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**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.

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. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

**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 May 5, 2014**

**ARCH THERAPEUTICS, INC.**

**PROSPECTUS**

**Up to 60,648,000 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 60,648,000 shares of common stock, par value \$0.001 per share. These shares include 11,400,000 issued and outstanding shares of common stock, 11,400,000 shares of common stock currently underlying Series A warrants, 11,400,000 shares of common stock currently underlying Series B warrants and 11,400,000 shares of common stock currently underlying Series C warrants, all issued and sold in a private placement offering completed in February 4, 2014 (the "Private Placement Financing"), as well as such number of additional shares of common stock to register an aggregate of 133% of the total number of shares issued and currently underlying warrants issued in the Private Placement Financing. The common stock sold in the Private Placement Financing was sold at a purchase price of \$0.25 per share, and the related warrants authorize the holders thereof to purchase shares of common stock at an exercise price of \$0.30 per share for the Series A warrants, which are exercisable immediately upon issuance and expire five years thereafter; \$0.35 per share for the Series B warrants, which are exercisable immediately upon issuance and expire on the earlier of 12 months thereafter and six months after the effective date of this registration statement; and \$0.40 per share for the Series C warrants, which are exercisable immediately upon issuance and expire on the earlier of 18 months thereafter and nine months after the effective date of this registration statement, all as further described in this prospectus.

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 sale 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 May 1, 2014, the closing price of our common stock was \$0.28 per share.

We originally offered and sold the securities issued in the 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 and Rule 506 of Regulation D promulgated thereunder.

**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 “Risk Factors” beginning on page 9 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           , 2014**

**TABLE OF cONtENTS**

|   |            |
|---|------------|
| <b>SUMMARY</b>  | <b>3</b>   |
| <b>RISK FACTORS</b>   | <b>9</b>   |
| <b>Forward-Looking Statements</b>   | <b>25</b>  |
| <b>Selling SECURITYholders</b>  | <b>26</b>  |
| <b>Determination of Offering Price</b>  | <b>30</b>  |
| <b>PLAN OF DISTRIBUTION</b>   | <b>30</b>  |
| <b>Use of Proceeds</b>  | <b>32</b>  |
| <b>DESCRIPTION OF SECURITIES</b>  | <b>32</b>  |
| <b>MARKET PRICE OF AND DIVIDENDS ON COMMON STOCK AND RELATED MATTERS</b>                              | <b>37</b>  |
| <b>MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</b>          | <b>39</b>  |
| <b>our BUSINESS</b>   | <b>50</b>  |
| <b>DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</b>   | <b>62</b>  |
| <b>EXECUTIVE COMPENSATION</b>   | <b>64</b>  |
| <b>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</b>                      | <b>68</b>  |
| <b>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</b> | <b>69</b>  |
| <b>LEGAL MATTERS</b>  | <b>70</b>  |
| <b>EXPERTS</b>  | <b>70</b>  |
| <b>WHERE YOU CAN FIND MORE INFORMATION</b>  | <b>71</b>  |
| <b>CONSOLIDATED FINANCIAL STATEMENTS</b>  | <b>F-1</b> |

**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”, and “our” 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.

We have pending trademark applications for 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, the risks of purchasing our common stock discussed in this prospectus under “Risk Factors” beginning on page 9 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 “hemostasis”), controls leaking (referenced as “sealant”), 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, 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 currently have no products that have obtained marketing approval in any jurisdiction, we have not generated revenues since inception and 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, 2013 and for the three months ended December 31, 2013 of \$1,853,791, \$808,441, respectively, and we had an accumulated deficit as of September 30, 2013 of \$4,631,871. To date, we have financed our operations primarily through funding received from private placement equity offerings, such as the Private Placement Financing, and under a loan agreement. 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 “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 8 of this prospectus.

### **Private Placement Financing**

On January 30, 2014, we entered into a securities purchase agreement (the “Securities Purchase Agreement”) with nine accredited investors 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 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 our common stock (collectively, the “Warrants”), for aggregate gross proceeds to us of \$2.85 million (the “Private Placement Financing”). The Private Placement Financing closed on February 4, 2014.

Upon the closing of the 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 Private Placement Financing. The Series A warrants have an exercise price of \$0.30 per share, are exercisable immediately upon their issuance and have a term of exercise equal to five years after their issuance date. The Series B warrants have an exercise price of \$0.35 per share, are exercisable immediately upon their issuance and have 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 C warrants have an exercise price of \$0.40 per share, are exercisable immediately upon their issuance and have a 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. The number of shares of our common stock into which each of the Warrants is exercisable and the exercise price therefor are subject to adjustment as set forth in the Warrants, including, without limitation, adjustment to the exercise price of the Warrants 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 Warrants, in which case the exercise price of the Warrants will be adjusted to equal such lower price per share, as well as customary adjustments in the event of stock dividends and splits, subsequent rights offerings and pro rata distributions to our common stockholders. The 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.

Also upon the closing of the Private Placement Financing, we entered into a registration rights agreement (the "Registration Rights Agreement") with the investors in the financing, pursuant to which we became obligated to file with the Securities and Exchange Commission (the "SEC") on or before March 21, 2014 one or more registration statements to register for resale under the Securities Act (i) the shares of common stock issued and underlying the Warrants issued in the Private Placement Financing, plus (ii) an additional number of shares of common stock equal to 33% of the total number of shares of common stock issued and underlying the Warrants issued in the Private Placement Financing, to account for adjustments, if any, to the number of shares underlying the Warrants as provided therein and as described above. As a result, we are registering for resale under this registration statement the 45,600,000 shares of common stock issued and underlying the Warrants issued in the Private Placement Financing, together with an additional 15,048,000 shares of common stock that may never become issuable by us if no such adjustments occur. Pursuant to our filing of this registration statement, we are in compliance with such filing obligation under the registration rights agreement. Our failure to satisfy certain other deadlines with respect to this registration statement, including with respect to the effectiveness hereof, and certain other requirements set forth in the registration rights agreement may require us to pay monetary penalties.

Under the 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 or may be sold without restriction pursuant to Rule 144 promulgated under the Securities Act ("Rule 144"). If there is not an effective registration statement covering the resale of any of the shares to be registered hereunder at any time during the period required by the Registration Rights Agreement, then the selling securityholders 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.

The terms of the Securities Purchase Agreement we entered into with the investors in the Private Placement Financing provide that, among other things: during the period commencing on January 30, 2014 and ending on the 90-day anniversary of the first date on which all the Registrable Securities (as defined in the Securities Purchase Agreement) are covered by one or more effective registration statements, we may not offer, sell or issue any securities, except for equity awards granted to service providers and securities issued in connection with certain types of strategic transactions; during the period commencing on January 30, 2014 and ending on the six-month anniversary of the first date on which all the Registrable Securities (as defined in the Securities Purchase Agreement) are covered by one or more effective registration statements, such investors shall have certain notice and participation rights with respect to offers and sales of securities that we may pursue; and until the earlier of the 12-month anniversary of the first date on which all the Registrable Securities (as defined in the Securities Purchase Agreement) are covered by one or more effective registration statements and the date on which all such investors have sold all of the shares of common stock to be registered hereunder, we may not effect or enter into an agreement for the issuance and sale of securities at a future-determined price or with a conversion or exercise price that varies with the trading price of our common stock or is subject to reset following the date of such issuance. In addition, the Securities Purchase Agreement contains provisions that would obligate us to make certain payments to the investors thereunder if we or our transfer agent were to fail to timely remove certain restrictive legends from certificates representing the shares of common stock being offered hereby following the eligibility of such shares for resale under this registration statement or Rule 144.

On the date of our entry into the Securities Purchase Agreement, the Series A warrants and Series B warrants had an exercise price lower than the market value of our common stock, which closed at \$0.38 on the OTCQB, resulting in an aggregate discount to the market price of our common stock of \$912,000 for the Series A warrants and \$342,000 for the Series B warrants on that date. The Series C warrants were issued with an exercise price higher than the market value of our common stock on the date of our entry into the Securities Purchase Agreement, 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 January 30, 2014 for the shares of our common stock underlying the Series A warrants and the Series B warrants, as well as similar information for the Series C warrants. The last trading price of our common stock on the OTCQB on February 4, 2014, the date of the closing of the Private Placement Financing, was \$0.30. As a result, as of such date, there was no discount to the market price of our common stock for the Series A warrants, Series B warrants or Series C warrants. Additionally, all of the Warrants have an exercise price that is higher than the closing price of our common stock on May 1, 2014, which closed at \$0.28 on such date.

#### Series A Warrants

|   |             |
|---|-------------|
| Market price per share of our common stock on January 30, 2014, the date of the Securities Purchase Agreement:  | \$0.38      |
| Exercise price per share of the Series A warrants on the date of issuance and as of the date of this prospectus:  | \$0.30      |
| Total possible shares of common stock underlying the Series A warrants on the date of issuance and as of the date of this prospectus:   | 11,400,000  |
| Aggregate market price of all shares of common stock underlying the Series A warrants, based on the market price of our common stock on January 30, 2014:                           | \$4,332,000 |
| Aggregate exercise price of all shares of common stock underlying the Series A warrants, based on the exercise price on the date of issuance and as of the date of this prospectus: | \$3,420,000 |
| Total possible discount of the exercise price of the Series A warrants to the market price of our common stock as of January 30, 2014:  | \$912,000   |

#### Series B Warrants

|  |         |
|--|---------|
| Market price per share of our common stock on January 30, 2014, the date of the Securities Purchase Agreement:   | \$ 0.38 |
| Exercise price per share of the Series B warrants on the date of issuance and as of the date of this prospectus: | \$ 0.35 |

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|   |              |
|---|--------------|
| Total possible shares of common stock underlying the Series B warrants on the date of issuance and as of the date of this prospectus:   | 11,400,000   |
| Aggregate market price of all shares of common stock underlying the Series B warrants, based on the market price of our common stock on January 30, 2014:                           | \$ 4,332,000 |
| Aggregate exercise price of all shares of common stock underlying the Series B warrants, based on the exercise price on the date of issuance and as of the date of this prospectus: | \$ 3,990,000 |
| Total possible discount of the exercise price of the Series B warrants to the market price of our common stock as of January 30, 2014:  | \$ 342,000   |

Series C Warrants

|   |              |
|---|--------------|
| Market price per share of our common stock on January 30, 2014, the date of the Securities Purchase Agreement:  | \$ 0.38      |
| Exercise price per share of the Series B warrants on the date of issuance and as of the date of this prospectus:  | \$ 0.40      |
| Total possible shares of common stock underlying the Series C warrants on the date of issuance and as of the date of this prospectus:   | 11,400,000   |
| Aggregate market price of all shares of common stock underlying the Series C warrants, based on the market price of our common stock on January 30, 2014:                           | \$ 4,332,000 |
| Aggregate exercise price of all shares of common stock underlying the Series C warrants, based on the exercise price on the date of issuance and as of the date of this prospectus: | \$ 4,560,000 |

We did not engage any underwriter or placement agent in connection with the Private Placement Financing. We also have made no payments, in cash or equity, to any of the selling securityholders in connection with this offering, except that we have reimbursed, or have agreed to reimburse, Cranshire Capital Master Fund, Ltd. (“Cranshire Master Fund”), one of the selling securityholders named herein, 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 Private Placement Financing and the registration of the securities being registered hereby.

After deducting for the expense reimbursement to Cranshire Master Fund, the net proceeds to us from the Private Placement Financing were approximately \$2.815 million. The table below describes in more detail these costs associated with the Private Placement Financing:

|   |                  |
|---|------------------|
| Gross proceeds of the Private Placement Financing:  | \$ 2,850,000 (1) |
| Total potential payment to Cranshire Master Fund as expense reimbursement:  | \$ 35,000 (2)    |
| Resulting net proceeds to the Company:  | \$ 2,815,000 (3) |
| Total possible profit to be realized by the selling securityholders as a result of any exercise discounts underlying the Series A warrants and the Series B warrants: | \$ 1,254,000 (4) |

(1)

Does not include the potential gross proceeds payable to us upon exercise of the Warrants issued in connection with the Private Placement Financing, which could equal up to \$11,970,000.

- This amount includes \$25,000 that was withheld from the purchase price paid to us by Cranshire Master Fund for the securities it purchased in the Private Placement Financing, and up to \$10,000 that we have agreed to pay to Cranshire Master Fund as additional expense reimbursement. This amount does not include our fees and expenses associated with the Private Placement Financing, including our legal fees and registration fees, estimated to total \$188,047. This amount also does not include additional payments that we may be required to make under certain circumstances but that are not currently determinable, including (a) potential partial damages for failure to register the common stock issued or issuable upon exercise of the Warrants (in a cash amount equal to 1% of the price paid to us by each investor in the Private Placement Financing on the date of and on each 30-day anniversary of such failure until the cure thereof); (b) amounts payable if we and our transfer agent fail to timely remove certain restrictive legends from certificates representing shares of common stock issued in the Private Placement Financing or issuable upon exercise of the Warrants; and (c) payments in respect of claims for which we provide indemnification.
- (2)
- (3) Calculated by subtracting the total possible and currently determinable cash payments to selling securityholders or their affiliates from the gross proceeds to us from the Private Placement Financing.
- (4) Calculated by adding the total possible discount of the exercise prices of the Series A warrants and the Series B warrants to the market price of our common stock as of January 30, 2014, as reflected in the tables set forth above.

## 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 Arch Biosurgery, Inc. (“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 20 William St., Suite #270, Wellesley, Massachusetts 02481. The telephone number of our principal executive offices is (617) 475-5254. 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 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 60,648,000 shares of our common stock issued or underlying the Warrants issued in the Private Placement Financing. None of the shares to be registered hereby are being offered for sale by us.

|   |   |
|---|---|
| Common stock outstanding prior to offering          | 72,076,487 (1)  |
| Common stock offered by the selling securityholders | 45,600,000 (2)  |
| Common stock to be outstanding after the offering   | 106,276,487 (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 9 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 May 1, 2014. Includes 11,400,000 shares of our common stock issued to the selling securityholders in the Private Placement Financing. Includes 18,637,849 shares of common stock held by our affiliates.

(2) Consists of: (a) 11,400,000 issued and outstanding shares of common stock, (b) an aggregate of 34,200,000 shares of common stock issuable upon exercise of the Warrants as of the date of this prospectus, and (c) an additional 15,048,000 shares of common stock being registered hereunder to account for adjustments, if any, to the number of shares underlying the Warrants. We may not be required to make any such adjustment to the number of shares underlying the Warrants and, as a result, such additional shares may never become issuable by us.

(3) Assumes (a) no adjustments to the number of shares underlying the Warrants, and (b) the full exercise of the Warrants, resulting in the issuance of 34,200,000 shares of common stock. Excludes (a) 10,231,197 shares of common stock that are reserved for future issuance under our 2013 Stock Incentive Plan (the “2013 Plan”), of which 6,869,212 shares are subject to outstanding option awards granted under the 2013 Plan at exercise prices ranging from \$0.19 to \$0.40 per share and with a weighted average exercise price of \$0.37 per share, and (b) 4,145,985 shares of common stock issuable upon the exercise of outstanding warrants issued in transactions unrelated to the Private Placement

Financing, with exercise prices ranging from \$0.274 to \$0.75 per share, 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**

*We have incurred significant losses since inception. We expect to continue to incur losses for the foreseeable future as we pursue our operations as a combined enterprise, and we may never generate revenue or achieve or maintain profitability.*

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 pertaining to the closing of the Merger and related regulatory filings, 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;
- hire additional regulatory, clinical, quality control, scientific, financial, and management consultants and personnel;
- and
- support and add operational, financial, accounting, facilities engineering and information systems consultants and personnel to further our operations.

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 the earliest 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 decline in the prices of our common stock could cause our stockholders to lose all or a part of their investment in the Company.

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

We have not generated any revenue from operations since inception, and we have incurred substantial net losses to date. Further, our operating expenses will likely increase in the foreseeable future, as we seek to increase operations as a life sciences medical device company. 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.

*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 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 additional investment before it could potentially be commercialized. We anticipate that none of our product candidates will be commercially available for several years, if at all.

We believe that our current cash and cash equivalents on hand will be sufficient to meet our anticipated cash requirements through October 2014; however, based on our current operating expenses and working capital requirements, we do not currently believe our existing cash resources are sufficient to meet our anticipated needs for the next twelve months. In addition to the funds raised from our equity financings and debt financings, 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 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, and that we will need to raise significant additional funds to continue operations. 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, results, costs, timing and outcomes of any 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, investor relations, and corporate communications;
- the costs of additional general and administrative personnel, including accounting and finance, legal and human resources employees; and
- operating revenues, if any, received from sales of our product candidates, if any are approved by the FDA or other applicable regulatory agencies.

As a result of these and other factors, we expect that we will need substantial additional funding in the future. We would likely seek such funding through public or private securities offerings, incurrence of indebtedness, or some combination of those sources. We may also seek funding through collaborative arrangements 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. Additional funding may not be available from any of these sources when needed on acceptable terms, or at all. In addition, 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 restrictions in our loan agreement on our ability to incur certain types of additional indebtedness, discussed in further detail in these Risk Factors below, and certain terms of the Private Placement Financing, including those discussed in these Risk Factors below. These restrictions and provisions could make it more challenging for us to raise capital through the incurrence of additional debt or through future equity issuances. Further, if we do raise capital through the sale of equity, or securities convertible into equity, the ownership of our then existing stockholders would be diluted, which dilution could be significant depending on the price at which we may be able to sell our securities. Also, if we raise additional capital through the incurrence of indebtedness, we may become subject to additional covenants restricting our business activities, and the holders of debt instruments may have rights and privileges senior to those of our equity investors. In addition, servicing the interest and principal repayment obligations under debt facilities could divert funds that would otherwise be available to support research and development, clinical or commercialization activities.

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

***The terms of the Private Placement Financing could impose additional challenges on our ability to raise funding in the future.***

The Securities Purchase Agreement related to the Private Placement Financing imposes certain restrictions on our ability to issue equity or debt securities, including the following: during the period commencing on January 30, 2014 and ending on the 90-day anniversary of the first date on which all the Registrable Securities (as defined in the Securities Purchase Agreement) are covered by one or more effective registration statements, we may not offer, sell or issue any securities, except for equity awards granted to service providers and securities issued in connection with certain types of strategic transactions; during the period commencing on January 30, 2014 and ending on the six-month anniversary of the first date on which all the Registrable Securities (as defined in the Securities Purchase Agreement) are covered by one or more effective registration statements, such investors shall have certain notice and participation rights with respect to offers and sales of securities that we may pursue; and until the earlier of the 12-month anniversary of the first date on which all the Registrable Securities (as defined in the Securities Purchase Agreement) are covered by one or more effective registration statements and the date on which all such investors have sold all of the shares of common stock to be registered hereunder, we may not effect or enter into an agreement for and VRT, where a “VRT” is a transaction in which we (i) issue convertible securities at (A) a conversion, exercise or exchange rate or other price that is based upon and/or varies with the trading prices of, or quotations for, the shares of our common stock at any time after the initial issuance of such convertible securities, or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such convertible securities or upon the occurrence of specified or contingent events directly or indirectly related to our business or the market for the common stock, other than pursuant to a customary “weighted average” anti-dilution provision or (ii) enter into any agreement whereby we or any subsidiary may sell securities at a future determined price. In addition, the Warrants contain certain anti-dilution protections that adjust downward the exercise price of the Warrants in the event we offer, sell and issue securities at a lower consideration price per share than the then-effective exercise price of the Warrants. Those provisions could make our securities less attractive to investors and could limit our ability to obtain adequate financing on a timely basis or on acceptable terms in the future, which could have harmful effects on our financial condition and operations. Additionally, certain of those provisions could dilute the ownership interests of our other current common stockholders.

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

On September 30, 2013, we entered into the Life Sciences Accelerator Funding Agreement (the “MLSC Loan Agreement”) with the Massachusetts Life Sciences Center (“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 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 the 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 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 Dr. 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 statements.***

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”). Management has identified material weaknesses in our internal control over financial reporting as of December 31, 2013. A material weakness 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 that our internal control over financial reporting was not effective based on criteria set forth by the Committee of Sponsoring Organization of the Treadway Commission in 2013 Internal Control—Integrated Framework. We have developed proposed actions aimed at remediating some of these material weaknesses. If our remedial measures are insufficient to address the material weaknesses, 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. If that were to occur, we could be required to restate our financial results, which could lead to substantial additional costs for accounting and legal fees and litigation. In addition, even if we are successful in strengthening our controls and procedures, in the future 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 may 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, or the market price of our stock could decline significantly. Moreover, our reputation with lenders, investors, securities analysts and others may be adversely affected.

*We may become involved in litigation and administrative proceedings that may materially affect us.*

From time to time, we may become involved in various legal proceedings relating to matters incidental to the ordinary course of our business, including commercial, employment, class action, whistleblower and other litigation and claims, and governmental and other regulatory investigations and proceedings. Such matters can be time-consuming, divert management's attention and resources and cause us to incur significant expenses. Furthermore, because litigation is inherently unpredictable, there can be no assurance that the results of any of these actions will not have a material adverse effect on our business, results of operations or financial condition.

*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 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 which 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.

***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 we or our contractors 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. However, the FDA and other applicable foreign agencies 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 othe