Arch Therapeutics, Inc.
Form 424B3
August 07, 2015

Filed Pursuant to Rule 424(b)(3)

Registration No. 333-194745

PROSPECTUS SUPPLEMENT NO. 8 DATED AUGUST 7, 2015

TO

PROSPECTUS DATED MAY 22, 2015

(AS SUPPLEMENTED)

ARCH THERAPEUTICS, INC.

PROSPECTUS

Up to 31,279,926 Shares of Common Stock

This Prospectus Supplement No. 8 supplements the prospectus of Arch Therapeutics, Inc. ("the "**Company**", "**we**", "**us**", or "**our**") dated May 22, 2015 (as supplemented to date, the "**Prospectus**") with the following attached document which we filed with the Securities and Exchange Commission on August 7, 2015:

A. Our Quarterly Report on Form 10-Q for the period ended June 30, 2015 filed with the Securities and Exchange Commission on August 7, 2015

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

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

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

You should rely only on the information contained in the Prospectus, as supplemented or amended by this Prospectus Supplement No. 8 and any other prospectus supplement or amendment thereto. We have not authorized anyone to provide you with different information.

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

The date of this Prospectus Supplement No. 8 is August 7, 2015

INDEX TO FILINGS

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

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

THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2015

Commission File Number: **000-54986**

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

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

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

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

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

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

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

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

As of August 5, 2015, 100,627,241 shares of the registrant’s common stock were outstanding.

ARCH THERAPEUTICS, INC.

Quarterly Report on Form 10-Q

For the Three and Nine Months Ended June 30, 2015

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Arch Therapeutics, Inc.
Consolidated Balance Sheets
As of June 30, 2015 (Unaudited) and September 30, 2014

	June 30, 2015 (Unaudited)	September 30, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$3,273,764	$833,520
Prepaid expenses and other current assets	44,091	43,470
Total current assets	3,317,855	876,990
Total assets	$3,317,855	$876,990
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$499,682	$175,832
Accrued expenses and other liabilities	481,904	267,835
Convertible notes, net of unamortized discount	498,550	-
Current derivative liabilities	411,753	2,280,000
Total current liabilities	1,891,889	2,723,667
Long-term liabilities:		
Note payable, net of unamortized discount	964,060	955,766
Accrued interest, net of current portion	182,500	100,000
Derivative liabilities, net of current portion	6,344,817	3,990,000
Total long-term liabilities	7,491,377	5,045,766
Total liabilities	9,383,266	7,769,433
Commitments and contingencies		
Stockholders’ deficit:		
Common stock, $0.001 par value, 300,000,000 shares authorized, 92,702,854 and 72,076,487 shares issued and outstanding as of June 30, 2015 and September 30, 2014, respectively	92,702	72,051
Common Stock Subscribed $0.001 par value	454	-

Additional paid in capital	8,566,193	5,810,200
Stock Subscription Receivable	(100,000)	-
Accumulated deficit	(14,624,760)	(12,774,694)
Total stockholders' deficit	(6,065,411)	(6,892,443)
Total liabilities and stockholders' deficit	$3,317,855	$876,990

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

Arch Therapeutics, Inc.
Consolidated Statements of Operations (Unaudited)
For the Three and Nine Months Ended June 30, 2015 and 2014

	Three Months Ended June 30, 2015	Three Months Ended June 30, 2014	Nine Months Ended June 30, 2015	Nine Months Ended June 30, 2014
Revenues	$ -	$ -	$ -	$ -
Operating expenses:				
General and administrative expenses	813,122	825,951	2,536,654	2,271,443
Research and development expenses	525,107	320,345	1,327,337	951,101
Total operating expenses	1,338,229	1,146,296	3,863,991	3,222,544
Operating loss	(1,338,229)	(1,146,296)	(3,863,991)	(3,222,544)
Other income (expense):				
Interest expense	(134,326)	(27,763)	(212,647)	(83,293)
Fair value of derivative liabilites in excess of proceeds	-	-	-	(7,541,693)
Gain on exercise of warrants	75,321	-	299,321	-
Gain/(loss) on warrant derivative modification	927,373	-	(996,813)	-
(Increase)/decrease to fair value of derivative	(925,384)	1,584,818	2,924,064	2,069,693
Total other income (expense)	(57,016)	1,557,055	2,013,925	(5,555,293)
Net (Loss)/income	$ (1,395,245)	$ 410,759	$ (1,850,066)	$ (8,777,837)
Basic earnings per share				
Net (loss) income per common share basic	$ (0.02)	$ 0.01	$ (0.02)	$ (0.13)
Weighted common shares - basic	76,804,674	71,949,564	75,396,047	65,933,378
Diluted earnings per share				
Net (loss) income per common share diluted	$ (0.02)	$ 0.01	$ (0.02)	$ (0.13)
Weighted common shares - diluted	76,804,674	72,084,748	75,396,047	65,933,378

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

Arch Therapeutics, Inc.
Consolidated Statements of Cash Flows (Unaudited)
For the Nine Months Ended June 30, 2015 and 2014

	Nine Months Ended June 30, 2015	Nine Months Ended June 30, 2014
Cash flows from operating activities:		
Net Loss	$ (1,850,066)	$ (8,777,837)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation Expense	-	322
Stock-based compensation	859,627	748,600
Noncash interest expense on notes payable	212,332	83,295
Issuance of common stock for services	8,625	77,625
Gain on exercise of warrants	(299,321)	-
Loss on warrant derivative modification, net of inducement shares	996,813	-
Decrease to fair value of derivative	(2,924,064)	(2,069,693)
Non cash expense for issuance of warrants	-	7,541,693
Other noncash adjustments	-	92,500
Changes in operating assets and liabilities:		
(Increase) decrease in:		
Prepaid expenses and other current assets	(621)	(2,515)
Increase (decrease) in:		
Accounts payable	323,850	(148,758)
Accrued expenses and other liabilities	46,069	75,270
Net cash used in operating activities	(2,626,756)	(2,379,498)
Cash flows from financing activities:		
Proceeds from exercise of warrants	1,251,000	-
Proceeds from issuance of common stock and warrants	3,066,000	2,624,703
Proceeds from issuance of convertible notes	750,000	-
Proceeds from issuance of notes payable	-	1,000,000
Net cash provided by financing activities	5,067,000	3,624,703
Net incerease in cash and cash equivalents	2,440,244	1,245,205
Cash and cash equivalents, beginning of period	833,520	557,319
Cash and cash equivalents, end of period	$ 3,273,764	$ 1,802,524
Non-cash financing activities		
Issuance of Inducement shares	$ 100,050	$ -

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

For financial reporting purposes, the Merger represented a "reverse merger". ABS was deemed to be the accounting acquirer in the transaction and the predecessor of Arch. Consequently, the accumulated deficit and the historical operations that are reflected in the Company's consolidated financial statements prior to the Merger are those of ABS. All share information has been restated to reflect the effects of the Merger. The Company's financial information has been consolidated with that of ABS after consummation of the Merger on June 26, 2013, and the historical financial statements of the Company before the Merger have been replaced with the historical financial statements of ABS before the Merger in this report.

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

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

The Company expects to incur substantial expenses for the foreseeable future relating to research, development and commercialization of its potential products. The Company will be required to raise additional capital, obtain alternative means of financial support, or both prior to or during April 2016 in order to continue to fund operations. However, there can be no assurance that the Company will be successful in securing additional resources when needed, on terms acceptable to the Company, if at all. Therefore, there exists substantial doubt about the Company's ability to continue as a going concern. The 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, 2014, filed with the SEC on December 12, 2014.

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, 2014. There have been no material changes to our significant accounting policies during the nine months ended June 30, 2015.

Basis of Accounting

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

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

Use of Estimates

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

Recently Issued Accounting Guidance

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

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

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

ASU 2014-15, “Presentation of Financial Statements-Going Concern (Subtopic 205-40) – Disclosure of Uncertainties about an Entity’s Ability to ‘Continue as a Going Concern” was issued by the FASB in August 2014. The primary purpose of the ASU is to provide guidance in GAAP about management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and to provide related footnote disclosures. The amendment should reduce diversity in the timing and content of footnote disclosure. ASU 2014-15 is effective for the annual period ending after December 15, 2016, and for the annual periods and interim periods thereafter. Early adoption is permitted. The Company does not believe that this guidance will have a material impact on its consolidated results of operations or financial position or disclosures.

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

public business entities for annual periods and interim periods within the annual periods beginning after December 15, 2015. Early adoption is permitted. The Company is currently assessing the impact of this guidance, but does not believe that it will have a material impact on its consolidated results of operations, financial position or disclosures.

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

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

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents.

Concentration of Credit Risk

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

Property and Equipment

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

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment when circumstances indicate the carrying value of an asset may not be recoverable in accordance with ASC 360, *Property, Plant and Equipment*. For assets that are to be held and used, impairment is recognized when the estimated undiscounted cash flows associated with the asset or group of assets is less than their carrying value. If impairment exists, an adjustment is made to write the asset down to its fair value, and a loss is recorded as the difference between the carrying value and fair value. Fair values are determined based on quoted market values, discounted cash flows or internal and external appraisals, as applicable. Assets to be disposed of are carried at the lower of carrying value or estimated net realizable value. For the three and nine month periods ended June 30, 2015 and 2014 there were no impairments of long-lived assets.

Convertible Debt

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

Income Taxes

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

The Company provides reserves for potential payments of tax to various tax authorities related to uncertain tax positions when management determines that it is probable that a loss will be incurred related to these matters and the amount of the loss is reasonably determinable. The Company has no reserves related to uncertain tax positions as of June 30, 2015 and September 30, 2014.

Research and Development

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

Accounting for Stock-Based Compensation

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

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

The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by the fair value of the common stock and a number of other assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. The Company has a limited history of market prices of the common stock, and as such volatility is estimated in accordance with ASC 718-10-S99 Staff Accounting Bulletin (“SAB”) No. 107, *Share-Based Payment* (“SAB No. 107”), using historical volatilities of similar public entities. The Company uses a simplified method for all “plain vanilla” options, as defined in SAB No. 107 and the contractual term for all other employee and non-employee awards to estimate the expected life. The risk-free interest rate assumption is based on observed interest rates appropriate for the terms of our awards. The dividend yield assumption is based on history and the expectation of paying no dividends. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Stock-based compensation expense, when recognized in the consolidated financial statements, is based on awards that are ultimately expected to vest.

Fair Value Measurements

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

The Company's financial instruments include cash and cash equivalents. Because of their short maturity, the carrying amount of cash and cash equivalents are considered to approximate fair value.

Subsequent Events

The Company evaluated all events or transactions that occurred through August 7, 2015 the date which these unaudited interim consolidated financial statements were available to be issued. The Company disclosed material subsequent events in Note 9 of these financial statements.

Going Concern Basis of Accounting

The Company does not currently believe its existing cash resources are sufficient to meet its anticipated needs during the next twelve months. As reflected in the financial statements, the Company has an accumulated deficit, has suffered significant net losses and negative cash flows from operations, and has limited working capital. The continuation of our business as a going concern is dependent upon raising additional capital and eventually attaining and maintaining profitable operations. As of June 30, 2015, there is substantial doubt about our ability to continue as a going concern. The unaudited interim consolidated financial statements included in this report do not include any adjustments that might be necessary should operations discontinue. The Company expects to incur substantial expenses for the foreseeable future for the research, development and commercialization of its potential products. In addition, the Company will require additional financing in order to seek to license or acquire new assets, research and develop any potential patents and the related compounds, and obtain any further intellectual property that the Company may seek to acquire. The Company does not have sufficient cash and cash equivalents to support its current operating plan. The Company will be required to raise additional capital, obtain alternative means of financial support, or both, in order to continue to fund operations. Therefore, there exists substantial doubt about the Company's ability to continue as a going concern. Historically, the Company has funded its operations primarily through equity and debt financings.

3.STOCK-BASED COMPENSATION

2013 Stock Incentive Plan

On June 18, 2013, the Company established the 2013 Stock Incentive Plan (the "2013 Plan"). Under the 2013 Plan, during the fiscal year ended September 30, 2014, a maximum number of 10,231,197 shares of the Company's authorized and available common stock could be issued in the form of: options, stock appreciation rights, sales or bonuses of restricted stock, restricted stock units or dividend equivalent rights, and an award may consist of one such security or benefit, or two or more of them in any combination or alternative. The 2013 Plan provides that on the first business day of each fiscal year commencing with fiscal year 2014, the number of shares of our common stock reserved for issuance under the 2013 Plan for all awards except for incentive stock option awards will be subject to increase by an amount equal to the lesser of (A) 3,000,000 Shares, (B) four (4) percent of the number of shares outstanding on the last day of the immediately preceding fiscal year of the Company, or (C) such lesser number of shares as determined by the Company's Board of Directors (the "Board"). The exercise price of each option shall be the

fair market value as determined in good faith by the Board at the time each option is granted. On October 1, 2014, the aggregate number of authorized shares under the Plan was further increased by 2,883,059 shares to a total of 13,114,256 shares.

As of June 30, 2015, a total of 7,254,212 options had been issued to employees and directors and 4,602,500 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 nine months ended June 30, 2015, the Company granted options to employees and directors to purchase 1,950,000 and to consultants to purchase 1,037,500 shares of common stock under the 2013 Plan. The options have terms ranging from 1 to 10 years, are subject to vesting terms over periods ranging up to 3 years and have exercise prices ranging from $0.17 to $0.22.

During the three months ended June 30, 2015, the Company did not grant any options to employees and directors or to consultants to purchase shares of common stock under the 2013 Plan.

The Company recognizes compensation expense for stock option awards on a straight-line basis over the applicable service period of the award. The service period is generally the vesting period, with the exception of options granted subject to a consulting agreement, whereby the option vesting period and the service period are defined pursuant to the terms of the consulting agreement. Share-based compensation expense for awards granted during the nine months ended June 30, 2015 was based on the fair market value at period end or grant date fair value estimated using the Black-Scholes Option Pricing Model. The following assumptions were used to calculate the fair value of share based compensation for the three and nine months ended June 30, 2015; expected volatility, 76.6% - 119.4%, risk-free interest rate, 0.25% - 2.40%, expected forfeiture rate, 0.00%, expected dividend yield, 0.00%, expected term, 1 to 10 years.

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

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

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

Stock compensation plan activity is as follows:

Common Stock Options

Stock compensation activity under the 2013 Plan for the nine months ended June 30, 2015 follows:

	Option Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value ($0's)
Outstanding at September 30, 2014	8,637,962	$ 0.34	-	$ -
Awarded	2,987,500	0.19	-	-
Exercised	-	-	-	-
Forfeited	(515,625)	$ 0.35	-	-
Outstanding at June 30, 2015	11,109,837	$ 0.31	5.36	292,860
Vested	8,051,432	$ 0.32	4.74	160,901
Vested and expected to vest at June 30, 2015	11,109,837	$ 0.31	5.36	292,860

As of June 30, 2015, 1,257,544 shares are available for future grants under the 2013 Plan. Share-based compensation expense recorded in the Company's unaudited interim consolidated statement of operations for the three months ended June 30, 2015 and 2014 resulting from stock options awarded to the Company's employees, directors and consultants was approximately $250,000 and $245,000, respectively. Of this amount during the three months ended June 30, 2015 and 2014, $122,342 and $112,304 respectively was recorded to Research and Development expenses, and $128,013 and $132,941, respectively was recorded in general and administrative expenses in the Company's unaudited interim consolidated statement of operations. Share-based compensation expense recorded in the Company's consolidated statement of operations for the nine months ended June 30, 2015 and 2014 resulting from stock options awarded to the Company's employees, directors and consultants was approximately $859,626 and $748,600 respectively. Of this amount during the nine months ended June 30, 2015 and 2014, $396,668 and $461,312, respectively, was recorded to Research and Development expenses, and $462,958 and $287,287, respectively, was recorded in General and Administrative expenses in the Company's unaudited interim consolidated statement of operations

As of June 30, 2015, there is approximately $549,278 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 1.72 years.

4.8% CONVERTIBLE NOTES

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

The Notes become due and payable on March 13, 2016 (the "Stated Maturity Date") and may not be prepaid. The Notes bear interest on the unpaid principal balance at a rate equal to eight percent (8.0%) (computed on the basis of the actual number of days elapsed in a 360-day year) per annum until either (a) converted into shares of the Company's common stock, $0.001 par value per share ("Common Stock") or (b) the outstanding principal and accrued interest on the Notes is paid in full by the Company. Interest on the Notes becomes due and payable upon their conversion or the Stated Maturity Date and may become due and payable upon the occurrence of an event of default under the Notes. The Notes contain customary events of default, which include, among other things, (i) the Company's failure to pay other indebtedness of $100,000 or more within the specified cure period for such breach; (iii) the acceleration of the stated maturity of such indebtedness; (iii) the insolvency of the Company; and (iv) the receipt of final, non-appealable judgments in the aggregate amount of $100,000 or more.

At any time prior to the Stated Maturity Date, the holders of the Notes have the right to convert some or all of such Notes into the number of shares of Common Stock determined by dividing (a) the aggregate sum of the (i) principal amount of the Note to be converted, and (ii) amount of any accrued but unpaid interest with respect to such portion of the Note to be converted; and (b) the conversion price then in effect (the shares of Common Stock issuable upon such conversion, the "Conversion Shares"). The initial conversion price is $0.20 per share, and it may be (A) reduced to any amount and for any period of time deemed appropriate by the Board of Directors of the Company, or (B) reduced or increased proportionately as a result of stock splits, stock dividends, recapitalizations, reorganizations, and similar transactions. A holder shall not have the right to convert any portion of a Note, if after giving effect to such conversion, the holder, together with its affiliates collectively, would beneficially own more than 4.99% or 9.99% (at the holder's discretion) of the shares of Common Stock outstanding immediately after giving effect to such conversion.

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

Derivative Liabilities

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

On the closing date, the derivative liability was recorded at fair value of $354,988 with the remaining proceeds of $395,012 allocated to the Notes. The allocation of funds to the derivative liability resulted in a discount on the loan, which is accreted to interest expense over the life of the loan. For the three and nine months ended June 30, 2015, $88,747 and $103,538 respectively of the loan discount has been accreted to interest expense. As of June 30, 2015 the accreted balance of the Notes was $498,550.

The value of the derivative liability as of June 30, 2015 was $411,753. As a result of a change in the estimated fair market value of the derivative liability we recorded other expense of $149,622 and $56,765 for the three and nine months ended June 30, 2015, respectively.

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)	
	Convertible Debt Derivative Liability
Beginning balance at September 30, 2014	$ -
Issuances	354,988

Adjustments to estimated fair value		56,765
Ending balance at June 30, 2015	$	411,753

The derivative liability was valued as of March 15, 2015 and June 30, 2015 using Monte Carlo Simulations with the following assumptions:

	March 15, 2015	June 30, 2015
Stated interest rate	8.0 %	8.0 %
Exercise price per share	$ 0.20	$ 0.20
Expected volatility	90.0 %	70.0 %
Risk-free interest rate	0.24 %	0.18 %
Credit adjusted discount rate	20.0 %	19.0 %
Remaining expected term of underlying securities (years)	1.00	.75

5. NOTE PAYABLE

On September 30, 2013, the Company entered into the Life Sciences Accelerator Funding Agreement (the "MLSC Loan Agreement") with the Massachusetts Life Sciences Center ("MLSC"), pursuant to which MLSC provided an unsecured subordinated loan in the amount of $1,000,000. The loan bears interest at a rate of 10% per annum, and will become fully due and payable on the earlier of (i) September 30, 2018, (ii) the occurrence of an event of default under the MLSC Loan Agreement, or (iii) the completion of a sale of substantially all of our assets, a change-of-control transaction or one or more financing transactions in which we receive from third parties other than our then existing shareholders net proceeds of $5,000,000 or more in a 12-month period. The MLSC Loan Agreement includes warrants to purchase 145,985 shares of the Company's Common Stock at an exercise price of $0.27 per share. None of the warrants, which expire on September 30, 2023, have been exercised as of June 30, 2015.

Of the $1,000,000, the Company allocated $944,707 to the loan and $55,293 to the warrants. The warrant valuation was derived with the Black-Scholes option pricing model with the following assumptions: risk free rate 2.64%, dividend yield 0.0%, expected life of 10 years, and volatility 114%. The fair value of the warrants was recorded as an increase to additional paid-in capital. The allocation of funds to the warrants resulted in a discount on the loan, which is accreted to interest expense over the life of the loan. For each of the three and nine months ended June 30, 2015 and 2014, $2,765 and $8,294, respectively of the loan discount have been accreted to interest expense. As of June 30, 2015 and September 30, 2014 the accreted balance of the MLSC Loan was $964,060 and $955,766, respectively.

6. PRIVATE PLACEMENT FINANCING

On January 30, 2014, the Company entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with nine separate accredited investors ("2014 Investors") providing for the issuance and sale by the Company to the 2014 Investors, in a private placement, of an aggregate of 11,400,000 shares of Common Stock (collectively, the "2014 Shares") at a purchase price of $0.25 per share and three series of warrants, the Series A warrants, the Series B warrants and the Series C warrants, to purchase up to an aggregate of 34,200,000 shares of the Company's Common Stock (collectively, the "2014 Warrants," and the shares issuable upon exercise of the 2014 Warrants, collectively, the "2014 Warrant Shares"), for aggregate gross proceeds to the Company of approximately $2,850,000 (the "2014 Private Placement Financing").

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

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

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

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

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

with the December 2014 Amendment, the Company recognized a loss on the modification of 2014 Warrants in the amount of $1,300,170, which was determined using Monte Carlo Simulation.

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

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

During the quarter ended June 30, 2015, Series C Warrants had been exercised for an aggregate issuance of 2,255,000 shares of the Company's Common Stock resulting in gross proceeds to the Company of $451,000. In conjunction with the exercise of the Series C Warrants, their corresponding fair value at the exercise dates of $75,321 were extinguished from the derivative liabilities balance.

On June 22, 2015 the Company entered into the Amendment to the Series A Warrants and Series C Warrants to purchase Common Stock (the "June 2015 Amendment"), with Cranshire Capital Master Fund, Ltd. ("Cranshire"), to (i) delete the full ratchet anti-dilution provisions set forth in the Series A Warrants and Series C Warrants; and (ii) extend the expiration date of the Series C Warrants from to 5:00 p.m., New York time, on July 2, 2015 to 5:00 p.m., New York time, on July 2, 2016. In consideration of Cranshire's entrance into the June 2015 Amendment (and for no additional consideration), the Company agreed to issue to the holders of the 2014 Warrants up to 570,000 shares of Company's Common Stock subject to the delivery by each such holder of an investor certificate to the Company (such shares of Common Stock, the "Inducement Shares"). In conjunction with the modifications to the Series A and Series C Warrants in the June 2015 Amendment, the corresponding fair values at the modification date, net of Inducement Shares totaling $927,373 were extinguished from the derivative liabilities balance.

For the period ended June 30, 2015, 435,000 Inducement Shares had been issued of the potential 570,000 and an additional 125,000 shares were issued during July 2015 for a total of 560,000.

Derivative Liabilities

The Company accounted for the 2014 Warrants relating to the aforementioned 2014 Private Placement Financing in accordance with ASC 815-10, *Derivatives and Hedging*. Because the 2014 Warrants are not indexed to the Company's stock and 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 February 4, 2014, the initial closing date of the 2014 Private Placement Financing, the derivative liabilities were recorded at fair value of $10,391,693. Given that the fair value of the derivative liabilities exceeded the total proceeds of the 2014 Private Placement Financing of $2,850,000, no net amounts were available to be allocated to the Common Stock. The $7,541,693 amount by which the recorded liabilities exceeded the proceeds was charged to other expense as of February 4, 2014 closing date.

The value of the derivative liability as of June 30, 2015 and September 30, 2014 was $3,886,613 and $6,270,000, respectively. As a result of a change in the estimated fair market value of the derivative liability we recorded other expense of $925,384 for the three months ended June 30, 2015 and other income of $2,980,829 for nine months ended June 30, 2015 and other income of $1,584,818 and $2,069,693 for the three and nine months ended June 30, 2014, respectively. In addition, during the three months ended June 30, 2015, we recorded a gain on modification of warrants, net of Inducement Shares in the amount of $927,373 and a loss of $896,763 for the nine months ended June 30, 2015. Lastly, we recognized a gain on the exercise of warrants in the amount of $75,321, and $299,321, respectively for the three and nine months ended June 30, 2015 as described above. For the three months ended June 30, 2015, the change in the estimated fair value was primarily due to the elimination of the anti-dilution provisions of the Series A Warrants and Series C Warrants and extending the expiration date of the Series C Warrants to July 2, 2016. For the nine months ended June 30, 2015, the change in the estimated fair value was primarily due to the

reduction of the exercise prices of the 2014 Warrants, the exercise of 4,000,000 shares of the Series B Warrants and the exercise of 2,255,000 shares of the Company's Common Stock.

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)	**Warrant Derivative Liability**
Beginning balance at September 30, 2014	$ 6,270,000
Modification of warrants, net of Inducement Shares	896,763
Exercises of warrants	(299,321)
Adjustments to estimated fair value	(2,980,829)
Ending balance at June 30, 2015	$ 3,886,613

The derivative liabilities were valued as of September 30, 2014, December 1, 2014, March 15, 2015, June 22, 2015, and June 30, 2015 using Monte Carlo Simulation or Black Schole, as appropriate, with the following assumptions:

	September 30, 2014	December 1, 2014	March 15, 2015	June 22, 2015	June 30, 2015
Closing price per share of Common Stock	$ 0.18	$ 0.25	$0.21	$0.23	$ 0.26
Exercise price per share	$ 0.30 - 0.40	$ 0.20 - $0.30	$ 0.20 - $0.30	$0.20	$ 0.20
Expected volatility	85 - 90 %	80 – 90 %	80 – 110 %	55- 85 %	75-85 %
Risk-free interest rate	0.02 - 1.55 %	.01 – 1.39 %	0.03 – 1.41%	0.27 - 1.68 %	0.28 – 1.63 %
Dividend yield	—	—	—	—	—
Remaining expected term of underlying securities (years)	0.33 - 4.33	0.33 – 4.6	0.22 – 4.3	1.03 – 4.03	1.01 – 4.01

Common Stock

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

7. 2015 PRIVATE PLACEMENT FINANCING

Beginning June 22, 2015 and through June 30, 2015, the Company entered into a series of substantially similar subscription agreements (each a “Subscription Agreement”) with 20 accredited investors (collectively, the “2015 Investors”) providing for the issuance and sale by the Company to the 2015 Investors, in a private placement, of an aggregate of 14,390,754 Units (“Unit”) at a purchase price of $0.22 per Unit (the “2015 Private Placement Financing”). Each Unit consisted of a share of Common Stock (the “2015 Shares”) and a Series D Warrant to purchase a share of Common Stock at an exercise price of $0.25 per share at any time prior to the fifth anniversary of the issuance date of the Series D Warrant (the “Series D Warrants,” and the shares issuable upon exercise of the Series D Warrants, collectively, the “2015 Warrant Shares”). The Company did not engage any underwriter or placement agent in connection with the 2015 Private Placement Financing, and the aggregate gross proceeds raised by the Company in the 2015 Private Placement Financing totaled approximately $3,100,000.

The Company’s obligation to issue and sell the 2015 Shares and the Series D Warrants and the corresponding obligation of the 2015 Investors to purchase such 2015 Shares and Series D Warrants were subject to a number of conditions precedent including, but not limited to, the amendment of the Company’s Series A Warrants and Series C Warrants to delete certain of the anti-dilution provisions contained therein, as described in Footnote 6, Private Placement Financing, and other customary closing conditions. The conditions precedent were satisfied June 30, 2015 (the “Initial Closing Date”), and the Company conducted an initial closing (the “Initial Closing”) pursuant to which it sold and 19 of the 2015 Investors (the “Initial Investors”) purchased 13,936,367 Units at an aggregate purchase price of $3,066,000. On July 2, 2015, the Company conducted a second closing (the “Second Closing” and together with the

Initial Closing, the “Closings”) pursuant to which it sold and one of the 2015 Investors purchased 454,387 Units at an aggregate purchase price of $100,000. The 454,387 Units have been recorded as Common Stock subscribed and the $100,000 has been recorded as a stock subscription receivable as of June 30, 2015.

On the Initial Closing Date, the Company entered into a registration rights agreement with the Initial Investors (the “ 2015 Registration Rights Agreement”), pursuant to which the Company will be obligated, subject to certain conditions, to file with the Securities and Exchange Commission within 90 days after the closing of the 2015 Private Placement Financing one or more registration statements (any such registration statement, a “Resale Registration Statement”) to register the 2015 Shares and the 2015 Warrant Shares for resale under the Securities Act of 1933, as amended (the “Securities Act”). The remaining 2015 Investor became a party to the 2015 Registration Rights Agreement upon the consummation of the Second Closing. The Company’s failure to satisfy certain filing and effectiveness deadlines with respect to a Resale Registration Statement and certain other requirements set forth in the 2015 Registration Rights Agreement may subject the Company to payment of monetary penalties.

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 therefor are subject to adjustment, as set forth in the Series D Warrants, including adjustments for stock subdivisions or combinations (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise). In addition, at anytime during the term of the Series D Warrants, the Company may reduce the then current exercise price to any amount and for any period of time deemed appropriate by the Board of Directors of the Company.

Derivative Liabilities

The Company accounted for the Series D Warrants relating to the aforementioned 2015 Private Placement Financing in accordance with ASC 815-10, *Derivatives and Hedging*. Because the Series D Warrants are not indexed to the Company's stock and 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 Initial Closing Date, the derivative liabilities were recorded at fair value of $2,458,204. Given that the fair value of the derivative liabilities were less than the total proceeds of the 2015 Private Placement Financing of $3,066,000, the remaining proceeds of $607,796 were allocated to the Common Stock and additional paid in capital.

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

	Warrant Derivative Liability
Beginning balance at September 30, 2014	$ -
Issuances	2,458,204
Adjustments to estimated fair value	-
Ending balance at June 30, 2015	$ 2,458,204

The derivative liabilities were valued as of June 30, 2015 using Monte Carlo Simulation with the following assumptions:

	June 30, 2015	
Closing price per share of common stock	$ 0.26	
Exercise price per share	$ 0.25	
Expected volatility	85	%
Risk-free interest rate	1.63	%
Dividend yield	—	
Remaining expected term of underlying securities (years)	5.00	

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 and recorded the par value of the shares issued of $13,936 (at par value of $0.001 per share) with the remaining proceeds of $593,860 allocated to additional paid-in capital. On July 2, 2015, the Company conducted the Second Closing pursuant to which it sold and one of the 2015 Investors purchased 454,387 Units at an aggregate purchase price of $100,000. The 454,387 Units have been recorded as Common Stock subscribed and the $100,000 has been recorded as a stock subscription receivable as of June 30, 2015.

8. COLDSTREAM FINANCING

In contemplation of the Merger, on April 19, 2013, the Company entered into a financing agreement (the "Financing Agreement") with Coldstream Summit Ltd. ("Coldstream") pursuant to which we agreed to issue and sell, and Coldstream agreed to purchase or assist in securing the purchase of $2,000,000 worth of units in a private offering within the 12-month period following the closing of the Merger (the "Coldstream Financing"). Each unit issued in the Coldstream Financing was to be sold at a price of $0.50 per share and was to consist of (i) one share of common stock and (ii) one warrant to purchase one share of common stock at an exercise price of $0.75 per share and with a term of 12 months. Pursuant to the Coldstream Financing, we issued and sold units consisting of 4,000,000 shares of common stock and warrants to purchase 4,000,000 shares of common stock for aggregate gross proceeds of $2,000,000. As of September 30, 2014, all warrants issued in connection with the Coldstream Financing had expired.

9. SUBSEQUENT EVENTS

During the period commencing July 1, 2015 and ending on August 5, 2015, additional Series A and Series C Warrants have been exercised for an aggregate issuance of 7,345,000 shares of the Company's Common Stock at an exercise price of $0.20 per share, resulting in gross proceeds to the Company of $1,469,000.

As part of the amendment made to the Series A Warrants and Series C Warrants to delete the full ratchet anti-dilution provisions set forth in the Series A Warrants and Series C Warrants and to extend the expiration date of the Series C Warrants, an additional 125,000 shares of the Inducement Shares have been issued during July 2015. The remaining 10,000 Inducement Shares will be issued upon the execution and delivery by remaining holders of an investor certificate to the Company.

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, 2014 filed with the Securities and Exchange Commission ("SEC").

This report contains forward looking statements. We make forward-looking statements, as defined by the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, and in some cases, you can identify these statements by forward-looking words such as "if," "shall," "may," "might," "will likely result," "should," "expect," "plan," "an "believe," "estimate," "project," "intend," "goal," "objective," "predict," "potential" or "continue," or the negative of these ter

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

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

Corporate Overview

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

For financial reporting purposes, the Merger represented a “reverse merger”. ABS was deemed to be the accounting acquirer in the transaction and the predecessor of Arch. Consequently, the assets, liabilities, accumulated deficit and the historical operations that are reflected in the Company’s unaudited interim consolidated financial statements are those of ABS. All share information has been restated to reflect the effects of the Merger. The Company’s financial information was consolidated with that of ABS after consummation of the Merger on June 26, 2013, and the historical financial statements of the Company before the Merger have been replaced with the historical financial statements of ABS before the Merger in this report.

Business Overview

We are a life science medical device company in the development stage with limited operations to date. We aim to develop products that make surgery and interventional care faster and safer by using a novel approach to stop bleeding (referenced as “hemostatic” or “hemostasis”), control leaking (referenced as “sealant” or “sealing”), and provide other advantages during surgery and trauma care. Our core technology is based on a self-assembling peptide that creates a physical, mechanical barrier, which could be applied to seal organs or wounds that are leaking blood and other fluids. We believe our technology could support an innovative platform of potential products in the field of stasis and barrier applications. Our lead product candidate, AC5 Surgical Hemostatic Device™ (which we sometimes refer to as “AC5™”), is designed to achieve hemostasis in minimally invasive and open surgical procedures, and we hope to develop other hemostatic or sealant product candidates in the future based on our self-assembling peptide technology platform. Our plan and business model is to develop products that apply that core technology to use with human bodily fluids and connective tissues.

AC5 is designed to be a biocompatible synthetic peptide comprising naturally occurring amino acids. When applied to a wound, AC5 intercalates into the interstices of the connective tissue where it self-assembles into a physical, mechanical structure that provides a barrier to leaking substances, such as blood. AC5 is designed for direct application as either a liquid or a spray, which we believe will make it user-friendly and able to conform to irregular wound geometry. Additionally, AC5 is not sticky or glue-like, which we believe will enhance its utility in the setting of minimally invasive and laparoscopic surgeries. Further, AC5 is transparent, which should make it easier for surgeons or other healthcare providers to maintain a clear field of vision during a surgical procedure and prophylactically stop bleeding as it starts, which we call Crystal Clear Surgery™.

We have devoted much of our operations to date to the development of our core technology, including selecting our lead product composition, conducting initial safety and other related tests, generating scale-up, reproducibility and manufacturing and formulation methods, and developing and protecting the intellectual property rights underlying our technology platform. Formulation optimization is an important part of peptide development. AC5 formulation optimization, which is done with extensive collaboration among our team and partners, is focused on optimizing traditional product parameters to target specifications covering performance, physical appearance, stability, and handling characteristics, among others. Arch intends to monitor formulation optimization closely, as success or failure in setting and realizing appropriate specifications may directly impact our anticipated clinical trial and subsequent commercialization timeline.

Our long-term business plan includes the following goals:

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

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

- seek additional funding to support the milestones described above and our operations generally;
- work with our large scale manufacturing partners to continue to scale up production of product compliant with current good manufacturing practices (“cGMP”), which activities will be ongoing as we seek to advance toward, enter into, and, if successful, subsequently increase commercialization activities;

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

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

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

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

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

With respect to our goals relating to AC5, we currently project requiring up to $3,000,000 - $5,000,000 of additional expenditures to complete the milestones to obtain regulatory approval in Europe. We expect that obtaining regulatory approvals in the U.S., including conducting additional required clinical trials, would require at least an additional $7,000,000 - $19,000,000 in capital. These estimated capital requirements potentially could increase significantly if a number of risks relating to conducting these activities were to occur, including without limitation those set forth under the heading “Risk Factors” in this filing.

Merger with ABS and Related Activities

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

Liquidity

We are in the development stage and have generated no operating revenues to date and do not expect to do so in the foreseeable future due to the early stage nature of our current product candidates. We currently do not have any products that have obtained marketing approval in any jurisdiction. We have net losses for the three months ended June 30, 2015, of $1,395,245 and net income of $410,759 for the three months ended June 30, 2014. The loss for the three months ended June 30, 2015 can be attributed to general and administrative costs and increased research and development expenses associated with pre-clinical development expenses and manufacturing and quality management system consulting and advisory related expenses. Net income for the three months ended June 30, 2014, includes a decrease on the fair value on derivative liabilities related to our outstanding warrants of $1,584,818. For the nine months ended June 30, 2015, we have net loss of $1,850,066 versus a net loss of $8,777,837 in the comparable period in the prior year. The loss for the nine months ended June 30, 2014 is primarily attributable to the $7,541,693 expense we recorded upon the issuance of the 2014 Warrants associated with the 2014 Private Placement Financing. We devote a significant amount of our efforts towards fundraising and product research.

Recent Developments

The Company entered into an agreement to amend certain provisions of the Series A, Series B and Series C Warrants (collectively, the “2014 Warrants”) issued by the Company in February 2014 (the “December 2014 Amendment”) that it

issued in connection with the securities purchase agreement that it entered into on January 31, 2014 (the "Securities Purchase Agreement"). Under the terms of the December 2014 Amendment, which became effective December 1, 2014, the 2014 Warrants were amended to (i) reduce the exercise price of the Series B Warrants from $0.35 to $0.20, (ii) reduce the exercise price of the Series C Warrants from $0.40 to $0.20, and (iii) clarify that each Series of 2014 Warrants may be amended without having to amend all three series of 2014 Warrants. The number of shares of the Company's common stock, par value $0.001 per share ("Common Stock") that may be purchased from the Company upon exercise of each 2014 Warrant remained unchanged.

Prior to their expiration on January 3, 2015, certain holders of the Warrants exercised portions of their Series B Warrants, resulting in an aggregate issuance of 4,000,000 shares of the Company's Common Stock and gross proceeds to the Company from that exercise of $800,000.

On March 13, 2015, the Company issued unsecured 8% Convertible Notes (the "Notes") in the aggregate principal amount of $750,000 in a private placement. The principal and all accrued and unpaid interest on the Notes shall mature and become payable on March 13, 2016, and the Notes (and all interest accrued thereunder) are currently convertible into Common Stock, par value $0.001 per shares of the Company, at a conversion price of $0.20 per share, resulting in up to an additional 4,050,000 shares of Common Stock becoming issuable under these Notes if they are held to maturity and the accrued interest thereunder is converted, along with the outstanding principal, into shares of Common Stock at the current conversion price.

The Company's issuance of the Notes triggered the anti dilution provisions of the Series A Warrants and, as a result, the exercise price of the Series A Warrants was reduced to $0.20 per share and the aggregate number of shares issuable under the Series A Warrants increased by 5,700,000 shares from 11,400,000 shares to 17,100,000 shares. In addition, pursuant to separate amendments entered into between the Company and Cranshire Capital Master Fund, Ltd. ("Cranshire") on March 13, 2015, and May 30, 2015, respectively the expiration date of the Series C Warrants was extended to June 2, 2015, and July 2, 2015, respectively.

During the quarter ended June 30, 2015, certain holders of the Series C Warrants exercised a portion of their warrants for an aggregate issuance of 2,255,000 shares of the Company's Common Stock resulting in gross proceeds to the Company of $451,000.

On June 22, 2015, the Company entered into the Amendment to Series A Warrants and Series C Warrants to Purchase Common Stock (the "June 2015 Amendment") with Cranshire to (i) delete the full ratchet anti-dilution provisions set forth in the Series A Warrants and Series C Warrants and (ii) extend the expiration date of the Series C Warrants from to 5:00 p.m., New York time, on July 2, 2015 to 5:00 p.m., New York time, on July 2, 2016. In consideration of Cranshire's entrance into the June 2015 Amendment (and for no additional consideration), the Company agreed to issue to the holders of the 2014 Warrants up to 570,000 shares of Company's Common Stock subject to the delivery by each such holder of an investor certificate to the Company (such shares of Common Stock, the "Inducement Shares").

Beginning June 22, 2015 and through June 30, 2015, Arch Therapeutics, Inc. (the "Company") entered into a series of substantially similar subscription agreements (each a "Subscription Agreement") with 20 accredited investors (collectively, the "2015 Investors") providing for the issuance and sale by the Company to the 2015 Investors, in a private placement, of an aggregate of 14,390,754 Units at a purchase price of $0.22 per Unit (the "2015 Private Placement Financing"). Each Unit consisted of a share of the Company's Common Stock and a Series D Warrant to purchase a share of Common Stock at an exercise price of $0.25 per share at any time prior to the fifth anniversary of the issuance date of the Series D Warrant (the "Warrants," and the shares issuable upon exercise of the Series D Warrants, collectively, the "2015 Warrant Shares"). The aggregate gross proceeds raised by the Company in the 2015 Private Placement Financing totaled approximately $3,100,000.

As part of 2015 Private Placement Financing, the Company conducted an initial closing (the "Initial Closing") pursuant to which it sold, and 19 of the 2015 Investors (the "Initial Investors") purchased 13,936,367 Units at an aggregate purchase price of $3,066,000. On July 2, 2015, the Company conducted a second closing (the "Second Closing" and together with the Initial Closing, the "Closings") pursuant to which it sold, and 1 of the 2015 Investors purchased 454,387 Units at an aggregate purchase price of $100,000.

On June 1, 2015, the Company executed a collaboration agreement with CÚRAM Centre for Research in Medical Devices, a new center of excellence for research based in Galway, Ireland that aims to radically improve health outcomes for patients by developing and collaborating on the development of "smart" medical devices. As part of the

collaboration agreement, Arch and CÚRAM intend to deploy resources in Ireland to advance Arch's technology, ranging from early stage research to late stage development. Under Arch oversight and guidance, personnel from Arch and CÚRAM will work closely together on diverse pipeline projects, including new potential indications and products as well as human clinical trial planning. In addition to receiving infrastructure support, for each €1 up to an annual maximum of €250,000 that Arch contributes to its own R&D activities within CÚRAM, CÚRAM will contribute €2 up to an annual maximum of €500,000 to those same activities, made possible by its grant funding from Science Foundation Ireland (SFI).

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. The period to period comparisons of our interim results of operations that follow are not necessarily indicative of future results.

Three Months Ended June 30, 2015 Compared to Three Months Ended June 30, 2014

	June 30, 2015 ($)	June 30, 2014 ($)	Increase (Decrease) ($)
Revenue	-	-	-
Operating Expenses			
General and administrative	813,122	825,951	(12,829)
Research and development	525,107	320,345	204,762
Loss from operations	(1,338,229)	(1,146,296)	(191,933)
Other income (expense)	(57,016)	1,557,055	(1,614,071)
Net income (loss)	(1,395,245)	410,759	(1,806,004)

Revenue

We did not generate revenue in either of the three months ended June 30, 2015 and 2014.

General and Administrative Expense

General and administrative expenses during the three months ended June 30, 2015 were $813,122, a decrease of $12,829 compared to $825,951 for the three months ended June 30, 2014. The decrease in general and administrative expense is primarily attributable to additional expenses being allocated to research and development offset by an increase in legal and patent expenses.

Research and Development Expense

Research and development expense during the three months ended June 30, 2015 was $525,107, an increase of $204,762 compared to $320,345 for the three months ended June 30, 2014. The increase in research and development expense is primarily attributed to an increase in expenses associated with pre-clinical development expenses and manufacturing and quality management system consulting and advisory related expenses. Research and development expenses are expected to increase as a result of our plans to commence clinical studies as resources permit. The Company anticipates that the first clinical trial will commence during the fourth quarter of calendar 2015.

Other Income (Expense)

Other expense during the three months ended June 30, 2015 was $57,016 a decrease of $1,614,071 compared to other income of $1,557,055 for the three months ended June 30, 2014. This decrease resulted from a change in adjustments to derivative liabilities of $1,507,508 during fiscal 2015 as compared to fiscal 2014. Other income during the three months ended June 30, 2014 was primarily related to the recording of the value of the derivative liability.

Nine Months Ended June 30, 2015 Compared to Nine Months Ended June 30, 2014

	June 30, 2015 ($)	June 30, 2014 ($)	Increase (Decrease) ($)
Revenue	-	-	-
Operating Expenses			
General and administrative	2,536,654	2,271,443	234,789
Research and development	1,327,337	951,101	376,236
Loss from operations	(3,863,991)	(3,222,544)	(641,447)
Other income (expense)	2,013,925	(5,555,293)	(7,569,218)
Net loss	(1,850,066)	(8,777,837)	(6,927,771)

Revenue

We did not generate revenue in either of the nine months ended June 30, 2015 and 2014.

General and Administrative Expense

General and administrative expenses during the nine months ended June 30, 2015 were $2,536,654, an increase of $234,789 compared to $2,271,443 for the nine months ended June 30, 2014. The increase in general and administrative expense is primarily attributable to increased legal costs related to patents, and stock-based compensation expenses incurred in connection with attracting and retaining key employees. General and administrative expenses are generally expected to increase as a result of the full year impact of new hires and stock based compensation.

Research and Development Expense

Research and development expense during the nine months ended June 30, 2015 was $1,327,337, an increase of $376,236 compared to $951,101 for the nine months ended June 30, 2014. The increase in research and development expense is primarily attributed to an increase in expenses associated with pre-clinical development expenses and manufacturing and quality management system consulting and advisory related expenses. Research and development expenses are expected to increase as a result of our plans to commence clinical studies as resources permit. The Company anticipates that the first clinical trial will commence during the fourth quarter of calendar 2015.

Other Income (Expense)

Other income during the nine months ended June 30, 2015 was $2,013,925 an increase of $7,569,218 compared to other expense of $5,555,293 for the nine months ended June 30, 2014. The increase in other income (expense) during the nine months ended June 30, 2015 resulted from a change in adjustments to derivative liabilities of $7,698,572 during fiscal 2015 as compared to fiscal 2014. Other expenses during the nine months ended June 30, 2014 were primarily related to the recording of the value of the derivative liability.

Liquidity and Capital Resources

To date, we have not generated revenues from the sale of any products and have principally raised capital through borrowings and the issuance of convertible debt and units consisting of Common Stock and warrants to fund our operations. At June 30, 2015, we had cash and cash equivalents of $3,273,764 and positive working capital of $1,425,966.

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

On March 13, 2015, the Company issued Notes in the aggregate principal amount of $750,000. The Company's issuance of the Notes triggered the anti dilution provisions of the Series A Warrants and, as a result, the exercise price of the Series A Warrants was reduced to $0.20 per share and the aggregate number of shares issuable under the Series A Warrants increased by 5,700,000 shares from 11,400,000 shares to 17,100,000 shares. In addition, pursuant to separate amendments entered into between the Company and Cranshire on March 13, 2015 and May 30, 2015, respectively the expiration date of the Series C Warrants was extended to June 2, 2015 and July 2, 2015, respectively.

On June 22, 2015, the Company entered into the June 2015 Amendment with Cranshire to (i) delete the full ratchet anti-dilution provisions set forth in the Series A Warrants and Series C Warrants and (ii) extend the expiration date of the Series C Warrants from to 5:00 p.m., New York time, on July 2, 2015 to 5:00 p.m., New York time, on July 2, 2016. In consideration of Cranshire's entrance into the Amendment (and for no additional consideration), the Company agreed to issue to the holders of the 2014 Warrants up to 570,000 Inducement Shares, subject to the delivery by each such holder of an investor certificate to the Company.

As of June 30, 2015, 4,000,000 Series B Warrants had been exercised for an aggregate of 4,000,000 shares of our common stock, resulting in gross proceeds to the Company of $800,000. In addition, 2,255,000 Series C Warrants had been exercised for an aggregate of 2,255,000 shares of our Common Stock, resulting in gross proceeds to the Company of $451,000.

Cash Used in Operating Activities

Working Capital

At June 30, 2015, we had total current assets of $3,317,855 (including cash and cash equivalents of $3,273,764) and working capital of $1,425,966. Our working capital as of June 30, 2015 and September 30, 2014 is summarized as follows:

	June 30, 2015	September 30, 2014
Total Current Assets	$3,317,855	$ 876,990
Total Current Liabilities	1,891,889	2,723,667
Working Capital	$1,425,966	$ (1,846,677)

Total current assets as of June 30, 2015 were $3,317,855, an increase of $2,440,865 compared to $876,990 as of September 30, 2014. The increase in current assets is primarily attributable to an $800,000 in gross proceeds received from the exercise of our Series B Warrants, $750,000 proceeds received from our Notes, $451,000 proceeds received from the exercise of our Series C Warrants and $3,066,000 proceeds received from the 2015 Private Placement Financing. This was partially offset by an increase in general and administrative expense 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 June 30, 2015 and September 30, 2014 were comprised primarily of cash and cash equivalents, prepaid expenses and other current assets.

Total current liabilities as of June 30, 2015 were $1,891,889, a decrease of $831,778 compared to $2,723,667 as of September 30, 2014. The decrease is primarily due to the decrease in the current derivative liabilities partially offset by the timing of payments in accounts payable. Our total current liabilities as of June 30, 2015 and September 30, 2014 were comprised primarily of the current portion of the derivative liability, the Notes, accounts payable and accrued expenses.

Cash Flow

	June 30, 2015	June 30, 2014
Cash Used in Operating Activities	$(2,626,756)	$(2,379,498)
Cash Used in Investing Activities	-	-
Cash Provided by Financing Activities	5,067,000	3,624,703
Net increase in cash and cash equivalents	$2,440,244	$1,245,205

Cash Used in Operating Activities

Cash used in operating activities increased $247,258 during the nine months ended June 30, 2015 to $2,626,756, compared to $2,379,498 during the nine months ended June 30, 2014. The increase was primarily due to an increase in general and administrative expense primarily attributable to increased intellectual property costs and research and development expenses incurred in connection with activities to develop our primary product candidate.

Cash Used in Investing Activities

There was no cash used in investing activities during the nine months ended June 30, 2015 and 2014, respectively.

Cash Provided by Financing Activities

Cash provided by financing activities increased $1,442,297 to $5,067,000 during the nine months ended June 30, 2015, compared to $3,624,703 during the nine months ended June 30, 2014. For the nine months ended June 30, 2015, the cash provided by financing resulted from the $800,000 in proceeds received by us from the exercise of Series B Warrants to purchase 4,000,000 shares of our Common Stock, proceeds received of $451,000 from the exercise of the Series C Warrants to purchase 2,255,000 shares of our Common Stock, proceeds received of $750,000 from the issuance of the 8% Convertible Note and proceeds received of $3,066,000 from 2015 Private Placement Financing to purchase 13,936,363 shares of our Common Stock and Series D Warrants exercisable for an equivalent number of shares. For the nine months ended June 30, 2014, cash provided by financing activities resulted from the $1,000,000 funding obtained under the MLSC Loan Agreement and $2,624,703 from the issuance of Common Stock and 2014 Warrants.

Cash Requirements

We anticipate that our operating and other expenses will increase significantly as we continue to implement our business plan and pursue our operational goals. We estimate that our cash requirements for our fiscal year ending September 30, 2015 will be approximately $4,000,000. We estimate that we currently have sufficient cash to operate our business through April 2016. We will require additional financing to fund our planned future operations, including the continuation of our ongoing research and development efforts, seeking to license or acquire new assets, and researching and developing any potential patents, the related compounds and any further intellectual property that we may acquire. In addition, our estimates of the amount of cash necessary to operate our business may prove to be wrong and we could spend our available financial resources much faster than we currently expect. Further, our estimates regarding our use of cash could change if we encounter unanticipated difficulties or other issues arise, in which case our current funds may not be sufficient to operate our business for the period we expect.

We do not presently have, nor do we expect in the near future to have, revenue to fund our business from our operations, and will need to obtain all of our necessary funding from external sources for the foreseeable future. We do not have any commitments for future capital. Significant additional financing will be required to fund our planned operations in the near term and in future periods, including research and development activities relating to our principal product candidate, seeking regulatory approval of that or any other product candidate we may choose to develop, commercializing any product candidate for which we are able to obtain regulatory approval or certification, seeking to license or acquire new assets or businesses, and maintaining our intellectual property rights and pursuing rights to new technologies. We may not be able to obtain additional financing on commercially reasonable or acceptable terms when needed, or at all. We are bound by certain terms and obligations that may limit or otherwise impact our ability to raise additional funding in the near-term, including restrictive covenants in the MLSC Loan Agreement that limit our ability to incur certain types of additional indebtedness. These restrictions and provisions could make it more challenging for us to raise capital through the incurrence of debt or through equity issuances. If we cannot raise the money that we need in order to continue to develop our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations. If any of these were to occur, there is a substantial risk that

our business would fail and our stockholders could lose all of their investments.

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

Going Concern

From inception through June 30, 2015 we have not earned operating revenues from sales of products or services, and have recurring losses from operations. The continuation of our business as a going concern is dependent upon raising additional capital and eventually attaining and maintaining profitable operations. As of June 30, 2015, there is substantial doubt about the Company's ability to continue as a going concern. The unaudited interim consolidated financial statements included in this Quarterly Report on Form 10-Q do not include any adjustments that might be necessary should operations discontinue.

Critical Accounting Policies and Significant Judgments and Estimates

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

Basis of Presentation

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

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

Income Taxes

In accordance with FASB ASC 740, Income Taxes, we recognize deferred tax assets and liabilities for the expected future tax consequences or events that have been included in our financial statements and/or tax returns. Deferred tax assets and liabilities are based upon the differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities and for loss and credit carryforwards using enacted tax rates expected to be in

effect in the years in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

We provide reserves for potential payments of tax to various tax authorities related to uncertain tax positions when management determines that it is probable that a loss will be incurred related to these matters and the amount of the loss is reasonably determinable. We have no reserves related to uncertain tax positions as of June 30, 2015 and September 30, 2014.

Accounting for Stock-Based Compensation

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

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

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

Derivative Liabilities

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

Recent Accounting Guidance

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

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

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

ASU 2014-15, “Presentation of Financial Statements-Going Concern (Subtopic 205-40) – Disclosure of Uncertainties about an Entity’s Ability to ‘Continue as a Going Concern” was issued by the FASB in August 2014. The primary purpose of the ASU is to provide guidance in GAAP about management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and to provide related footnote disclosures. The amendments should reduce diversity in the timing and content of footnote disclosure. ASU 2014-15 is effective for the annual period ending after December 15, 2016, and for the annual periods and interim periods thereafter. Early adoption is permitted. While we are a development stage company and do not currently generate revenue, we currently anticipate generating revenue by the effective date of this ASU and therefore will be subject to this guidance. The Company is currently assessing the impact of this guidance, but does not believe that it will have a material impact on its consolidated results of operations, financial position or disclosures.

ASU 2014-12, “Compensation-Stock Compensation (Topic 718) – Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period” was issued by the FASB in June 2014. ASU 2014-12 requires that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. ASU 2014-12 is effective for public business entities for annual periods and interim periods within the annual periods beginning after December 15, 2015. Early adoption is permitted. The Company is currently assessing the impact of this guidance, but does not believe that it will have a material impact on its consolidated results of operations, financial position or disclosures.

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

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

Off-Balance Sheet Arrangements

We have no significant off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, 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 June 30, 2015, pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were not effective as of June 30, 2015 in ensuring that information required to be disclosed by us in reports that we file or furnish under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. This conclusion is based on findings that constituted material weaknesses in our internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Internal control over financial reporting is a process designed by, or under the supervision of, the Principal Executive Officer and Principal Financial Officer and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Under the supervision and with the participation of our Principal Executive Officer and Principal Financial Officer, management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control — Integrated Framework* issued in 2013 by the Committee of Sponsoring Organizations (COSO). Based on such evaluation, management concluded that the Company's internal control over financial reporting was ineffective as of September 30, 2014. Such conclusion is based on findings that constituted material weaknesses. A material weakness is a deficiency, or a combination of control deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's interim financial statements will not be prevented or detected on a timely basis.

As of June 30, 2015 management has identified the following material weaknesses in our internal control over financial reporting:

- We have not achieved the optimal level of segregation of duties relative to key financial reporting functions;
- We do not have an independent audit committee, which is an important entity-level control over our financial statements and the engagement of our independent auditors;
- We did not perform an entity-level risk assessment to evaluate the implication of relevant risks, including the impact of potential fraud-related risks and the risks related to non-routine transactions, if any, as a result of the material weaknesses in our internal control over financial reporting. Lack of an entity-level risk assessment constituted an internal control design deficiency;
- We have not completed an annual fiscal budget for the upcoming fiscal year due to our short term cash position. An annual budget would assist in evaluating and allocating spending for the upcoming year and provide guidance in determining milestone achievement and additional cash needs.

Remediation Efforts

We have added certain members to our management team and staff who we believe have sufficient experience to review and design adequate internal control over financial reporting and the experience and formal training to properly analyze and record complex transactions in accordance with U.S. GAAP. As such, we concluded that we have remediated the associated material weakness previously reported, and have removed it from our previous disclosure.

We expect to implement additional changes to our disclosure controls and procedures and internal control over financial reporting as resources permit, including identifying specific changes to be made within our governance, accounting and financial reporting processes to address our material weaknesses and adding personnel to our finance and accounting staff to achieve adequate segregation of duties to key financial reporting functions. In lieu of an audit committee comprised of independent directors, we currently rely on our full Board of Directors as an important entity-level control over our financial statements and the engagement of our independent auditors. We are currently seeking an external financial expert to serve on our Board of Directors, as well as other persons to serve as independent directors.

Our management team will continue to monitor and evaluate the effectiveness of our disclosure controls and procedures and our internal control over financial reporting on an ongoing basis and is committed to taking further action and implementing additional enhancements or improvements as resources permit.

Changes in Internal Control Over Financial Reporting

Other than the ongoing remediation efforts identified above, there were no changes in our internal controls over financial reporting that occurred during the quarter ended June 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

RISK FACTORS

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

Risks Related to our Business

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

We are a development stage company with no commercial products. Our primary product candidate is in the process of being developed, and will require significant additional clinical development and investment before it could potentially be commercialized. As a result, we have not generated any revenue from operations since inception, and we have incurred substantial net losses to date. Moreover, our cash position is vastly inadequate to support our business plans and substantial additional funding will be needed in order to pursue those plans, which include research and development of our primary product candidate, seeking regulatory approval for that product candidate, and pursuing its commercialization in the U.S., Europe and other markets. Those circumstances raise substantial doubt about our ability to continue as a going concern. In particular and as discussed in greater detail below under the risk factor entitled "We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts and could cause our business to fail," we believe that our current cash and cash equivalents on hand will only be sufficient to meet our anticipated cash requirements through April 2016.

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

As noted above under the risk factor entitled "There is substantial doubt about our ability to continue as a going concern," we are a development stage company with no commercial products. Consequently, we have incurred losses in each year since our inception and we expect that losses will continue to be incurred in the foreseeable future in the operation of our business. To date, we have financed our operations entirely through equity and debt investments by founders, other investors and third parties, and we expect to continue to rely on these sources of funding, to the extent available in the foreseeable future. Losses from operations have resulted principally from costs incurred in research and development programs and from general and administrative expenses, including significant costs associated with establishing and maintaining intellectual property rights, significant legal and accounting costs incurred in connection with both the closing of the Merger and complying with public company reporting and control obligations, and personnel expenses. We have devoted substantially all of our time, money and efforts to date to the advancement of our technology and raising capital to support our business, and expect to continue to devote significant time, money and efforts to such activities going forward.

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

- develop our principal product candidate, AC5, including further development of the product's composition and conducting preclinical biocompatibility studies;
- raise capital needed to fund our operations;
- build and enhance investor relations and corporate communications capabilities;
- conduct clinical trials relating to AC5 and any other product candidate we seek to develop;
- attempt to gain regulatory approvals for any product candidate that successfully completes clinical trials;
- establish relationships with contract manufacturing partners, and invest in product and process development through such partners;
- maintain, expand and protect our intellectual property portfolio;
- advance additional candidates through our research and development pipeline;
- seek to commercialize selected product candidates for which we may obtain regulatory approval; and
- hire additional regulatory, clinical, quality control, scientific, financial, and management, consultants and advisors.

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

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

Based on our current operating expenses and working capital requirements, we believe that our current cash and cash equivalents on hand will only be sufficient to meet our anticipated cash requirements through April 2016. In addition to the funds raised from our previous equity and convertible debt financings and borrowings under the Life Sciences Accelerator Funding Agreement (the "MLSC Loan Agreement") that we entered into with the Massachusetts Life Sciences Center ("MLSC"), we will need to obtain additional financing on or prior to April 2016 to continue operations and fund our planned future operations, including the continuation of our ongoing research and development efforts, the licensing or acquisition of new assets, and researching and developing any potential patents, the related compounds and any further intellectual property that we may acquire. In addition, our plans may change and/or we may use our capital resources more rapidly than we currently anticipate. We presently expect that our expenses will

increase in connection with our ongoing activities, particularly as we commence preclinical and clinical development for our lead product candidate, AC5. In particular, we currently estimate that we will require up to $10,000,000 to $14,000,000 and potentially more in additional capital to obtain regulatory approval of AC5 in the U.S. and Europe. Our future capital requirements will depend on many factors, including:

- the scope, progress and results of our research and preclinical development activities;
- the scope, progress and results of our research and development collaborations;

- the extent of potential direct or indirect grant funding for our research and development activities;
- the scope, progress, results, costs, timing and outcomes of any regulatory process and clinical trials conducted for any of our product candidates;
- the timing of entering into, and the terms of, any collaboration agreements with third parties relating to any of our product candidates;
- the timing of and the costs involved in obtaining regulatory approvals for our product candidates;
- the costs of operating, expanding and enhancing our operations to support our clinical activities and, if our product candidates are approved, commercialization activities;
- the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities;
- the costs associated with maintaining and expanding our product pipeline;
- the costs associated with expanding our geographic focus;
- operating revenues, if any, received from sales of our product candidates, if any are approved by the U.S. Food and Drug Administration ("FDA") or other applicable regulatory agencies;
- the cost associated with being a public company, including obligations to regulatory agencies, and increased investor relations and corporate communications expenses; and
- the costs of additional general and administrative personnel, including accounting and finance, legal and human resources employees.

We intend to obtain additional financing for our business through public or private securities offerings, the incurrence of additional indebtedness, or some combination of those sources. We have sought funding through collaborative arrangements, such as the Project Agreement that we entered into with the National University of Ireland Galway ("NUIG") on May 28, 2015, and we may continue to seek funding through additional collaborative arrangements with strategic partners if we determine them to be necessary or appropriate, although these arrangements could require us to relinquish rights to our technology or product candidates and could result in our receipt of only a portion of any revenues associated with the partnered product. We cannot provide any assurance that additional financing from these sources will be available on favorable terms, if at all. In addition, we are bound by certain contractual terms and obligations that may limit or otherwise impact our ability to raise additional funding in the near-term, including restrictions in the MLSC Loan Agreement on our ability to incur certain types of additional indebtedness. These restrictions and provisions could make it more challenging for us to raise capital through the incurrence of additional debt or through future equity issuances. Further, if we do raise capital through the sale of equity, or securities convertible into equity, the ownership of our then existing stockholders would be diluted, which dilution could be significant depending on the price at which we may be able to sell our securities. Also, if we raise additional capital through the incurrence of indebtedness, we may become subject to additional covenants restricting our business activities, and the holders of debt instruments may have rights and privileges senior to those of our equity investors. Finally, servicing the interest and principal repayment obligations under our debt facilities and the Convertible Notes that we issued in the Notes Offering could divert funds that would otherwise be available to support research and development, clinical or commercialization activities.

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

Our current and any future debt facilities or instruments may require us to use our limited capital to repay amounts owed and may impose limitations on our operations, which could negatively affect our business plans.

On the Closing of the Notes Offering on March 13, 2015, we issued to each Convertible Notes Investor a Convertible Note in the principal amount of $250,000. Unless converted on or prior to March 13, 2016 into shares of our Common Stock, we will be obligated to repay the $750,000 in principal borrowed under and up to an aggregate of $60,000 in interest incurred in connection with the Convertible Notes on that date, which we may not have or be able to obtain.

On September 30, 2013, we entered into the MLSC Loan Agreement with MLSC pursuant to which MLSC has provided us an unsecured subordinated loan in principal amount of $1,000,000 (such loan, the "MLSC Loan"). The MLSC Loan bears interest at a rate of 10% per annum, and will become fully due and payable on the earlier of (i) September 30, 2018, (ii) the occurrence of an event of default under the MLSC Loan Agreement, or (iii) the completion of a sale of substantially all of our assets, a change-of-control transaction or one or more financing transactions in which we receive from third parties other than our then existing shareholders net proceeds of $5,000,000 or more in a 12-month period. We will need substantial amounts of cash in order to repay the principal and interest owed under MLSC Loan, as it becomes due, which we may not have or be able to obtain. Any failure to make payments as required under the MLSC Loan Agreement would constitute an event of default, and could result in, among other things, MLSC's acceleration of all amounts due thereunder.

Further, the MLSC Loan Agreement restricts our use of the proceeds of the MLSC Loan to funding working capital requirements and/or the purchase of capital assets in the life sciences field, and we are expressly prohibited from using any such proceeds for any severance payment, investment in certain securities or payment for goods or services to a related party of the Company. Additionally, the MLSC Loan Agreement provides that, for so long as any of the MLSC Loan remains outstanding, our headquarters and at least a majority of our employees must be located in Massachusetts and we must not take certain actions without obtaining MLSC's prior consent, including without limitation paying dividends on our capital stock, redeeming any of our outstanding securities, and completing a sale of substantially all of our assets or a change-of-control transaction. Further, our failure to remain a "certified life sciences company" under the Massachusetts General Law would constitute an event of default under the MLSC Loan Agreement. Our ability to pursue our business plans during the term of the MLSC Loan may be severely limited as a result of those restrictions, which could cause our operations and financial condition to suffer.

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

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

We are a development stage company subject to the risks, uncertainties and difficulties frequently encountered by early-stage companies in evolving markets. Our operations to date have been primarily limited to organizing and staffing, developing and securing our technology and undertaking or funding preclinical studies of our lead product candidate. We have not demonstrated our ability to successfully complete large-scale, pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization.

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

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

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

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

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

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

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). As disclosed in Item 9A of Part II of our Annual Report filed December 12, 2014 and in Item 4 of Part I of our Quarterly Reports on Form 10-Q that we filed on February 9, 2015, May 7, 2015 and August 7, 2015, management has identified material weaknesses in our disclosure controls and procedures and our internal control over financial reporting as of September 30, 2014. A material weakness in internal control over financial reporting is defined as a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our consolidated financial statements will not be prevented or detected on a timely basis. As a result of these material weaknesses, our management concluded in our latest annual assessment that our internal control over financial reporting was not effective as of September 30, 2014, based on criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework.

During the quarter ended September 30, 2014, we took steps to remediate certain material weaknesses we have identified in our internal control over financial reporting. On July 7, 2014, we hired a new Chief Financial Officer who serves on a full-time basis. He has, working with the CEO and the Board of Directors, implemented increased segregation of responsibilities, improved policies and procedures relating to purchases of materials and supplies, and developed increased checks and balances as they relate to financial reporting and control policies and procedures. If our remedial measures are insufficient to address the material weaknesses we have identified, or if additional material weaknesses or significant deficiencies in our internal control are discovered or occur in the future, there may be an increased likelihood that our consolidated financial statements contain material misstatements. A restatement of our financial results could result in substantial costs to us for accounting and legal fees and could lead to litigation against us. In addition, even if we are successful in strengthening our controls and procedures, those controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our consolidated financial statements. If we fail to achieve and maintain the adequacy of our internal controls in accordance with applicable standards, we would be unable to conclude that we have effective internal controls over financial reporting. If we cannot produce reliable financial reports, our business and financial condition could be harmed, investors could lose confidence in our reported financial information, and the market price of our stock could decline significantly. Moreover, our reputation with lenders, investors, securities analysts and others may be adversely affected.

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

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

Risks Related to the Development and Commercialization of our Product Candidates

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

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

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

Because of the complexity of our lead product candidate, the CMC process, including product scale-up activities, may be difficult to complete successfully within the parameters required by the FDA or its foreign counterparts. Peptide formulation optimization is particularly challenging, and any delays could negatively impact our anticipated clinical trial and subsequent commercialization timeline. Furthermore, we have, and the third parties with whom we may establish relationships may also have, limited experience with attempting to commercialize a self-assembling peptide as a medical device, which increases the risks associated with completing the CMC process successfully, on time, or within the projected budget. Failure to complete the CMC process successfully would impact our ability to start a clinical trial and could severely limit the long-term viability of our business.

Our principal product candidate is inherently risky because it is based on novel technologies.

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

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

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

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

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

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

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

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

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

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

Clinical trials are lengthy, complex and extremely expensive processes with uncertain expenditures and results and frequent failures. While we believe that the first clinical trial for AC5 will be initiated during the fourth quarter of calendar year 2015 clinical trials that are planned or which commence for any of our product candidates could be delayed, limited or fail for a number of reasons, including if:

- the FDA or other regulatory authorities, or other relevant decision making bodies do not grant permission to proceed or place a trial on clinical hold due to safety concerns or other reasons;
- sufficient suitable subjects do not enroll or remain in our trials;
- we fail to produce necessary amounts of product candidate;
- subjects experience an unacceptable rate of efficacy of the product candidate;
- subjects experience an unacceptable rate or severity of adverse side effects, demonstrating a lack of safety of the product candidate;
- any portion of the trial or related studies produces negative or inconclusive results or other adverse events;
- reports from preclinical or clinical testing on similar technologies and products raise safety and/or efficacy concerns;
- third-party clinical investigators lose their licenses or permits necessary to perform our clinical trials, do not perform their clinical trials on the anticipated schedule or consistent with the clinical trial protocol, GCP or regulatory requirements, or other third parties do not perform data collection and analysis in a timely or accurate manner;

- inspections of clinical trial sites by the FDA or an institutional review board ("IRB") or other applicable regulatory authorities find violations that require us to undertake corrective action, suspend or terminate one or more testing sites, or prohibit us from using some or all of the resulting data in support of our marketing applications with the FDA or other applicable agencies;
- manufacturing facilities of our third party manufacturers are ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of current good manufacturing practices ("cGMP") or other applicable requirements;
- third-party contractors become debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements;
- the FDA or other regulatory authorities impose requirements on the design, structure or other features of the clinical trials for our product candidates that we and/or our third party contractors are unable to satisfy;
- one or more IRBs refuses to approve, suspends or terminates a trial at an investigational site, precludes enrollment of additional subjects, or withdraws its approval of the trial;
- the FDA or other regulatory authorities seek the advice of an advisory committee of physician and patient representatives that may view the risks of our product candidates as outweighing the benefits;
- the FDA or other regulatory authorities require us to expand the size and scope of the clinical trials, which we may not be able to do; or
- the FDA or other regulatory authorities impose prohibitive post-marketing restrictions on any of our product candidates that attain regulatory approval.

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

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

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

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

We believe that the pathway to marketing approval in the U.S. for our lead product candidate will likely require the process of FDA Premarket Approval ("PMA") for the product, which is based on novel technologies and likely will be

classified as a Class III medical device. This approval pathway can be lengthy and expensive, and is estimated to take from one to three years or longer from the time the PMA application is submitted to the FDA until approval is obtained, if approval can be obtained at all.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We will rely on the manufacturers of our product candidates to purchase from third party suppliers the materials necessary to produce the compounds for preclinical and clinical studies, and may continue to rely on those suppliers for commercial distribution if we obtain marketing approval or other required certifications for any of our product candidates. The materials to produce our products may not be available when needed or on commercially reasonable terms, and the prices for such materials may be susceptible to fluctuations. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently do not have any agreements relating to the commercial production of any of these materials. If these materials cannot be obtained for our preclinical and clinical studies, product testing and potential regulatory approval of our product candidates would be delayed, which would significantly impact our ability to develop our product candidates and materially adversely affect our ability to meet our objectives and obtain operations success.

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to our Intellectual Property

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

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

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

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

As of December 31, 2014, we jointly owned a small number of U.S. patents, U.S. patent applications and international (PCT) patent applications with certain of our collaborators. The rights of our collaborators to these patents, patent applications and other compounds under the collaborations may in the future restrict our ability to further develop or generate revenues from those compounds except through the collaborations.

Our patent portfolio, which covers self-assembling peptides and methods of use thereof, include 14 applications, one of which has been allowed and 13 of which are pending in a total of five jurisdictions. We have also entered into a license agreement with MIT pursuant to which we have been granted exclusive rights under one portfolio of patents and non-exclusive rights under another portfolio of patents. The portfolio exclusively licensed from MIT includes seven patents that have been either allowed, issued or granted and 15 applications that are pending in a total of 10 jurisdictions. The portfolio non-exclusively licensed from MIT includes 7 issued patents in three jurisdictions that expire between 2016 and 2027 (absent patent term extension), and three pending patent applications in four jurisdictions. Because a portion of our patent portfolio has been 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 prospects.

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

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

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

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

Risks Related to Ownership of our Common Stock

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

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

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

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

Our Common Stock is a "penny stock."

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

If we issue additional shares in the future, including issuances of shares upon exercise of the Series D Warrants, the 2014 Warrants or conversion of our Convertible Notes, our existing stockholders will be diluted.

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

Similarly, between March 11, 2015 and through March 13, 2015, we entered into substantially similar Convertible Notes Subscription Agreements with each of the Convertible Notes Investors pursuant to which we issued Convertible Notes to the Convertible Notes Investors in the aggregate principal amount of $750,000. The Convertible Notes, which become due and payable on March 13, 2016, bear interest on the unpaid principal balance at a rate equal to eight percent (8.0%) (computed on the basis of the actual number of days elapsed in a 360-day year) per annum until either (a) converted into shares of our Common Stock; or (b) the outstanding principal and accrued interest on the Convertible Notes is paid in full by us. Interest on the Convertible Notes becomes due and payable upon their conversion or March 13, 2016 and may become due and payable upon the occurrence of an event of default under the Convertible Notes, as defined in the Convertible Notes. At any time prior to March 13, 2016, the holders of the Convertible Notes have the right to convert some or all of such Convertible Notes into the number of shares of our Common Stock determined by dividing (A) the aggregate sum of the (i) principal amount of the Convertible Note to be converted; and (ii) amount of any accrued but unpaid interest with respect to such portion of the Convertible Note to be converted; and (B) the conversion price then in effect, which was $0.20 per share on the date the Notes Offering closed. Assuming that the Convertible Notes are held to maturity and the accrued interest thereunder is converted, along with the outstanding principal, into shares of our Common Stock, a total of 4,050,000 shares may be issued upon the conversion of the Convertible Notes.

Upon the closing of the 2014 Private Placement Financing on February 4, 2014, we issued an aggregate of 11,400,000 shares of our Common Stock, which equaled approximately 16% of our currently issued and outstanding Common Stock on the date the 2014 Private Placement Financing closed. Upon the closing of the 2014 Private Placement Financing, we also issued three series of Warrants to acquire up to an additional 34,200,000 shares of our Common Stock at initial exercise prices ranging from $0.30 per share (the Series A Warrants), $0.35 per share (the Series B Warrants), and $0.40 per share (the Series C Warrants). On December 1, 2014, the Company entered into that certain Amendment to Series A Warrants, Series B Warrants and Series C Warrants to Purchase Common Stock, dated as of December 1, 2014, with Cranshire Capital Master Fund, Ltd., pursuant to which, among other things, the exercise prices of the Series B Warrants and Series C Warrants were lowered to $0.20 per share. Following the December 1, 2014 amendment, 4,000,000 shares underlying the Series B Warrants were exercised, and the remaining 7,400,000 expired unexercised on January 3, 2015 when the term of the Series B Warrants expired. As a result of the conversion price of our Convertible Notes, the closing of the Notes Offering and the subsequent issuance of the Convertible Notes triggered the anti-dilution provisions of the Series A Warrants, which in turn reduced the exercise price of the Series A Warrants to $0.20 per share and increased the aggregate number of shares issuable under the Series A Warrants by 5,700,000 shares (or fifty-percent (50%)) from 11,400,000 shares to 17,100,000 shares. As of August 5, 2015, up to 3,950,000 shares may be acquired upon the exercise of the Series C Warrants and up to 14,950,000 shares may be acquired upon the exercise of the Series A Warrants.

Additionally, pursuant to the 2013 Plan, as of August 5, 2015, we were authorized to grant equity awards to our employees, directors and consultants for up to an aggregate of 12,583,006 shares (net of 231,250 options already exercised and 300,000 shares of restricted stock awarded) of our Common Stock (and such authorized amount may increase by up to 3 million shares on the first business day of each following fiscal year as set forth in the 2013 Plan), and in addition to the Series D Warrants granted in connection with the 2015 Private Placement Financing, the 2014 Warrants granted in connection with the 2014 Private Placement Financing and the Convertible Notes issued in the Notes Offering, there are currently outstanding warrants to acquire up to 145,985 shares of our Common Stock. Any future grants of options, warrants or other securities exercisable or convertible into our Common Stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our Common Stock.

In addition to capital raising activities, other possible business and financial uses for our authorized Common Stock include, without limitation, future stock splits, acquiring other companies, businesses or products in exchange for shares of Common Stock, issuing shares of our Common Stock to partners in connection with strategic alliances, attracting and retaining employees by the issuance of additional securities under our various equity compensation plans, compensating consultants by issuing shares or options to purchase shares of our Common Stock, or other transactions and corporate purposes that our Board of Directors deems are in the Company's best interest. Additionally, shares of Common Stock could be used for anti-takeover purposes or to delay or prevent changes in control or management of the Company. We cannot provide assurances that any issuances of Common Stock will be consummated on favorable terms or at all, that they will enhance stockholder value, or that they will not adversely affect our business or the trading price of our Common Stock. The issuance of any such shares will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our Common Stock. If we issue any such additional shares, such issuance will reduce the proportionate ownership and voting power of all current shareholders. Further, such issuance may result in a change of control of our corporation.

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

As noted above under the risk factor entitled, "We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts and could cause our business to fail," we will need to obtain additional financing prior to or during April 2016 to continue operations and fund our planned future operations. To raise capital, we may sell Common Stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. Any such sales of our Common Stock by us or resale of our Common Stock by our existing stockholders could cause the market price of our Common Stock to decline.

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

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

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

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

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

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

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

Certain of our directors and executive officers own a significant percentage of our outstanding capital stock. Dr. Terrence W. Norchi, our President, Chief Executive Officer and a director, and Dr. Avtar Dhillon, the Chairman of our Board of Directors, collectively hold or control approximately 20% of our outstanding shares of Common Stock. Accordingly, these members of our Board of Directors and management team have substantial voting power to approve matters requiring stockholder approval, including without limitation the election of directors, and have significant influence over our affairs. This concentration of ownership could have the effect of delaying or preventing a change in control of our Company, even if such a change in control would be beneficial to our stockholders.

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

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

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

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

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

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

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

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

We have never declared or paid any dividends on our shares and do not anticipate paying any such dividends in the foreseeable future. Any future payment of cash dividends would depend on our financial condition, contractual restrictions, solvency tests imposed by applicable corporate laws, results of operations, anticipated cash requirements and other factors and will be at the discretion of our Board of Directors. In addition, under the terms of the MLSC Loan Agreement, we must obtain MLSC's prior consent before declaring or paying any dividends during the term of the MLSC Loan Agreement. As a result, our stockholders should not expect that we will ever pay cash or other dividends on our outstanding capital stock.

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

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

Item 6. Exhibits

Exhibit	Description
10.1*†	Project Agreement by and between Arch Therapeutics, Inc. and the National University of Ireland Galway dated May 28, 2015
10.2	Amendment to Series C Warrants to Purchase Common Stock dated May 30, 2015 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Company with the SEC on June 1, 2015) (File Number 000-54986)
10.3*	Separation Agreement dated June 15, 2015 by and between Arch Therapeutics, Inc. and William M. Cotter
10.4	Amendment to Series A and Series C Warrants to Purchase Common Stock dated June 22, 2015 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Company with the SEC on June 23, 2015) (File Number 000-54986)
10.5	Form of Subscription Agreement (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Company with the SEC on July 6, 2015) (File Number 000-54986)
10.6	Form of Series D Warrants (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed by the Company with the SEC on July 6, 2015) (File Number 000-54986)

10.7	Registration Rights Agreement dated June 30, 2015, by and among Arch Therapeutics, Inc. and the Purchasers set forth on the signature pages thereto (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed by the Company with the SEC on July 6, 2015) (File Number 000-54986)
10.8#	First Amendment to Executive Employment Agreement, dated July 27, 2015, by and between Arch Therapeutics, Inc. and Richard E. Davis (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Company with the SEC on July 31, 2015) (File Number 000-54986)
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities and Exchange Act of 1934
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities and Exchange Act of 1934
32.1*	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, executed by Terrence W. Norchi, President and Chief Executive Officer, and Richard E. Davis, Chief Financial Officer
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

† Confidential treatment has been requested for certain portions of the Exhibit pursuant to Rule 24b-2 promulgated under the Securities Exchange Act of 1934. Such portions have been omitted and filed separately with the Securities and Exchange Commission.

Management contract or compensatory plan or arrangement.

SIGNATURE

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

ARCH THERAPEUTICS, INC.

Date: August 7, 2015 By: /s/ TERRENCE W. NORCHI, MD
Terrence W. Norchi, MD
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 7, 2015 By: /s/ RICHARD E. DAVIS
Richard E. Davis
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 10.1

CERTAIN MATERIAL (INDICATED BY AN ASTERISK) HAS BEEN OMITTED FROM THIS DOCUMENT PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

(1) NATIONAL UNIVERSITY OF IRELAND, GALWAY

(2) ARCH THERAPEUTICS, INC.

PROJECT AGREEMENT

SFI Centre for Research in Medical Devices

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THIS AGREEMENT made this the 28th day of May 2015 BETWEEN:

1. **NATIONAL UNIVERSITY OF IRELAND, GALWAY**, University Road, Galway, Ireland (hereinafter "**NUIG**"); and
2. **ARCH THERAPEUTICS, INC** a company incorporated in Nevada, USA (NV20091379642 and having its registered office at 235 Walnut Street, Suite 6, Framingham, MA 01702, USA (hereinafter "**Industry Party**")

WHEREAS:

1. SFI has agreed to provide the Grant Funding to NUIG to support the Centre.
2. NUIG has accepted the Grant Funding on behalf of the RPO's.
3. The Industry Party wishes to collaborate with NUIG to perform the Project.
4. NUIG and the Industry Party wish to enter into this Agreement to set out their respective rights and obligations in relation to the performance of the Project.

1. INTERPRETATION

1.1 Definitions: In this Agreement:

"**Background**" means any Intellectual Property or Material (regardless of the form or medium in which they are disclosed or stored): (i) owned by or licensed to a Party before the date of this Agreement; or (ii) generated by that Party's Personnel independently of the Project to which they are to be introduced, excluding any Foreground;

"**Background Register**" is set out in Schedule 1, Part 1 and has the meaning assigned to it in Clause 1.2.3 of Schedule 2;

"**Centre**" means the SFI Centre for Research in Medical Devices;

"**Centre Director**" means the academic and administrative lead for the Centre;

"**CEO**" means the Chief Executive Officer of the Centre;

"**Commercial Licence**" means an exclusive or non-exclusive royalty bearing license to commercialise the Foreground;

"**Commercial Licence Term Sheet**" means the proposed terms for a Commercial License that are attached to this Agreement as Schedule 4;

"**Confidential Information**" means, in relation to a Party's obligations under this Agreement, any information acquired by that Party at any time during the course of this Agreement arising out of its participation in the Project belonging or relating to another Party, its business or its affairs that is not publicly known (including, without limitation, any Background of that Party or any information which was provided to that Party under an obligation of confidence) and which (a) that other Party has marked as confidential or proprietary, or (b) has been deemed as confidential by that other Party to the recipient in writing, marked confidential; furthermore, all non-public information pertaining either to Non-Severable Foreground or to Industry Party's Background, business or other affairs, shall be deemed the Industry Party's Confidential Information and shall not be deemed NUIG's Confidential Information; but, for the avoidance of doubt: (i) information shall not be deemed to be publicly known, merely because it is known to a Third Party having experience in the relevant field; and (ii) any combination of elements of

information shall not be deemed to be publicly known, merely because individual elements of that combination are publicly known;

"**Contract Period**" means the period commencing on the Effective Date and continuing until the earlier of (a) the completion of the Project or (b) six (6) years from the Effective Date, unless otherwise amended as agreed by the parties in accordance with Clause 13.2; or (c) termination of this Agreement by a Party in accordance with Clause 13;

"**Defaulting Party**" has the meaning assigned to it in Clause 13.5;

"**Disclosing Party**" has the meaning assigned to it in Clause 8.9;

"**Effective Date**" means 28th May 2015;

"**Evaluation**" means the technical evaluation of Foreground for the purposes of determining the applicability of the Foreground to the Field to be carried out internally at the Industry Party, on the terms outlined in this Agreement;

"**Evaluation Licence**" means a royalty-free exclusive, non-transferable (except as permitted under Clause 17.2) licence, with no right to sublicence, of Foreground but only for the purpose of the Evaluation and only for the Evaluation Period in the format set out in the attached Schedule 3;

"**Evaluation Period**" means a period of **[***]**[1] from the Notification Date;

"**Field**" means **[***]**[1];

"**Financial Contribution**" means the cash or in-kind financial contribution which is to be provided by the Industry Party to NUIG to fund the Project which is approved by the POT, which is more particularly described in Schedule 1, Part 3;

"**Force Majeure**" has the meaning assigned it in Clause 10.8;

"**Foreground**" means all IP and Materials which are invented or discovered and subsequently reduced to practice by any Party in the course of the Project, whether on its own or in collaboration with the other Party, excluding the Non-Severable Foreground;

"**Grant Funding**" means the funds being made available by SFI to support the Centre;

"**Indemnified Loss**" has the meaning assigned to it in Clause 10.11;

"**Indemnified Party**" has the meaning assigned it in Clause 10.10;

"**Indemnifying Party**" has the meaning assigned it in Clause 10.10;

"**Industrial Program Manager**" means the person designated by NUIG to act as the Industrial Program Manager as set out in Schedule1, Part 1;

"**Intellectual Property**" or "**IP**" means patents, trademarks, service marks, registered designs, drawings, utility models, design rights, business ideas, concepts, inventions, discoveries, breeders' rights, copyright (including the copyright in software in any code), database rights, Know-how, trade secrets and other confidential information, technology, business or trade names, goodwill and all other rights of a similar or corresponding nature in any part of the world, whether registered or not or capable of registration or not, and including all applications and the right to apply for any of the foregoing rights;

"**Invention Disclosure Form**" or "**IDF**" means the form provided by NUIG for the purposes of recording of inventions;

[1] ***Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

"**IP Protocol**" means the National IP Protocol entitled "Putting Public Research to Work for Ireland" published in 2012 by the Irish Department of Jobs, Enterprise and Innovation and a copy of which is available at http://www.djei.ie/publications/science/2012/Intellectual_Property_Protocol_Putting_Public_Research_to_Work_for_Ireland.p

"**Know-how**" means unpatented technical information (including, without limitation, information relating to tools, technologies, discoveries, concepts, methodologies, models, research, development and testing procedures, the results of experiments, tests and trials, manufacturing processes, techniques and specifications, quality control data, analyses, reports and submissions) that is not in the public domain;

"**Liability**" or "**Loss**" or "**Losses**" unless the context otherwise requires, includes claims, demands, proceedings, suits, judgements, damages, losses, costs, expenses, fees, penalties or fines;

"**Loaned Equipment**" means any equipment provided by the Industry Party to NUIG on a temporary basis;

"**Materials**" means any and all works of authorship and materials, including, without limitation, data, any functional, technical and/or performance specification, devices, machinery, samples, products, sensors and data derived therefrom, biological materials, software programs, any other inanimate or animate matter, any and all reports, studies, data, diagrams, drawings, charts, specifications, and such other materials in whatever medium (including without limitation, written or printed, electronic or otherwise, computer discs, floppy discs, CDs, diskettes, tapes or other formats);

"**Negotiation Period**" has the meaning assigned to it in Clause 2.3.5 of Schedule 2;

"**NERF**" means non-exclusive royalty free;

"**Non-Performing Party**" has the meaning assigned to it in Clause 10.8;

"**Non-Severable Foreground**" shall mean improvements to, or developments of, the Industry Party's Background or the Field developed during the course of the Project;

"**Notice Period**" has the meaning assigned to it in Clause 9.1;

"**Notification Date**" means the date on which the TTO notifies the Industry Party that an IDF has been submitted;

"**Party**" means either NUIG or Industry Party and "**Parties**" shall mean NUIG and Industry Party collectively;

"**Personnel**" means in relation to any Party, that Party’s officers, employees, visiting scholars and students, as well as consultants, advisors, directors, subcontractors, and any other individuals engaged by that person on the basis of a contract for services;

"**PMT**" means the Project Management Team;

"**POT**" means the Project Oversight Team;

"**Principal Investigator**" means the person designated by NUIG to be the principal investigator for the Project as set out in Schedule 1, Part 1;

"**Project**" means the project to be performed pursuant to this Agreement by NUIG in collaboration with the Industry Party as more particularly described in Schedule 1, Part 1;

"**Project Equipment**" means each piece of equipment purchased from the Grant Funding;

"**Project Manager**" means the person designated by the Industry Party as its lead project manager for the Project and as set out in Schedule 1, Part 1;

"**Publication**" means disclosing into the public domain of any aspects of the Foreground, including but not limited to, by means of: (a) submission of any paper, abstract, article or similar document to a journal, newspaper, magazine or periodical, whether in written, electronic or any other form; (b) verbal or poster presentation at a conference, seminar, workshop or similar event;

"**Registered Background**" means any Background provided by a Party in accordance with the provisions of Clause 1.2 of Schedule 2 for use in connection with the Project and that is specified as such in the Background Register;

"**RPO's**" means the Research Performing Organisations that are participating in the Centre;

"**SFI**" means Science Foundation Ireland, a committee established by Forfás, a statutory body established under the laws of Ireland;

"**Specified Background**" means that part of a Party's Background that it is willing to license to the other Party pursuant to Schedule 2 and that is specified as such in the Background Register;

"**Statement of Work**" means the project plan and deliverables for the Project as set out in Schedule 1, Part 1 as extended or otherwise modified by agreement in writing between the Parties from time to time ;

"**Sub-Contracting Party**" has the meaning assigned to it in Clause 12.2;

"**Terminating Party**" has the meaning assigned to it in Clause 13.5;

"**Third Party**" means any party that is neither a Party nor a Party's Affiliates;

"**TTO**" shall mean NUIG's Technology Transfer Office; and

"**Unapproved Activity**" means (a) supplying goods or services of a pornographic nature, or which form part of the adult entertainment industry; (b) supplying a service which includes "a lottery" or "Gaming", as those terms are defined in the Gaming and Lotteries Act, 1956; or (c) supplying goods or services of a harmful nature.

1.2 Construction: In this Agreement, unless the contrary intention is stated, a reference to: (a) 'this Agreement' means the Clauses of, and the Schedules to, this Agreement, all of which shall be read as one document; (b) 'writing' includes a reference to any electronic mode of representing or reproducing words in visible form; (c) the division of this Agreement to Clauses and sub-Clauses, and the headings used in this Agreement, are for convenience only, and shall not affect the interpretation of this Agreement; and (d) 'business day' means a reference to a day (other than a Saturday or Sunday or public holiday in Ireland).

2. THE PROJECT

2.1 Prior to commencing the Project, the Parties shall mutually agree to a Statement of Work in respect thereof. Each Party shall carry out the Project in accordance with the Statement of Work and shall provide the human resources, materials, facilities and equipment that are designated as its responsibility in the Statement of Work.

2.2 The Project shall be carried out under the direction and supervision of the Principal Investigator. The Industry Party shall nominate a suitably qualified person to act as the Project Manager for the Project.

2.3 Each Party shall carry out its obligations in respect of the Project: (a) in accordance with all applicable laws; (b) in good faith and in a manner that reflects the good name, goodwill and reputation of such Party; (c) with due regard to the health and safety of those involved in the carrying out of that work; and (d) to notify the other Party promptly of any delay in the performance of its obligations or of any event that may impact on the Project.

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2.4 Each Party shall ensure that each member of its Personnel who is involved in the Project: (a) observes the conditions attaching to any regulatory and ethical licences, consents and approvals; and (b) keeps complete and accurate records of all research, development and other work carried out in connection with the Project and of all Foreground.

2.5 Each Party shall adhere to all applicable export laws and regulations administered by Ireland and the EU and shall not export, re-export, resell, transfer, or disclose, directly or indirectly, any technical data or products received from the other to any proscribed person, entity, or country, or foreign national thereof, unless properly authorized by the appropriate authority. The Industry Party shall advise NUIG of any export control rules that may apply to the Project and the extent to which such rules restrict the use of any Registered Background or Materials to be provided by the Industry Party to NUIG in connection with the Project.

2.6 Although each Party shall use reasonable endeavours to carry out the Project in accordance with the Statement of Work, neither Party undertakes or warrants that any research will lead to any particular result. It is hereby acknowledged that there are inherent uncertainties involved in research and such uncertainties form part of the business risk involved in undertaking the Project. Accordingly, NUIG shall have no liability to the Industry Party as a result of any failure or delay of the Project to achieve one or more of desired results set out in the Statement of Work.

2.7 The Industry Party undertakes to NUIG to comply with all provisions of the Grant Funding and do all acts and things as may reasonably be required of it by NUIG in order to facilitate compliance by NUIG with the requirements of the Grant Funding insofar as they relate to the Parties participation in the Project. If there are any conflicts or inconsistencies between the provisions of this Agreement and the Grant Funding, the latter shall prevail to the extent of the inconsistency or conflict and this Agreement will be deemed to have been amended accordingly to the extent necessary to resolve the conflict or inconsistency concerned from the Effective Date.

2.8 This Agreement is subject to the Grant Funding, and shall take effect with such modifications as may be required by SFI or which the parties may otherwise mutually agree to from time to time as being necessary to ensure that the Project is conducted in all respects in accordance with the provisions of the Grant Funding.

2.9 **Cúram Centre Website**: The Industry Party shall provide NUIG with a brief description of the Industry Party ("**Industry Party Description**"). The Industry Party hereby consents to the following being placed on the Cúram Centre website: (a) its name, logo and Industry Party Description; and (b) a link to the Industry Party's website.

2.10 **Industry Party Website**: NUIG shall provide the Industry Party with a brief description of the Cúram Centre ("**Cúram Centre Description**"). NUIG hereby consents to the following being placed on the Industry Party website: (a) NUIG name, NUIG logo, Cúram Centre name, Cúram Centre logo, and Cúram Centre Description; and (b) a link to the Cúram Centre website.

3. PROJECT OVERSIGHT AND MANAGEMENT

3.1 The PMT shall have responsibility for the day-to-day co-ordination and operational issues of the Project in accordance with the Statement of Work.

3.2 The POT shall have responsibility for governance issues with respect to the Project.

3.3 The POT shall consist of: the Centre Director; the CEO; the Principal Investigator; and a representative from the Industry Party. The PMT shall consist of: the Industrial Program Manager; the Project Manager; and the Principal Investigator. For the avoidance of doubt, the Personnel funded by the Project can liaise directly with the Industrial Program Manager and the Program Manager with respect to day-to-day tasks.

3.4 In the event that there is a dispute between members of the PMT and same cannot be resolved, the matter shall be referred to the POT. All decisions of the POT will be made by unanimous decision. In the event that there is a dispute between members of the POT, the matter can be resolved by invoking the Dispute Resolution process as set out in Clause 15.

3.5 The POT will be responsible for: (a) approving any changes to the Project and for approving any sub-projects; (b) acting as an escalation point in relation to any dispute resolution issues; and (c) reviewing and signing off of deliverables. The POT shall meet every six (6) months at such other times that are reasonably necessary to ensure the continued progress of the Project, and at the request of the Industry Party. Meetings shall take place as agreed between the Parties.

4. FINANCIAL CONTRIBUTION

4.1 The Industry Party shall pay any cash portion of the Financial Contribution to NUIG in accordance with Schedule 1, Part 3. NUIG shall issue invoices to the Industry Party on the dates specified in Schedule 1, Part 3.

4.2 The Industry Party shall compile and maintain at all times detailed documentary evidence of the in-kind portion of the Financial Contribution and shall provide such documentation to NUIG on request. NUIG shall be entitled to include such documentary evidence in financial reports to SFI or as may be otherwise required pursuant to the requirements of the Grant Funding.

4.3 All amounts payable to NUIG by the Industry Party under this Agreement: (a) shall be paid in Euro; (b) shall be paid by electronic funds transfer to such bank account of NUIG as specified in Schedule 1, Part 3 or such other bank account as NUIG may specify in writing to the Industry Party from time to time, or in such other manner as NUIG may from time to time stipulate; (c) shall be paid without set-off or counterclaim, and free and clear of and without any deduction or withholding; and (d) are exclusive of value added tax (if applicable) and, accordingly, are to be construed as a reference to that amount plus any value added tax payable in respect of it, and any such value added tax shall be paid by the Industry Party to NUIG in addition to the amount in question upon presentation by NUIG to the Industry Party of a payment request for the amount in question, plus value added tax, showing as a separate figure the amount of value added tax due. Following receipt of the payments as detailed in Schedule 1, Part 3, NUIG shall issue a VAT invoice with respect to the payment plus the applicable amount of VAT.

4.4 If the Industry Party fails to pay to NUIG any amount payable to it under this Agreement on the applicable due date unless the Industry Party disputes the amount due in good faith, then the Industry Party shall pay on demand from time to time to NUIG, interest (as well after as before any judgment) on that amount, from the due date to the date of payment in full, at the rate per cent per annum as may be specified from time to time pursuant to the regulation 5 of the European Communities (Late Payment in Commercial Transactions) Regulations 2012 (S.I. No. 580 of 2012).

4.5 NUIG shall ensure that all of the Financial Contribution paid to it in connection with the Project is applied in accordance with the Statement of Work. NUIG shall keep complete and accurate accounts of its expenditure on the Project.

4.6 The Industry Party acknowledges and agrees that the use of any Grant Funding by NUIG in the performance of the Project does not imply any warranty or covenant on the part of NUIG as to compliance or otherwise of any such funding with any tax or "State Aid" rules, the responsibility for which shall rest solely with the Industry Party. The Industry Party will bear responsibility for its compliance with "State-Aid" guidelines as they apply to this Agreement and will provide an annual compliance statement to NUIG.

4.7 During the Contract Period, for every one (1) euro of cash actually contributed to the Project by the Industry Party, the Centre shall contribute a total of two (2) euros of Grant Funding toward the direct and indirect costs of the Project.

5. RESEARCH EQUIPMENT

5.1 NUIG shall own all Project Equipment purchased or constructed by it, or for it, using the Financial Contribution.

5.2 Any Loaned Equipment shall be marked as owned by the Industry Party and shall remain the property of the Industry Party. NUIG shall be responsible for insuring such Loaned Equipment against loss, theft or damage and replacing such Loaned Equipment in the event it is lost, stolen, destroyed or damaged.

6. RECORDS AND REPORTING

6.1 The Industry Party will cooperate with NUIG and do all such acts and things which may be reasonably required of it to facilitate the discharge by NUIG of its obligations under the Grant Funding.

6.2 Each of the Parties will adhere to any reporting and auditing requirements of SFI for the Project.

6.3 NUIG shall provide the Industry Party with reports summarising the progress of the Project in the manner and at the intervals as may be specified in the Statement of Work.

6.4 During the Term, the Principal Investigator will meet with representatives of the Industry Party at the premises of NUIG at the times specified in the Statement of Work, or at such times and places as otherwise mutually agreed upon, to discuss the progress and results, as well as on-going plans, or changes therein, of the Project.

7. INTELLECTUAL PROPERTY

7.1 The Parties agree that all Background being introduced to, and Foreground arising from, the Project shall be managed and commercialised in accordance with Schedule 2 and the IP Protocol.

8. CONFIDENTIALITY

8.1 Each Party shall (and shall procure that its Personnel shall) at all times keep confidential the Confidential Information and shall use Confidential Information solely as is necessary for the performance of its obligations or the exercise of its rights in connection with the Project. For the avoidance of doubt, all Foreground shall be deemed Confidential Information. Furthermore, all non-public information pertaining either to Non-Severable Foreground or to Industry Party's Background, business or other affairs, shall be deemed the Industry Party's Confidential Information and shall not be deemed NUIG's Confidential Information.

8.2 Each Party may only disclose Confidential Information to those of its Personnel to whom, and to the extent to which, such disclosure is necessary for the exercise of its rights, and performance of its obligations, under this Agreement.

8.3 The restrictions in Clauses 8.1 and 8.2 do not apply to any information which: (a) becomes public knowledge after its disclosure through no fault of any receiving Party; or (b) was already known to the receiving Party free from any obligation of confidentiality prior to its disclosure hereunder as evidenced by its written records; or (c) the receiving Party can demonstrate was independently developed by the receiving Party without reference to the Confidential Information in question; or (d) is required by law or order of any court or governmental or regulatory authority to be disclosed.

8.4 Nothing in this Clause 8 prohibits: (a) NUIG from providing any information relevant to the Project to SFI provided that such information is marked "**Confidential Information**" if appropriate; and/or (b) the disclosure solely for scholarly purposes of the results of any research carried on pursuant to this Agreement, subject to and respecting the terms as set forth in Clause 9; or (c) the Industry Party from (i) disclosing the existence of the Project; (ii) information pertaining to Industry Party Background or Non-Severable Foreground; or (iii) plans for the Project, including but not limited to the timelines.

8.5 Save as provided for in Clauses 8.4 and 8.9, or agreed in writing with the POT from time to time: (a) no announcement in relation to the Project may be made by any Party or any of its Personnel; and (b) no reference to the Project may be made in any advertising or publicity material issued by a Party.

8.6 Each Party shall (and shall procure that its Personnel shall) do all such acts and things as may reasonably be requested of it by the other Party with a view to compliance with legislation concerning privacy and data protection.

8.7 Each Party shall give notice to the other Party of any unauthorised use, disclosure, theft or other loss of that other Party's Confidential Information as soon as is practicable after becoming aware of it.

8.8 Upon the expiry of the Contract Period or if earlier, upon termination of the Project and/or this Agreement, each Party shall, upon request of the other Party, either return or, at the option of the Party whose information is concerned, destroy, any Confidential Information which is in tangible form which it or its Personnel possess, together with all copies thereof. However, the receiving Party is entitled to retain one (1) copy of the Confidential Information in a secure location solely for archival purposes in order to comply with law or the terms of this Agreement.

8.9 Notwithstanding the above, and with the exception of disclosures that the Industry Party must make either to or on account of requirements of regulatory authorities including but not limited to, the Securities and Exchange Commission, the Food and Drug Administration, the European Medicines Agency or comparable bodies in other jurisdictions, if either Party is required to disclose the Confidential Information of the other Party (the "**Disclosing Party**") to satisfy an order or request of a competent court of law or governmental or regulatory body, or to comply with applicable law including, but not limited to, requests under the Freedom of Information Acts 2014 ("**FOIA**"), then the Party making such disclosure shall, unless prohibited from doing so, notify the Disclosing Party in writing of such order, request or applicable law and its terms, consult with the Disclosing Party on what steps should be taken to avoid or restrict the order or request or applicable law, afford the Disclosing Party the opportunity to defend or limit the order, request or applicable law and only disclose that part of the Confidential Information that it is legally required to disclose and try to procure confidentiality treatment with respect to any such required disclosure.

8.10 Except as otherwise stated in Clauses 2.9 and 2.10, neither Party shall use the other Party's name or logo in any press release or product advertising, or for any other promotional purpose, without first obtaining the other Party's written consent; save that NUIG may identify the sums received from the Industry Party in NUIG's funding applications, annual report and similar publications or as required in order for NUIG to comply with the terms of the Grant Funding.

8.11 The restrictions on the use of Confidential Information in this Clause 8 shall bind each of the Parties for the Contract Period and for a period of seven (7) years thereafter.

9. ACADEMIC PUBLICATION

9.1 In the event that NUIG, or any of its Personnel, wishes to publish any Foreground, NUIG shall submit a copy of the proposed Publication to the Industry Party at least [***][2] before the date of the proposed Publication ("**Notice Period**"), and shall not make any such Publication before the said Notice Period has expired, unless it has received the prior written consent of the Industry Party to do so.

9.2 The Industry Party may, by giving written notice to NUIG at any time during the Notice Period: (a) require that some or all of the Confidential Information of the Industry Party or Background introduced by the Industry Party or Non-Severable Foreground be removed from said Publication and NUIG shall forthwith comply with any such request; and/or (b) require that the Publication be delayed for a period of up to **[***][2] from the date of receipt of such Publication by the Industry Party, if in the reasonable opinion of the Industry Party it is needed to seek patent or similar protection for the Industry Party's Background; or (c) recommend to NUIG that the Foreground described in the Publication should be patent protected **[***][2] prior to the publication. In addition, NUIG shall consider in good faith all reasonable comments made by the Industry Party with respect to such planned academic publication made pursuant to this Clause 9.

9.3 If NUIG does not receive any notice in accordance with this Clause 9, it may proceed with the proposed Publication after the Notice Period.

9.4 The provisions of Clauses 8 and 9 shall not prevent any registered student of NUIG from submitting for a degree, a thesis based on any Foreground, examination of such thesis by NUIG examiners or deposit in NUIG's library, provided the thesis is subject to restricted access, as required, and as per the provisions of Clauses 9.1-9.3.

[2] ***Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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10. LIABILITY AND WARRANTIES

10.1 Each Party undertakes to perform its part of the Project at its own risk.

10.2 Each Party represents and warrants to the other Party that as of the date of this Agreement: (a) it has the power to enter into and perform, and has taken all necessary action to authorise the entry into, and performance and delivery of, this Agreement; (b) the entry into and performance by it of this Agreement does not and will not conflict with its constitutional documents and/or any agreements to which it is a party; (c) so far as concerns its obligations under this Agreement, all authorisations, consents, registrations and notifications required in connection with the entry into, performance, validity and enforceability of this Agreement have been obtained or effected (as appropriate) and are in full force and effect.

10.3 Any Intellectual Property of NUIG which is made available to the Industry Party and/or used in the Project, including but not limited to any advice or information given by NUIG or any of its Personnel, or the content or use of any results, know-how, materials, works or information provided in connection with the Project, is provided on an "**AS IS**" basis. NUIG makes no representations or warranties, express or implied, including but not limited to any warranty of accuracy, completeness, performance, merchantability, fitness for a particular purpose, commercial utility or non-infringement.

10.4 The express undertakings and warranties given by the Parties in this Agreement are in lieu of all other warranties, conditions, terms, undertakings and obligations, whether express or implied by statute, common law, custom, trade usage, course of dealing or in any other way. All of these are excluded to the fullest extent permitted by law.

10.5 Nothing in this Agreement limits or excludes any Party's Liability: (a) for death or personal injury; (b) for any actual fraud; or (c) for any other sort of Liability that, by law, cannot be limited or excluded or (d) under Clauses 10.9 and 10.10.

10.6 Subject to Clause 10.5, no Party shall be liable to the other Party for any loss of profit, loss of revenue, or loss of contracts, loss of goodwill, loss of reputation, or any indirect or consequential Loss howsoever caused arising out of or in connection with the performance or non-performance (as the case may be) by that Party of its obligations under this Agreement regardless of whether such losses were in the contemplation of the Parties.

10.7 Subject to Clause 10.5, the aggregate liability of NUIG to the Industry Party in contract, tort (including, without limitation, negligence), statute or otherwise arising out of or in connection with or in relation to this Agreement, shall be limited to the total Financial Contribution paid by the Industry Party to NUIG. Subject to Clauses 10.5 and 10.9, the aggregate liability of the Industry Party to NUIG in contract, tort (including, without limitation, negligence), statute or otherwise arising out of or in connection with or in relation to this Agreement, shall be limited to the total Financial Contribution payable by the Industry Party to NUIG.

10.8 If the performance by any Party (a "**Non-Performing Party**") of any of its obligations under this Agreement (except a payment obligation) is delayed or prevented by circumstances beyond its reasonable control including but not limited to an act of god; an act of any sovereign; law, judgment, order, decree, embargo, blockade; labour dispute; or interruption or failure of utility service ("**Force Majeure**"), that Non-Performing Party shall not be in breach of this Agreement because of that delay in performance. However, if the delay in performance exceeds **[***]**[3], the other Party may terminate the Agreement with immediate effect by giving written notice to the Non-Performing Party.

10.9 The Industry Party shall indemnify and keep indemnified NUIG on demand against all Losses suffered or incurred by NUIG: (a) in respect of any claims made or threatened by SFI, as a consequence of any failure by the Industry Party to perform the whole or part of its obligations under this Agreement; (b) arising in any way out of or in connection with the use by NUIG of the Industry Party's Background and Confidential Information pursuant to the Project including but not limited to any infringement of the Intellectual Property of any Third Party; and/or (c) arising in any way out of or in connection with the use or exploitation by the Industry Party of NUIG's Registered Background and/or Foreground whether during the Project or pursuant to any subsequent licence from NUIG as provided for herein, including but not limited to any infringement of the Intellectual Property of any Third Party.

10.10 If a Party (the "**Indemnified Party**") becomes aware of any Loss which is reasonably likely to give rise to a right on its part to indemnity from the other Party (the "**Indemnifying Party**") under this Agreement (an "**Indemnified Loss**"), then that Indemnified Party shall: (a) promptly give written notice of that Indemnified Loss to the Indemnifying Party; (b) make no admission of liability to any Third Party in relation to any such Indemnified Loss without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld, conditioned or delayed; (c) give to the Indemnifying Party in a timely way such information and access to its Personnel, documents and records as the Indemnifying Party may request from time to time in connection with the Indemnified Loss; (d) consult as fully as is reasonably practicable with the Indemnifying Party as regards the conduct of any proceedings arising out of or in connection with any such Indemnified Loss; (e) subject to being indemnified and secured to its reasonable satisfaction by the Indemnifying Party from and against any Losses which it may reasonably suffer or reasonably incur in so doing, take such action as the Indemnifying Party may reasonably request from time to time to avoid, dispute, resist, mitigate, settle, compromise, defend or appeal the Indemnified Loss or any claim, proceedings or determination in respect thereof.

11. INSURANCES

11.1 Each of the Parties shall effect and maintain for the duration of this Agreement and for a period of one (1) year following completion of the Project insurance as deemed adequate by a prudent person for a Project of this nature. **[***]**[3]

11.2 At least once every year during the continuance of this Agreement, and from time to time upon request, each Party shall provide to the other Party written evidence of compliance by that Party with its insurance obligations under this Clause 11. Without prejudice to the generality of the foregoing, each Party must promptly notify the other Party of any material changes in any policies of insurance contemplated by this Clause 11 or circumstances affecting any such policies of insurance. NUIG may retain for reference, and permit access by its insurance and professional advisers to, a copy of each document provided to it pursuant to this Clause 11.

[3] ***Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

12. SUB-CONTRACTING:

12.1 No Party may sub-contract or delegate any of its obligations under this Agreement (including, without limitation, the performance of any part of the research which it is specified to perform in connection with the Project) without the prior approval of the other Party, such approval not to be unreasonably withheld, delayed or conditioned.

12.2 Any Party wishing to sub-contract or delegate any of its obligations under this Agreement (including, without limitation, the performance of any part of the research which it is specified to perform in connection with the Project) (a "**Sub-Contracting Party**") shall notify the other Party prior to sub-contracting or delegating any of its obligations under this Agreement and shall provide such information in relation to the proposed sub-contractor as the other Party may reasonably request from time to time in order to verify the identity of that person and their ability to carry out the Sub-Contracting Party's obligations under this Agreement.

12.3 Each Sub-Contracting Party shall ensure that all sub-contractors engaged by it in connection with the Project comply with the terms of the Grant Funding and this Agreement. Each Sub-Contracting Party remains responsible for all acts and omissions of its sub-contractors and the acts and omissions of those employed or engaged by the sub-contractors as if they were its own. An obligation on a Sub-Contracting Party to do, or to refrain from doing, any act or thing shall include an obligation on it to procure that its Personnel and the sub-contractors' Personnel also do, or refrain from doing, such act or thing.

13. TERM AND TERMINATION

13.1 It is agreed, notwithstanding the date of execution of this Agreement, that the relationship between the Parties in connection with the Project is deemed to have been governed by this Agreement since the Effective Date, as if this Agreement had been executed, and had come into force, on that date (but no Party shall be liable in respect of any failure to implement any of the procedures or structures contemplated by Clause 3 at any time before the execution of this Agreement).

13.2 The Agreement shall continue in effect for the full duration of the Contract Period unless sooner terminated in accordance with the provisions of this Agreement. The Parties may, however, by mutual agreement extend the term of this Agreement for any additional period, at additional cost to the Industry Party, as may be necessary for the completion of the Project.

13.3 Unless otherwise agreed, this Agreement shall terminate if the Grant Funding is definitively cancelled, terminated or revoked. In the event NUIG determines, at its sole discretion, that it cannot continue the Project, or the Parties cannot agree upon any necessary amendments to the Statement of Work and related budget, either Party may terminate this Agreement by giving not less than **[***]**[4] notice to the other Party to that effect. In addition, Industry Party may terminate this Agreement for convenience at any time upon **[***]**[5] notice to NUIG.

[4] ***Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

13.4 If the Principal Investigator becomes unable or unwilling to continue the Project, and a mutually acceptable substitute is not available, either Party may terminate this Agreement by giving not less than **[***]** [5] notice to the other Party to that effect.

13.5 Either Party (each a "**Terminating Party**") may terminate this Agreement forthwith upon written notice to the other Party (a "**Defaulting Party**") to that effect if any of the following events occur in respect of the Defaulting Party: (a) where the Industry Party is the Defaulting Party, it fails to pay any amount due from it under this Agreement within **[***]** [5] of the due date; (b) the Defaulting Party fails to comply with any obligation on its part under this Agreement (other than, in the case of the Industry Party, the obligation contemplated by Clause 13.5(a)) which failure is material, and either that failure is not susceptible to remedy or, if it is susceptible to remedy, it is not remedied within **[***]** [5] of notice having been given by the Terminating Party to the Defaulting Party requiring that failure to be remedied; (c) the Defaulting Party is, or is deemed for the purposes of any relevant law to be, unable to pay its debts as they fall due or to be insolvent, or admits inability to pay its debts as they fall due; or the Defaulting Party suspends making payments on all or any class of its debts or announces an intention to do so, or a moratorium is declared in respect of any of its indebtedness; or (d) any step (including the making of any proposal, the convening of any meeting, the passing of any resolution, the presenting of any petition or the making of any order) is taken with a view to a composition, assignment or arrangement with any creditors of, or the winding up, liquidation or dissolution of, the Defaulting Party; or any liquidator, provisional liquidator, receiver or examiner is appointed to or in respect of the Defaulting Party or any of its assets.

14. CONSEQUENCES OF TERMINATION

14.1 On the termination of this Agreement (other than by the Industry Party pursuant to Clause 13.5): (a) the Industry Party shall pay NUIG for all work done prior to termination; (b) the Industry Party shall reimburse NUIG for any costs irrevocably committed by NUIG in connection with the Project at the date of termination. Where the Industry Party has paid any of the Financial Contribution in advance and the whole of that contribution has not, by the end of the Contract Period or the termination of this Agreement, been used by NUIG for the purposes for which it was provided, NUIG shall return to the Industry Party the portion of that contribution in excess of the proportion of the Project completed, (if relevant) unless it is stated to be non-refundable in the Statement of Work; (c) where the Financial Contribution includes the costs of employing any Personnel of NUIG involved in the Project, the Industry Party shall continue to reimburse, in accordance with Clause 4, the actual direct employment costs of any Personnel who were appointed by NUIG to work on the Project before the service of the notice, provided that NUIG takes all reasonable steps to minimise those costs. The Industry Party's obligation to reimburse NUIG pursuant to this Clause 14.1(c) shall continue until the effective date of termination of the employment of the Personnel concerned or the date on which the Project was to have ended (whichever is the earlier). Those direct employment costs will include a proportion of any redundancy costs that have been incurred by NUIG as a direct result of the termination of this Agreement, that proportion to be calculated by dividing the individual's involvement in the Project by the duration of his period of employment by NUIG.

[5] ***Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

14.2 On termination of this Agreement howsoever arising: (a) the licence granted from one Party to the other Party pursuant to Clause 1.3 of Schedule 2 (related to use of Registered Background for the Project) shall terminate with immediate effect; (b) the options and other rights granted to the Industry Party pursuant to Schedule 2 shall lapse with immediate effect, and NUIG shall cease to have any further obligation under Schedule 2 (except for any Evaluation Licence and/or Commercial Licence already granted to the Industry Party, each of which shall survive in accordance with their respective terms); (c) all Confidential Information shall be returned or destroyed in accordance with the provisions of Clause 8.8.

14.3 Notwithstanding the expiry or termination of this Agreement for any reason the provisions of Clauses 1, 4.5, 6.1 to 6.3, 7, 8, 9, 10, 11, 14, 15, and 17 shall continue to bind the Parties in accordance with their respective terms.

14.4 Termination of this Agreement shall not affect any rights of the Parties accrued up to the date of termination.

15. DISPUTE SETTLEMENT

15.1 The Parties shall make every reasonable effort to resolve all issues fairly by negotiation. All disputes arising in connection with this Agreement, which cannot be settled amicably, shall first be managed by the PMT. Should a dispute fail to be resolved by the PMT within **[***]**[6] of such dispute's referral to the PMT, it shall be escalated to the POT. Should the dispute fail to be resolved by the POT within **[***]**[6] of such dispute's referral to the POT, the matter shall be referred to the Director of the TTO (in the case of NUIG) and the Chief Executive Officer (in the case of the Industry Party) (or each of their respective nominees).

15.2 If the dispute cannot be resolved with **[***]**[6] of the referral to the Director of the TTO, or such other longer period as may be agreed upon between the Parties in writing, the Parties shall refer the dispute to a single mediator to be appointed in accordance with the mediation procedures of the Centre for Effective Dispute Resolution in Dublin or such other organisation that provides mediation services as may be agreed in writing between the Parties from time to time. The cost of such mediator shall be borne equally by Parties.

15.3 If the dispute cannot be resolved within **[***]**[6] of the dispute being referred to a mediator, or such other longer period as may be agreed upon between the Parties in writing from time to time, either of the parties may refer the matter to court (and the provisions of Clause 17.1 shall apply).

15.4 Nothing in this Clause 15 shall prevent a Party from applying to a court of competent jurisdiction for injunctive relief against the other Party for the purpose of protecting its Intellectual Property or Confidential Information provided that there is no delay in the prosecution of that application. Nothing herein shall be construed as NUIG acquiescing to any such application for injunctive relief.

[6] ***Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

16. NOTICES

16.1 Notices and other communications under or in connection with this Agreement may be given in writing by hand, by pre-paid or registered post or by e-mail (save that e-mail shall not be used for any exercise of any option, notice of termination or service of any legal process). Any such notice, if so given, shall be deemed to have been served: (a) if sent by hand, when delivered; (b) if sent by post within Ireland, one (1) business day after posting; (c) if sent by post to or from overseas, five (5) business days after posting; and (d) if sent by e-mail upon production by the sender's email system of a delivery receipt (or equivalent) confirming delivery of the communication to the correct e-mail address.

16.2 The contacts between the Parties for the purposes of the Agreement are as follows:

NATIONAL UNIVERSITY OF IRELAND, GALWAY

Principal Investigator

Professor Abhay Pandit

National University of Ireland, Galway

Tel: **[***]**[7]

Email: **[***]** [7]

Legal, Intellectual Property and Confidentiality

Ms Lily O'Brien, Technology Transfer Office, Research and Innovation Centre Building, National University of Ireland, Galway

Tel: **[***]** [7]

Email: **[***]** [7]

Post Award Financial / Administration Issues

Ms Orla Timon, Research Financial Reporting Manager, Unit 2, Business and Innovation Centre, Research and Innovation Centre, National University of Ireland, Galway

Tel: **[***]** [7]

Email: **[***]** [7]

ARCH THERAPEUTICS, INC.

Project Manager

Terrence W. Norchi, MD

235 Walnut Street, Suite 6, Framingham, MA 01702 United States

Tel: **[***]** [7]

Email: **[***]** [7]

[7] ***Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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Legal

Michael Lerner

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Intellectual Property & Confidentiality

Patrea Pabst

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Tel: **[***]**[8]

Email: **[***]**[8]

Post Award Financial / Administration Issues

Richard Davis

235 Walnut Street, Suite 6, Framingham, MA 01702 United States

Tel: **[***]**[8]

Email: **[***]**[8]

17. GENERAL PROVISIONS

17.1 This Agreement, and any non-contractual obligations arising out of or in connection with this Agreement, are governed by and shall be construed in accordance with the laws of Ireland. Save as provided in Clause 15, the Irish courts have exclusive jurisdiction to settle any dispute arising out of or in connection with this Agreement and the Parties submit to the exclusive jurisdiction of the Irish courts for that purpose.

17.2 This Agreement may not be assigned wholly or in part to a Third Party or to any legal successors by any Party without the prior written consent of the other Party; provided, however, that notwithstanding the foregoing, no such consent shall be required with respect to any assignment of this Agreement by a Party to any acquirer of all or substantially all of such Party's assets or business or of any line of business to which this Agreement relates, PROVIDED that (a) the assigning Party shall promptly give notice to the other Party of any assignment; and (b) the assignee undertakes not to carry on an Unapproved Activity; and (c) the assignee undertakes to the other Party to be bound by and perform the obligations of the assignor under this Agreement.

17.3 Nothing in this Agreement shall create, or be deemed to create, a partnership, joint venture, or the relationship of principal and agent, between the Parties, and no Party shall have any right or authority to act on behalf of the other Party or to bind the other Party in any way. No Party shall have any Liability for any activities of the other Party. Furthermore, nothing in this Agreement shall be construed as providing for the sharing of profits or losses under or in connection with this Agreement.

[8] ***Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

17.4 All amendments and modifications to this Agreement including any additional agreements and notices pursuant to this Agreement shall require the written form duly signed for and on behalf of each of the Parties. Unless expressly so agreed or introduced, no such modification or variation shall constitute or be construed as a general waiver of any provisions of this Agreement, nor shall it affect any rights, obligations or Liabilities under this Agreement which have already accrued up to the date of such modification or waiver, and the rights and obligations of the Parties under this Agreement shall remain in full force and effect, except and only to the extent that they are so modified or varied.

17.5 If any provisions of this Agreement are or become ineffective or if any omission is discovered, the validity of the remaining provisions shall not thereby be affected. In place of the ineffective provisions or for the purpose of rectifying the omission a reasonable arrangement shall operate being the nearest legally possible approach to that which the Parties desired or would have desired in consideration of the spirit and object of this Agreement had they considered the point. The Parties agree, in the circumstances referred to in this Clause 17.5 to attempt in good faith to substitute for any invalid or unenforceable provision a valid or enforceable provision which achieves to the greatest extent possible the same effect as would have been achieved by the invalid or unenforceable provision.

17.6 The Parties acknowledge that they have been afforded the opportunity to take independent legal advice on the terms of this Agreement prior to entering into it. Each Party further acknowledges that it understands the effect and implications of this Agreement. Each Party shall pay its own costs in connection with or incidental to the preparation, negotiation and execution of this Agreement. If any ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties and no presumption or burden of proof shall arise favouring or disfavouring any Party by virtue of the authorship of any of the provisions of this Agreement.

17.7 The express terms of this Agreement constitute the sole and entire agreement between the Parties in relation to its subject matter and supersedes all prior written and oral arrangements, understandings, representations, warranties and agreements between them in that regard (if any) including but not limited to any term sheet that may have been signed by the Parties. Each Party acknowledges that it is not relying, and will not seek to rely, on any arrangement, understanding, representation, warranty, agreement, term or condition which is not expressly set out in this Agreement.

17.8 Each of the rights of the Parties under this Agreement may be exercised as often as is necessary, is cumulative and not exclusive of any other rights which that Party may have under this Agreement, law or otherwise; and may be waived only in writing. Delay by a Party in exercising, or the non-exercise by a Party of, any such right shall not constitute a waiver of that right.

17.9 This Agreement may be executed in two or more counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument. A signed copy of this Agreement delivered by e-mail or other electronic means shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

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SCHEDULE 1

PART 1

STATEMENT OF WORK

The Statement of Work shall contain the following information:

Project Title: Decathlon;

Project Number: S3-AP-01;

Project Description: Further Research and Development of the Industry Party's medical device, AC5™;

Principal Investigator (NUIG): Professor Abhay Pandit;

Project Manager (Industry Party): Terence Norchi;

Industrial Program Manager: Dr Neil Ferguson;

Centre Director: Prof Abhay Pandit;

Milestones and Deliverables: TBD;

HR Requirements: Senior Research Fellow and other Personnel as agreed between the Parties;

Equipment Requirements: TBD; and

Requirement and Responsibility for Obtaining any Regulatory and/or Ethical Licenses/Consent: Industry Party.

SCHEDULE 1

PART 2

BACKGROUND AND FOREGROUND REGISTER

BACKGROUND

Background introduced by NUIG: None as of Execution Date
Description
Any encumbrances or restrictions?
Specified Background – yes or no

Background introduced by Industry Party: None as of Execution Date
Description
Any encumbrances or restrictions?
Specified Background – yes or no

FOREGROUND

Description of IP
Disclosure ID
Date of Disclosure
Type of IP - Foreground or Nonseverable Foreground
Signed by the Industry Party
Signed by PI

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SCHEDULE 1

PART 3

FINANCIAL AND/OR IN KIND CONTRIBUTION

1. Cash Contribution:
The Industry Party shall contribute between zero and two hundred and fifty thousand euro (€250,000) per year (exclusive of VAT) in cash payment toward the cost of the Project.

The Industry Party shall make the cash payments to NUIG to cover costs associated with the SOW (up to the (€250,000) per year limit stated above) according to a cost schedule, which shall be agreed to prior to recruiting Personnel (on an incremental basis). Cash payments, which are expected to commence on 1st June 2015 and continue through the duration of the project, shall be adjusted from time to time in accordance with changes in the SOW and changes in Personnel, such as the expiration of a contract.

The Parties shall determine the breakdown of costs in due course after the signature date of the Agreement. The cost schedule shall be in the following format:

Amount	**Due Date**	**Costs to cover the following**
€[insert amount]	[insert date]	[insert detail, researcher title, other project costs]
€[insert amount]	[insert date]	
€[insert amount]	[insert date]	
€[insert amount]	[insert date]	

For the avoidance of doubt, NUIG shall not be obligated to hire any Personnel until it is put in funds by the Industry Party.

2. In-kind Contribution
The total in-kind contribution being made by the Industry Party amounts to [insert amount in words] thousand euro (€[insert amount in figures]) which is payable as follows:

Amount	**Due Date**
€[insert amount]	On or before [insert date]
€[insert amount]	On or before [insert date]
€[insert amount]	On or before [insert date]

The amounts set out above are an estimate only and can be adjusted from time to time.

3. Industry Cost Report

The Industry Party shall provide periodic financial reports detailing both cash and in-kind (Labour, Equipment, Materials, Travel and Other) contributions in the format as set out below. These financial reports will be provided on a half yearly basis.

Research Centre: Cúram
Research Centre Award Ref: [insert ref number]
Industry Party
Industry Party Project Manager:
Project No.:
Start Date:
Reporting Period

	Cash €	In-kind €
Cash		
Labour		
Equipment/Equipment access		
Materials		
Travel		
Other		
Total		

Approval by Industry Party:
Date:
Approved by Principal Investigator:
Date:

Please complete columns headed "Cash", "Labour", "Equipment", "Materials", "Travel" and "Other" as applicable.

All amounts in this Schedule exclude value added tax.

All payments of the Financial Contribution shall be made by bank transfer to the following bank account:

Bank: Bank of Ireland
Branch: 43 Eyre Square, Galway, Ireland
Sort Code: **[***]**[9]
Account No: **[***]**[9]
IBAN: **[***]**[9]
Reference: [This reference number will be provided by NUIG once the contract has been signed]

1. Where the Project is liable to value added tax, NUIG shall issue a payment request to the Industry Party with respect to the payments outlined above for the amount in question plus VAT. Following receipt of the payment, a VAT invoice with respect to the payment plus the applicable amount of VAT will be issued by NUIG.

2. Where the Project is not liable to value added tax, NUIG shall issue an invoice with respect to each of the payments outlined above.

3. NUIG's Finance Officer is Orla Timon or such other person notified by NUIG to the Industry Party from time to time.

[9] ***Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

SCHEDULE 2

INTELLECTUAL PROPERTY

1. Background

1.1 Ownership: This Agreement does not affect the ownership of any Background. Background shall remain the property of the Party that contributes it to a Project. No licence to use any Background is granted or implied by this Agreement except the rights expressly granted in this Agreement.

1.2 Background Register:

1.2.1 No Background may be made available for use in a Project other than Registered Background.

1.2.2 Each Party who proposes to contribute Background to a Project, whether prior to commencement of, or during the Project, must first notify the other Party in writing providing details of the Background. Any Background so notified shall be "**Registered Background**" and the introducing Party shall provide the information requested in Schedule 1, Part 2 (i.e., any restrictions or encumbrances on the use of that Background and detailing if it is Specified Background).

1.2.3 The POT shall maintain a register of Background contributed to the Project detailing the name of the contributing Party together with any restrictions or encumbrances on its uses imposed by the contributing Party ("**Background Register**").

1.2.4 Each Party may withdraw or make additions or other amendments to Registered Background made available by it for use in the Project upon prior written notice to the other Party.

1.3 Licence to use Background for the Project: Each Party grants to the other Party a royalty-free, non-exclusive licence to use its Registered Background for the purpose of carrying out the Project, but for no other purpose. No Party may grant any sub-licence to use the other Party‘s Background.

1.4 Commercial Licence to use Specified Background: In the event that Specified Background of NUIG is necessary to commercially exploit the Foreground or Non-Severable Foreground, then NUIG shall grant to the Industry Party an option to negotiate a royalty-bearing, exclusive licence to use that Specified Background but only to the extent necessary to commercialise the Foreground and only: (a) in conjunction with and as an integral component of the Foreground; (b) in a defined field and defined territory; (c) on fair, equitable and non-discriminatory commercial terms; (d) subject to the terms of access to Specified Background as described in the Background Register; (e) and subject to the terms set forth in the Commercial License Term Sheet.

2. Foreground

2.1 Ownership:

2.1.1 All right and title to, and interest in, any and all Foreground generated during and in the direct course of the Project by the Personnel of either Party shall vest and remain vested in NUIG.

2.1.2 To the extent that any Foreground is capable of prospective assignment, the Industry Party hereby assigns that Foreground to NUIG; and to the extent that any Foreground cannot be prospectively assigned, the Industry Party undertakes to NUIG to assign such of that Foreground as it owns to NUIG as and when that Foreground is created, at the request of NUIG from time to time.

2.1.3 The Industry Party irrevocably and unconditionally waives any rights, including all rights in the nature of moral rights, in respect of the Foreground to which it is now or may in the future be entitled, to the extent it is legally able to do so.

2.1.4 NUIG may take such steps as it may decide from time to time, **[***]**[10], to register and maintain any protection for any Foreground, including filing and prosecuting patent applications for that Foreground.

2.1.5 Each Party shall ensure that any member of its Personnel: (a) assign any Foreground that she/he may have in any Foreground in order to be able to give effect to the provisions of this Clause 2.1; and (b) irrevocably and unconditionally waive any rights, including all rights in the nature of moral rights, in respect of the Foreground to which she/he now or may in the future be entitled, to the extent she/he is legally able to do so.

2.1.6 The Industry Party shall ensure that any member of its Personnel involved in the creation of any Foreground give NUIG such assistance as NUIG may reasonably request in connection with the registration and protection of the Foreground, including filing and prosecuting patent applications for that Foreground, and taking any action in respect of any alleged or actual infringement of that Foreground.

2.2 Management and Notification of Foreground

2.2.1 Any Foreground created by either Party will be described in an IDF and submitted to the TTO. The NUIG research team are subject to NUIG's policy on declaration of inventions.

2.2.2 All IDFs will be notified in writing by the TTO to the Industry Party.

2.3 Options to Foreground

2.3.1 Within **[***]**[10] of the Notification Date, the Company must notify NUIG if it is interested in obtaining an Evaluation Licence.

2.3.2 The Evaluation Licence shall be in the format set out in the attached Schedule 3.

2.3.3 Any Evaluation Licence granted to the Industry Party by NUIG will be subject to the Industry Party paying any protection costs for the Foreground which have been incurred by NUIG in accordance with the terms of such Evaluation Licence.

2.3.4 Within the Evaluation Period, the Industry Party must notify NUIG if it wishes to obtain a Commercial Licence.

2.3.5 Subject to the Industry Party notifying NUIG in writing within the Evaluation Period, NUIG shall negotiate on an exclusive basis with the Industry Party for a period of no more than **[***]**[10] from such date of notification ("**Negotiation Period**") for a Commercial Licence on the terms that are consistent with those set forth in the Commercial License Term Sheet (or, if acceptable to Industry Party, such other terms as may be agreed upon by the Parties).

2.3.6 All royalty or fee based payments payable to NUIG pursuant to any royalty bearing licence for the Foreground will be on reasonable commercial terms, taking into account the Financial Contribution of the Industry Party to the Project.

[10] ***Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

2.3.7 In the event that NUIG and the Industry Party do not reach agreement on the terms of a Commercial Licence within the Negotiation Period, the Industry Party's option to negotiate such a Commercial Licence shall thereafter terminate with immediate effect.

2.3.8 Know-How which forms part of the Foreground shall only be licensed to the Industry Party on a non-exclusive basis as part of any licence of Foreground.

2.3.9 Up until such time as the Negotiation Period has elapsed, NUIG shall not grant any rights or enter into negotiations with any Third Party in relation to the Foreground which would be inconsistent with the terms outlined herein.

2.4 NERF Licence: In accordance with the IP Protocol, only in very exceptional circumstances will an option to negotiate a NERF licence to Foreground in a defined field and territory be granted by NUIG, provided the following criteria are fulfilled: (a) the Industry Party has declared prior to the start of the Project that it wants an option to negotiate a NERF licence to the Foreground; and (b) determination by NUIG and approval by SFI that the commercial interests of the Irish State are best advanced through the issuance of a NERF licence to the Foreground (subject to compliance with EU state aid rules) with NUIG and SFI taking into account, but not being limited to the following considerations for granting an option to negotiate a NERF licence: (i) to deliver significant economic and societal impact, to perform research excellence with impact which will align with areas of strategic opportunity for Ireland, as outlined, for example, in the report of the National Research Prioritisation Exercise; (ii) to attract large foreign direct investments in corporate R&D laboratories; (iii) to transfer knowledge, expertise and know-how to multinational companies and small and medium sized enterprises based in Ireland; (iv) to increase the level of industrial and commercial investment in R&D activities; (v) to attract additional non-exchequer funding through industry sources and external research-funding organisations; and/or (vi) to deliver tangible societal benefits to Ireland in areas such as health care, education, security, through measures such as improving the efficiency or effectiveness of the public sector. All negotiations on this matter will be the subject of a separate agreement.

2.5 Non-Severable Foreground:

2.5.1 In the event that any Non-Severable Foreground is created, NUIG shall assign such Non-Severable Foreground to the Industry Party for a fee of **[***]**[11].

2.5.2 Industry Party may take such steps as it may decide from time to time**[***]**[11], to register and maintain any protection for any Non-Severable Foreground, including filing and prosecuting patent applications.

2.5.3. NUIG shall ensure that any member of its Personnel involved in the creation of any Non-Severable Foreground give Industry Party such assistance as Industry Party may reasonably request in connection with the registration and protection of the Non-Severable Foreground.

2.5.4 Non-Several Foreground and Foreground, should any be developed, shall be determined and tracked by the following process: **[***]**[11]

[11] ***Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

3. Reporting Obligations: All licences of Foreground shall be subject to the reporting and exploitation requirements of SFI.

4. Academic License: NUIG shall always reserve unto itself the right to use the Foreground for the purpose of academic teaching and research including research sponsored by a Third Party, subject to the confidentiality, publication and IP obligations of this Agreement and/or any licence entered into with the Industry Party.

SCHEDULE 3

FORM OF EVALUATION AGREEMENT

DRAFT

THIS EVALUATION AGREEMENT (the "**Agreement**") is made and entered into on [insert date] 2015

BETWEEN

(1) NATIONAL UNIVERSITY OF IRELAND, GALWAY, having its principal address at University Road, Galway, Ireland (hereinafter referred as "**NUIG**"); and,

(2) ARCH THERAPEUTICS, INC, a company incorporated in Nevada, (company number NV20091379642) and having its registered address at 235 Walnut Street, Suite 6, Framingham, MA 01702, USA (the "**Industry Party**").

(hereinafter collectively referred to as the "**Parties**" and individually a "**Party**")

WHEREAS

(A) Pursuant to a Targeted Project Agreement between the Parties dated [ ] April, 2015 (the "**Targeted Project Agreement**"), NUIG and the Industry Party collaborated on a project entitled [ ] pursuant to which [describe the Foreground technology] as described in the attached Annex 1 (the "**Technology**") was created. NUIG owns such Technology;

(B) The Industry Party has an interest in licensing the Technology to evaluate its usefulness and NUIG is willing to allow the Industry Party access to the Technology for such purposes; and

(C) The Parties wish to enter into an agreement that allows the Industry Party to carry out an internal evaluation of the Technology and to set out the terms and conditions attached thereto.

NOW THEREFORE IT IS HEREBY AGREED AS FOLLOWS:

1. Capitalized terms that are used but not defined herein have the meanings assigned to those terms in the Project Agreement. Subject to the terms of this Agreement and in consideration of the performance of its obligations under this Agreement, NUIG hereby grants the Industry Party for the Evaluation Period an Evaluation Licence.

2. The Industry Party shall not reproduce, modify, reverse engineer, distribute, market, sub-licence or sell the Technology or any product, process or other commercial offering incorporating the Technology or permit any third party to do any of the foregoing. The Industry Party expressly acknowledges and represents that it will only use the Technology for internal evaluation purposes in accordance with the terms of this Agreement.

3. Subject to the terms of this Agreement, NUIG shall deliver one copy of the Technology, in the form of executables and documentation to the Industry Party, on or about [insert date] 2015. Delivery may take place electronically to such electronic address as the Industry Party may designate.

4. The Industry Party shall provide NUIG with a written report on its evaluation of the Technology within [insert number months/days] month(s) following the expiration of the Evaluation Period or the termination of this Agreement, whichever occurs first. The report shall be treated as the Industry Party's Confidential Information for the purposes of and shall be subject to the provisions of Clause 8 of the Targeted Project Agreement; *provided, however*, that upon NUIG's request, the Industry Party shall destroy all but one copy of the report, which report shall be stored by the Industry Party in a secure location solely for archival purposes in order to comply with law or the terms of this Agreement.

5. For the duration of the Evaluation Period (provided this Agreement has not been terminated earlier for cause) NUIG hereby grants the Industry Party an option to request in writing from NUIG and agree to a commercial licence to the Technology upon fair and reasonable commercial terms that are consistent with those set forth in the Commercial Licence Term Sheet (or if acceptable to the Industry Party, such other terms as may be agreed upon by the Parties). If the Industry Party has not exercised this option by the expiry of the Evaluation Period or if the Parties have not entered into the required licence agreement within **[***]**