Arch Therapeutics, Inc.
Form 10-Q
February 01, 2019

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, 2018

Commission File Number: **000-54986**

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes x No ¨

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

Large accelerated filer ¨ Accelerated filer ¨

Non-accelerated filer x Smaller reporting company x

Emerging growth company ¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

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

As of January 31, 2019, 164,961,849 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, 2018

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Arch Therapeutics, Inc.
Consolidated Balance Sheets
As of December 31, 2018 (Unaudited) and September 30, 2018

	December 31, 2018 (Unaudited)	September 30, 2018
ASSETS		
Current assets:		
Cash	$3,377,653	$4,667,410
Prepaid expenses and other current assets	240,012	151,794
Total current assets	3,617,665	4,819,204
Long-term assets:		
Property and equipment, net	15,480	17,261
Other assets	3,500	3,500
Total long-term assets	18,980	20,761
Total assets	$3,636,645	$4,839,965
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$130,632	$160,946
Accrued expenses and other liabilities	145,920	127,439
Total current liabilities	276,552	288,385
Long-term liabilities:		
Long-term derivative liability	4,024,165	3,191,752
Total long-term liabilities	4,024,165	3,191,752
Total liabilities	4,300,717	3,480,137
Commitments and contingencies		
Stockholders’ equity (deficit):		
Common stock, $0.001 par value, 300,000,000 shares authorized, 164,961,849 and 164,297,013 shares issued and outstanding as of December 31, 2018 and September 30, 2018, respectively	162,197	159,815
Additional paid-in capital	36,091,446	35,517,491
Accumulated deficit	(36,917,715)	(34,317,478)
Total stockholders’ equity (deficit)	(664,072)	1,359,828
Total liabilities and stockholders' equity (deficit)	$3,636,645	$4,839,965

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, 2018 and 2017

	Three Months Ended December 30, 2018	Three Months Ended December 30, 2017
Revenues	$ -	$ -
Operating expenses:		
General and administrative expenses	1,178,622	1,001,511
Research and development expenses	589,202	580,862
Total operating expenses	1,767,824	1,582,373
Operating loss	(1,767,824)	(1,582,373)
Other income (expense):		
(Increase)/decrease to fair value of derivative	(832,413)	1,971,549
Total other income (expense)	(832,413)	1,971,549
Net income (loss)	$ (2,600,237)	$ 389,176
Earnings per share - basic		
Net income (loss) per common share - basic	$ (0.02)	$ -
Weighted common shares - basic	161,057,300	150,144,575
Earnings per share - diluted		
Net income (loss) per common share - diluted	$ (0.02)	$ -
Weighted common shares - diluted	161,057,300	163,527,032

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, 2018 and 2017

	Three Months Ended December 31, 2018	Three Months Ended December 31, 2017
Cash flows from operating activities:		
Net (loss) income	$ (2,600,237)	$ 389,176
Adjustments to reconcile net (loss) income loss to cash used in operating activities:		
Depreciation	1,781	724
Stock-based compensation	522,437	434,820
Issuance of restricted stock for services	21,500	-
Increase (decrease) to fair value of derivative	832,413	(1,971,549)
Changes in operating assets and liabilities:		
(Increase) decrease in:		
Prepaid expenses and other current assets	(88,218)	13,939
Increase (decrease) in:		
Accounts payable	(30,314)	24,400
Accrued expenses and other liabilities	18,481	12,586
Net cash used in operating activities	(1,322,157)	(1,095,904)
Cash flows from investing activities:		
Purchases of property and equipment	-	(3,463)
Net cash used in investing activities	-	(3,463)
Cash flows from financing activities:		
Proceeds from exercise of warrants	-	63,388
Proceeds from exercise of stock options	32,400	-
Net cash provided by financing activities	32,400	63,388
Net (decrease) in cash	(1,289,757)	(1,035,979)
Cash, beginning of year	4,667,410	5,994,052
Cash, end of period	$ 3,377,653	$ 4,958,073
Non-cash financing activities:		
Exercise of stock options - cashless	$ 477	$ 117
Restricted stock - vested	$ 1,817	$ -

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

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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.". Effective June 26, 2013, the Company completed a merger (the "Merger") with Arch Biosurgery, Inc. (formerly known as Arch Therapeutics, Inc.), a Massachusetts corporation ("ABS"), and Arch Acquisition Corporation ("Merger Sub"), the Company's wholly owned subsidiary formed for the purpose of the transaction, pursuant to which Merger Sub merged with and into ABS and ABS thereby became the wholly owned subsidiary of the Company. As a result of the acquisition of ABS, the Company abandoned its prior business plan and changed its operations to the business of a biotechnology company. Our 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 the Commonwealth of Massachusetts on March 6, 2006 as Clear Nano Solutions, Inc. On April 7, 2008, ABS changed its name from Clear Nano Solutions, Inc. to Arch Therapeutics, Inc. Effective upon the closing of the Merger, ABS changed its name from Arch Therapeutics, Inc. to Arch Biosurgery, Inc.

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

The Company expects to incur substantial expenses for the foreseeable future relating to research, development and commercialization of its potential products. 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 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, 2018, filed with the SEC on December 18, 2018.

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, 2018. There have been no material changes to our significant accounting policies during the three months ended December 31, 2018.

Basis of Presentation

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 and retaining 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) 2018-07, “Compensation—Stock Compensation (Topic 718) Improvements to Nonemployee Share-Based Payment Accounting” was issued by the Financial Accounting Standards Board (FASB) in June 2018. The purpose of this amendment is to address aspects of the accounting for nonemployee share-based payment transactions. The amendments in this Update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted. The Company does not believe that this guidance will have a material impact on its consolidated results of operations, financial position or disclosures.

ASU 2016-15, “Statement of Cash Flows (Topic 230) Classification of Certain Cash Receipts and Payments” was issued by the Financial Accounting Standards Board (FASB) in August 2016. The purpose of this amendment is to address eight specific cash flow issues with the objective of reducing the existing diversity in practice. The amendments in this Update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2017. Early adoption is permitted. The Company adopted ASU 2016-15 during our first quarter of fiscal year 2019, which had no impact on our consolidated financial statements, and will apply the new guidance in future periods.

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

Cash

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. The Company had no cash equivalents as of December 31, 2018 and September 30, 2018.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist primarily of cash. The Company maintains its cash in bank deposits 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.

Deferred Offering Costs

Deferred Offering Costs consist of fees and expenses incurred in connection with the public offering and sale of the Company’s common stock, including legal, accounting, printing and other related expenses. These costs are netted against the proceeds received as a reduction to additional paid-in capital.

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 months ended December 31, 2018 and September 30, 2018 there has not been any impairment of long-lived assets.

Income Taxes

In accordance with FASB ASC 740, *Income Taxes*, we recognize deferred tax assets and liabilities for the expected future tax consequences or events that have been included in our consolidated financial statements and/or tax returns. Deferred tax assets and liabilities are based upon the differences between the 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.

On December 22, 2017, the Tax Cuts and Jobs Act (“TCJA”) was signed into United States law. The TCJA includes a number of changes to existing tax law, including, among other things, a permanent reduction in the federal corporate income tax rate to a flat rate of 21%, effective January 1, 2018, as well as the elimination of net operating loss carrybacks for losses arising in taxable years beginning after December 31, 2017. Further, operating losses arising in tax years after December 31, 2017, are carried forward indefinitely. Due to the TCJA, the Company’s deferred tax assets and liabilities recognized prior to 2017 were revalued at the newly enacted tax rates, which resulted in a corresponding adjustment in the valuation allowance.

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 FASB ASC Topic 718, *Compensation-Stock Compensation* ("FASB ASC Topic 718"), which requires all share-based payments to employees, including grants of employee stock options, to be recognized in the consolidated financial statements based on their fair values. The Company accounts for non-employee stock-based compensation in accordance with the guidance of FASB ASC Topic 505, *Equity* ("FASB ASC Topic 505"), which requires that companies recognize compensation expense based on the estimated fair value of options granted to non-employees over their vesting period, which is generally the period during which services are rendered by such non-employees. FASB ASC Topic 505 requires the Company to re-measure the fair value of stock options issued to non-employee at each reporting period during the vesting period or until services are complete. In accordance with FASB ASC Topic 718, 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. Prior to January 1, 2018, the Company did not have a sufficient history of market prices of the common stock, and as such volatility was 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. Effective January 1, 2018, the Company is using its historical market prices to calculate the volatility of its common stock. The life term for awards uses simplified method for all "plain vanilla" options, as defined in ASC 718-10-S99 and the contractual term for all other employee and non-employee awards. The risk-free interest rate assumption is based on observed interest rates appropriate for the terms of our awards. The dividend yield assumption is based on history and the expectation of paying no dividends. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Stock-based compensation expense, when recognized in the consolidated financial statements, is based on awards that are ultimately expected to vest.

Fair Value Measurements

The Company measures both financial and nonfinancial assets and liabilities in accordance with FASB ASC Topic 820, *Fair Value Measurements and Disclosures*, including 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 own views about the assumptions market participants would use in pricing the asset or liability.

At December 31, 2018 and September 30, 2018, the carrying amounts of cash, prepaid expenses and other current assets, accounts payable, accrued expenses and other liabilities, approximate fair value because of their short-term nature.

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 FASB ASC Topic 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 expected volatility, expected life, yield, and risk-free interest rate.

Subsequent Events

The Company evaluated all events or transactions that occurred commencing from January 1, 2019 and ending on January 31, 2019 the date which these consolidated financial statements were issued. The Company disclosed material subsequent events in Note 10.

Going Concern Basis of Accounting

As reflected in the consolidated financial statements, the Company has an accumulated deficit, has suffered significant net losses and negative cash flows from operations, has not generated operating revenues, 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. In particular, as of December 31, 2018, the Company will be required to raise additional capital, obtain alternative means of financial support, or both, in order to continue to fund operations, and therefore there is substantial doubt about our ability to continue as a going concern. The Company expects to incur substantial expenses into 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. Historically, the Company has principally funded operations through debt borrowings, the issuance of convertible debt, and the issuance of units consisting of common stock and warrants. Provisions in the Securities Purchase Agreements that the Company entered into on February 20, 2017 (“2017 SPA”) and on June 28, 2018 (“2018 SPA”) restrict the Company’s ability to effect or enter into an agreement to effect any issuance by the Company or any of its subsidiaries of Common Stock or securities convertible, exercisable or exchangeable for Common Stock (or a combination of units thereof) involving a Variable Rate Transaction (as defined in the 2017 SPA and 2018 SPA) including, but not limited to, an equity line of credit or “At-the-Market” financing facility until the three lead investors in the 2017 Financing and the institutional investors in the 2018 SPA collectively own less than 20% of the Series F Warrants and the Series G Warrants purchased by them pursuant to the 2017 SPA and 2018 SPA, respectively. In addition, the 2018 SPA restricted, subject to certain customary exemptions, from June 28, 2018 until 90 days after July 2, 2018 (i.e., September 30, 2018), the Company and its subsidiaries from entering into any agreement to issue or announcing the issuance or proposed issuance of any shares of Common Stock or securities convertible, exercisable or exchangeable for Common Stock.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. Which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The consolidated financial statements do not include any adjustments that might result from this uncertainty.

3. PROPERTY AND EQUIPMENT

At December 31, 2018 and September 30, 2018, property and equipment consisted of:

	Estimated Useful Life	December 31, 2018	**September 30, 2018**
Furniture and fixtures	5 years	$ 9,357	$ 9,357
Leasehold improvements	3 years	8,983	8,983
Computer equipment	3 years	8,686	8,686
Lab equipment	5 years	1,000	1,000
		28,026	28,026
Less – accumulated depreciation		12,546	10,765
Property and equipment, net		$ 15,480	$ 17,261

For the three months ended December 31, 2018 and 2017 depreciation expense recorded was $1,781 and $724, respectively.

4.STOCK-BASED COMPENSATION

2013 Stock Incentive Plan

On June 18, 2013, the Company established the 2013 Stock Incentive Plan ("2013 Plan"). Under the 2013 Plan, during the fiscal year ended September 30, 2018, a maximum number of 22,114,256 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 ("Board"). The exercise price of each option shall be the fair value as determined in good faith by the Board at the time each option is granted. On October 1, 2018, the aggregate number of authorized shares under the Plan was further increased by 3,000,000 shares to a total of 25,114,256 shares.

As of December 31, 2018, a total of 15,669,212 options had been issued to employees and directors and 6,127,500 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, 2018, the Company granted 100,000 options to employees and directors, and 100,000 options 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 granted during the three months ended December 31, 2018 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, 2018; expected volatility, 93.15% - 119.44%, risk-free interest rate, 1.38% - 3.23%, expected forfeiture rate, 0%, expected dividend yield, 0%, expected term, 5.75 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. Prior to January 1, 2018, 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 groups as determined by the Company. Effective January 1, 2018, 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.

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

Stock-based compensation expense recognized in the Company's consolidated statements of operations is based on awards ultimately expected to vest, reduced for estimated forfeitures. Authoritative guidance requires forfeitures to be estimated at the time of grant, and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Since the Company has a limited history of occurrences of stock option forfeitures and a small number of employees it continues to estimate the forfeiture rate of its outstanding stock options as zero, but will continually evaluate its historical data as a basis for determining expected forfeitures.

Common Stock Options

Stock compensation activity under the 2013 Plan for the three months ended December 31, 2018 follows:

	Option Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at September 30, 2018	15,684,210	$ 0.40	3.89	$1,142,521
Awarded	200,000	$ 0.39	-	-
Exercised	(1,525,000)	$ 0.37	-	-
Forfeited/Cancelled	(104,212)	$ 0.37	-	-
Outstanding at December 31, 2018	14,254,998	$ 0.40	3.75	$2,237,885
Exercisable at December 31, 2018	11,720,960	$ 0.38	4.14	$2,040,184
Vested and expected to vest at December 31, 2018	14,254,998	$ 0.40	3.75	$2,237,885

As of December 31, 2018, 5,743,356 shares are available for future grants under the 2013 Plan. Share-based compensation expense recorded in the Company's Consolidated Statements of Operations for the three months ended December 31, 2018 and 2017 resulting from stock options awarded to the Company's employees, directors and consultants was approximately $339,000 and $193,000, respectively. Of this amount during the three months ended December 31, 2018 and 2017, $66,000 and $62,000, respectively, was recorded to research and development expenses, and $273,000 and $131,000, respectively was recorded in general and administrative expenses in the Company's Consolidated Statements of Operations.

During the three months ended December 31, 2018, 87,567 stock options awarded under the 2013 Stock Incentive Plan were exercised for cash resulting in proceeds to the Company of $32,400. During the three months ended December 31, 2018, 1,437,433 stock options awarded under the 2013 Stock Incentive Plan were exercised on a cashless basis for an aggregate issuance of 477,269 shares of the Company's Common Stock.

As of December 31, 2018, there is approximately $540,000 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 1.32 years.

Restricted Stock

On February 3, 2017, the Company awarded 1,750,000 shares of Restricted Stock to members of the Board of Directors and management. The shares subject to this grant are awarded under the 2013 Plan and 100% shall fully vest on the second anniversary of the date of grant. In addition, in the event of a Change of Control (as such term is defined in the 2013 Plan), 100% of the grants will immediately vest.

On July 19, 2018, the Company awarded 745,000 shares of Restricted Stock to members of the Board of Directors and management and 220,000 shares of Restricted Stock to Dr. Dhillon in his capacity as a consultant. The shares subject to this grant are awarded under the 2013 Plan and 100% shall fully vest on the second anniversary of the date of grant. In addition, in the event of a Change of Control (as such term is defined in the 2013 Plan), 100% of the grants will immediately vest.

On September 5, 2018, the Company awarded 100,000 shares of Restricted Stock to a consultant. The shares subject to this grant are awarded under the 2013 Plan and 50,000 vest 90 days from the date of the award and 50,000 vest 365 days from the date of the award. In addition, in the event of a Change of Control (as such term is defined in the 2013 Plan), 100% of the grants will immediately vest.

Restricted stock activity under the 2013 Plan for the three months ended December 31, 2018 and 2017 follows:

	2018	2017
Non Vested at September 30, 2018 and 2017	2,815,000	1,750,000
Awarded	-	-
Vested	(50,000)	-
Forfeited	-	-
Non Vested at December 31, 2018 and 2017	2,765,000	1,750,000

The weighted average restricted stock award date fair value information for the three months ended December 31, 2018 and 2017 follows:

	2018	2017
Non Vested at September 30, 2018 and 2017	$0.57	$0.39
Awarded	-	-
Vested	(0.43)	-
Forfeited	-	-
Non Vested at December 31, 2018 and 2017	$0.57	$0.39

Non-employee restricted shares subject to vesting are revalued at each vesting date and at the end of the reporting period, with all changes in fair value recorded as stock-based compensation expense. For the three months ended December 31, 2018 and 2017 compensation expense recorded for the restricted stock awards was approximately $205,000 and $143,000, respectively.

5. Restricted Stock Awarded Outside the 2013 Stock Incentive Plan

On May 3, 2016, the Company awarded 2,000,000 shares of Restricted Stock to members of the Board of Directors and management in a private placement in reliance upon an exemption from registration afforded by Section 4(a)(2) of the Securities Act. The shares subject to this grant are outside the 2013 Plan and 100% shall fully vest on the second anniversary of the date of grant. On May 1, 2018, the vesting date for 1,767,000 shares was amended to November 2018. In addition, in the event of a Change of Control (as such term is defined in the 2013 Plan), 100% of the grants will immediately vest. During the three months ended December 31, 2018, 1,767,000 shares of restricted stock awarded outside the 2013 Plan vested.

Restricted Stock activity for the three months ended December 31, 2018 and 2017 is as follows:

	2018	2017
Non Vested at September 30, 2018 and 2017	1,767,000	2,000,000
Awarded	-	-
Vested	(1,767,000)	-
Forfeited	-	-
Non Vested at December 31, 2018 and 2017	-	2,000,000

The weighted average restricted stock award date fair value information for the three months ended December 31, 2018 and 2017 follows:

	2018	2017
Non Vested at September 30, 2018 and 2017	$0.39	$0.39
Awarded	-	-
Vested	0.39	-
Forfeited	-	-
Non Vested at December 31, 2018 and 2017	$-	$0.39

For the three months ended December 31, 2018 and 2017, compensation expense recorded for the restricted stock awards was approximately $0 and $98,000, respectively.

6. 2015 PRIVATE PLACEMENT FINANCING

Beginning June 22, 2015 and through June 30, 2015, the Company entered into a series of substantially similar subscription agreements (“Subscription Agreement”) with 20 accredited investors (“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 (“2015 Private Placement Financing”). Each Unit consisted of a share of Common Stock (“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 (“Series D Warrants”) and the shares issuable upon exercise of the Series D Warrants, (“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 $3,200,000.

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, and other customary closing conditions. The conditions precedent were satisfied June 30, 2015 ("Initial Closing Date"), and the Company conducted an initial closing ("Initial Closing") pursuant to which it sold and 19 of the 2015 Investors ("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 ("Second Closing") and together with the Initial Closing, ("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 ("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. 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 ("2015 S-1") which satisfied some of our obligation to register these securities with the SEC.

The 2015 Registration Rights Agreement also obligated the Company to register the resale of all securities covered by the 2015 Registration Rights Agreement on a short-form registration statement on Form S-3 as soon as the Company becomes eligible to use Form S-3. On October 31, 2016, the Company filed a resale registration statement on Form S-3 ("2015 S-3") to register the remaining securities covered by the 2015 Registration Rights Agreement, and the 2015 S-3 was declared effective on November 23, 2016. Pursuant to Rule 429 promulgated under the Securities Act, the 2015 S-3 contained a combined prospectus that covered the securities that remained unsold under the 2015 S-1 and also registered those same securities under the 2015 S-3. Under Rule 429, the 2015 S-3 also constituted a post-effective amendment to the 2015 S-1, which became effective on the date that the 2015 S-3 was declared effective.

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 any time during the term of the Series D Warrants, the Company may reduce the then-current exercise price to any amount and for any period of time deemed appropriate by the Board of the Company.

During the three months ended December 31, 2018 and 2017, Series D Warrants had been exercised on a cash basis for an aggregate issuance of 0 and 227,273 shares respectively of the Company's Common stock resulting in gross proceeds to the Company of $0 and $56,818, respectively. As of December 31, 2018, up to 8,974389 shares may be acquired upon the exercise of the Series D Warrants.

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 (deficit) in the accompanying consolidated financial statements.

7. 2016 PRIVATE PLACEMENT FINANCING

Beginning May 24, 2016 and through May 26, 2016, we entered into a series of substantially similar subscription agreements (each a "2016 Subscription Agreement") with 18 accredited investors ("2016 Investors") providing for the issuance and sale by the Company to the 2016 Investors, in a private placement, of an aggregate of 9,418,334 Units at a purchase price of $0.36 per Unit ("2016 Private Placement Financing"). Each Unit consisted of a share of Common Stock, and a Series E Warrant to purchase 0.75 shares of Common Stock at an exercise price of $0.4380 per share at any time prior to the fifth anniversary of the issuance date of the Series E Warrant ("Series E Warrants") and the shares issuable upon exercise of the Series E Warrants, ("Series E Warrant Shares"). The exercise price of the Series E Warrants was set to equal the closing price of our Common Stock on the date of their issuance (May 26, 2016), which was $0.4380, and therefore the Series E Warrants were not issued at a discount to the market price of our Common Stock as of such date. The gross proceeds to Arch were approximately $3.4 million before deducting financing costs of approximately $281,000.The number of shares of Common Stock into which each of the Series E Warrants is exercisable and the exercise price therefor are subject to adjustment as set forth in the Series E Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise). In addition, (i) at any time during the term of the Series E Warrants, we may reduce the then-current exercise price to any amount and for any period of time deemed appropriate by our Board of Directors ("Board"); and (ii) certain of the Series E Warrants 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 Series E Warrant, together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder's, would be deemed to beneficially own more than 4.99% of the Common Stock; *provided, however* , the holder, upon notice to us, may increase or decrease the ownership limitation, *provided that* any increase is limited to a maximum of 9.99% of the Company's Common Stock, and any increase in the ownership limitation will not become effective until the 61st day after delivery of such notice.

We engaged Maxim Group LLC ("Maxim") as our exclusive institutional investor placement agent in connection with the 2016 Private Placement Financing, and in consideration for the services provided by it, Maxim was entitled to receive cash fees equal to 8.2% of the gross proceeds received by us from certain institutional investors participating in the 2016 Private Placement Financing ("Maxim Investors"), as well as reimbursement for all reasonable expenses incurred by it in connection with its engagement. We received gross proceeds of approximately $3,390,600 in the aggregate, of which approximately $2,084,000 was attributable to the Maxim Investors, resulting in a fee of approximately $171,000.

On May 26, 2016, we entered into a registration rights agreement with the 2016 Investors ("2016 Registration Rights Agreement"), pursuant to which we became obligated, subject to certain conditions, to file with the Securities and Exchange Commission ("SEC") within 45 days after the closing of the 2016 Private Placement Financing one or more registration statements (the "2016 S-1") to register the shares of Common Stock issued in the Closings and the Series E Warrant Shares for resale under the Securities Act of 1933, as amended ("Securities Act"). As a result, we registered for resale under the 2016 S-1 an aggregate of 16,482,082 shares of Common Stock, representing the 9,418,334 shares issued at the closing of the 2016 Private Placement Financing and the 7,063,748 shares underlying the Series E Warrants. On July 13, 2016, we received from the SEC a Notice of Effectiveness of the 2016 S-1, which satisfied some of our obligation to register these securities with the SEC.

The 2016 Registration Rights Agreement also obligated the Company to register the resale of all securities covered by the 2016 Registration Rights Agreement on a short-form registration statement on Form S-3 as soon as the Company becomes eligible to use Form S-3. On October 31, 2016, the Company filed a resale registration statement on Form S-3 ("2016 S-3") to register the remaining securities covered by the 2016 Registration Rights Agreement, and the 2016 S-3 was declared effective on November 23, 2016. Pursuant to Rule 429 promulgated under the Securities Act, the 2016 S-3 contained a combined prospectus that covered the securities that remained unsold under the 2016 S-1 and also registered those same securities under the 2016 S-3. Under Rule 429, the 2016 S-3 also constituted a post-effective amendment to the 2016 S-1, which became effective on the date that the 2016 S-3 was declared effective.

Following the Closing, each 2016 Investor was also issued Series E Warrants to purchase shares of the Company's Common Stock up to 75% of the 2016 Shares purchased by such 2016 Investor under such 2016 Investor's Subscription Agreement. The Series E Warrants have an exercise price of $0.438 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 E Warrants is exercisable and the exercise price therefore are subject to adjustment, as set forth in the Series E Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise). In addition, at any time during the term of the Series E Warrants, the Company may reduce the then-current exercise price to any amount and for any period of time deemed appropriate by the Board of the Company.

During the three months ended December 31, 2018 and 2017, Series E Warrants had been exercised on a cash basis for an aggregate issuance of 0 and 15,000 shares, respectively of the Company's Common stock resulting in gross proceeds to the Company of $0 and $6,570, respectively. As of December 31, 2018, up to 4,214,582 shares may be acquired upon the exercise of the Series E Warrants.

Common Stock

At May 26, 2016, the Closing Date of the 2016 Private Placement Financing, the Company issued 9,418,334 shares of Common Stock.

Equity Value of Warrants

The Company accounted for the Series E Warrants relating to the aforementioned 2016 Private Placement Financing in accordance with ASC 815-40, *Derivatives and Hedging*. Because the Series E Warrants are indexed to the Company's stock, they are classified within stockholders' equity (deficit) in the accompanying consolidated financial statements.

8. 2017 REGISTERED DIRECT OFFERING

On September 30, 2016, the Company filed a registration statement with the SEC utilizing a "shelf" registration process, which was subsequently declared effective by the SEC on October 20, 2016 (such registration statement, the "Shelf Registration Statement"). Under the Shelf Registration Statement, the Company may offer and sell any combination of its Common Stock, warrants, debt securities, subscription rights, and/or units comprised of the foregoing to raise up to $50,000,000 in gross proceeds.

On February 20, 2017, the Company entered into Securities Purchase Agreement with 6 accredited investors ("2017 Investors") providing for the issuance and sale by the Company to the 2017 Investors of an aggregate of 10,166,664 units at a purchase price of $0.60 per Unit in a registered offering ("2017 Financing"). The securities comprising the units sold in the 2017 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, and 0.55 of a Series F Warrant to purchase one share of Common Stock at an exercise price of $0.75 per share at any time prior to the fifth anniversary of the issuance date of the Series F Warrant subject to certain restrictions on exercise ("2017 Warrants") and the shares issuable upon exercise of the 2017 Warrants, ("2017 Warrant Shares"). Provisions in the 2017 SPA restrict the Company's ability to effect or enter into an agreement to effect any issuance by the Company or any of its subsidiaries of Common Stock or securities convertible, exercisable or exchangeable for Common Stock (or a combination of units thereof) involving a Variable Rate Transaction (as defined in the 2017 SPA) including, but not limited to, an equity line of credit or "At-the-Market" financing facility until the three lead investors in the 2017 Financing collectively own less than 20% of the Series F Warrants purchased by them pursuant to the 2017 SPA. The gross proceeds to Arch from the 2017 Financing, which closed on February 24, 2017, were approximately $6.1 million before deducting financing costs of approximately $112,000.

The number of shares of the Company's Common Stock into which each of the Series F Warrants is exercisable and the exercise price therefore are subject to adjustment, as set forth in the Series F Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise). In addition, if the Company undergoes a change of control or is involved in a similar transaction, the holder may cause the Company or any successor entity to purchase its Series F Warrant for an amount of cash equal to $0.18 for each share of Common Stock underlying the Series F Warrant.

As of December 31, 2018, no Series F Warrants have been exercised. As of December 31, 2018, up to 5,591,664 shares may be acquired upon the exercise of the Series F Warrants.

Common Stock

At February 24, 2017, the Closing Date of the 2017 Financing, the Company issued 10,166,664 shares of Common Stock.

Derivative Liabilities

The Company accounted for the Series F Warrants relating to the aforementioned 2017 Financing in accordance with ASC 815-10, *Derivatives and Hedging*. Since the Company may be required to purchase its Series F Warrants for an amount of cash equal to $0.18 for each share of Common Stock the underlying Series F Warrants are not classified within stockholders' equity, they are recorded as liabilities at fair value. They are marked to market each reporting period through the consolidated statement of operations.

On the Closing Date, February 24, 2017 the derivative liabilities were recorded at fair value of $2,996,110. Given that the fair value of the derivative liabilities were less than the net proceeds of the 2017 Financing of $5,987,122, the remaining proceeds of $2,991,012 were allocated to the Common Stock and additional paid in capital. During the three months ended December 31, 2018 and 2017, $(385,106) and $1,971,549 was recorded to (increase)/decrease the fair value of derivative, respectively.

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

	December 31, 2018	September 30, 2018
Balance at September 30, 2018 and 2017	$ 1,274,404	$ 3,430,033
Adjustments to estimated fair value	385,106	(2,155,629)

Ending balance at December 31, 2018 and September 30, 2018	$ 1,659,510	$ 1,274,404

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The derivative liabilities were valued as of December 31, 2018 and September 30, 2018 using the Black Scholes Model with the following assumptions:

	December 31, 2018		September 30, 2018	
Closing price per share of common stock	$ 0.53		$ 0.42	
Exercise price per share	$ 0.75		$ 0.75	
Expected volatility	97.96	%	98.43	%
Risk-free interest rate	2.46	%	2.88	%
Dividend yield	—		—	
Remaining expected term of underlying securities (years)	3.13		3.38	

9. 2018 REGISTERED DIRECT OFFERING

On June 28, 2018, the Company entered into a Securities Purchase Agreement ("2018 SPA") with 8 accredited investors ("2018 Investors") providing for the issuance and sale by the Company to the 2018 Investors of an aggregate of 9,070,000 units at a purchase price of $0.50 per Unit in a registered offering ("2018 Financing"). The securities comprising the units sold in the 2018 Financing were issued under the Shelf Registration Statement, and consisted of a share of Common Stock, and 0.75 of a Series G Warrant to purchase one share of Common Stock at an exercise price of $0.70 per share at any time prior to the fifth anniversary of the issuance date of the Series G Warrant subject to certain restrictions on exercise ("2018 Warrants") and the shares issuable upon exercise of the 2018 Warrants, ("2018 Warrant Shares"). As of June 30, 2018, the Company recorded the 9,070,000 shares as Common Stock Subscribed but Unissued. At July 2, 2018, the Closing Date of the 2018 Financing, the Company issued 9,070,000 shares of Common Stock.

The 2018 SPA contains certain restrictions in the Company's ability to conduct subsequent sales of its equity securities. In particular, subject to certain customary exemptions, from June 28, 2018 until 90 days after July 2, 2018 (i.e., September 30, 2018), neither the Company nor any subsidiary shall issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of Common Stock or securities convertible, exercisable or exchangeable for Common Stock. Similarly, until such time the three lead investors collectively own less than 20% of the Series G Warrants purchased by them pursuant to the 2018 SPA, the Company is prohibited from effecting or entering into an agreement to effect any issuance by the Company or any of its subsidiaries of Common Stock or securities convertible, exercisable or exchangeable for Common Stock (or a combination of units thereof) involving a Variable Rate Transaction (as defined in the 2018 SPA) including, but not limited to, an equity line of credit or "At-the-Market" financing facility. The gross proceeds to Arch from the 2018 Financing, which were received as of June 29, 2018, were approximately $4.5 million before deducting financing costs of approximately $74,000.

The number of shares of the Company's Common Stock into which each of the Series G Warrants is exercisable and the exercise price therefore are subject to adjustment, as set forth in the Series G Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise). In addition, if the Company undergoes a change of control or is involved in a similar transaction, the holder may cause the Company or any successor entity to purchase its Series G Warrant for an amount of cash equal to $0.11 for each share of Common Stock underlying the Series G Warrant.

As of December 31, 2018, no Series G Warrants have been exercised. As of December 31, 2018, up to 6,802,500 shares may be acquired upon the exercise of the Series G Warrants.

Common Stock

At July 2, 2018, the Closing Date of the 2018 Financing, the Company issued 9,070,000 shares of Common Stock.

Derivative Liabilities

The Company accounted for the Series G Warrants relating to the aforementioned 2018 Financing in accordance with ASC 815-10, *Derivatives and Hedging*. Since the Company may be required to purchase its Series G Warrants for an amount of cash equal to $0.11 for each share of Common Stock and the underlying Series G Warrants are not classified within stockholders' equity, they are recorded as liabilities at fair value. They are marked to market each reporting period through the consolidated statement of operations.

On June 30, 2018 the derivative liabilities were recorded at fair value of $2,397,454. Given that the fair value of the derivative liabilities were less than the net proceeds of the 2018 Financing of $4,535,000, the remaining proceeds of $2,137,546 were allocated to the Common Stock Subscribed but Unissued. During the three months ended December 31, 2018 and 2017, $447,307 and $0, respectively, was recorded to increase the fair value of derivative.

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

	December 31, 2018	September 30, 2018

Balance at September 30, 2018 and 2017	$ 1,917,348	$ -
Issuances	-	2,397,454
Adjustments to estimated fair value	447,307	(480,106)
Ending balance at December 31, 2018 and September 30, 2018	$ 2,364,655	$ 1,917,348

The derivative liabilities were valued as of December 31, 2018 using the Black Scholes Model with the following assumptions:

	December 31, 2018	September 30, 2018
Closing price per share of common stock	$ 0.53	$ 0.42
Exercise price per share	$ 0.70	$ 0.70
Expected volatility	94.41 %	100.18 %
Risk-free interest rate	2.51 %	2.94 %
Dividend yield	—	—
Remaining expected term of underlying securities (years)	4.49	4.74

10. SUBSEQUENT EVENTS

The Company evaluated subsequent events from January 1, 2019 through January 31, 2019, and concluded that no subsequent events have occurred that would require recognition or disclosure in the consolidated financial statements.

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, 2018 filed with the Securities and Exchange Commission ("SEC").

This report contains forward looking statements. We make forward-looking statements, as defined by the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, and in some cases, you can identify these statements by forward-looking words such as "if," "shall," "may," "might," "will likely result," "should," "expect," "plan," "an "believe," "estimate," "project," "intend," "goal," "objective," "predict," "potential" or "continue," or the negative of these ter other comparable terminology. Such forward-looking statements contained in this report on Form 10-Q are based on various underlying assumptions and expectations and are subject to risks, uncertainties and other unknown factors, may include projections of our future financial performance based on our growth strategies and anticipated trends in our business and include risks and uncertainties relating to Arch's current cash position and its need to raise additional capital in order to be able to continue to fund its operations; the stockholder dilution that may result from future capital raising efforts and the exercise or conversion, as applicable of Arch's outstanding options and warrants; anti-dilution protection afforded investors in prior financing transactions that may restrict or prohibit Arch's ability to raise capital on terms favorable to the Company and its current stockholders; Arch's limited operating history which may make it difficult to evaluate Arch's business and future viability; Arch's ability to timely commercialize and generate revenues or profits from our anticipated products; Arch's ability to achieve the desired regulatory approvals in the United States or elsewhere; Arch's ability to retain its managerial personnel and to attract additional personnel; the strength of Arch's intellectual property, the intellectual property of others and any asserted claims of infringement; and other risk factors identified 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., (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 ("Merger") with Arch Biosurgery, Inc. (formerly known as Arch Therapeutics, Inc.), a Massachusetts corporation ("ABS"), and Arch Acquisition Corporation ("Merger Sub"), the Company's wholly owned subsidiary formed for the purpose of the transaction, pursuant to which Merger Sub merged with and into ABS and ABS thereby became the wholly owned subsidiary of the Company. As a result of the acquisition of ABS, the Company abandoned its prior business plan and changed its operations to the business of a biotechnology company. Our 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 the Commonwealth of Massachusetts on March 6, 2006 as Clear Nano Solutions, Inc. On April 7, 2008, ABS changed its name from Clear Nano Solutions, Inc. to Arch Therapeutics, Inc. Effective upon the closing of the Merger, ABS changed its name from Arch Therapeutics, Inc. to Arch Biosurgery, Inc.

Business Overview

We are a biotechnology company in the development stage. We have generated no revenues to date and are devoting substantially all of our operational efforts to the development of our core technology. We are developing a novel approach to stop bleeding ("hemostasis"), control leaking ("sealant") and manage wounds during surgery, trauma and interventional care. Arch is developing products based on an innovative self-assembling barrier technology platform with the goal of making care faster and safer for patients. We believe our technology could support an innovative platform of potential products in the field of stasis and barrier applications. Our plan and business model is to develop products that apply that core technology for use with bodily fluids and tissues.

To date, the Company has principally raised capital through borrowings and the issuance of convertible debt and units consisting of its common stock, par value $0.001 per share ("Common Stock"), and warrants. The Company expects to incur substantial expenses for the foreseeable future relating to the research, development, clinical trials, and commercialization of its potential products. As of January 31, 2019, we believe that our current cash on hand will meet our anticipated cash requirements into the third quarter of fiscal 2019. The Company will be required to raise additional capital in order to continue to fund operations. 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.

Our flagship development stage product candidates, known collectively as the AC5™ Devices (which we sometimes refer to as "AC5™", "AC5™ Topical Gel", "AC5™ Surgical Hemostatic Device", "AC5™ Surgical Hemostat", "AC5™ Topi Hemostatic Device", or "AC5™ Topical Hemostat"), are being designed to achieve hemostasis during surgical, wound and interventional care. They rely on our self-assembling peptide ("SAP") technology and are being designed to achieve hemostasis in skin wounds and in minimally invasive and open surgical procedures. We intend to develop other product candidates based on our technology platform for use in a range of indications. AC5 is being designed as a product containing synthetic biocompatible peptides comprising L-amino acids, commonly referred to as naturally occurring amino acids. When applied to a wound, AC5 intercalates into the interstices of the connective tissue where it self-assembles into a physical, mechanical nanoscale structure that provides a barrier to leaking substances, such as blood. AC5 may be applied directly as a liquid, which we believe will make it user-friendly and able to conform to irregular wound geometry. Additionally, AC5 does not possess sticky or glue-like handling characteristics, which we believe will enhance its utility in several settings, including minimally invasive surgical procedures. Further, in certain settings, AC5 lends itself to a concept that we call Crystal Clear Surgery™; the transparency and physical properties of AC5 may enable a surgeon to operate through it in order to maintain a clearer field of vision and prophylactically stop or lessen bleeding as it starts.

We believe that the results of early data from preclinical tests as well as certain clinical investigations have shown quick and effective hemostasis with the use of AC5 relative to that reported with other types of hemostatic agents, and that time to hemostasis is comparable among test subjects regardless of whether such test subject had or had not been treated with therapeutic doses of anticoagulant or antiplatelet medications, commonly called "blood thinners". Based on testing results, we believe that AC5 is biocompatible. Arch Therapeutics' technology has demonstrated hemostasis in liver and other organs in *in vivo* surgical models, including rapid hemostasis within 15 seconds. In a range of small and large animal models, our SAP compositions have been shown to stop bleeding, seal leaking, allow for normal healing, and mitigate inflamation while being biocompatable.

We have devoted much of our operational effort to date to the research and development of our core technology, including selecting our initial product composition, conducting safety and other related tests, conducting a human trial for safety and performance of AC5, developing methods for manufacturing scale-up, reproducibility, and validation, and developing and protecting the intellectual property rights underlying our technology platform. Manufacturing method and formulation optimization and validation are important parts of peptide development. Manufacturing and formulation optimization for our product candidates has been and continues to be done with extensive collaboration among our team and partners. The processes are focused on optimizing traditional product parameters to target

specifications covering performance, biocompatibility, physical appearance, stability, and handling characteristics, among others. We and our partners intend to continue to monitor manufacturing processes and formulation methods closely, as success or failure in both setting and realizing appropriate specifications may directly impact our ability to conduct additional preclinical and clinical trials as we establish and execute our commercialization efforts.

Our long-term business plan includes the following goals:

- conducting biocompatibility, pre-clinical, and clinical studies on AC5 and related products;
- expanding and maintaining protection of our intellectual property portfolio;
- developing additional third party relationships to manufacture, distribute, market and otherwise commercialize AC5;
- obtaining regulatory certification or clearance of AC5 and related products in the EU, the U.S., and other jurisdictions as we may determine;
- continuing or 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 as required to support the milestones described previously and our operations generally;
- work with our large scale manufacturing partners 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;
- further clinical development of our product platform;
- pursue regulatory clearance for commercialization;
- continue to expand and enhance our financial and operational reporting and controls;
- seek commercial partnerships;
- expand and enhance our intellectual property portfolio by filing new patent applications, obtaining allowances on currently filed patent applications, and/or 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;
- obtain regulatory input into subsequent clinical trial designs;
- assess our self-assembling peptide platforms in order to identify and select product candidates for advancement into development.

We believe that the Company has cash on hand to meet its anticipated cash requirements into the third quarter of Fiscal 2019. Notwithstanding this, depending upon additional input from EU and US regulatory authorities, we may need to raise additional capital prior to the third quarter of Fiscal 2019. In addition to the foregoing, our 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. On December 17, 2018, we announced that the 510(k) premarket notification for AC5™ Topical Gel has been reviewed and cleared by the FDA, allowing for the product to be marketed. We devote a significant amount of our efforts on fundraising, planning and conducting clinical trials, activities in connection with obtaining regulatory approval, and product research. For the three months ended December 31, 2018, we had a net loss of $2,600,237 versus a net income of $389,176 in the comparable period in the prior year. The loss for the three months ended December 31, 2018 can be attributable to research and development expenses, including regulatory approval and product research, general and administrative costs, primarily relating to legal costs associated with intellectual property and patent application costs, general corporate legal expenses and by an adjustment of $832,413, to the derivative liabilities. The income for the three months ended December 31, 2017 is attributable to the decrease in the fair value of the derivative liability.

Cash used in operating activities increased $226,253, during the three months ended December 31, 2018 to $1,322,157, compared to $1,095,904 for the three months ended December 31, 2017. Cash at December 31, 2018 decreased by $1,289,757 to $3,377,653 compared to $4,667,410 as of September 30, 2018.

Recent Developments

On October 1, 2018 the Company announced that it submitted a 510(k) notification to the U.S. Food and Drug Administration (FDA or "the Agency") for its AC5™ Topical Gel (AC5) has received acknowledgement from the Agency that the submission has been received. On December 17, 2018, we announced that the 510(k) premarket notification for AC5™ Topical Gel has been reviewed and cleared by the FDA, allowing for the product to be marketed.

On November 28, 2018, the Company announced that it has submitted the required documents for AC5™ Topical Hemostat (AC5) to its Notified Body as it seeks a CE mark, which is a next step on the path to commercialization in countries governed by the European Medical Devices Directive (MDD). We expect that the review process could take up to 6 months.

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, 2018 Compared to Three Months Ended December 31, 2017

	December 31, 2018 ($)	December 31, 2017 ($)	Increase (Decrease) ($)
Revenue	-	-	-
Operating Expenses			
General and administrative	1,178,622	1,001,511	177,111
Research and development	589,202	580,862	8,340
Loss from operations	(1,767,824)	(1,582,373)	185,451
Other (expense) income	(832,413)	1,971,549	2,803,962
Net (loss) income	(2,600,237)	389,176	2,989,413

Revenue

We did not generate revenue in either of the three months ended December 31, 2018 and 2017.

General and Administrative Expense

General and administrative expenses during the three months ended December 31, 2018 were $1,178,622, an increase of $177,111 compared to $1,001,511 for the three months ended December 31, 2017. The increase in general and administrative expense is primarily attributable to consulting costs and stock based compensation partially offset by payroll costs. General and administrative expenses are generally expected to increase as a result of additional staffing, increased stock based compensation as well as increased costs associated with the company's continued fundraising efforts.

Research and Development Expense

Research and development expense during the three months ended December 31, 2018 was $589,202**,** an increase of $8,340 compared to $580,862 for the three months ended December 31, 2017. The increase in research and development expense is primarily attributable to an increase in product and development costs. Research and development expenses are expected to increase as a result of our plans for additional product development, clinical and regulatory programs.

Other (expense) income

Other expense during the three months ended December 31, 2018 was $832,413, an increase of $2,803,962 compared to total other income of $1,971,549 for the three months ended December 31, 2017. The increase in other (expense) was the result of the change in the fair value of derivative liabilities.

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, 2018, we had cash of $3,377,653 and positive working capital of $3,341,113.

Working Capital

At December 31, 2018, we had total current assets of $3,617,665 (including cash of $3,377,653) and working capital of $3,341,113. Our working capital as of December 31, 2018 and September 30, 2018 is summarized as follows:

	December 31, 2018	September 30, 2018
Total Current Assets	$ 3,617,665	$ 4,819,204
Total Current Liabilities	276,552	288,385
Working Capital	$ 3,341,113	$ 4,530,819

Total current assets as of December 31, 2018 were $3,617,665 a decrease of $1,201,539 compared to $4,819,204 as of September 30, 2018. 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, 2018 and September 30, 2018 were comprised primarily of cash and prepaid expenses.

Total current liabilities as of December 31, 2018 were $276,552, a decrease of $11,833 compared to $288,385 as of September 30, 2018. The decrease is primarily due to the timing of product and development costs. Our total current liabilities as of December 31, 2018 and September 30, 2018 were comprised of accounts payable and accrued expenses and other liabilities.

Cash Flow for the three months ended

	December 31, 2018	December 31, 2017
Cash Used in Operating Activities	$ (1,322,157)	$ (1,095,904)
Cash Used in Investing Activities	-	(3,463)
Cash Provided by Financing Activities	32,400	63,388
Net decrease in cash	$ (1,289,757)	$ (1,035,979)

Cash Used in Operating Activities

Cash used in operating activities increased $226,253 to $1,322,157 during the three months ended December 31, 2018 compared to $1,095,904 during the three months ended December 31, 2017. The increase in operating expenses is primarily attributable to consulting costs and product and development costs partially offset by payroll costs.

Cash Used in Investing Activities

Cash used in investing activities decreased $3,463 to $0 during the three months ended December 31, 2018, compared to $3,463 during the three months ended December 31, 2017. For the three months ended December 31, 2017 the cash used in investing activities is attributed to leasehold improvements for the Company’s additional office space.

Cash Provided by Financing Activities

Cash provided by financing activities decreased $30,988 to $32,400 during the three months ended December 31, 2018, compared to $63,388 during the three months ended December 31, 2017. For the three months ended December 31, 2018, the cash provided by financing resulted from $32,400 from the exercise of option to purchase 87,567 shares of our Common Stock. For the three months ended December 31, 2017, the cash provided by financing resulted from $56,818 from the exercise of Series D Warrants to purchase 227,273 shares of our Common Stock, and $6,570 from the exercise of the Series E Warrants to purchase 15,000 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. As of January 31, 2019, we believe that our current cash on hand will meet our anticipated cash requirements into the third quarter of Fiscal 2019. Notwithstanding this, depending upon additional input from EU and US regulatory authorities, we do not expect to generate revenues from operations before we need to raise additional capital. Further, our estimates regarding our use of cash could change if we encounter unanticipated difficulties or other issues arise, including without limitation those set forth under the heading "**RISK FACTORS**" in this filing, in which case our current funds may not be sufficient to operate our business for the period we expect.

We are in the development stage and have generated no operating revenues to date. 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 2017 SPA and 2018 SPA restricting our ability to effect or enter into an agreement to effect any issuance by the Company or any of its subsidiaries of Common Stock or securities convertible, exercisable or exchangeable for Common Stock (or a combination of units thereof) involving a Variable Rate Transaction (as defined in the 2017 SPA and 2018 SPA) including, but not limited to, an equity line of credit or "At-the-Market" financing facility until the three lead investors in the 2017 Financing and the 2018 Financing collectively own less than 20% of the Series F Warrants and Series G Warrants purchased by them pursuant to the 2017 SPA and 2018 SPA. 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. 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. In addition, as described in greater detail under the Risk Factor entitled "***The terms of the 2017 Financing and 2018 Financing could impose additional challenges on our ability to raise funding in the future***," included in this Quarterly Report on Form 10-Q, the 2017 SPA and the 2018 SPA imposes certain restrictions on our ability to issue equity or debt securities

Going Concern

From inception, we have not earned operating revenues from sales of products or services, and have recurring losses from operations. While the Company anticipates that it will have enough cash on hand into the third quarter of fiscal 2019, 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, 2018, there is substantial doubt about the Company's ability to continue as a going concern. The 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 consolidated financial statements presented with this Form 10-Q 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.

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.

Research and Development

We expense 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 FASB ASC Topic 718, *Compensation-Stock Compensation* ("FASB ASC Topic 718"), which requires all share-based payments to employees, including grants of employee stock options, to be recognized in the consolidated financial statements based on their fair values. We account for non-employee stock-based compensation in accordance with the guidance of FASB ASC Topic 505, *Equity* ("FASB ASC Topic 505"), which requires that companies recognize compensation expense based on the estimated fair value of options granted to non-employees over their vesting period, which is generally the period during which services are rendered by such non-employees. FASB ASC Topic 505 requires us to re-measure the fair value of stock options issued to non- employee at each reporting period during the vesting period or until services are complete.

In accordance with FASB ASC Topic 718, we have elected to use the Black-Scholes option-pricing model to determine the fair value of options granted and we recognize 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. Prior to January 1, 2018, the Company did not have a sufficient history of market prices of the Common Stock, and as such volatility is estimated in accordance with ASC 718-10-S99 *Compensation-Stock Compensation* ("ASC 718-10-S99"). Prior to January 1, 2018, the Company's expected volatility was 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 groups as determined by the Company. Effective January 1, 2018, the Company is using its historical market prices to calculate the volatility of its common stock. The life term for awards uses the simplified method for all "plain vanilla" options, as defined in ASC 718-10-S99 and the contractual term for all other employee and non-employee awards. The risk-free interest rate assumption is based on observed interest rates appropriate for the terms of our awards. The dividend yield assumption is based on history and the expectation of paying no dividends. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Stock-based compensation expense, when recognized in the financial statements, is based on awards that are ultimately expected to vest.

Fair Value Measurements

We measure both financial and nonfinancial assets and liabilities in accordance with FASB ASC Topic 820, *Fair Value Measurements and Disclosures*, including those that are recognized or disclosed in the 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 our own views about the assumptions market participants would use in pricing the asset or liability.

Income Taxes

In accordance with FASB ASC 740, *Income Taxes*, we recognize deferred tax assets and liabilities for the expected future tax consequences or events that have been included in our consolidated financial statements and/or tax returns. Deferred tax assets and liabilities are based upon the differences between the 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.

On December 22, 2017, the Tax Cuts and Jobs Act (“TCJA”) was signed into United States law. The TCJA includes a number of changes to existing tax law, including, among other things, a permanent reduction in the federal corporate income tax rate to a flat rate of 21%, effective January 1, 2018, as well as the elimination of net operating loss carrybacks for losses arising in taxable years beginning after December 31, 2017. Further, operating losses arising in tax years after December 31, 2017, are carried forward indefinitely. Due to the TCJA, the Company’s deferred tax assets and liabilities recognized prior to 2017 were revalued at the newly enacted tax rates, which resulted in a corresponding adjustment in the valuation allowance.

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 FASB ASC Topic 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 expected volatility, expected life, yield, and risk-free interest rate.

Recent Accounting Guidance

Accounting Standards Update (ASU) 2018-07, "Compensation—Stock Compensation (Topic 718) Improvements to Nonemployee Share-Based Payment Accounting" was issued by the Financial Accounting Standards Board (FASB) in June 2018. The purpose of this amendment is to address aspects of the accounting for nonemployee share-based payment transactions. The amendments in this Update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted. The Company does not believe that this guidance will have a material impact on its consolidated results of operations, financial position or disclosures.

ASU 2016-15, "Statement of Cash Flows (Topic 230) Classification of Certain Cash Receipts and Payments" was issued by the Financial Accounting Standards Board (FASB) in August 2016. The purpose of this amendment is to address eight specific cash flow issues with the objective of reducing the existing diversity in practice. The amendments in this Update are effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2017. Early adoption is permitted. The Company adopted ASU 2016-15 during our first quarter of fiscal year 2019, which had no impact on our consolidated financial statements, and will apply the new guidance in future periods.

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

financial position or disclosures.

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, 2018, 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 are effective as of December 31, 2018 in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal controls over financial reporting that occurred during the quarter ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. The impact and outcome of litigation, if any, is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. We are not currently a party to any proceedings the adverse outcome of which, individually or in the aggregate, would have a material adverse effect on our financial position or results of operations.

Item 1A. Risk Factors

Risks Related to our Business

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

We are a development stage company with no commercial products. Our primary product candidate is in the process of being developed, and will require additional investment before it could potentially be commercialized. As a result, we have not generated any revenue from operations since inception, and we have incurred substantial net losses to date. While as of January 31, 2019, we believe that our current cash on hand will meet our anticipated cash requirements into the third quarter of fiscal 2019, depending upon additional input from EU and US regulatory authorities, we do not expect to generate revenues from operations before we need to raise additional capital. For example, on December 18, 2017, we voluntarily withdrew a 510(k) notification for AC5 Topical Gel after receiving questions from the FDA for which an adequately comprehensive response could not be provided within the FDA's congressionally-mandated 90-day review period. While on October 1, 2018, we announced that we both completed the necessary steps required to re-file our 510(k) submission for our AC5™ Topical Gel, and filed a 510(k) submission during the third calendar quarter, the resubmission process required us to expend a minimum of $100,000 that we had not previously anticipated spending.

In any event, during or prior to the third quarter of Fiscal 2019, we will need to obtain additional cash to continue operations and fund our planned future operations, which include research and development of our primary product candidate, seeking regulatory approval for that product candidate, and pursuing its commercialization in the U.S., Europe and other markets. Those circumstances raise substantial doubt about our ability to continue as a going concern.

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

As noted above under the risk factor entitled "***There is substantial doubt about our ability to continue as a going concern***," we are a development stage company with no commercial products. Consequently, we have incurred losses in each year since our inception and we expect that losses will continue to be incurred in the foreseeable future in the operation of our business. To date, we have financed our operations entirely through equity and debt investments by founders, other investors and third parties, and we expect to continue to rely on these sources of funding, to the extent available in the foreseeable future. Losses from operations have resulted principally from costs incurred in research and development programs and from general and administrative expenses, including significant costs associated with establishing and maintaining intellectual property rights, significant legal and accounting costs incurred in connection with both the closing of the Merger and complying with public company reporting and control obligations, and personnel expenses. We have devoted much of our operations to date to the research and development of our core technology, including selecting our initial product composition, conducting initial safety and other related tests, generating scale-up, reproducibility and manufacturing and formulation methods, conducting our initial clinical trial for AC5, and developing and protecting the intellectual property rights underlying our technology platform.

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

- develop our principal product candidate, AC5, and the underlying technology, including advancing applications and conducting biocompatibility and other preclinical studies;
- raise capital needed to fund our operations;
- build and enhance investor relations and corporate communications capabilities;
- conduct additional clinical trials relating to AC5 and any other product candidate we seek to develop;
- attempt to gain regulatory approvals for product candidates;
- build relationships with contract manufacturing partners, and invest in product and process development through such partners;
- maintain, expand and protect our intellectual property portfolio;

- advance additional product candidates and technologies through our research and development pipeline;

- seek to commercialize selected product candidates which may require regulatory approval; and

- hire additional regulatory, clinical, quality control, scientific, financial, and management, consultants and advisors.

To become and remain profitable, we must succeed in developing and eventually commercializing product candidates with significant market potential. This will require us to be successful in a number of challenging activities, including successfully completing preclinical testing and clinical trials of product candidates, obtaining regulatory approval for our product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of many of those activities. We may never succeed in those activities and may never generate operating revenues or achieve profitability. Even if we do generate operating revenues sufficient to achieve profitability, we may not be able to sustain or increase profitability. Our failure to generate operating revenues or become and remain profitable would impair our ability to raise capital, expand our business or continue our operations, all of which would depress the price of our Common Stock. A further decline or lack of increase in the prices of our Common Stock could cause our stockholders to lose all or a part of their investment in the Company.

We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts and could cause our business to fail.

Based on our current operating expenses and working capital requirements, as of January 31, 2019, we believe that our current cash on hand will meet our anticipated cash requirements into the third quarter of fiscal 2019. Notwithstanding that, depending upon additional input from EU and US regulatory authorities, we do not expect to generate revenues from operations before we need to raise additional capital. For example, on December 18, 2017, we voluntarily withdrew a 510(k) notification for AC5 Topical Gel after receiving questions from the FDA for which an adequately comprehensive response could not be provided within the FDA's congressionally-mandated 90-day review period. While on October 1, 2018, we announced that we both completed the necessary steps required to re-file our 510(k) submission for our AC5™ Topical Gel, and filed a 510(k) submission during the third calendar quarter, the resubmission process required us to expend a minimum of $100,000 that we had not anticipated spending and delayed the clearance of our 510(k) submission.

In any event, during or prior to the third quarter of Fiscal 2019, we will need to obtain additional cash to continue operations and fund our planned future operations, including the continuation of our ongoing research and development efforts, the licensing or acquisition of new assets, and researching and developing any potential patents, the related compounds and any further intellectual property that we may acquire. In addition, our plans may change and/or we may use our capital resources more rapidly than we currently anticipate. We presently expect that our expenses will increase in connection with our ongoing activities to support our business operations inclusive of regulatory applications and approval of AC5 in the U.S. and Europe and therefore we will require additional funding. Our future capital requirements will depend on many factors, including:

- the scope, progress and results of our research and development collaborations;
- the extent of potential direct or indirect grant funding for our research and development activities;
- the scope, progress, results, costs, timing and outcomes of any regulatory process and clinical trials conducted for any of our product candidates;
- the timing of entering into, and the terms of, any collaboration agreements with third parties relating to any of our product candidates;
- the timing of and the costs involved in obtaining regulatory approvals for our product candidates;
- the costs of operating, expanding and enhancing our operations to support our clinical activities and, if our product candidates are approved, commercialization activities;
- the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities;
- the costs associated with maintaining and expanding our product pipeline;
- the costs associated with expanding our geographic focus;
- operating revenues, if any, received from sales of our product candidates, if any are approved by the FDA or other applicable regulatory agencies;
-

- the cost associated with being a public company, including obligations to regulatory agencies, and increased investor relations and corporate communications expenses; and

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

We intend to obtain additional financing for our business through public or private securities offerings, the incurrence of additional indebtedness, or some combination of those sources. We have obtained research and development support through collaborative arrangements, such as the Project Agreement that we entered into with the National University of Ireland Galway ("NUIG") on May 28, 2015 and which concluded in the third quarter of fiscal 2018, and we may continue to seek funding through additional collaborative arrangements with strategic partners if we determine them to be necessary or appropriate, although these arrangements could require us to relinquish rights to our technology or product candidates and could result in our receipt of only a portion of any revenues associated with the partnered product. We cannot provide any assurance that additional financing from these sources will be available on favorable terms, if at all.

In addition, we are bound by certain contractual terms and obligations that may limit or otherwise impact our ability to raise additional funding in the near-term including, but not limited to, provisions in the Securities Purchase Agreements that we entered into on February 20, 2017 ("2017 SPA") and June 28, 2018 (the "2018 SPA") in connection with the registered direct financings that closed on February 24, 2017 ("2017 Financing") and July 2, 2018 (the "2018 Financing"), respectively, in each case as described in greater detail in the risk factor entitled "***The terms of the 2017 Financing and 2018 Financing could impose additional challenges on our ability to raise funding in the future***" below.

These restrictions and provisions could make it more challenging for us to raise capital through the incurrence of additional debt or through future equity issuances. Further, if we do raise capital through the sale of equity, or securities convertible into equity, the ownership of our then existing stockholders would be diluted, which dilution could be significant depending on the price at which we may be able to sell our securities. Also, if we raise additional capital through the incurrence of indebtedness, we may become subject to covenants restricting our business activities, and the holders of debt instruments may have rights and privileges senior to those of our equity investors. Finally, servicing the interest and principal repayment obligations under any debt facilities that we may enter into in the future could divert funds that would otherwise be available to support research and development, clinical or commercialization activities.

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

The terms of the 2017 Financing and 2018 Financing could impose additional challenges on our ability to raise funding in the future.

In particular, both the 2017 SPA and 2018 SPA contain provisions that provide that until such time as the three lead investors in the 2017 Financing and 2018 Financing, respectively, collectively own less than 20% of the Series F Warrants or Series G Warrants, as applicable, purchased by them pursuant to the 2017 SPA or 2018 SPA, as applicable, the Company is prohibited from effecting or entering into an agreement to effect any issuance by the Company or any of its subsidiaries of Common Stock or securities convertible, exercisable or exchangeable for Common Stock (or a combination of units thereof) involving a Variable Rate Transaction including, but not limited to, an equity line of credit or "At-the-Market" financing facility.

As of January 31, 2019, none of the lead investors for either the 2017 Financing or 2018 Financing have exercised or transferred any of their Series F Warrants or Series G Warrants. As defined in both the 2017 SPA and 2018 SPA, Variable Rate Transaction means a transaction in which the Company (a) issues or sells any debt or equity securities that are convertible into, exchangeable or exercisable for, or include the right to receive additional shares of Common Stock either (A) at a conversion price, exercise price or exchange rate or other price that is based upon and/or varies with the trading prices of or quotations for the shares of Common Stock at any time after the initial issuance of such debt or equity securities, or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such debt or equity security or upon the occurrence of specified or contingent events directly or indirectly related to the business of the Company or the market for the Common Stock (excluding adjustments under customary anti-dilution provisions) or (b) enters into, or effects a transaction under, any agreement, including, but not limited to, an equity line of credit, whereby the Company may issue securities at a future determined price. These provisions could make our securities less attractive to investors and could limit our ability to obtain adequate financing on a timely basis or on acceptable terms in the future, which could have significant harmful effects on our financial condition and business and could include substantial limitations on our ability to continue to conduct operations.

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

We are a development stage company subject to the risks, uncertainties and difficulties frequently encountered by early-stage companies in evolving markets. Our operations to date have been primarily limited to organizing and staffing, developing and securing our technology and undertaking funding preclinical studies of our lead product candidates, and funding one clinical trial. We have not demonstrated our ability to successfully complete large-scale,

pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale product or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization.

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

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

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

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

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

If we fail to maintain appropriate internal controls in the future, we may not be able to report our financial results accurately, which may adversely affect our stock price and our business.

Our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and the related regulations regarding our required assessment of our internal controls over financial reporting requires the commitment of significant financial and managerial resources. Internal control over financial reporting has inherent limitations, including human error, the possibility that controls could be circumvented or become inadequate because of changed conditions, and fraud. If we are unable to maintain effective internal controls, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations as a publicly traded company or comply with the requirements of the SEC or the Sarbanes-Oxley Act of 2002. This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our stock, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our stock and our business.

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

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

Risks Related to the Development and Commercialization of our Product Candidates

Applications for regulatory approval, clearance or certification for commercialization of our products may not be accepted, or if accepted, may be voluntarily withdrawn or eventually rejected, and the future success of our business is significantly dependent on the success of our being able to obtain regulatory approval, clearance or certification for our development stage candidates.

On July 17, 2017, we filed a 510(k) notification with the FDA for our AC5™ Topical Gel. As previously announced on December 18, 2017, we voluntarily withdrew the submission after receiving a communication from FDA near the end of the agency's 90-day review period for a final decision on 510(k) notifications. The communication contained questions for which a comprehensive response could not be provided in the limited review time remaining on the submission. Given that it was not possible to respond in the time available, the Company made the decision to withdraw the 510(k) notification, but noted at the time that it remained committed to continued collaboration with FDA to appropriately address the outstanding questions and planned to submit a new 510(k) notification as soon as possible following further discussion with the agency. On March 12, 2018, we announced that we were utilizing the FDA's pre-submission process to submit a proposed development strategy to the FDA to address the agency's comments on our 510(k) notification. As indicated in that March 12, 2018 announcement, we determined that providing additional data to the FDA would be the most expeditious path forward for addressing the FDA's comments, subject to any further comments that we may receive from the FDA.

On May 8, 2018, the Company announced that it would initiate the previously disclosed study designed to address FDA comments on Arch's previous 510(k) notification for its AC5™ Topical Gel. The agency provided feedback via the pre-submission process and indicated that the proposed study design was acceptable to support the Company's future marketing application. On June 15, 2018, the Company further announced that it completed enrollment for its human skin sensitization study and that applications of the Company's AC5™ Topical Gel were underway for all subjects.

On October 1, 2018 the Company announced that it submitted a 510(k) notification to the FDA for its AC5™ Topical Gel (AC5) and received acknowledgement from the FDA that the submission has been received. On December 17, 2018, we announced that the 510(k) premarket notification for AC5™ Topical Gel has been reviewed and cleared by the FDA, allowing for the product to be marketed.

In addition to our 510(k) notification, we filed our first CE Mark application in Europe in December 2018, and we currently anticipate seeking regulatory approval for expanded indications, and to pursue internal use commercial opportunities for other AC5-related products through the premarket authorization process.

Our business plan is dependent on the success of our development stage product candidates.

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

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

Because of the complexity of our lead product candidates, the CMC process, including but not limited to product scale-up activities and cGMP manufacturing for human use, may be difficult to complete successfully within the parameters required by the FDA or its foreign counterparts. Peptide formulation optimization is particularly challenging, and any delays could negatively impact our ability to conduct clinical trials and our subsequent commercialization timeline. Furthermore, we have, and the third parties with whom we may establish relationships may also have, limited experience with attempting to commercialize a self-assembling peptide as a medical device, which increases the risks associated with completing the CMC process successfully, on time, or within the projected budget. Failure to complete the CMC process successfully would impact our ability to complete product development activities, such as conducting clinical trials and submitting applications for regulatory approval, which could affect the long-term viability of our business.

Our principal product candidates are inherently risky because they are based on novel technologies.

We are subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of the AC5 devices creates significant challenges with respect to product development and optimization, engineering, manufacturing, scale-up, quality systems, pre-clinical in vitro and in vivo testing, government regulation and approval, third-party reimbursement and market acceptance. Our failure to overcome any one of those challenges could harm our operations, ability to complete additional clinical trials, and overall chances for success.

If we are required or voluntarily decide to change manufacturers for commercial or other reasons, the FDA and any other applicable regulatory bodies would also require that we demonstrate structural and functional comparability between the same products manufactured by our current and any new manufacturer and may

require comparability studies to be performed before qualifying such new manufacturer.

As noted above, we are dependent on third-party manufacturers, and this dependence exposes us to increased risks associated with delivery schedules, manufacturing capability, quality control, quality assurance and costs. Our contract manufacturers may not perform as agreed. If we are required to or voluntarily decide to find a new contract manufacturer, qualifying such new contract manufacturer may be expensive and time consuming since, among other things, the FDA and any other applicable regulatory bodies would also require that we demonstrate structural and functional comparability between the same products manufactured by our current and any new manufacturer and may require comparability studies to be performed before qualifying such new manufacturer. This qualification process may affect product availability, which may in turn adversely affect our business.

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

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

Compliance with governmental regulations regarding the treatment of animals used in research could increase our operating costs, which would adversely affect the commercialization of our technology.

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

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

The development plan for our lead product candidates is based on our anticipation of pursuing the medical device regulatory pathway, and in February 2015 we received confirmation from The British Standards Institution ("BSI"), a Notified Body (which is a private commercial entity designated by the national government of a European Union ("EU") member state as being competent to make independent judgments about whether a medical device complies with applicable regulatory requirements) in the EU, confirmed that AC5 fulfills the definition of a medical device within the EU and will be classified as such in consideration for CE mark designation. The FDA and other regulatory authorities or related bodies separately determine the classification of AC5. The FDA also determined our current product to be a medical device. If the FDA or similar foreign agencies or intermediaries deem our product to be a member of a category other than a medical device, such as a drug or biologic, or impose additional requirements on our pre-clinical and clinical development than we presently anticipate, financing needs would increase, the timeline for product approval would lengthen, the program complexity and resource requirements world increase, and the probability of successfully commercializing a product would decrease. Any or all of those circumstances would materially adversely affect our business.

We are subject to extensive and dynamic medical device regulations outside of the United States, which may impede or hinder the approval or sale of our products and, in some cases, may ultimately result in an inability to obtain approval of certain products or may result in the recall or seizure of previously approved products.

In the European Union, we are required to comply with applicable medical device directives, including the Medical Devices Directive, and obtain CE Marking in order to market medical device products. The CE Mark is applied following approval from an independent notified body or declaration of conformity. As is the case in the United States, the process of obtaining marketing approval or clearance from comparable agencies in foreign countries for new products, or with respect to enhancements or modifications to existing products, could:

- take a significant period of time;
- require the expenditure of substantial resources;
- involve rigorous pre-clinical and clinical testing;
- require extensive post-marketing surveillance;

· require changes to products; and

· result in limitations on the indicated uses of products.

In addition, exported devices are subject to the regulatory requirements of each country to which the device is exported. Most foreign countries possess medical devices regulations and require that they be applied to medical devices before they can be commercialized. There can be no assurance that we will receive the required approvals for our products on a timely basis or that any approval will not be subsequently withdrawn or conditioned upon extensive post-market study requirements.

Our global regulatory environment is becoming increasingly stringent and unpredictable, which could increase the time, cost and complexity of obtaining regulatory approvals for our products, as well as the clinical and regulatory costs of supporting those approvals. Several countries that did not have regulatory requirements for medical devices have established such requirements in recent years and other countries have expanded existing regulations. Certain regulators are exhibiting less flexibility by requiring, for example, the collection of local preclinical and/or clinical data prior to approval. While harmonization of global regulations has been pursued, requirements continue to differ significantly among countries. We expect the global regulatory environment to continue to evolve, which could impact our ability to obtain future approvals for our products and increase the cost and time to obtain such approvals. By way of example, the European Union regulatory bodies recently finalized a new Medical Device Regulation ("MDR"). The MDR changes several aspects of the existing regulatory framework, such as clinical data requirements, and introduces new ones, such as Unique Device Identification ("UDI"). We, and the Notified Bodies who will oversee compliance to the new MDR, face uncertainties in the upcoming years as the MDR is rolled out and enforced, creating risks in several areas, including the CE Marking process, data transparency and application review timetables.

If we are not able to secure and maintain relationships with third parties that are capable of conducting clinical trials on our product candidates and support our regulatory submissions, our product development efforts, and subsequent regulatory approvals could be adversely impacted.

Our management has limited experience in conducting preclinical development activities and clinical trials. As a result, we have relied and will need to continue to rely on third-party research institutions, organizations and clinical investigators to conduct our preclinical and clinical trials and support our regulatory submissions. If we are unable to reach agreement with qualified research institutions, organizations and clinical investigators on acceptable terms, or if any resulting agreement is terminated prior to the completion of our clinical trials, then our product development efforts could be materially delayed or otherwise harmed. Further, our reliance on third parties to conduct our clinical trials and support our regulatory submissions will provide us with less control over the timing and cost of those trials, the ability to recruit suitable subjects to participate in the trials, and the timing, cost, and probability of success for the regulatory submissions. Moreover, the FDA and other regulatory authorities require that we comply with standards, commonly referred to as good clinical practices ("GCP"), for conducting, recording and reporting the results of our preclinical development activities and our clinical trials, to assure that data and reported results are credible and accurate and that the rights, safety and confidentiality of trial participants are protected. Additionally, both we and any third-party contractor performing preclinical and clinical studies are subject to regulations governing the treatment of human and animal subjects in performing those studies. Our reliance on third parties that we do not control does not relieve us of those responsibilities and requirements. If those third parties do not successfully carry out their

contractual duties, meet expected deadlines or conduct our preclinical development activities or clinical trials in accordance with regulatory requirements or stated protocols, we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. Any of those circumstances would materially harm our business and prospects.

Any clinical trials that are planned or are conducted on our product candidates may not start or may fail.

Clinical trials are lengthy, complex and extremely expensive processes with uncertain expenditures and results and frequent failures. While the Company has completed its first clinical trial in Western Europe, clinical trials that are planned or which have or shall commence for any of our product candidates could be delayed or fail for a number of reasons, including if:

- the FDA or other regulatory authorities, or other relevant decision-making bodies do not grant permission to proceed or place a trial on clinical hold due to safety concerns or other reasons;
- sufficient suitable subjects do not enroll, enroll more slowly than anticipated or remain in our trials;
- we fail to produce necessary amounts of product candidate;
- subjects experience an unacceptable rate of efficacy of the product candidate;
- subjects experience an unacceptable rate or severity of adverse side effects, demonstrating a lack of safety of the product candidate;
- any portion of the trial or related studies produces negative or inconclusive results or other adverse events;
- reports from preclinical or clinical testing on similar technologies and products raise safety and/or efficacy concerns;
- third-party clinical investigators lose their licenses or permits necessary to perform our clinical trials, do not perform their clinical trials on the anticipated schedule or consistent with the clinical trial protocol, GCP or regulatory requirements, or other third parties do not perform data collection and analysis in a timely or accurate manner;
- inspections of clinical trial sites by the FDA or an institutional review board ("IRB") or other applicable regulatory authorities find violations that require us to undertake corrective action, suspend or terminate one or more testing sites, or prohibit us from using some or all of the resulting data in support of our marketing applications with the FDA or other applicable agencies;
- manufacturing facilities of our third-party manufacturers are ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of current good manufacturing practices

("cGMP") or other applicable requirements;

- third-party contractors become debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements;

- the FDA or other regulatory authorities impose requirements on the design, structure or other features of the clinical trials for our product candidates that we and/or our third-party contractors are unable to satisfy;

- one or more IRB refuses to approve, suspends or terminates a trial at an investigational site, precludes enrollment of additional subjects, or withdraws its approval of the trial;

- the FDA or other regulatory authorities seek the advice of an advisory committee of physician and patient representatives that may view the risks of our product candidates as outweighing the benefits;

- the FDA or other regulatory authorities require us to expand the size and scope of the clinical trials, which we may not be able to do; or

- the FDA or other regulatory authorities impose prohibitive post-marketing restrictions on any of our product candidates that attain regulatory approval.

Any delay or failure of one or more of our clinical trials may occur at any stage of testing. Any such delay could cause our development costs to materially increase, and any such failure could significantly impair our business plans, which would materially harm our financial condition and operations.

We cannot market and sell any product candidate in the U.S. or in any other country or region if we fail to obtain the necessary regulatory approvals, clearances or certifications from applicable government agencies.

We cannot sell our product candidates in any country until regulatory agencies grant marketing approval, clearance or other required certification. The process of obtaining such approval is lengthy, expensive and uncertain. If we are able to obtain such approvals for our lead product candidate or any other product candidate we may pursue, which we may never be able to do, it would likely be a process that takes many years to achieve.

To obtain marketing approvals in the U.S. for our product candidates, we believe that we must, among other requirements, complete carefully controlled and well-designed clinical trials sufficient to demonstrate to the FDA that the product candidate is safe and effective for each indication for which we seek approval. As described above, many factors could cause those trials to be delayed or to fail.

We believe that the pathway to marketing approval in the U.S. for our lead product candidate for internal use will likely require the process of FDA Premarket Approval (“PMA“) for the product, which is based on novel technologies and likely will be classified as a Class III medical device. This approval pathway can be lengthy and expensive, and is estimated to take from one to three years or longer from the time the PMA application is submitted to the FDA until approval is obtained, if approval can be obtained at all.

Similarly, to obtain approval to market our product candidates outside of the U.S., we will need to submit clinical data concerning our product candidates to and receive marketing approval or other required certifications from governmental or other agencies in those countries, which in certain countries includes approval of the price we intend to charge for a product. For instance, in order to obtain the certification needed to market our lead product candidate in the EU, we believe that we will need to obtain a CE mark for the product, which entails scrutiny by applicable regulatory agencies and bears some similarity to the PMA process, including completion of one or more successful

clinical trials.

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

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

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

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

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

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

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

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

Current or future legislation may make it more difficult and costly for us to obtain marketing approval or other certifications of our product candidates.

In 2007, the Food and Drug Administration Amendments Act of 2007 ("FDAAA") was adopted. This legislation grants significant powers to the FDA, many of which are aimed at assuring the safety of medical products after approval. For example, the FDAAA grants the FDA authority to impose post-approval clinical study requirements, require safety-related changes to product labeling and require the adoption of complex risk management plans. Pursuant to the FDAAA, the FDA may require that a new product be used only by physicians with specialized training, only in specified health care settings, or only in conjunction with special patient testing and monitoring. The legislation also includes requirements for disclosing clinical study results to the public through a clinical study registry, and renewed requirements for conducting clinical studies to generate information on the use of products in pediatric patients. Under the FDAAA, companies that violate these laws are subject to substantial civil monetary penalties. The requirements and changes imposed by the FDAAA, or any other new legislation, regulations or policies that grant the FDA or other

regulatory agencies additional authority that further complicates the process for obtaining marketing approval and/or further restricts or regulates post-marketing approval activities, could make it more difficult and more costly for us to obtain and maintain approval of any of our product candidates.

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

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

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

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

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

- the failure of the third-party to maintain regulatory compliance, quality assurance, and general expertise in advanced manufacturing techniques and processes that may be necessary for the manufacture of our product candidates;
- limitations on supply availability resulting from capacity and scheduling constraints of the third parties;
- failure of the third-party manufacturers to meet the demand for the product candidate, either from future customers or for preclinical or clinical trial needs;
- the possible breach of the manufacturing agreement by the third-party; and
- the possible termination or non-renewal of the agreement by the third-party at a time that is costly or inconvenient for us.

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

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

We will rely on the manufacturers of our product candidates to purchase from third-party suppliers the materials necessary to produce the compounds for preclinical and clinical studies, and may continue to rely on those suppliers for commercial distribution if we obtain marketing approval or other required certifications for any of our product candidates. The materials to produce our products may not be available when needed or on commercially reasonable

terms, and the prices for such materials may be susceptible to fluctuations. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently do not have any agreements relating to the commercial production of any of these materials. If these materials cannot be obtained for our preclinical and clinical studies, product testing and potential regulatory approval of our product candidates would be delayed, which would significantly impact our ability to develop our product candidates and materially adversely affect our ability to meet our objectives and obtain operations success.

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

As demonstrated by the Project Agreement that we entered into with NUIG on May 28, 2015, we are interested in collaborating with physicians, patient advocacy groups, foundations, government agencies, and/or other third parties to assist with the development of our product candidates. If required regulatory approvals are obtained for any of our product candidates, then we may consider entering into additional collaboration arrangements with medical technology, pharmaceutical or biotechnology companies and/or seek to establish strategic relationships with marketing partners for the development, sale, marketing and/or distribution of our products within or outside of the U.S. If we elect to expand our current relationship with NUIG and/or seek additional collaborators in the future but are unable to reach agreements with NUIG and/or such other collaborators, as applicable, then we may fail to meet our business objectives for the affected product or program. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement, and we may not be successful in our efforts, if any, to establish and implement additional collaborations or other alternative arrangements. The terms of any collaboration or other arrangements that we establish may not be favorable to us, and the success of any such collaboration will depend heavily on the efforts and activities of our collaborators. Any failure to engage successful collaborators could cause delays in our product development and/or commercialization efforts, which could harm our financial condition and operational results.

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

The medical device, pharmaceutical and biotechnology industries are highly competitive. If our product candidates become available for commercial sale, we will compete in that competitive marketplace. There are several products on the market or in development that could be competitors with our lead product candidates. Further, most of our competitors have greater resources or capabilities and greater experience in the development, approval and commercialization of medical devices or other products than we do. We may not be able to compete successfully against them. We also compete for funding with other companies in our industry that are focused on discovering and developing novel improvements in surgical bleeding prevention.

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

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

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

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

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

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

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

We face an inherent risk of product liability claims and currently have clinical trial liability coverage. We will need to obtain additional product liability insurance coverage if and when we begin commercialization of any of our product candidates. If claims against us exceed any applicable insurance coverage we may obtain, then our business could be adversely impacted. Regardless of whether we would be ultimately successful in any product liability litigation, such litigation could consume substantial amounts of our financial and managerial resources, which could significantly harm our business.

Risks Related to our Intellectual Property

If we are unable to obtain and maintain protection for intellectual property rights that we own, seek, or have licensed from other parties, the value of our technology and products will be adversely affected.

Our success will depend in large part on our ability to obtain and maintain protection in the U.S. and other countries for the intellectual property rights covering or incorporated into our technology and products. The ability to obtain patents covering technology in the field of medical devices generally is highly uncertain and involves complex legal, technical, scientific and factual questions. We may not be able to obtain and maintain patent protection relating to our technology or products. Many of our owned or licensed patent applications are pending. Even if issued, patents issued or licensed to us may be challenged, narrowed, invalidated, held to be unenforceable or circumvented, or determined not to cover our product candidates or our competitors' products, which could limit our ability to stop competitors from marketing identical or similar products. Because our patent portfolio includes certain patents and applications that are in-licensed on a non-exclusive basis, other parties may be able to develop, manufacture, market and sell products with similar features covered by the same patent rights and technologies, which in turn could significantly undercut the value of any of our product candidates and adversely affect our business. Our licensed MIT European patent No. 1879606 was opposed; however, this patent was maintained in amended form following an administrative hearing. Both parties have appealed this decision. A decision is not expected before the end of 2019. If the Opponents prevail in the appeal, European Patent No. 1879606 will be fully or partially invalidated, resulting in potential loss of rights. Our licensed MIT Japanese patent No. 5204646 was challenged in a Japanese court. The Japanese Court issued a decision in our favor to maintain the patent in its entirety. The Opponent appealed the decision. On October 30, 2018, the Japanese IP High Court issued a decision in our favor to maintain the patent in its entirely. The appeal decision has now become final and binding. European patent No. 2581097 has been opposed. If the Opponents prevail, European Patent No. 2581097 could be fully or partially invalidated, resulting in potential loss of rights. Further, we cannot be certain that we were the first to make the inventions claimed in the patents we own or license, or that protection of the inventions set forth in those patents was the first to be filed in the U.S. Third parties that have filed patents or patent applications covering similar technologies or processes may challenge our claim of sole right to use the intellectual property covered by the patents we own or exclusively license. Moreover, changes in applicable intellectual property laws or interpretations thereof in the U.S. and other countries may diminish the value of our intellectual property rights or narrow the scope of our patent protection. Any failure to obtain or maintain adequate protection for our intellectual property would materially harm our business, product development programs and prospects. In addition, our proprietary information, trade secrets and know-how are important components of our intellectual property rights. We seek to protect our proprietary information, trade secrets, know-how and confidential information, in part, with confidentiality agreements with our employees, corporate partners, outside scientific collaborators, sponsored researchers, consultants and other advisors. We also have invention or patent assignment agreements with our employees and certain consultants and advisors. If our employees or consultants breach those agreements, we may not have adequate remedies for any of those breaches. In addition, our proprietary information, trade secrets and know-how may otherwise become known to or be independently developed by others. Enforcing a claim that a party illegally obtained and/or for which a party is using our proprietary information, trade secrets and/or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek to defend, enforce and/or determine the scope of our intellectual property rights, and failure to obtain or maintain protection thereof could adversely affect our competitive business position and results of operations.

Many of our owned or licensed patent applications are pending, and our patent portfolio includes certain patents and applications that are in-licensed on a non-exclusive basis.

As of January 8, 2019, we either own or license from others a number of U.S. patents, U.S. patent applications, foreign patents and foreign patent applications.

Five patent portfolios assigned to Arch Biosurgery, Inc. include a total of 30 patents and pending applications in a total of nine jurisdictions, including ten patents and pending applications in the US. These portfolios cover self-assembling peptides and methods of use thereof and self-assembling peptidomimetics and methods of use thereof, including five issued US patents (US 9,415,084; US 9,162,005; US 9,789,157; US 9,821,022; and US 9,339,476) that expire between 2026 and 2034 (absent patent term extension) as well as ten patents that have been either allowed, issued or granted in foreign jurisdictions.

We have entered into a license agreement with Massachusetts Institute of Technology and Versitech Limited ("MIT") pursuant to which we have been granted exclusive rights under two portfolios of patents and non-exclusive rights under another three portfolios of patents.

The two portfolios exclusively licensed from MIT include a total of 23 patents and pending applications drawn to self-assembling peptides and methods of use thereof and self-assembling peptidomimetrics and methods of use thereof in a total of nine jurisdictions. The portfolios include five issued US patents (US 9,511,113; US 9,084,837; US 10,137,166; US 9,327,010; and US 9,364,513) that expire between 2026 and 2027 (absent patent term extension), as well as fourteen patents that have been either allowed, issued or granted in foreign jurisdictions.

The three portfolios non-exclusively licensed from MIT include a number of US and foreign applications, including four issued US patents (US 7,449,180; US 7,846,891; US 7,713,923; and US 8,901,084) that expire between 2021 and 2027 (absent patent term extension), as well as four patents that have been either allowed, issued or granted in foreign jurisdictions.

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

We have entered into certain in-license agreements with MIT and with certain other third parties, and may seek to enter into additional in-license agreements relating to other intellectual property rights in the future. To the extent we and our product candidates rely heavily on any such in-licensed intellectual property, we are subject to our and the counterparty's compliance with the terms of such agreements in order to maintain those rights. Presently, we, our lead

product candidates and our business plans are dependent on the patent and other intellectual property rights that are licensed to us under our license agreement with MIT. Although that agreement has a durational term through the life of the licensed patents, it also imposes certain diligence, capital raising, and other obligations on us, our breach of which could permit MIT to terminate the agreement. Further, we are responsible for all patent prosecution and maintenance fees under that agreement, and a failure to pay such fees on a timely basis could also entitle MIT to terminate the agreement. Any failure by us to satisfy our obligations under our license agreement with MIT or any other dispute or other issue relating to that agreement could cause us to lose some or all of our rights to use certain intellectual property that is material to our business and our lead product candidates, which would materially harm our product development efforts and could cause our business to fail.

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

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

Risks Related to Ownership of our Common Stock

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

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

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

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

Our Common Stock is a "penny stock."

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

If we issue additional shares in the future, including issuances of shares upon exercise of the Series G Warrants, Series F Warrants, Series E Warrants, and/or the Series D Warrants, our existing stockholders will be diluted.

Our articles of incorporation authorize the issuance of up to 300,000,000 shares of Common Stock. In connection with the 2018 Financing that closed on July 2, 2018, we issued an aggregate of 9,070,000 shares of our Common Stock, which equaled approximately 6% of the 154,052,013 shares of our Common Stock that were issued and outstanding immediately prior to the commencement of the 2018 Financing. Upon the closing of the 2018 Financing, we also issued Series G Warrants to acquire up to an additional 6,802,500 shares of our Common Stock at an initial exercise price of $0.70 per share. As of January 31, 2019 up to 6,802,500 shares may be acquired upon the exercise of the Series G Warrants.

In connection with the 2017 Financing that closed on February 24, 2017, we issued an aggregate of 10,166,664 shares of our Common Stock, which equaled approximately 7% of the 136,745,712 shares of our Common Stock that were issued and outstanding immediately prior to the commencement of the 2017 Financing. Upon the closing of the 2017 Financing, we also issued Series F Warrants to acquire up to an additional 5,591,664 shares of our Common Stock at an initial exercise price of $0.75 per share. As of January 31, 2019 up to 5,591,664 shares may be acquired upon the exercise of the Series F Warrants.

In connection with the 2016 Private Placement Financing that closed on May 26, 2016, we issued an aggregate of 9,418,334 shares of our Common Stock, which equaled approximately 8% of the 118,592,070 shares of our Common Stock that were issued and outstanding immediately prior to the commencement of the 2016 Private Placement Financing. Upon the closing of the 2016 Private Placement Financing, we also issued Series E Warrants to acquire up to an additional 7,063,748 shares of our Common Stock at an initial exercise price of $0.4380 per share. As of January 31, 2019 up to 4,214,582 shares may be acquired upon the exercise of the Series E Warrants. Similarly, in connection with our private placement financing that concluded on July 2, 2015 (“2015 Private Placement Financing”), we issued an aggregate of 14,390,754 shares of our Common Stock, which equaled approximately 18% of the 78,766,487 shares of our Common Stock that were issued and outstanding immediately prior to the commencement of the 2015 Private Placement Financing. Upon the closing of the 2015 Private Placement Financing, we also issued Series D Warrants to acquire up to an additional 14,390,754 shares of our Common Stock at an initial exercise price of $0.25 per share. As of January 31, 2019, up to 8,974,389 shares may be acquired upon the exercise of the Series D Warrants.

Additionally, as of January 31, 2019, 19,998,356 shares of Common Stock were reserved for future issuance under the 2013 Plan, of which 14,255,002 shares are subject to outstanding option awards granted under the 2013 Plan at exercise prices ranging from $0.17 to $0.50 per share and with a weighted average exercise price of $0.40 per share and the numbers issuable under the 2013 Plan will increase by up to 3 million shares on the first business day of each following fiscal year as set forth in the 2013 Plan. Finally, in addition to the Series G Warrants granted in connection with the 2018 Financing, the Series F Warrants granted in connection with the 2017 Financing, the Series E Warrants granted in connection with the 2016 Private Placement Financing, and the Series D Warrants granted in connection with the 2015 Private Placement Financing, there are currently outstanding warrants to acquire up to 145,985 shares of

our Common Stock. Any future grants of options, warrants or other securities exercisable or convertible into our Common Stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our Common Stock.

In addition to capital raising activities, other possible business and financial uses for our authorized Common Stock include, without limitation, future stock splits, acquiring other companies, businesses or products in exchange for shares of Common Stock, issuing shares of our Common Stock to partners in connection with strategic alliances, attracting and retaining employees by the issuance of additional securities under our various equity compensation plans, compensating consultants by issuing shares or options to purchase shares of our Common Stock, or other transactions and corporate purposes that our Board of Directors deems are in the Company's best interest. By way of example, on (i) August 9, 2016, we issued 225,000 shares of restricted stock and options to purchase up to an additional 375,000 shares of Common Stock at an exercise price of price of $0.72 per share in connection with our entrance into a consulting agreement with Acorn Management Partners, LLC ("Acorn") in consideration of the services to be provided under and in accordance with the terms of such consulting agreement; and (ii) August 6, 2015, we issued an aggregate of 600,000 shares of restricted stock in connection with our entrance into separate consulting agreements with two investor relations firms, Excelsior Global Advisors LLC and Acorn, in each case in consideration of the services to be provided under and in accordance with the terms of each consulting agreement. Additionally, shares of Common Stock could be used for anti-takeover purposes or to delay or prevent changes in control or management of the Company. We cannot provide assurances that any issuances of Common Stock will be consummated on favorable terms or at all, that they will enhance stockholder value, or that they will not adversely affect our business or the trading price of our Common Stock. The issuance of any such shares will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our Common Stock. If we issue any such additional shares, such issuance will reduce the proportionate ownership and voting power of all current shareholders. Further, such issuance may result in a change of control of our corporation.

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

As noted above under the risk factor entitled, "***We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts and could cause our business to fail***," as of January 31, 2019 we believe that our current cash on hand will meet our anticipated cash requirements into the third quarter of fiscal 2019. To raise capital, we may sell Common Stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. Any such sales of our Common Stock by us or resale of our Common Stock by our existing stockholders could cause the market price of our Common Stock to decline.

Financial Industry Regulatory Authority ("FINRA") sales practice requirements may limit a stockholder's ability to buy and sell our stock.

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

There may be additional risks because we completed a reverse merger transaction in June 2013.

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

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

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

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

Certain of our directors and executive officers own a significant percentage of our outstanding capital stock. As of January 31, 2019, Dr. Terrence W. Norchi, our Chairman of the Board, President and Chief Executive Officer, James R. Sulat, a director and Punit Dhillon, a director beneficially own (as determined under Section 13(d) of the Exchange Act and the rules and regulations thereunder) approximately 13% of our shares of Common Stock. Accordingly, these members of our Board of Directors and management team have substantial voting power to approve matters requiring stockholder approval, including without limitation the election of directors, and have significant influence over our affairs. This concentration of ownership could have the effect of delaying or preventing a change in control of our Company, even if such a change in control would be beneficial to our stockholders.

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

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

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

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

Our present management team has limited experience in managing public companies. It will be time consuming, difficult and costly for our management team to acquire additional expertise and experience in operating a public company, and to develop and implement the additional internal controls and reporting procedures required by Sarbanes-Oxley and other applicable securities laws.

Shares of our Common Stock that have not been registered under federal securities laws are subject to resale restrictions imposed by Rule 144. In addition, any shares of our Common Stock that are held by affiliates, including any that are registered, will be subject to the resale restrictions of Rule 144.

Rule 144 imposes requirements on us and our stockholders that must be met in order to effect a sale thereunder. As a result, it will be more difficult for us to raise funding to support our operations through the sale of debt or equity securities unless we agree to register such securities under the Securities Act, which could cause us to expend significant additional time and cash resources and which we presently have no intention to pursue. Further, it may be more difficult for us to compensate our employees and consultants with our securities instead of cash. We were a shell company prior to the closing of the Merger, and such status could also limit our use of our securities to pay for any acquisitions we may seek to pursue in the future (although none are currently planned), and could cause the value of our securities to decline. In addition, any shares held by affiliates, including shares received in any registered offering, will be subject to certain additional requirements in order to effect a sale of such shares under Rule 144.

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

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

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

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

FORWARD-LOOKING STATEMENTS

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

- Our ability to continue as a going concern;
- Our ability to obtain financing necessary to operate our business;
- Our limited operating history;
- The results of our research and development activities, including uncertainties relating to the preclinical and clinical testing of our product candidates;

- The early stage of our primary product candidate presently under development;

- Our ability to develop, obtain required approvals for and commercialize our product candidates;

- Our ability to recruit and retain qualified personnel;

- Our ability to obtain and maintain protection of our intellectual property;

- Our dependence on third-party manufacturers, suppliers, research organizations, academic institutions, testing laboratories and other potential collaborators;

- The size and growth of the potential markets for any of our approved product candidates, and the rate and degree of market acceptance of any of our approved product candidates;

- Our ability to successfully complete potential acquisitions and collaborative arrangements;

- Competition in our industry;

- General economic and business conditions; and

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

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

Item 6. Exhibits

			Incorporated By Reference			
Exhibit No.	**Exhibit Title**	**Filed Herewith**	**Form**	**Exhibit No.**	**File No.**	**Filing Date**
3.1	Restated Articles of Incorporation of Arch Therapeutics, Inc.		10-K	3.1	000-54986	12/12/2014
3.2	Amended and Restated Bylaws of Arch Therapeutics, Inc.		8-K	3.1	333-178883	6/24/2013
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities and Exchange Act of 1934	X				
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities and Exchange Act of 1934	X				

32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, executed by Terrence W. Norchi, President and Chief Executive Officer, and Richard E. Davis, Chief Financial Officer and Treasurer	X
101.INS	XBRL Instance Document	X
101.SCH	XBRL Taxonomy Extension Schema Document	X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	X

SIGNATURE

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

ARCH THERAPEUTICS, INC.

Date: February 1, 2019 By: /s/ TERRENCE W. NORCHI, MD
Terrence W. Norchi, MD
President and Chief Executive Officer
(Principal Executive Officer)

Date: February 1, 2019 By: /s/ RICHARD E. DAVIS
Richard E. Davis
Chief Financial Officer
(Principal Financial and Accounting Officer)