

Arch Therapeutics, Inc.
Form S-1/A
October 16, 2015

As filed with the U.S. Securities and Exchange Commission on October 16, 2015

Registration No. 333-206873

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 1

to

FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

ARCH THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

| | | |
|---|---|--|
| Nevada | 3841 | 46-0524102 |
| (State or other jurisdiction of incorporation or organization) | (Primary Standard Industrial Classification Code Number) | (I.R.S. Employer Identification Number) |

235 Walnut St., Suite 6

Framingham, MA 01702

(617) 431-2313

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Terrence W. Norchi

President and Chief Executive Officer

235 Walnut St., Suite 6

Framingham, MA 01702

(617) 431-2313

(Name, address, including zip code, and telephone number, including area code, of agent for service)

With Copies to:

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John "Jack" D. Hogoboom

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(973) 597-6394

Approximate date of commencement of proposed sale to the public: As soon as possible after the effective date hereof.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. x

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If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

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

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission acting pursuant to said section 8(a), may determine.

The information in this prospectus is not complete and may be changed. The selling securityholders named herein may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED October 16, 2015

ARCH THERAPEUTICS, INC.

PROSPECTUS

Up to 28,781,508 Shares of Common Stock

This prospectus relates to the offering and resale by the selling securityholders of Arch Therapeutics, Inc. named herein of up to 28,781,508 shares of common stock, par value \$0.001 per share (“**Common Stock**”). These shares include 14,390,754 shares of issued and outstanding Common Stock currently held by the selling securityholders and 14,390,754 shares of Common Stock currently underlying Series D Warrants held by the selling securityholders, all of which were initially issued and sold in a private placement offering that was concluded on July 2, 2015 (the “**2015 Private Placement Financing**”). The Common Stock issued in the 2015 Private Placement Financing was sold as a part of a unit (“**Unit**”) consisting of a share of our Common Stock and a Series D Warrant at a purchase price of \$0.22 per Unit. The Series D Warrants entitle the holders thereof to purchase shares of Common Stock at an initial exercise price of \$0.25 per share, were exercisable immediately upon issuance and expire five years thereafter.

The selling securityholders may sell the shares of Common Stock to be registered hereby from time to time on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale, in the over-the-counter market, in one or more transactions otherwise than on these exchanges or systems or in the over-the-counter market, such as privately negotiated transactions, or using a combination of these methods, and at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. See the disclosure under the heading “**Plan of Distribution**” in this prospectus for more information.

We will not receive any proceeds from the resale of Common Stock by the selling securityholders.

Our Common Stock is traded on the QB tier of the OTC Marketplace (“**OTCQB**”) under the symbol “**ARTH**”. On October 15, 2015, the closing price of our Common Stock was \$0.253 per share.

We originally offered and sold the securities issued in the 2015 Private Placement Financing under an exemption from the registration requirements of the Securities Act of 1933, as amended (the “**Securities Act**”), pursuant to Section 4(a)(2) thereof.

Investing in our Common Stock involves a high degree of risk. Before making any investment in our Common Stock, you should read and carefully consider the risks described in this prospectus under the heading “Risk Factors” beginning on page 12 of this prospectus.

You should rely only on the information contained in this prospectus or any 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.

This prospectus is dated _____, 2015

TABLE OF CONTENTS

| | |
|--|-----|
| <u>SUMMARY</u> | 5 |
| <u>RISK FACTORS</u> | 12 |
| <u>FORWARD-LOOKING STATEMENTS</u> | 29 |
| <u>SELLING SECURITYHOLDERS</u> | 30 |
| <u>DETERMINATION OF OFFERING PRICE</u> | 35 |
| <u>PLAN OF DISTRIBUTION</u> | 35 |
| <u>USE OF PROCEEDS</u> | 37 |
| <u>DESCRIPTION OF SECURITIES</u> | 37 |
| <u>MARKET PRICE OF AND DIVIDENDS ON COMMON STOCK AND RELATED MATTERS</u> | 42 |
| <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u> | 43 |
| <u>OUR BUSINESS</u> | 54 |
| <u>DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u> | 66 |
| <u>EXECUTIVE COMPENSATION</u> | 69 |
| <u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u> | 73 |
| <u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u> | 75 |
| <u>LEGAL MATTERS</u> | 76 |
| <u>EXPERTS</u> | 76 |
| <u>WHERE YOU CAN FIND MORE INFORMATION</u> | 76 |
| <u>CONSOLIDATED FINANCIAL STATEMENTS</u> | F-1 |

About This Prospectus

You should rely only on the information that we have provided or incorporated by reference in this prospectus, any applicable prospectus supplement and any related free writing prospectus that we may authorize to be provided to you. We have not authorized anyone to provide you with different information. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus, any applicable prospectus supplement or any related free writing prospectus that we may authorize to be provided to you. You must not rely on any unauthorized information or representation. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information in this prospectus, any applicable prospectus supplement or any related free writing prospectus is accurate only as of the date on the front of the document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus, any applicable prospectus supplement or any related free writing prospectus, or any sale of a security registered under the registration statement of which this prospectus is a part.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the heading “**Where You Can Find More Information.**”

As used in this prospectus, unless the context indicates or otherwise requires, the “**Company**”, “**we**”, “**us**”, “**our**” and “**Arch**” refer to Arch Therapeutics, Inc., a Nevada corporation, and its consolidated subsidiary, and the term “**ABS**” refers to Arch Biosurgery, Inc., a private Massachusetts corporation that, through a reverse merger acquisition completed on June 26, 2013, has become our wholly owned subsidiary.

On May 24, 2013, we effected a forward stock split, by way of a stock dividend, of our issued and outstanding shares of Common Stock at a ratio of 11 shares to each one issued and outstanding share. Unless the context indicates or otherwise requires, all share numbers and share price data included in this prospectus have been adjusted to give effect to that stock split.

Our trademarks include AC5 Surgical Hemostatic Device™, AC5™, Crystal Clear Surgery™, NanoDrape™ and NanoBioBarrier™. All other trademarks, trade names and service marks included in this prospectus are the property of their respective owners.

SUMMARY

This summary does not contain all of the information that should be considered before investing in our Common Stock. Investors should read the entire prospectus carefully, including the more detailed information regarding our business under the heading “OUR BUSINESS” beginning on page 54 of this prospectus, the risks of purchasing our Common Stock discussed in this prospectus under the heading “Risk Factors” beginning on page 12 of this prospectus and our consolidated financial statements and the accompanying notes beginning on page F-1 of this prospectus.

Our Company

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 that stops bleeding (referenced as “**hemostatic**” or “**hemostasis**”), controls leaking (referenced as “**sealant**” or “**sealing**”), and provides other advantages during surgery and trauma care. Our core technology is based on a self-assembling peptide solution that creates a physical, mechanical barrier, which could be applied to seal organs or wounds that are leaking blood and other fluids. We believe our technology could support an innovative platform of potential products in the field of stasis and barrier applications. Our lead product candidate, the AC5 Surgical Hemostatic Device™ (which we sometimes refer to as “**AC5™**”), is designed to achieve hemostasis in minimally invasive and open surgical procedures, and we hope to develop other hemostatic or sealant product candidates in the future based on our self-assembling peptide technology platform. Our plan and business model is to develop products that apply that core technology to use with human bodily fluids and connective tissues.

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

We currently have no products that have obtained marketing approval in any jurisdiction, we have not generated revenues since inception and we do not expect to do so in the foreseeable future due to the early stage nature of our current product candidates. We had net losses for the year ended September 30, 2014 and the nine months ended June 30, 2015 of \$8,142,823 and \$1,850,066, respectively, and we had an accumulated deficit as of June 30, 2015 of \$14,624,760. To date, we have financed our operations primarily through funding received from private placement

offerings, such as the 2015 Private Placement Financing, the 2014 Private Placement Financing (as later defined), the Notes Offering (as later defined), and under the MLSC Loan Agreement (as later defined). 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.

For more information regarding our business, see the disclosure under the headings “**Management’s Discussion and Analysis of Financial Condition and Results of Operations**” and “**Our Business**” included elsewhere in this prospectus. For a description of certain risks related to our business, see the disclosure under the heading “**Risk Factors**” beginning on page 12 of this prospectus.

2015 Private Placement Financing

Beginning June 22, 2015 and through June 30, 2015, we entered into a series of substantially similar subscription agreements (each a “**Subscription Agreement**”) with twenty accredited investors providing for the issuance and sale by us to such 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 our Common Stock and a Series D Warrant (“**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 shares issuable upon exercise of the Series D Warrants, the “**Series D Warrant Shares**”). The number of shares of 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, (i) at anytime during the term of the Series D Warrants, we may reduce the then current exercise price to any amount and for any period of time deemed appropriate by our Board of Directors (the “**Board**”); and (ii) certain of the Series D Warrants provide that they shall not be exercisable in the event and to the extent that the exercise thereof would result in the holder of the Series D Warrant or any of its affiliates beneficially owning more than 4.9% of our Common Stock, but such ownership limitation may be waived at the holder’s discretion, *provided that* such waiver will not become effective until the 6th day after delivery of such waiver notice. We did not engage any underwriter or placement agent in connection with the 2015 Private Placement Financing. The aggregate gross proceeds raised by us in the 2015 Private Placement Financing totaled approximately \$3,166,000, and upon the Second Closing (as later defined) on July 2, 2015, the number of shares of our Common Stock outstanding increased by over eighteen percent (18%) from 78,766,487 to 93,157,241.

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

Our existing stockholders will experience dilution upon any exercise of the Series D Warrants issued in the 2015 Private Placement Financing. Such Series D Warrants are currently exercisable for an aggregate of 14,390,754 shares of our Common Stock which, assuming no adjustments to and the full exercise of the Series D Warrants and no other issuances of our Common Stock would equal approximately 14% of the 108,169,804 shares of Common Stock outstanding as of the date of this prospectus, and approximately 12% of the 122,560,558 shares of Common Stock that would be outstanding after giving effect to the exercise of all such warrants.

On the Initial Closing Date, we entered into a registration rights agreement with the Initial Investors (the "**2015 Registration Rights Agreement**"), pursuant to which we became obligated, subject to certain conditions, to file with the Securities and Exchange Commission (the "**SEC**") within 90 days after the closing of the 2015 Private Placement Financing one or more registration statements to register the shares of Common Stock issued in the Closings and the Series D Warrant Shares for resale under the Securities Act of 1933, as amended (the "**Securities Act**"). The remaining investor became a party to the 2015 Registration Rights Agreement upon the consummation of the Second Closing. As a result, we are registering for resale under this registration statement an aggregate of 28,781,508 shares of Common Stock, representing the 14,390,754 shares issued at the closing of the 2015 Private Placement Financing and the 14,390,754 shares underlying the Series D Warrants.

Pursuant to our filing of this registration statement, we are in compliance with such filing obligation under the 2015 Registration Rights Agreement. Our failure to satisfy certain deadlines with respect to this registration statement, including with respect to the effectiveness hereof within five (5) business days after the SEC notifies us that no review of the registration statement will be made or that the SEC has no further comments on the registration statement, and certain other requirements set forth in the 2015 Registration Rights Agreement may require us to pay monetary penalties to the investors in the 2015 Private Placement Financing and/or their assignees. Because the Series D Warrants are subject to certain adjustments and permit, in certain circumstances, the "cashless" exercise thereof, the number of shares that will actually be issuable upon any exercise thereof may be more or less than the number of shares being offered by this prospectus. In the event of any such adjustment to the number of shares issuable upon exercise of the Series D Warrants, the provisions of the 2015 Registration Rights Agreement would obligate us to register for resale any additional shares of our Common Stock that may then be issuable upon exercise of the Series D Warrants.

Under the 2015 Registration Rights Agreement, subject to exception in certain circumstances, we have agreed to keep this registration statement effective until the earlier of the date on which all shares of Common Stock to be registered hereunder have been sold, and the twelve month anniversary of the date the registration statement of which this prospectus is a part is declared effective by the SEC. If there is not an effective registration statement covering the resale of any of the shares issued in or issuable upon exercise of the Series D Warrants issued in the 2015 Private Placement Financing, then the selling securityholders will be entitled to exercise their Series D Warrants on a “cashless exercise” or “net exercise” basis during the period when the shares issuable upon exercise of such Series D Warrants are not so registered.

Three of the selling securityholders, Anson Investments Master Fund LP (“**Anson**”), Intracoastal Capital, LLC (“**Intracoastal**”) and the Keyes Sulat Revocable Trust (the “**Trust**”), or their respective affiliates, have participated in previous financings that were either conducted by us or our affiliates. In particular, Anson and Equitec Specialists, LLC (“**Equitec**”), an affiliate of Intracoastal, were issued 2,000,000 and 800,000 shares of Common Stock, respectively, and Series A Warrants, Series B Warrants and Series C Warrants (collectively, the “**2014 Warrants**”), each exercisable for 2,000,000 and 800,000 shares, respectively, at the closing of the 2014 Private Placement Financing on February 4, 2014. On March 13, 2015, each of Anson and Equitec were issued a Convertible Note (as defined below) in the aggregate principal amount of \$250,000 upon the closing of the Notes Offering. In May 2015, Equitec assigned the remaining securities it acquired in the 2014 Private Placement Financing and Notes Offering to Intracoastal.

The Trust, in turn, previously purchased a promissory note in the aggregate principal amount of \$75,000 and warrants from our wholly-owned subsidiary, ABS, on June 19, 2013. In contemplation of the Merger (as later defined), the securities purchased by the Trust were amended and restated to provide for (i) the conversion of all amounts owed under the promissory note into an aggregate of 273,277 shares of the Company’s Common Stock upon the closing of the Merger, calculating to approximately one share of the Company’s Common Stock for each \$0.27 outstanding under the promissory note, and (ii) the cancellation of the warrants in full upon the closing of the Merger. Accordingly, upon the closing of the Merger on June 26, 2013, the promissory note was converted into 273,277 shares of our Common Stock and the warrants were cancelled. James R. Sulat, who was appointed as a member of our Board on August 19, 2015, is a co-trustee of the Trust along with his wife. On June 18, 2013, we awarded Mr. Sulat a stock option award to purchase 30,000 shares of Common Stock at an exercise price of \$0.37 per share in consideration for services rendered to us as a consultant, and on August 19, 2015, we awarded Mr. Sulat an additional stock option award to purchase 200,000 shares of Common Stock at an exercise price of \$0.27 per share in connection with his appointment to the Board.

On June 30, 2015, the Initial Closing Date, the Series D Warrants had an exercise price lower than the market value of our Common Stock, which closed at \$0.26 on the OTCQB on such date, resulting in an aggregate discount to the market price of our Common Stock of \$139,364. On July 2, 2015, the date of the Second Closing, Series D Warrants had an exercise price higher than the market value of our Common Stock, which closed at \$0.23 on the OTCQB on such date, and therefore did not have any discount to the market price of our Common Stock as of such date. The tables below indicate the total possible discount to the market price of our Common Stock as of June 30, 2015 for the shares of our Common Stock underlying the Series D Warrants issued upon the Initial Closing, as well as similar information for the Series D Warrants issued upon the Second Closing.

Series D Warrants Issued on June 30, 2015

| | |
|--|------------|
| Market price per share of our Common Stock on June 30, 2015, the Initial Closing Date: | \$0.26 |
| Exercise price per share of the Series D Warrants on the Initial Closing Date: | \$0.25 |
| Total possible shares of Common Stock underlying the Series D Warrants issued on the Initial Closing Date: | 13,936,367 |

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Aggregate market price of all shares of Common Stock underlying the Series D Warrants issued on the Initial Closing Date, based on the market price of our Common Stock on June 30, 2015: \$3,623,455

Aggregate exercise price of all shares of Common Stock underlying the Series D Warrants issued on the Initial Closing Date, based on the exercise price on the Initial Closing Date: \$3,484,092

Total possible discount of the exercise price of the Series D Warrants issued on the Initial Closing Date to the market price of our Common Stock as of June 30, 2015: \$139,364

Series D Warrants Issued on July 2, 2015

| | |
|--|------------|
| Market price per share of our Common Stock on July 2, 2015, the date of the Second Closing: | \$0.23 |
| Exercise price per share of the Series D Warrants on the date of the Second Closing: | \$0.25 |
| Total possible shares of Common Stock underlying the Series D Warrants issued on the date of the Second Closing: | 454,387 |
| Aggregate market price of all shares of Common Stock underlying the Series D Warrants issued on the date of the Second Closing, based on the market price of our Common Stock on July 2, 2015: | \$ 104,509 |
| Aggregate exercise price of all shares of Common Stock underlying the Series D Warrants issued on the date of the Second Closing, based on the exercise price on the date of the Second Closing: | \$ 113,597 |

The net proceeds to us from the 2015 Private Placement Financing, after giving effect to legal and other expenses incurred through the date of this prospectus, were approximately \$3.0 million. The table below describes in more detail these costs associated with the 2015 Private Placement Financing through the date of this prospectus:

| | |
|--|---------------------|
| Gross proceeds of the 2015 Private Placement Financing: | \$ 3,166,000 (1) |
| Legal and other expenses incurred in connection with the 2015 Private Placement Financing: | \$ 150,000 (2) |
| Resulting net proceeds to the Company: | \$ 3,016,000 (3) |
| Total possible profit to be realized by the selling securityholders and/or their assignees as a result of any exercise discounts underlying the Series D Warrants: | \$ 139,364 (4) |

Does not include potential gross proceeds payable to us upon exercise of the Series D Warrants issued in the 2015 Private Placement Financing, which would equal approximately \$3,597,689 if all of the Series D Warrants were exercised on a cash basis on the date of this prospectus.

(2) This amount represents our legal, accounting, registration and other fees and expenses associated with the 2015 Private Placement Financing (collectively, “**Transaction Expenses**”), which were estimated to total \$150,000. This amount does not include additional payments that we may be required to make under certain circumstances but that are not currently determinable, including the following: (a) potential partial damages for failure to register and keep registered for the period specified in the 2015 Registration Rights Agreement the Common Stock issued in the 2015 Private Placement Financing or issuable upon exercise of the Series D Warrants (in a cash amount equal

to 1.5% of the price paid to us by each investor in the 2015 Private Placement Financing on the date of and on each 30-day anniversary of such failure until the cure thereof, with no quantitative cap to the aggregate amount of such); and (b) payments in respect of claims for which we provide indemnification in the 2015 Registration Rights Agreement. Although we intend to comply with the requirements of the Subscription Agreements and the 2015 Registration Rights Agreement and do not currently expect to make any such payments, it is possible that such payments may be required.

- (3) Calculated by subtracting Transaction Expenses from the gross proceeds to us from the 2015 Private Placement Financing.
- (4) Calculated by adding the total possible discount of the exercise prices of the Series D Warrants to the market price of our Common Stock as of June 30, 2015, as reflected in the tables set forth above.

Notes Offering

Beginning March 11, 2015 and through March 13, 2015, we entered into a series of substantially similar subscription agreements (each a “**Convertible Notes Subscription Agreement**”) with each of Anson, Equitec and Capital Ventures International (collectively, the “**Convertible Notes Investors**”) pursuant to which we issued unsecured 2016 8% Convertible Notes (the “**Convertible Notes**”, and such transaction, the “**Notes Offering**”) to the Convertible Notes Investors in the aggregate principal amount of \$750,000. On the Closing of the Notes Offering on March 13, 2015, each Convertible Notes Investor was issued a Convertible Note in the principal amount of \$250,000. As noted above, Anson and Intracoastal, or their respective affiliates, also purchased Units in the 2015 Private Placement Financing. We did not engage any underwriter or placement agent in connection with the Notes Offering.

On September 8, 2015, we, along with the current holders of the Convertible Notes, entered into a series of substantially similar subordination agreements with the Massachusetts Life Sciences Center (“**MLSC**” and such agreements, the “**Subordination Agreements**”), pursuant to which the holders of the Convertible Notes agreed to subordinate their right to payment under the Convertible Notes to MLSC’s right to receive payments under the MLSC Loan Agreement. Under the terms of the Subordination Agreements, the indebtedness accrued under the Convertible Notes may not be repaid unless and until all indebtedness and fees owed to MLSC under the MLSC Loan Agreement are repaid in full, but the right to convert the Convertible Notes into shares of Common Stock is expressly allowed.

Subject to the terms and conditions of the Subordination Agreements, the Convertible Notes issued in the Notes Offering become due and payable on March 13, 2016 (the “**Stated Maturity Date**”) and may not be prepaid. The Convertible 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 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 the Stated Maturity Date and may become due and payable upon the occurrence of an event of default under the Convertible Notes. In the event that the Stated Maturity Date occurs and repayment of the indebtedness accrued under the Convertible Notes is not permitted under the Subordination Agreements, (1) the term of the Convertible Notes and the holders’ rights to convert such Convertible Notes into shares of Common Stock will automatically be extended until repayment is permitted under the Subordination Agreements; and (2) interest will continue to accrue 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. The Convertible Notes contain customary events of default, which include, among other things, (i) our failure to pay other indebtedness of \$100,000 or more within the specified cure period for such breach; (ii) the acceleration of the stated maturity of such indebtedness; (iii) our insolvency; 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 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 (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 our Board, 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 Convertible 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.

2014 Private Placement Financing

On January 30, 2014, we entered into a securities purchase agreement (the “**Securities Purchase Agreement**”) with nine accredited investors (which included Anson and Equitec) providing for our issuance and sale to such investors, in a private placement, of an aggregate of 11,400,000 shares of our Common Stock at a purchase price of \$0.25 per share and 2014 Warrants, for aggregate gross proceeds to us of \$2.85 million (the “**2014 Private Placement Financing**”). The 2014 Private Placement Financing closed on February 4, 2014.

Upon the closing of the 2014 Private Placement Financing, we issued to each investor therein a Series A Warrant, a Series B Warrant and a Series C Warrant, each to purchase up to a number of shares of our Common Stock equal to 100% of the shares of Common Stock purchased by such investor in the 2014 Private Placement Financing. The Series A Warrants had an initial exercise price of \$0.30 per share, were exercisable immediately upon their issuance and have a term of exercise equal to five years after their issuance date. The Series B Warrants had an initial exercise price of \$0.35 per share, were exercisable immediately upon their issuance and had a term of exercise equal to the shorter of 12 months after their issuance date and six months after the first date on which the resale of all Registrable Securities (as defined in the Securities Purchase Agreement) is covered by one or more effective registration statements. The Series B Warrants expired on January 3, 2015. The Series C Warrants had an initial exercise price of \$0.40 per share, were exercisable immediately upon their issuance and had an initial term of exercise equal to the shorter of 18 months after their issuance date and nine months after the first date on which the resale of all Registrable Securities (as defined in the Securities Purchase Agreement) is covered by one or more effective registration statements. As described below, the term of the Series C Warrants has been extended to July 2, 2016. The number of shares of our Common Stock into which each of the 2014 Warrants is exercisable and the exercise price therefor were subject to adjustment as set forth in the 2014 Warrants, including, without limitation, adjustments in the event of certain subsequent issuances and sales of shares of our Common Stock (or securities convertible or exercisable into shares of our Common Stock) at a price per share lower than the then-effective exercise price of the 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 “**Anti-Dilution Provisions**”), as well as customary adjustments in the event of stock dividends and splits, subsequent rights offerings and pro rata distributions to our Common Stockholders. As described below, the outstanding 2014 Warrants were amended on June 22, 2015 to remove the Anti-Dilution Provisions. 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 2014 Warrant or any of its affiliates beneficially owning more than 4.9% of our Common Stock.

On December 1, 2014, we entered into an agreement with Cranshire Capital Master Fund, Ltd. (“**Cranshire**”) 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 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 our Common Stock which could be purchased upon exercise of each 2014 Warrant remained unchanged following the December 2014 Amendment.

As noted above, 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. Because the conversion price of the Convertible Notes on the date the Notes Offering closed (\$0.20 per share) was below the then current exercise price of the Series A Warrants, the issuance of the Convertible 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 (or fifty-percent (50%)) from 11,400,000 shares to 17,100,000 shares, in each case effective as of March 13, 2015.

On March 13, 2015 and May 30, 2015, we also entered into amendment agreements with Cranshire to extend the expiration date of the Series C Warrants to 5:00 p.m., New York time, on June 2, 2015, and 5:00 p.m., New York time, on July 2, 2015, respectively. On June 22, 2015, we entered into an additional amendment agreement with Cranshire pursuant to which to the Anti-Dilution Provisions contained in the Series A Warrants and Series C Warrants were removed in consideration for (a) further extending the expiration date of the Series C Warrants to 5:00 p.m., New York time, on July 2, 2016; and (b) agreeing to issue the holders of the Series A Warrants and Series C Warrants up to an additional 570,000 shares of Common Stock, subject to the delivery by each such holder of an investor certificate (such shares of Common Stock, the “**Inducement Shares**”). As of the date of this prospectus, all 570,000 Inducement Shares have been issued.

Also upon the closing of the 2014 Private Placement Financing, we entered into a registration rights agreement (the “**2014 Registration Rights Agreement**”) with the investors in such financing pursuant to which we became obligated to file with the SEC one or more registration statements to register for resale under the Securities Act the shares of Common Stock issued in and underlying the 2014 Warrants issued in the 2014 Private Placement Financing. As a result, we initially registered for resale under a registration statement on Form S-1 (File Number 333-194745, and such registration statement, the “**2014 Registration Statement**”) an aggregate of 45,600,000 shares of Common Stock, representing the 11,400,000 shares issued at the closing of the 2014 Private Placement Financing and the 34,200,000 shares underlying the 2014 Warrants upon the closing of the 2014 Private Placement Financing. Our failure to satisfy certain other deadlines with respect to the 2014 Registration Statement and certain other requirements set forth in the 2014 Registration Rights Agreement may require us to pay monetary penalties to the investors in the 2014 Private Placement Financing. Additionally, we may be required in the future to amend the 2014 Registration Statement or to file a new registration statement in order to register additional shares of our Common Stock for resale by the investors in the 2014 Private Placement Financing to account for adjustments, if any, to the number of shares underlying the 2014 Warrants including, but not limited to, the additional 5,700,000 shares that became exercisable under the Series

A Warrants as a result of the Notes Offering. Under the 2014 Registration Rights Agreement, subject to exception in certain circumstances, we have agreed to keep the 2014 Registration Statement effective until the earlier of the date on which all shares of Common Stock to be registered thereunder have been sold or may be sold without restriction pursuant to Rule 144 promulgated under the Securities Act (“**Rule 144**”). If there is not, at any time during the period required by the 2014 Registration Rights Agreement, an effective registration statement covering the resale of any of the shares issued in or issuable upon exercise of the 2014 Warrants issued in the 2014 Private Placement Financing, then the investors in the 2014 Private Placement Financing or their assignees (collectively, the “**2014 Investors**”) (i) will have “piggyback” registration rights with respect to any such shares that are not eligible for resale pursuant to Rule 144 in connection with any other registration statement we determine to file that would permit the inclusion of those shares; and (ii) will be entitled to exercise their 2014 Warrants on a “cashless exercise” or “net exercise” basis during the period when the shares issuable upon exercise of such 2014 Warrants are not so registered.

We did not engage any underwriter or placement agent in connection with the 2014 Private Placement Financing. We also did not make any payments, in cash or equity, to any of the selling securityholders in connection with the 2014 Private Placement Financing, except that we have reimbursed, or have agreed to reimburse, Cranshire, one of the investors in the 2014 Private Placement Financing, an aggregate cash amount of up to \$35,000 for costs and expenses incurred by it or its affiliates in connection with the transactions contemplated by the 2014 Private Placement Financing and the registration of the securities issued in the 2014 Private Placement Financing. After deducting for the expense reimbursement to Cranshire, the net proceeds to us from the 2014 Private Placement Financing on the date it closed were approximately \$2.815 million.

Corporate Information

We were incorporated under the laws of State of Nevada on September 16, 2009 as Almah, Inc. On May 10, 2013, we entered into an Agreement and Plan of Merger (the “**Merger Agreement**”) with ABS and Arch Acquisition Corporation, our wholly owned subsidiary formed for the purpose of the transaction, pursuant to which Arch Acquisition Corporation merged with and into ABS and ABS thereby became our wholly owned subsidiary (the “**Merger**”). The Merger closed on June 26, 2013. In contemplation of the Merger, we changed our name from Almah, Inc. to Arch Therapeutics, Inc. Our principal executive offices are located at 235 Walnut St., Suite 6, Framingham, Massachusetts 01702. The telephone number of our principal executive offices is (617) 431-2313. Our website address is <http://www.archtherapeutics.com>. We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this document.

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

Prior to the completion of the Merger, we were a “shell company” under applicable rules of the SEC, and had no or nominal assets or operations. Upon the closing of the Merger, we abandoned our prior business plan and began pursuing, as our sole business, our current business as a life science medical device company.

The Offering

This prospectus relates to the resale from time to time by the selling securityholders identified in this prospectus of up to 28,781,508 shares of our Common Stock issued or underlying the Series D Warrants issued in the 2015 Private Placement Financing. None of the shares to be registered hereby are being offered for sale by us.

Common stock outstanding prior to offering 108,169,804 (1)

Common stock offered by the selling securityholders 28,781,508 (2)

Common stock to be outstanding after the offering 122,560,558 (3)

Use of proceeds We will not receive any proceeds from the sale of Common Stock offered by the selling securityholders under this prospectus.

OTCQB symbol "ARTH"

Risk Factors See "Risk Factors" beginning on page 12 and other information in this prospectus for a discussion of the factors you should consider before you decide to invest in our Common Stock and warrants.

(1) As of October 15, 2015, includes an aggregate of 14,390,754 shares of our Common Stock issued to the selling securityholders in connection with the Closings conducted under the 2015 Private Placement Financing. Includes 19,307,272 shares of Common Stock held by our affiliates.

(2) Consists of: (a) 14,390,754 shares of Common Stock that were issued in connection with the Closings conducted under the 2015 Private Placement Financing; and (b) 14,390,754 shares of Common Stock issuable upon exercise of the Series D Warrants determined as if the Series D Warrants were exercised in full (without regard to any limitations on exercise contained therein).

(3) Assumes (a) no further adjustment to the number of shares underlying the Series D Warrants; and (b) the full exercise of the Series D Warrants held by the selling securityholders as of the date of this prospectus, which would result in the issuance of an aggregate of 14,390,754 shares of Common Stock. Excludes (i) 15,120,708 shares of Common Stock that are reserved for future issuance under our 2013 Stock Incentive Plan (the "2013 Plan"), of which 10,776,504 shares are subject to outstanding option awards granted under the 2013 Plan at exercise prices ranging from \$0.17 to \$0.40 per share and with a weighted average exercise price of \$0.30 per share; (ii) 145,985 shares of Common Stock issuable upon the exercise of outstanding warrants issued in connection with the MLSC

Loan, with an exercise price of \$0.274 per share (the “**MLSC Warrant**”), none of which are being registered pursuant to the registration statement of which this prospectus forms a part; (iii) 2,516,766 shares of Common Stock issuable upon the conversion of the Convertible Notes (assuming, in each case, that the remaining principal outstanding on the Convertible Notes and the accrued interest thereunder is converted into shares of our Common Stock on March 13, 2016, the Stated Maturity Date), none of which are being registered pursuant to the registration statement of which this prospectus forms a part; (iv) 3,400,000 shares of Common Stock issuable upon the exercise of the Series C Warrants, none of which are being registered pursuant to the registration statement of which this prospectus forms a part; and (v) 9,350,000 shares of Common Stock issuable upon the exercise of the Series A Warrants, none of which are being registered pursuant to the registration statement of which this prospectus forms a part.

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 May 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 May 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 MLSC, we will need to obtain additional financing on or prior to May 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;

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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; *provided, however*, that in the event that the repayment of the indebtedness accrued under the Convertible Notes is not permitted under the Subordination Agreements, (1) the term of the Convertible Notes and the holders' rights to convert such Convertible Notes into shares of Common Stock will automatically be extended until repayment is permitted under the Subordination Agreements; and (2) interest will continue to accrue 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.

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.