Arch Therapeutics, Inc.
Form S-1
March 21, 2014

No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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)

20 William St., Suite 270

Wellesley, MA 02481

(617) 475-5254

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

Terrence W. Norchi

President and Chief Executive Officer

20 William St., Suite 270

Wellesley, MA 02481

(617) 475-5254

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

With Copies to:

Steven G. Rowles, Esq.

Morrison & Foerster LLP

12531 High Bluff Drive, Suite 100

San Diego, California 92130

(858) 720-5100

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

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. o

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. o

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. o

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

CALCULATION OF REGISTRATION FEE

Title of securities to be registered	Amount to be registered (1)	Proposed maximum offering price per share (2)	Proposed maximum aggregate offering price (2)	Amount of registration fee
Common Stock, par value $0.001 per share	60,648,000	$ 0.39	$ 23,652,720	$ 3,047

(1) Consists of 11,400,000 shares of common stock, an aggregate of 34,200,000 shares of common stock currently issuable upon the exercise of certain warrants, and an additional 15,048,000 shares of common stock that may become issuable upon exercise of such warrants pursuant to certain adjustment provisions therein. Pursuant to Rule 416 under the Securities Act of 1933, as amended, there is also being registered hereby such indeterminate number of additional shares of common stock of Arch Therapeutics, Inc. as may be issued or issuable because of stock splits, stock dividends, stock distributions, and similar transactions.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, as amended, and based on the average of the high and low bid prices of our common stock on March 17, 2014 as reported by on the QB tier of the OTC Marketplace.

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 MARCH 21, 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 March 20, 2014, the closing price of our common stock was $0.36 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 8 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

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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 8 of this prospectus and our 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”). We did not engage any underwriter or placement agent in connection with 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 such 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 effective date of the registration statement of which this prospectus forms a part. 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 effective date of the registration statement of which this prospectus forms a part. 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 shall 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 with the investors in such 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 provide for potential adjustments to the number of shares underlying the Warrants as provided therein. As a result, we are registering for resale under this registration statement the 45,600,000 shares of common stock issued or 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 for an aggregate discount to our market price of $912,000 for the Series A warrants and $342,000 for the Series B warrants on that date. The total value of the common stock underlying the Series A warrants and the Series B warrants, based on the exercise prices thereunder as of January 30, 2014, was $3,420,000 and $3,990,000, respectively. 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. 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 or the Series B warrants. Additionally, there was no discount to the market price as of January 30, 2014 or as of February 4, 2014 for the shares of our common stock underlying the Series C warrants.

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
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
	$4,332,000

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:	
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

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.

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	71,776,487 (1)
Common stock offered by the selling securityholders	60,648,000 (2)
Common stock to be outstanding after the offering	105,976,487 (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 7 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 March 20, 2014. Includes 11,400,000 shares of our common stock issued to the selling securityholders in the Private Placement Financing. Includes 15,968,480 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 5,447,962 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. The risk factors described below summarize some of the material risks inherent in and affecting our business. 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;
- 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 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.

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 other than a medical device, such as a drug or biologic, or impose additional requirements on our pre-clinical and clinical development than we presently anticipate, financing needs would increase, the timeline for product approval would lengthen, the program complexity and resource requirements world increase, and the probability of successfully commercializing a product would decrease. Any or all of those circumstances would materially adversely affect our business.

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

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

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

Clinical trials are lengthy, complex and extremely expensive processes with uncertain expenditures and results and frequent failures. Any clinical trials that are planned or which commence for any of our product candidates could be delayed, limited or fail for a number of reasons, including if:

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

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

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

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

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

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

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

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

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

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

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

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

regulatory requirements, may result in consequences to us such as:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

financial condition and operational results.

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

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

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

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

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

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

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

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

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

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

Risks Related to our Intellectual Property

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

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

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

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

We have entered into certain in-license agreements with MIT and with certain other third parties, and may seek to enter into additional in-license agreements relating to other intellectual property rights in the future. To the extent we

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

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

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

Risks Related to the Merger and Ownership of our Common Stock

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

There currently is a limited market for our common stock. Although our common stock is quoted on the OTCQB, an over-the-counter quotation system, trading of our common stock is extremely limited and sporadic and generally at very low volumes. Further, the price at which our common stock may trade is volatile and we expect that it will

continue to fluctuate significantly in response to various factors, many of which are beyond our control. The stock market in general, and securities of small-cap companies driven by novel technologies in particular, has experienced extreme price and volume fluctuations in recent years. Continued market fluctuations could result in further volatility in the price at which our common stock may trade, which could cause its value to decline. To the extent we seek to raise capital in the future through the issuance of equity, those efforts could be limited or hindered by low and/or volatile market prices for our common stock.

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

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

Our common stock is a "penny stock."

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

If we issue additional shares in the future, our existing shareholders will be diluted.

Our articles of incorporation authorize the issuance of up to 300,000,000 shares of common stock. Upon the closing of the Private Placement Financing, we issued an aggregate of 11,400,000 shares of our common stock, which equals approximately 16% of our currently issued and outstanding common stock. Upon the closing of the Private Placement Financing, we also issued Warrants to acquire up to an additional 34,200,000 shares of our common stock, which, assuming no adjustments to and the full exercise of the Warrants and no other issuances of our common stock, would equal approximately 32% of our then-issued and outstanding common stock. In addition to capital raising activities, other possible business and financial uses for our authorized common stock include, without limitation, future stock splits, acquiring other companies, businesses or products in exchange for shares of common stock, issuing shares of our common stock to partners in connection with strategic alliances, attracting and retaining employees by the issuance of additional securities under our various equity compensation plans, or other transactions and corporate purposes that our Board of Directors deems are in the Company's best interest. Additionally, shares of common stock could be used for anti-takeover purposes or to delay or prevent changes in control or management of the Company. We cannot provide assurances that any issuances of common stock will be consummated on favorable terms or at all, that they will enhance stockholder value, or that they will not adversely affect our business or the trading price of our common stock. The issuance of any such shares will reduce the book value per share and may contribute to a

reduction in the market price of the outstanding shares of our common stock. If we issue any such additional shares, such issuance will reduce the proportionate ownership and voting power of all current shareholders. Further, such issuance may result in a change of control of our corporation.

Certain terms of the Warrants could result in additional dilution to our existing stockholders.

The number of shares of our common stock into which each of the Warrants issued in connection with the Private Placement Financing 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 shall 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. In the event any such adjustment is triggered, the Warrants could become exercisable for a greater number of shares of our common stock and thereby dilute the ownership of our other stockholders if those Warrants are exercised. Depending on the terms of any subsequent issuance of securities or other circumstance that might trigger such an adjustment and the number of Warrants that are exercised, the amount of any such dilution could be significant.

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

After giving effect to the funds raised in the Private Placement Financing, we expect that significant additional capital will be needed in the near-term to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. Any such sales of our common stock by us or resales of our common stock by our existing stockholders could cause the market price of our common stock to decline.

Upon the effectiveness of the registration statement of which this prospectus forms a part, approximately 16% of our currently issued and outstanding common stock will become registered and freely tradable, and, assuming no adjustments to and the full exercise of the Warrants and no other issuances of our common stock, up to 32% of our then-issued and outstanding common stock would become registered and freely tradable. The sales of such shares in the market, or the perception that such sales could occur following the effectiveness of the registration statement of which this prospectus forms a part, could cause our stock price to fall. Additionally, pursuant to the 2013 Plan, we are authorized to grant equity awards to our employees, directors and consultants for up to an aggregate of 10,231,197 shares of our common stock, and there are additional currently outstanding warrants to acquire up to 4,145,985 shares of our common stock. Any future grants of options, warrants or other securities exercisable or convertible into our common stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our common stock.

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

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

There may be additional risks because we recently completed a reverse merger transaction.

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

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

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

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

Certain of our directors and executive officers own a significant percentage of our outstanding capital stock. Dr. Terrence W. Norchi, our President, Chief Executive Officer and a director, and Dr. Avtar Dhillon, the Chairman of our Board of Directors, collectively hold or control approximately 25% of our outstanding shares of common stock. Accordingly, these members of our Board of Directors and management team have substantial voting power to approve matters requiring stockholder approval, including without limitation the election of directors, and have significant influence over our affairs. This concentration of ownership could have the effect of delaying or preventing a change in control of our Company, even if such a change in control would be beneficial to our stockholders.

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

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

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

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

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

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Shares of our common stock that have not been registered under federal securities laws are subject to resale restrictions imposed by Rule 144, including those set forth in Rule 144(i) which apply to a former "shell company." In addition, any shares of our common stock that are held by affiliates, including any that are registered, will be subject to the resale restrictions of Rule 144.

Pursuant to Rule 144 under the Securities Act, a "shell company" is defined as a company that has no or nominal operations and either no or nominal assets; assets consisting solely of cash and cash equivalents; or assets consisting of any amount of cash and cash equivalents and nominal other assets. We were a shell company prior to the closing of the Merger, and as such, sales of our securities pursuant to Rule 144 are not permitted until at least 12 months have elapsed since June 26, 2013, the date on which our Current Report on Form 8-K, reflecting our status as a non-shell company, was filed with the SEC. Therefore, any outstanding restricted securities or any restricted securities we may sell in the future or issue to consultants or employees in consideration for services rendered or for any other purpose will have limited liquidity unless and until such securities are registered under the Securities Act and/or until at least June 26, 2014. Rule 144 also imposes other requirements on us and our stockholders that must be met in order to effect a sale thereunder. As a result, it will be more difficult for us to raise funding to support our operations through the sale of debt or equity securities unless we agree to register such securities under the Securities Act, which could cause us to expend significant additional time and cash resources and which we presently have no intention to pursue. Further, it may be more difficult for us to compensate our employees and consultants with our securities instead of cash. Our previous status as a shell company could also limit our use of our securities to pay for any acquisitions we may seek to pursue in the future (although none are currently planned), and could cause the value of our securities to decline. In addition, any shares held by affiliates, including shares received in any registered offering, will be subject to certain additional requirements in order to effect a sale of such shares under Rule 144.

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

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

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

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

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Forward-Looking Statements

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

- Our ability to continue as a going concern;
- Our ability to obtain financing necessary to operate our business;
- Our limited operating history;
- The results of our research and development activities, including uncertainties relating to the preclinical and clinical testing of our product candidates;
- The early stage of our primary product candidate presently under development;
- Our ability to develop, obtain required approvals for and commercialize our product candidates;
- Our ability to recruit and retain qualified personnel;
- Our ability to manage any future growth we may experience;
- Our ability to maintain and protect our intellectual property;
- Our dependence on third party manufacturers, suppliers, research organizations, testing laboratories and other potential collaborators;

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

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

- Competition in our industry;

- General economic and business conditions; and

- Other factors discussed under the section entitled “Risk Factors”.

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

Selling SECURITYholders

This prospectus covers the resale from time to time by the selling securityholders identified in the table below of up to an aggregate of 60,648,000 shares of our common stock, 11,400,000 of which were previously issued to the selling securityholders and 49,248,000 of which may be issuable upon exercise of the Series A warrants, Series B warrants and Series C warrants. The shares of common stock being offered by the selling securityholders and the Warrants, in each case, were issued to the selling securityholders in the Private Placement Financing. For additional information regarding the issuance of the shares of common stock and the Warrants, see the description under "Summary—Private Placement Financing" in this prospectus.

We are registering the shares of common stock pursuant to the terms of the registration rights agreement among us and the holders of the common stock and Warrants issued in the Private Placement Financing, in order to permit the selling securityholders identified in the table below to offer the shares for resale from time to time. In accordance with the terms of the registration rights agreement, this prospectus generally covers the resale of 133% of the sum of (i) the shares of common stock issued to the selling securityholders and (ii) the maximum number of shares of common stock issuable upon exercise of the Warrants determined as if the outstanding Warrants were exercised in full (without regard to any limitations on exercise contained therein) as of the trading day immediately preceding the date this registration statement was initially filed with the SEC. Because the exercise price of the Warrants is subject to anti-dilution and other adjustments as set forth therein and as further described elsewhere in this prospectus, the number of shares that will actually be issued may be more or less than the number of shares being offered by this prospectus. The Warrants issued in the Private Placement Financing also provide that a selling securityholder may not exercise its Warrants to the extent (but only to the extent) such selling securityholder or any of its affiliates would beneficially own a number of shares of our common stock which would exceed 4.9%. The number of shares to be registered by this prospectus generally does not take into account any such ownership limitation.

The table below has been prepared based upon information furnished to us by the selling securityholders as of as of February 4, 2014, or such other date as may be referenced in the table below and the related footnotes. The selling securityholders may sell all, some or none of their shares in this offering. See the disclosure under the heading "Plan of Distribution" elsewhere in this prospectus. The selling securityholders identified in the table below may have sold, transferred or otherwise disposed of some or all of their shares since the date on which the information in the following table is presented in transactions exempt from or not subject to the registration requirements of the Securities Act. Information concerning the selling securityholders may change from time to time and, if necessary, we will amend or supplement this prospectus accordingly and as required.

The table below lists the selling securityholders and other information regarding the beneficial ownership (as determined under Section 13(d) of the Exchange Act, and the rules and regulations thereunder) of our common stock by each of the selling securityholders. The second column of the table below lists the number of shares of common stock beneficially owned by the selling securityholders, based on their respective ownership of shares of common stock and Warrants as of the date presented. The third column of the table below lists the shares of common stock being offered by this prospectus by the selling securityholders and does not take into account the ownership

limitations on exercise of the Warrants set forth therein. The fourth column of the table below reflects the shares owned by each selling securityholder after completion of this offering, assuming the sale of all of the shares offered by the selling securityholders pursuant to this prospectus. The fifth column of the table below reflects the percentage of our common stock beneficially owned by each selling securityholder after completion of this offering, assuming the sale of all of the shares offered by such selling securityholder pursuant to this prospectus.

Name of Selling Securityholder	Number of Shares of Common Stock Beneficially Owned Prior to this Offering (1)	Maximum Number of Shares of Common Stock to be Sold Pursuant to this Prospectus (2)	Number of Shares of Common Stock Owned After This Offering (3)	Percentage of Shares of Common Stock Beneficially Owned After This Offering (4)	
Cranshire Capital Master Fund, Ltd. (5)	3,200,000	12,800,000	—	—	
Equitec Specialists, LLC (6)	800,000	3,200,000	—	—	
Anson Investments Master Fund, Ltd. (7)	3,517,047	8,000,000	—	—	
Capital Ventures International (8)	3,517,047	8,000,000	—	—	
Heng Hong Ltd (9)	3,517,047	8,400,000	—	—	
Punit Dhillon (10)	3,517,047	2,800,000	750,000	1.05	%
Ocean Creation Investments Limited (11)	800,000	800,000	—	—	
Ong Kim Kiat	800,000	800,000	—	—	
Karmdeep & Harpreet Bains	800,000	800,000	—	—	

(1) Except as expressly set forth in footnote 10 and the related line in this table, assumes that none of the shares of common stock or Warrants issued to the selling securityholders in the Private Placement Financing have been sold or otherwise transferred prior to the date of this prospectus in transactions exempt from the registration requirements of the Securities Act. The Warrants issued in the Private Placement Financing provide that a selling securityholder may not exercise its Warrants to the extent (but only to the extent) such selling securityholder or any of its affiliates would beneficially own a number of shares of our common stock which would exceed 4.9%. As a result, the number of shares of common stock reflected in this column as beneficially owned by each selling securityholder includes (a) the number of outstanding shares of common stock issued to such selling securityholder in the Private Placement Financing, and (b) if any, the number of shares of common stock underlying the Warrants issued to such selling securityholder that such selling securityholder has the right to acquire without it or any of its affiliates beneficially owning more than 4.9% of our currently outstanding common stock, based on 71,776,487 outstanding shares of our common stock as of March 20, 2014.

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(2) Includes all shares of common stock issued and issuable as of the date of this prospectus to the selling securityholders in connection with the Private Placement Financing, including all shares underlying the Warrants as of the date of this prospectus.

(3) Assumes that (i) all of the shares of common stock to be registered by the registration statement of which this prospectus is a part, including all shares of common stock issued and outstanding and all shares of common stock issuable upon exercise of the Warrants, are sold in this offering and (ii) the selling securityholders do not acquire additional shares of our common stock after the date of this prospectus and prior to completion of this offering.

(4) Percentage ownership for each selling securityholder is determined under Section 13(d) of the Exchange Act.

(5) Cranshire Capital Advisors, LLC ("CCA") is the investment manager of Cranshire Capital Master Fund, Ltd. ("Cranshire Master Fund") and consequently has voting control and investment discretion over securities held by Cranshire Master Fund. Mitchell P. Kopin ("Mr. Kopin"), the president, the sole member and the sole member of the Board of Managers of CCA, has voting control over CCA. As a result, each of Mr. Kopin and CCA may be deemed to have beneficial ownership (as determined under Section 13(d) of the Exchange Act) of the securities held by Cranshire Master Fund which are covered hereunder.

CCA serves as the investment manager to a managed account for Equitec Specialists, LLC ("Equitec"), and CCA has voting control and investment discretion over securities held in the managed account for Equitec. As described above, Mr. Kopin has voting control over CCA. As a result, each of Mr. Kopin and CCA may be deemed to have beneficial ownership (as determined under Section 13(d) of the Exchange Act) of (i) 3,200,000 shares of our common stock held by Cranshire Master Fund and (ii) 800,000 shares of our common stock held in such managed account by Equitec.

The foregoing excludes: (I) 9,600,000 shares of our common stock issuable upon exercise of Warrants held by Cranshire Master Fund (the "Master Fund Warrants") because each of the Master Fund Warrants contains a blocker provision as described in footnote 1, under which the holder thereof does not have the right to exercise the Master Fund Warrants to the extent (but only to the extent) that such exercise would result in beneficial ownership by the holder thereof or any of its affiliates of more than 4.9% of our common stock and (II) 2,400,000 shares of our common stock issuable upon exercise of Warrants held in the managed account by Equitec (the "Equitec Warrants") because each of the Equitec Warrants contains a blocker provision as described in footnote 1, under which the holder thereof does not have the right to exercise the Equitec Warrants to the extent (but only to the extent) that such exercise would result in beneficial ownership by the holder thereof or any of its affiliates of more than 4.9% of our common stock. Without such blocker provisions, Mr. Kopin and CCA may be deemed to have beneficial ownership of 16,000,000 shares of our common stock.

(6) CCA serves as the investment manager to a managed account for Equitec and consequently has voting control and investment discretion over securities held by Equitec in such managed account. As described above, Mr. Kopin has voting control over CCA. As a result, each of Mr. Kopin and CCA may be deemed to have beneficial ownership (as determined under Section 13(d) of the Exchange Act) of the securities held by Equitec in such managed account which are covered hereunder.

As described above, CCA is also the investment manager of Cranshire Master Fund, and Mr. Kopin has voting control over CCA. As a result, each of Mr. Kopin and CCA may be deemed to have beneficial ownership (as determined under Section 13(d) of the Exchange Act) of the securities held by Cranshire Master Fund that are described above in footnote (5).

Equitec is an affiliate of a broker-dealer. Equitec acquired the shares being registered hereunder in the ordinary course of business, and at the time of the acquisition of the shares and Warrants described herein, Equitec did not have any arrangements or understandings with any person to distribute such securities.

(7) M5V Advisors Inc. and Frigate Ventures LP ("M5V" and "Frigate", respectively), the Co-Investment Advisers of Anson Investments Master Fund LP ("Anson"), hold voting and dispositive power over the securities held by Anson. Bruce Winson is the managing member of Admiralty Advisors LLC, which is the general partner of Frigate. Moez Kassam and Adam Spears are directors of M5V. Mr. Winson, Mr. Kassam and Mr. Spears each disclaim beneficial ownership of the securities held by Anson that are covered hereunder except to the extent of their pecuniary interest therein. The principal business address of Anson is 190 Elgin Avenue, George Town, Grand Cayman.

(8) Heights Capital Management, Inc., the authorized agent of Capital Ventures International, has discretionary authority to vote and dispose of the shares held by Capital Ventures International. Martin Kobinger, in his capacity as Investment Manager of Heights Capital Management, Inc., also has investment discretion and voting power over the shares held by Capital Ventures International. As a result, each of Heights Capital Management, Inc. and Mr. Kobinger may be deemed to have beneficial ownership (as determined under Section 13(d) of the Exchange Act) of the securities held by Capital Ventures International that are covered hereunder. Mr. Kobinger disclaims any such beneficial ownership of such securities.

(9) Daniel MacMullin, in his capacity as the Managing Partner of Heng Hong Ltd, has investment discretion and voting power over the shares held by Heng Hong Ltd. As a result, Mr. McAllister may be deemed to have beneficial ownership (as determined under Section 13(d) of the Exchange Act) of the securities held by Heng Hong Ltd that are covered hereunder. Mr. McAllister disclaims any such beneficial ownership of such securities.

(10) Mr. Dhillon may be deemed to have beneficial ownership of (a) (i) 700,000 shares of common stock issued and sold to 0903746 B.C. Ltd. in the Private Placement Financing, and (ii) 2,067,047 shares underlying Warrants issued to 0903746 B.C. Ltd. in the Private Placement Financing, all of which were transferred to Punit Dhillon on February 28, 2014 in a private party transfer exempt from the registration requirements of the Securities Act, (b) 500,000 shares of common stock held of record by Mr. Dhillon that were previously issued in a transaction unrelated to the Private Placement Financing and none of which are being registered in the registration statement of which this prospectus forms a part, and (c) 250,000 shares of common stock held of record by Narinder Dhillon, Mr. Dhillon's spouse, that were previously issued in a transaction unrelated to the Private Placement Financing and none of which are being registered in the registration statement of which this prospectus forms a part. Mr. Dhillon may be deemed to beneficially own the shares of common stock held of record by Narinder Dhillon, and he disclaims any beneficial ownership of such securities except to the extent of his pecuniary interest therein. The foregoing excludes 32,953 shares of our common stock issuable upon exercise of Warrants held by Mr. Dhillon because such Warrants contain a blocker provision as described in footnote 1, under which the holder thereof does not have the right to exercise the Warrants to the extent (but only to the extent) that such exercise would result in beneficial ownership by the holder thereof or any of its affiliates of more than 4.9% of our common stock. The information set forth in this footnote and the related information set forth in the above table with respect to this selling securityholder was furnished to us by the selling securityholder as of February 28, 2014.

(11) Norman Winata, in his capacity as the Managing Member of Ocean Creation Investments Limited, has investment discretion and voting power over the shares held by Ocean Creation Investments Limited. As a result, Mr. Winata may be deemed to have beneficial ownership (as determined under Section 13(d) of the Exchange Act) of the securities held by Ocean Creation Investments Limited that are covered hereunder. Mr. Winata disclaims any such beneficial ownership of such securities.

Except for the ownership of the common stock and Warrants issued in the Private Placement Financing as reflected in the table above and as otherwise described in this "Selling Securityholder" section below, (a) we have not made, and are not required to make, any potential payments regarding the Private Placement Financing to any selling securityholder, any affiliate of a selling securityholder, or any person with whom any selling securityholder has a contractual relationship, other than as described below and (b) none of the selling securityholders has, or has had within the past three years, any material relationship with us. We have also been advised that none of the selling securityholders is a broker-dealer or an affiliate of a broker-dealer, other than Equitec Specialists, LLC, which has informed us that it is an affiliate of a broker-dealer.

The holders of the Warrants issued in the Private Placement Financing have ongoing rights to exercise those Warrants. We have described the material terms of the Warrants elsewhere in this prospectus. In addition, the participants in the Private Placement Financing have ongoing registration rights related to the securities issued therein pursuant to the terms of the registration rights agreement, which are described in more detail elsewhere in this prospectus.

We may be required to make certain payments to the investors in the Private Placement Financing under certain circumstances pursuant to the terms of the Securities Purchase Agreement and the registration rights agreement. These potential payments include: (a) potential partial damages for failure to register the common stock issued or issuable upon exercise of Warrants; (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; (c) expense reimbursement for the lead investor; and (d) payments in respect of claims for which we provide indemnification. We intend to comply with the requirements of the registration rights agreement and do not currently expect to make any such payments; however, it is possible that such payments may be required.

The Securities Purchase Agreement entered into in connection with the Private Placement Financing grants to the investors, until 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, the right to participate in any financing by us through an issuance of any of our securities up to an amount equal to the pro rata portion of the investor's subscription amount in the Private Placement Financing, on the same pricing and other terms and conditions as such subsequent financing, provided that the aggregate participation by all such investors collectively shall not exceed 50% of the subsequent financing amount. The terms and conditions of such subsequent financing shall not include any provision that requires a participating investor to agree to any restrictions on its trading of any of the shares acquired in connection with the Private Placement Financing without such investor's consent.

Determination of Offering Price

The selling securityholders will determine at what price they may sell the shares of common stock offered by this prospectus, and such sales may be made at prevailing market prices, at prices related to the prevailing market price or at privately negotiated prices.

PLAN OF DISTRIBUTION

We are registering (i) the shares of common stock issued and (ii) the shares of common stock issuable upon exercise of the Warrants, in each case, issued to the selling securityholders in the Private Placement Financing to permit the resale of these shares of common stock by the selling securityholders from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling securityholders of the shares of common stock. We will bear all fees and expenses incident to our obligation to register the shares of common stock.

The selling securityholders may sell all or a portion of the shares of common stock held by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of common stock are sold through underwriters or broker-dealers, the selling securityholders will be responsible for underwriting discounts or commissions or agent's commissions. The shares of common stock may be sold in one or more transactions 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. These sales may be effected in transactions, which may involve crosses or block transactions, pursuant to one or more of the following methods:

- 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 transactions otherwise than on these exchanges or systems or in the over-the-counter market;
- through the writing or settlement of options, whether such options are listed on an options exchange or otherwise;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales made after the date this registration statement is declared effective by the SEC that comply with the terms of the Securities Purchase Agreement;
- broker-dealers may agree with a selling securityholder to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling securityholders may also sell shares of common stock under Rule 144 promulgated under the Securities Act, if available, rather than under this prospectus. In addition, the selling securityholders may transfer the shares of common stock by other means not described in this prospectus. If the selling securityholders effect such transactions by selling shares of common stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling securityholders or commissions from purchasers of the shares of common stock for whom they may act as agent or to whom they may sell as principal (which discounts, concessions or commissions as to particular underwriters, broker-dealers or agents may be in excess of those customary in the types of transactions involved but, except as set forth in a supplement to this prospectus to the extent required, in the case of an agency transaction will not be in excess of a customary brokerage commission in compliance with FINRA Rule 5110 and in no event shall any broker-dealer receive fees, commissions and markups that, in the aggregate, would exceed eight percent (8%)).

In connection with sales of the shares of common stock or otherwise, the selling securityholders may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the shares of common stock in the course of hedging in positions they assume. The selling securityholders may also sell shares of common stock short and deliver shares of common stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling securityholders may also loan or pledge shares of common stock to broker-dealers that in turn may sell such shares.

The selling securityholders may pledge or grant a security interest in some or all of the Warrants or shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending, if necessary, the list of selling securityholders to include the pledgee, transferee or other successors in interest as selling s