

PROSPECTUS

Up to 25,590,599 Shares of Common Stock

This Prospectus Supplement No. 1 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 document which we filed with the Securities and Exchange Commission on February 12, 2016:

A. Our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on February 12, 2016

This Prospectus Supplement No. 1 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. 1 is February 16, 2016

INDEX TO FILINGS

The Company's Quarterly Report filed with the Securities and Exchange Commission on February 12, 2016 **Annex**
A

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

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

For the quarterly period ended December 31, 2015

Commission File Number: 000-54986

ARCH THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of incorporation or organization)

46-0524102

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

235 Walnut Street, Suite 6

Framingham, MA

(Address of principal executive offices)

01702

(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 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 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

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

As of February 11, 2016, 109,574,100 shares of the registrant’s common stock were outstanding.

ARCH THERAPEUTICS, INC.

Quarterly Report on Form 10-Q

For the Three Months Ended December 31, 2015

TABLE OF CONTENTS

<u>PART I – FINANCIAL INFORMATION</u>	3
<u>Item 1. Financial Statements</u>	3
<u>Consolidated Balance Sheets as of December 31, 2015 (unaudited) and September 30, 2015</u>	3
<u>Consolidated Statements of Operations for the three months ended December 31, 2015 and December 31, 2014 (unaudited)</u>	4
<u>Consolidated Statements of Cash Flows for the three months ended December 31, 2015 and December 31, 2014 (unaudited)</u>	5
<u>Notes to Consolidated Financial Statements (unaudited)</u>	6
<u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	18
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	27
<u>Item 4. Controls and Procedures</u>	27
<u>PART II - OTHER INFORMATION</u>	28
<u>Item 1. Legal Proceedings</u>	28
<u>Item 1A. Risk Factors</u>	28
<u>Item 6. Exhibits</u>	47

PART I – FINANCIAL INFORMATION**Item 1. Financial Statements**

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

	December 31, 2015 (Unaudited)	September 30, 2015
ASSETS		
Current assets:		
Cash	\$2,815,449	\$3,960,100
Prepaid expenses and other current assets	52,960	42,919
Total current assets	2,868,409	4,003,019
Total assets	\$2,868,409	\$4,003,019
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$267,863	\$231,761
Accrued expenses and other liabilities	146,429	245,478
Convertible notes, net of unamortized discount	265,898	473,747
Current derivative liabilities	68,485	335,092
Total current liabilities	748,675	1,286,078
Long-term liabilities:		
Note payable, net of unamortized discount	969,589	966,824
Accrued interest, net of current portion	240,250	210,000
Total long-term liabilities	1,209,839	1,176,824
Total liabilities	1,958,514	2,462,902
Commitments and contingencies		
Stockholders' equity		
Common stock, \$0.001 par value, 300,000,000 shares authorized, 109,171,684 and 107,592,205 shares issued and outstanding as of December 31, 2015 and September 30, 2015, respectively	109,172	107,392

Edgar Filing: Arch Therapeutics, Inc. - Form 424B3

Additional paid-in capital	17,679,598	17,154,945
Accumulated deficit	(16,878,875)	(15,722,220)
Total stockholders' equity	909,895	1,540,117
Total liabilities and stockholders' equity	\$ 2,868,409	\$ 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 Months Ended December 31, 2015 and 2014

	Three Months Ended December 31, 2015	Three Months Ended December 31, 2014
Revenues	\$ -	\$ -
Operating expenses:		
General and administrative expenses	865,512	870,355
Research and development expenses	414,003	399,735
Total operating expenses	1,279,515	1,270,090
Operating loss	(1,279,515) (1,270,090
Other income (expense):		
Interest expense	(143,747) (27,765
Gain on exercise of warrants and conversion of debt	129,461	224,000
Loss on warrant derivative modification	-	(1,300,170
Decrease to fair value of derivative	137,146	2,753,170
Total other income	122,860	1,649,235
Net (loss) income	\$ (1,156,655) \$ 379,145
Earnings per share - basic		
Net (loss) income per common share - basic	\$ (0.01) \$ 0.01
Weighted common shares - basic	108,620,575	73,337,085
Earnings per share - diluted		
Net (loss) income per common share - diluted	\$ (0.01) \$ 0.01
Weighted common shares - diluted	108,620,575	73,422,007

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

Arch Therapeutics, Inc.
 Consolidated Statements of Cash Flows (Unaudited)
 For the Three Months Ended December 31, 2015 and 2014

	Three Months Ended December 31, 2015	Three Months Ended December 31, 2014
Cash flows from operating activities:		
Net (loss) income	\$ (1,156,655) \$ 379,145
Adjustments to reconcile net (loss) income to cash used in operating activities:		
Stock-based compensation	148,037	278,212
Noncash interest expense on notes payable	143,747	27,764
Issuance of restricted stock for services	52,500	8,625
Gain on exercise of warrants and conversion of debt	(129,461) (224,000)
Loss on warrant derivative modification	-	1,300,170
Decrease to fair value of derivative	(137,146) (2,753,170)
Changes in operating assets and liabilities:		
(Increase) decrease in:		
Prepaid expenses and other current assets	(10,041) 1,704
Increase (decrease) in:		
Accounts payable	36,102	118,350
Accrued expenses and other liabilities	(91,734) 12,355
Net cash used in operating activities	(1,144,651) (850,845)
Cash flows from financing activities:		
Proceeds from exercise of warrants	-	800,000
Net cash provided by financing activities	-	800,000
Net decrease in cash	(1,144,651) (50,845)
Cash, beginning of period	3,960,100	833,520
Cash, end of period	\$ 2,815,449	\$ 782,675
Non-cash financing activities Conversion of 8% convertible notes and accrued interest to common stock	\$ 325,896	\$ -

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 has 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 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 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 June 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 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 8 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 three months ended December 31, 2015.

Basis of Accounting

The 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) 2015-17, “Income Taxes (Topic 740) – Balance Sheet Classification of Deferred Taxes” was issued by the Financial Accounting Standards Board (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. ASU 2015-17 is effective for financial statements issued for annual periods 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 application 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 application 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.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist primarily of cash and cash equivalents. 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 and cash equivalents.

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 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 month periods ended December 31, 2015 and 2014 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 to 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 December 31, 2015 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*, that 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 remeasure 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 the 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*, excluding those that are recognized or disclosed in the consolidated financial statements at fair value on a recurring basis. 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 December 31, 2015 and September 30, 2015, the carrying amounts of cash, accounts payable, accrued liabilities, and convertible notes payable 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 February 11, 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 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 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 December 31, 2015, 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 and cash equivalents to support its current operating plan. The Company will be required to raise additional capital, obtain alternative means of financial support, or both, in order to continue to fund operations. Therefore, there exists substantial doubt about the Company's ability to continue as a going concern. Historically, the Company has funded its operations primarily through equity and debt financings.

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 December 31, 2015, 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 months ended December 31, 2015, 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 months ended December 31, 2015 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 months ended December 31, 2015; expected volatility, 76.6% - 119.4%, risk-free interest

rate, 1.06% - 2.4%, expected forfeiture rate, 0.00%, 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 three months ended December 31, 2015 follows:

	Option Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (\$0's)
Outstanding at September 30, 2015	10,776,500	\$ 0.38	-	\$ -
Awarded	-	-	-	-
Exercised	-	-	-	-
Forfeited	(37,500)	\$ 0.22	-	-
Outstanding at December 31, 2015	10,739,000	\$ 0.30	6.63	51,400
Vested	8,849,563	\$ 0.32	4.66	35,567
Vested and expected to vest at December 31, 2015	10,739,000	\$ 0.30	6.63	51,400

As of December 31, 2015, 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 statement of operations for the three months ended December 31, 2015 and 2014 resulting from stock options awarded to the Company's employees, directors and consultants was approximately \$148,000 and \$278,000, respectively. Of this amount during the three months ended December 3, 2015 and 2014, approximately \$54,000 and \$121,000 respectively was recorded to research and development expenses, and approximately \$94,000 and \$157,000, respectively was recorded in general and administrative expenses in the Company's unaudited interim consolidated statement of operations.

As of December 31, 2015, there is approximately \$360,000 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 1.45 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 three months ended December 31, 2015 follows:

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

The weighted average restricted stock award date fair value information for the three months ended December 31, 2015 follows:

	2015
Non Vested at September 30, 2015	\$0.35
Awarded	-
Vested	0.35
Forfeited	-
Non Vested at December 31, 2015	\$-

For the three months ended December 31, 2015, compensation expense recorded for the restricted stock awards was approximately \$53,000.

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.

The Notes become due and payable on March 13, 2016 (the “Stated Maturity Date”) and may not be prepaid. The Notes bear 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 until either (a) converted into shares of the Company's common stock, \$0.001 par value per share ("Common Stock") or (b) the outstanding principal and accrued interest on the Notes is paid in full by the Company. Interest on the Notes becomes due and payable upon their conversion or the Stated Maturity Date and may become due and payable upon the occurrence of an event of default under the Notes. The Notes contain customary events of default, which include, among other things, (i) the Company's failure to pay other indebtedness of \$100,000 or more within the specified cure period for such breach; (ii) the acceleration of the stated maturity of such indebtedness; (iii) the insolvency of the Company; and (iv) the receipt of final, non-appealable judgments in the aggregate amount of \$100,000 or more.

At any time prior to the Stated Maturity Date, the holders of the Notes have the right to convert some or all of such Notes into the number of shares of Common Stock determined by dividing (a) the aggregate sum of the (i) principal amount of the Note to be converted, and (ii) amount of any accrued but unpaid interest with respect to such portion of the Note to be converted; and (b) the conversion price then in effect (the shares of Common Stock issuable upon such conversion, the "Conversion Shares"). The initial conversion price is \$0.20 per share, and it may be (A) reduced to any amount and for any period of time deemed appropriate by the Board of Directors of the Company, or (B) reduced or increased proportionately as a result of stock splits, stock dividends, recapitalizations, reorganizations, and similar transactions. A holder shall not have the right to convert any portion of a Note, if after giving effect to such conversion, the holder, together with its affiliates collectively, would beneficially own more than 4.99% or 9.99% (at the holder's discretion) of the shares of Common Stock outstanding immediately after giving effect to such conversion. During the three months ended December 31, 2015, \$310,000 of Notes and \$15,896 of interest were converted into 1,629,479 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 loan, which is being accreted to interest expense over the life of the loan. For the three months ended December 31, 2015, \$102,151 of the loan discount has been accreted to interest expense. As of December 31, 2015 the accreted balance of the outstanding Notes was \$265,898.

The value of the derivative liability as of December 31, 2015 was \$68,485. As a result of the conversion of notes and a change in the estimated fair value of the derivative liability we recorded other income of \$129,461 and \$137,146 for the three months ended December 31, 2015, respectively.

**Fair Value Measurements Using Significant Unobservable
Inputs
(Level 3)**

	Convertible Debt Derivative Liability
Beginning balance at September 30, 2015	\$ 335,092
Conversion of notes	(129,461)
Adjustments to estimated fair value	(137,146)
Ending balance at December 31, 2015	\$ 68,485

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 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 December 31, 2015.

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 each of the three months ended December 31, 2015 and 2014, \$2,765 of the loan discount has been accreted to interest expense. As of December 31, 2015 and September 30, 2015 the accreted balance of the MLSC Loan was \$969,589 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 and 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 and 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.

On June 22, 2015 the Company entered into the 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.

For the three months ended December 31, 2015, none of the Series A Warrants and Series C Warrants had been exercised. During the quarter ended December 31, 2014, 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.

Common Stock

At the February 4, 2014 closing date of the 2014 Private Placement Financing, the Company issued 11,400,000 shares of Common Stock and recorded the par value of the shares issued of \$11,400 (at par value of \$0.001 per share) with a corresponding reduction in additional paid-in capital, given that the fair value of the warrant liability recorded exceeded the total consideration received as of February 4, 2014.

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 Directors 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.

9. SUBSEQUENT EVENTS

The Company evaluated all events or transactions that occurred through February 11, 2016 the date which these unaudited interim consolidated financial statements were available to be issued. There were no material subsequent events.

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,” “anticipate,” “believe,” “estimate,” “project,” “intend,” “goal,” “objective,” “predict,” “potential” or “continue,” or the negative of these terms or 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, subsequently, 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 and complete a human clinical trial(s) for AC5, the timeframe for which is dependent upon successful completion of certain manufacturing, regulatory, and biocompatibility activities;

-20-

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 loss for the three months ended December 31, 2015 of \$1,156,655 and net income of \$379,145 for the three months ended December 31, 2014. The loss for the three months ended December 31, 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. Net income for the three months ended December 31, 2014, can be attributed primarily to a net gain on adjustments of derivative liabilities related to our outstanding warrants of \$1,677,000 partially offset by an increase in general and administrative costs attributable to attracting and retaining key employees, the expense of complying with public company reporting and control obligations and increased research and development expenses. We devote a significant amount of our efforts towards fundraising and product research.

Recent Developments

During the three months ended December 31, 2015, \$310,000 of convertible notes and \$15,896 of interest were converted into 1,629,479 shares of common stock.

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 December 31, 2015 Compared to Three Months Ended December 31, 2014

	December 31, 2015 (\$)	December 31, 2014 (\$)	Increase (Decrease) (\$)
Revenue	-	-	-
Operating Expenses			
General and administrative	865,512	870,355	(4,843)
Research and development	414,003	399,735	14,268
Loss from operations	(1,279,515)	(1,270,090)	9,425
Other income	122,860	1,649,235	(1,526,375)
Net (loss) income	(1,156,655)	379,145	(1,535,800)

Revenue

We did not generate revenue in either of the three months ended December 31, 2015 and 2014.

General and Administrative Expense

General and administrative expenses during the three months ended December 31, 2015 were \$865,512, a decrease of \$4,843 compared to \$870,355 for the three months ended December 31, 2014. The decrease in general and administrative expense is primarily attributable to a decrease in patent expenses partially offset by an increase in consulting expenses.

Research and Development Expense

Research and development expenses during the three months ended December 31, 2015 were \$414,003, an increase of \$14,268 compared to \$399,735 for the three months ended December 31, 2014. The increase 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 partially offset by a decrease in stock based compensation and payroll. Research and development expenses are expected to increase as a result of our plans to commence clinical studies as resources permit. Site initiation has been completed and patient screening for enrollment has commenced.

Other Income (Expense)

Other income during the three months ended December 31, 2015 was \$122,860 a decrease of \$1,526,375 compared to other income of \$1,649,235 for the three months ended December 31, 2014. This decrease resulted from a change in adjustments to derivative liabilities of \$1,410,393 during fiscal 2016 as compared to fiscal 2015. Other income during the three months ended December 31, 2014 was attributed primarily to a net gain on adjustments of derivative liabilities related to our outstanding warrants of \$1,677,000. As of June 22, 2015, the Company determined that its Series A and Series 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.

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 December 31, 2015, we had cash and cash equivalents of \$2,815,449 and positive working capital of \$2,119,734.

*Cash Used in Operating Activities**Working Capital*

At December 31, 2015, we had total current assets of \$2,868,409 (including cash of \$2,815,449) and working capital of \$2,119,734. Our working capital as of December 31, 2015 and September 30, 2015 is summarized as follows:

	December 31, 2015	September 30, 2015
Total Current Assets	\$ 2,868,409	\$ 4,003,019
Total Current Liabilities	748,675	1,286,078
Working Capital	\$ 2,119,734	\$ 2,716,941

Total current assets as of December 31, 2015 were \$2,868,409, a decrease of \$1,134,610 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 December 31, 2015 and September 30, 2015 were comprised primarily of cash, prepaid expenses and other current assets.

Total current liabilities as of December 31, 2015 were \$748,675, a decrease of \$537,403 compared to \$1,286,078 as of September 30, 2015. The decrease is primarily due to the conversion of \$310,000 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 December 31, 2015 and September 30, 2015 were comprised primarily of the current portion of the derivative liability, the Notes, accounts payable and accrued expenses.

Cash Flow for the Three Months Ended

	December 31, 2015	December 31, 2014
Cash Used in Operating Activities	\$ (1,144,651)	\$ (850,845)
Cash Used in Investing Activities	-	-
Cash Provided by Financing Activities	-	800,000
Net increase (decrease) in cash and cash equivalents	\$ (1,144,651)	\$ (50,845)

Cash Used in Operating Activities

Cash used in operating activities increased \$293,806 during the three months ended December 31, 2015 to \$1,144,651, compared to \$850,845 during the three months ended December 31, 2014. 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 three months ended December 31, 2015 and 2014, respectively.

Cash Provided by Financing Activities

Cash provided by financing activities decreased \$800,000 to \$0 during the three months ended December 31, 2015, compared to \$800,000 during the three months ended December 31, 2014. For the three months ended December 31, 2014, 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

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 through June 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 December 31, 2015 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 December 31, 2015, 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 December 31, 2015 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**”) that 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 the 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) 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. ASU 2015-17 is effective for financial statements issued for annual periods 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 application 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 application 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 December 31, 2015, 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 December 31, 2015 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.

-