AmpliPhi Biosciences Corp
Form S-1/A
November 20, 2014

As filed with the Securities and Exchange Commission on November 19, 2014

Registration No. 333-193458

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

AMENDMENT NO. 4 TO FORM S-1

REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

AMPLIPHI BIOSCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

Washington (prior to reincorporation) Delaware (after reincorporation) (State or other jurisdiction of incorporation or organization)	2836 (Primary Standard Industrial Classification Code Number	91-1549568 (I.R.S. Employer Identification No.)

4870 Sadler Road, Suite 300
Glen Allen, Virginia 23060
(804) 205-5069

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

Jeremy Curnock Cook
Interim Chief Executive Officer
AmpliPhi Biosciences Corporation
4870 Sadler Road, Suite 300
Glen Allen, Virginia 23060
(804) 205-5069

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

Copies to:

Stephen Thau
Morrison & Foerster LLP
2000 Pennsylvania Avenue NW
Washington, DC 20006
(202) 887-1500

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement, as determined by selling stockholders.

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

The registrant is an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012. This registration statement complies with the requirements that apply to an issuer that is an emerging growth company.

CALCULATION OF REGISTRATION FEE

Title of each class 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[2]
Common Stock, par value $0.01 per share	73,362,164	$ 0.57	$41,449,622.66	$ 5,338.71

(1) Represents shares of Common Stock, par value $0.01 per share that may be sold by the selling stockholders named in this registration statement. Pursuant to Rule 416 of the Securities Act of 1933, as amended, this registration statement also covers such an indeterminate amount of shares of Common Stock as may become issuable to prevent dilution resulting from stock splits, stock dividends and similar events.

(2) Previously paid.

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.

TABLE OF CONTENTS

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

Prospectus (Subject to Completion) Dated November 19, 2014.

73,362,164 Shares

Common Stock

This prospectus covers the sale of an aggregate of up to 73,362,164 shares, or the Shares, of our common stock, par value $0.01 per share, by the selling stockholders identified in this prospectus (collectively with any such holder s transferee, pledgee, donee or successor, referred to below as the Selling Stockholders). The Shares consist of 72,007,000 shares of our common stock that were issued pursuant to a Subscription Agreement, dated as of December 19, 2013 and 1,355,164 shares underlying the exercise of warrants held by certain of the Selling Stockholders.

We will not receive any proceeds from the sale by the Selling Stockholders of the shares covered by this prospectus. We are paying the cost of registering the shares covered by this prospectus, as well as various related expenses. The shares included in this prospectus may be offered and sold directly by the Selling Stockholders in accordance with one or more of the methods described in the plan of distribution, which begins on page 30 of this prospectus. The Selling Stockholders are responsible for all selling commissions, transfer taxes and other costs related to the offer and sale of their shares under this prospectus. If required, the number of shares to be sold, the public offering price of those shares, the names of any broker-dealers and any applicable commission or discount will be included in a supplement to this prospectus, called a prospectus supplement.

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012 and a smaller reporting company as that term is defined in Rule 12b-2 under the Securities Exchange Act of 1934, and as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings. See Prospectus Summary Implications of Being an Emerging Growth Company.

Our business and an investment in our common stock involve significant risks. These risks are described under the caption Risk Factors beginning on page 5 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation

to the contrary is a criminal offense.

The date of this prospectus is November 19, 2014.

TABLE OF CONTENTS

TABLE OF CONTENTS

	Page
Prospectus Summary	1
Risk Factors	5
Special Note Regarding Forward-Looking Statements	25
Use of Proceeds	27
Selling Stockholders	27
Plan of Distribution	30
Dividend Policy	31
Dilution	31
Market Price of and Dividends on Common Stock and Related Matters	32
Management s Discussion and Analysis of Financial Condition and Results of Operations	34
Business	45
Management	68
Executive and Director Compensation	75
Certain Relationships and Related Party Transactions	82
Principal Stockholders	84
Description of Capital Stock	86
Shares Eligible for Future Sale	91
Legal Matters	91
Experts	91
Where You Can Find More Information About Us	91
Index to Consolidated Financial Statements	93

TABLE OF CONTENTS

EXPLANATORY NOTE REGARDING AMENDMENT AND RESTATEMENT

Unless the context otherwise requires, we use the terms AmpliPhi Biosciences, AmpliPhi, we, us, the Company our in this report to refer to AmpliPhi Biosciences Corporation and its subsidiaries.

This Registration Statement on Form S-1 includes restatement of the following previously filed consolidated financial statements and data (and related disclosures): (1) our consolidated balance sheet as of December 31, 2013, and our consolidated statements of operations and comprehensive loss, consolidated statement of stockholders equity (deficit), and consolidated statement of cash flows for the fiscal year ended December 31, 2013; (2) our consolidated balance sheet as of December 31, 2012, and our consolidated statements of operations and comprehensive loss, consolidated statement of stockholders equity (deficit), and consolidated statement of cash flows for the fiscal year ended December 31, 2012; (3) our management s discussion and analysis of financial condition and results of operations as of and for our fiscal years ended December 31, 2013 and 2012; and (4) our management s discussion and analysis of financial condition and results of operations as of and for our fiscal years ended December 31, 2012 and 2011, contained in the Management s Discussion and Analysis of Financial Condition and Results of Operations and the Index to the Consolidated Financial Statements of this Registration Statement on Form S-1. All the aforementioned periods are collectively referenced as Affected Periods .

The Company s previously issued December 31, 2013 financial statements have been restated to remove deemed dividends booked on the issuance of preferred shares and to recognize the increase in derivative expense due to adding several features to the valuation model used to measure the compound derivatives and changing from a Black-Scholes valuation model to a Monte Carlo valuation model. Additional paid in capital and accumulated deficit have been reduced by $8,464,000 after removing the deemed dividends. Loss on derivative liabilities increased by $1,755,000 to $42,317,000 due to the change in the valuation model.

The Company also contracted a valuation team to review the purchase price allocation of Biocontrol. As a result, in process research and development (IPR&D) was restated and a new intangible asset, patents, was recognized. For the Biocontrol acquisition, $493,000 of IPR&D was reclassified to patents. In addition, amortization expense for patents of $31,000 was recognized in both 2012 and 2013.

As a result of these corrections, the Company s net loss in 2013 increased $1,787,000 to $57,648,000. The net loss per share decreased by $0.07 per share to $(0.57) per share which also reflects the removal of the deemed dividends.

For more information regarding the restatement, please refer to Management s Discussion and Analysis of Financial Condition and Results of Operations and Correction of Errors in Note 14 to the Notes to our Consolidated Financial Statements for the Year Ended December 31, 2013 and Note 12 to the Notes to our Consolidated Financial Statements for the Years Ended December 31, 2012 and 2011.

TABLE OF CONTENTS

You should rely only on the information contained in this prospectus. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

PROSPECTUS SUMMARY

This summary provides an overview of selected information contained elsewhere in this prospectus and does not contain all of the information you should consider before investing in our common stock. You should carefully read this prospectus and the registration statement of which this prospectus is a part in their entirety before investing in our common stock, including the information discussed under Risk Factors beginning on page 5 and our financial statements and notes thereto that appear elsewhere in this prospectus. As used in this prospectus, unless the context requires otherwise, the Company, we, us and our refer to AmpliPhi Biosciences Corporation, a Washington corporation, or, where appropriate, Targeted Genetics Corporation or AmpliPhi Biosciences Corporation, a Delaware corporation to be formed in connection with the Company s planned reincorporation.

Our Company

We are a biotechnology company focused on the discovery, development and commercialization of novel phage therapeutics. Our proprietary pipeline is based on the use of bacteriophages, a family of viruses that infect only bacteria. Phages have powerful and highly selective mechanisms of action that permit them to target and kill specific bacterial pathogens, including the so-called multi-drug-resistant (MDR) or Superbug strains.

We believe that we are a leading developer of phage-based therapeutics. We are combining our proprietary approach and expertise in identifying, characterizing and developing naturally occurring bacteriophages with that of our collaboration partners in bacteriophage biology, drug engineering, development and manufacturing, to develop second-generation bacteriophage products. We believe that phages represent a promising means to treat bacterial infections, especially those that have developed resistance to current medicines.

The extensive use of antibiotics, since their discovery in the 1940s, has resulted in drug resistance among many disease-causing bacteria. Resistance to antibiotics, according to the Centers for Disease Control (CDC), threatens to reverse the medical advances of the last half-century. Examples of clinically important microbes that are rapidly developing resistance to available antimicrobials include bacteria that cause skin, bone, lung and bloodstream infections (e.g., *S. aureus* and MRSA), pneumonia and lung infections in the community, hospital and cystic fibrosis (e.g., *A. baumanii, P. aeruginosa,* and *K. pneumoniae*), meningitis (e.g., *S. pneumonia*), urinary tract and gastrointestinal infections (e.g., *E. coli* and *C. difficile*). As a phage kills bacteria in ways entirely unlike the mechanisms used by antibiotics, multi-drug resistant bacteria are not resistant to a phage in the same manner. Furthermore, as new resistant bacteria emerge, it should be possible to identify new phages that will still have efficacy.

Our lead program is AmpliPhage-002, for the treatment of *S. aureus* infections (including methicillin-resistant MRSA). We also have two other product candidates in development: AmpliPhage-001 for the treatment of *P. aeruginosa* lung infections in CF patients, and AmpliPhage-004 for the treatment of *C. difficile* infections.

We are developing these phage product candidates using our proprietary discovery and development platform, which is designed for rapid identification, characterization and manufacturing of multiple phage therapies. Each product candidate combines several carefully chosen phages which target a specific disease-causing bacterial pathogen such as MRSA, *P. aeruginosa* and *C. difficile*. We believe that our understanding of unique regulatory and development requirements of bacteriophage biology combined with the scientific expertise of our collaboration partners will enable the rapid advancement of phage treatments through the clinic and eventually to the market.

TABLE OF CONTENTS

In March 2013, we entered into an Exclusive Channel Collaboration (ECC) with Intrexon Corporation, which we refer to as Intrexon, directed towards the research, development and commercialization of new bacteriophage-based therapies to target specific antibiotic-resistant infections, including for use in the treatment of bacterial infections associated with acute and chronic wounds, the treatment of acute and chronic *P. aeruginosa* lung infections, and the treatment of infections of *C. difficile*.

In April 2013, we entered into a collaboration agreement, which we refer to as the April Collaboration Agreement, and on September 5, 2013, we entered into a license agreement, which we refer to as the Leicester License Agreement, with the University of Leicester to develop a phage therapy that targets and kills all toxin types of *C. difficile*. Pursuant to the Leicester License Agreement, we may be obligated to pay the University of Leicester a percentage royalty in the single digits and an aggregate of up to €575,000 in milestone payments. We also entered into a collaboration agreement on August 1, 2013, which we refer to as the August Collaboration Agreement, with the University of Leicester and the University of Glasgow, whereby the University of Glasgow will carry out certain animal model development work. Pursuant to the August Collaboration Agreement, we may be obligated to pay up to a total of approximately €205,000 in milestone payments.

In June 2013, we entered a cooperative research and development agreement (CRADA) with the United States Army Reserve Medical Corps (USAMRMC) and the Walter Reed Army Institute of Research (WRAIR) focusing on developing bacteriophage therapeutics to treat *S. aureus*, *E. coli* and *P. aeruginosa* infections.

We plan to initiate a clinical trial in 2015 in collaboration with the U.S. Army that will support the development of a treatment for *S. Aureus* infections for wound and skin infections.

Our Risks

An investment in our common stock involves a high degree of risk. You should carefully consider the risks summarized below. These risks are discussed more fully in the Risk Factors section of this prospectus immediately following this prospectus summary. These risks include, but are not limited to, the following:

we are seeking to develop antibacterial agents using bacteriophage technology, which has not resulted in any approved product on the market to date;
we have incurred losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future, and our future profitability is uncertain;
we must hire additional members of our senior management team, including a Chief Executive Officer, and we must retain and motivate our personnel;
we must develop commercial-scale manufacturing capabilities;
we are dependent on patents and proprietary technology. If we fail to adequately protect our intellectual property or if we otherwise do not have exclusivity for the marketing of our products, our ability to commercialize products could suffer;
if our competitors are able to develop and market products that are more effective, safer or more affordable than ours, or obtain marketing approval before we do, our commercial opportunities may be limited;
the price of our common stock has been and may continue to be volatile; and
our auditors have expressed substantial doubt about our ability to continue as a going concern and we must raise additional capital to continue operations.

Implications of Being an Emerging Growth Company

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until the earliest of (1) the last day of the first fiscal year (a) following the fifth anniversary of the completion of an initial public offering, (b) in which we have total annual gross revenue of at least $1.0 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeded $700.0 million as of the prior June 30th; or (2) the date on which we have issued more than $1.0 billion in non-convertible debt

TABLE OF CONTENTS

during the prior three-year period. We refer to the Jumpstart Our Business Startups Act of 2012 herein as the JOBS Act and references herein to emerging growth company shall have the meaning associated with it in the JOBS Act.

As an emerging growth company, we intend to take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

only two years of audited consolidated financial statements in addition to any required unaudited interim financial statements with correspondingly reduced Management s Discussion and Analysis of Financial Conditions and Results of Operations disclosure;

reduced disclosure about our executive compensation arrangements;

no requirement that we hold non-binding advisory votes on executive compensation or golden parachute arrangements; and

exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We also qualify as a smaller reporting company, as defined by Regulation S-K under the Securities Act of 1933, as amended, which we refer to as the Securities Act. As such, we also are exempt from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and also are subject to less extensive disclosure requirements regarding executive compensation in our periodic reports and proxy statements, and to exemptions from the requirements to hold a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We will continue to be deemed a smaller reporting company until our public float exceeds $75 million on the last day of our second fiscal quarter in any fiscal year.

Corporate Information

We were incorporated under the laws of the State of Washington in March 1989 as a wholly owned subsidiary of Immunex Corporation and began operations as an independent company in 1992 as Targeted Genetics Corporation.

In January 2011, we completed the acquisition of Biocontrol Ltd, which we refer to as Biocontrol, an antimicrobial biotechnology company based in the United Kingdom, with the goal of developing their phage therapy programs using funding from the sale of our legacy gene therapy assets. On February 22, 2011, we changed our name to AmpliPhi Biosciences Corporation.

In November 2012, we completed the acquisition of Special Phage Holdings Pty Ltd, a company based in Australia, which we refer to as SPH, pursuant to our offer to acquire all outstanding shares of SPH from its shareholders under the terms of a Shareholder Sale Agreement and a Managers Warranty Deed. SPH was formed in 2004 to address the rapidly escalating problem of antibiotic resistance through the development of a series of bacteriophage-based treatments.

We intend to reincorporate as AmpliPhi Biosciences Corporation in the State of Delaware.

Our principal executive offices are located at 4870 Sadler Road, Suite 300, Glen Allen, VA 23060. The telephone number at our principal executive office is (804) 205-5069. Our website address is *http://www.ampliphibio.com*. Our

website and the information contained on, or that can be accessed through, our website will not be deemed to be incorporated by reference in, and are not considered part of, this prospectus. You should not rely on our website or any such information in making your decision whether to purchase our common stock.

TABLE OF CONTENTS

THE OFFERING

Common stock covered by this prospectus

73,362,164 shares

Common stock outstanding as of October 20, 2014

273,869,493 shares

Use of proceeds

The Selling Stockholders will receive all of the proceeds from the sale of the shares offered for sale by them under this prospectus. We will not receive proceeds from the sale of the shares by the Selling Stockholders. See Use of Proceeds.

We may receive proceeds upon the cash exercise of warrants held by the Selling stockholders, the underlying shares of which are offered under this prospectus. Any proceeds of such warrant exercises will be used for general corporate purposes.

Risk factors

See the section entitled Risk Factors and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.

Dividend policy

We currently intend to retain any future earnings to fund the development activities and operation of our business. Therefore, we do not currently anticipate paying cash dividends on our common stock.

Trading symbol

Our common stock is quoted on the OTCQB market under the symbol APHB.

The number of shares of our common stock outstanding as of October 20, 2014 is 273,869,493, which consists of 187,159,093 shares of common stock outstanding as of October 20, 2014, and 86,710,400 shares of common stock issuable upon conversion of all outstanding shares of Series B Convertible Preferred Stock as of October 20, 2014 (assuming a conversion ratio equal to ten (10) common shares for each share of Series B Convertible Preferred Stock), and does not include the following:

25,555,000 shares of our common stock issuable upon the exercise of stock options outstanding under our 2012 Stock Incentive Plan, or the 2012 Plan, at a weighted-average exercise price of $0.19 per share;

9,322,964 shares of our common stock reserved for future issuance under the 2012 Plan;

164,000 shares of our common stock issuable upon the exercise of stock options outstanding under our Targeted Genetics Corporation Stock Incentive Plan, or the 2009 Plan, at a weighted-average exercise price of $0.75 per share;

1,306,760 shares of our common stock reserved for future issuance under the 2009 Plan;

750,000 shares of Common Stock issuable upon the exercise of stock options outstanding under our 2013 Stock Incentive Plan, or the 2013 Plan, at a weighted-average exercise price of $10.28 per share;

39,250,000 shares of common stock reserved for future issuance under the 2013 Plan; and

38,890,451 shares of our common stock issuable upon the exercise of outstanding warrants, at a weighted-average exercise price of $0.15 per share.

TABLE OF CONTENTS

RISK FACTORS

An investment in our common stock involves a high degree of risk. We operate in an industry that involves numerous risks and uncertainties. The risks and uncertainties described below are not the only ones we face. Other risks and uncertainties, including those that we do not currently consider material, may impair our business. If any of the risks discussed below actually occur, our business, financial condition, operating results or cash flows could be materially adversely affected. This could cause the trading price of our common stock to decline, and you may lose all or part of your investment.

Risks Related to Our Business

We are seeking to develop antibacterial agents using bacteriophage technology, which has not resulted in any approved product on the market to date.

We are developing our product candidates with bacteriophage technology. We have not, nor to our knowledge has any other company, received regulatory approval from the U.S. Food and Drug Administration, or FDA or equivalent foreign agencies for a pharmaceutical drug based on this approach. While *in vitro* studies have characterized the behavior of bacteriophages in cell cultures and there exists a body of literature regarding the use of phage therapy in humans, the safety and efficacy of phage therapy in humans has not been extensively studied in well-controlled modern clinical trials. Most of the prior research on phage-based therapy was conducted in the former Soviet Union prior to and immediately after World War II and lacked appropriate control group design or lacked control groups at all. Furthermore, the standard of care has changed substantially during the ensuing decades since those studies were performed, making claims of improved cure rates open for debate. We cannot be certain that our approach will lead to the development of approvable or marketable drugs.

Developing phage-based therapies on a commercial scale will also require developing new manufacturing processes and techniques. We and our third-party collaborators may experience delays in developing manufacturing capabilities for our product candidates, and may not be able to do so at the scale required to conduct efficiently the clinical trials required to obtain regulatory approval of our products, or to manufacture commercial quantities of our products, if approved.

In addition, the FDA or other regulatory agencies may lack experience in evaluating the safety and efficacy of drugs based on these targeting approaches, which could lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our product candidates.

Delays in our clinical trials could result in us not achieving anticipated developmental milestones when expected, increased costs and delay our ability to obtain regulatory approval and commercialize our product candidates.

Delays in our ability to commence or enroll patients for our clinical trials could result in us not meeting anticipated clinical milestones and could materially impact our product development costs and delay regulatory approval of our product candidates. We do not know whether planned clinical trials will be commenced or completed on schedule, if

at all. Clinical trials can be delayed for a variety of reasons, including:

- delays in the development of manufacturing capabilities for our product candidates to enable their consistent production at clinical trial scale;
- delays in the commencement of clinical trials as a result of clinical trial holds or the need to obtain additional information to complete an Investigational New Drug Application (IND);
- delays in obtaining regulatory approval to commence new trials;
- adverse safety events experienced during our clinical trials;
- delays in obtaining clinical materials;
- slower than expected patient recruitment for participation in clinical trials; and
- delays in reaching agreement on acceptable clinical trial agreement terms with prospective sites or obtaining institutional review board approval.

Delays in our clinical trials could result in us not achieving anticipateddevelopmental milestones when expected, inc

TABLE OF CONTENTS

If we do not successfully commence or complete our clinical trials on schedule, the price of our common stock may decline.

We have not completed formulation development of any of our product candidates.

The development of our bacteria phage product candidates requires that we isolate, select and combine a number of bacteria phages that target the desired bacteria for that product candidate. The selection of bacteria phages for any of our product candidates is based on a variety of factors, including without limitation the ability of the selected phages, in combination, to successfully kill the targeted bacteria, the degree of cross-reactivity of the individual phages with the same part of the bacterial targets, the ability of the combined phages to satisfy regulatory requirements, our ability to manufacture sufficient quantities of the phages, intellectual property rights of third parties, and other factors. While we have selected an initial formulation of AmpliPhage-002 for the treatment of methicillin-resistant S. aureus (MRSA) infections, there can be no assurance that this will be the final formulation of AmpliPhage-002 for commercialization. In addition, we are still finalizing initial formulations of AmpliPhage-001 and AmpliPhage-004. If we are unable to complete formulation development of our product candidates in the time frame that we have anticipated, then our product development timelines, and the regulatory approval of our product candidates, could be delayed.

We must hire a new chief executive officer and additional members of our senior management team.

By mutual agreement of the Board of Directors of the Company and Philip J. Young, Mr. Young stepped down from his role as President and Chief Executive Officer of the Company in September 2014. We are looking to replace Mr. Young with a new Chief Executive Officer, and in the interim, Jeremy Curnock Cook, the Chairman of our Board of Directors, is acting as interim Chief Executive Officer, and Wendy Johnson, a member of our Board of Directors, is acting as interim Chief Operating Officer. If we are unable to find a suitable Chief Executive Officer, we may have difficulty executing our business plans, which could cause delays in the commencement of clinical trials or other business activities. The change in Chief Executive Officer may also make it difficult to retain other personnel, and the loss of additional personnel could also have an adverse impact on our business and operations. We are also looking to add additional members to the Company s management team, including the possible additions of senior staff to manage key functions in research, clinical and non-clinical development. . If we do not hire additional senior management personnel, we may not be able to effectively manage our business and operations.

Our auditors have expressed substantial doubt about our ability to continue as a going concern and we must raise additional capital to continue operations.

Our consolidated financial statements were prepared under the assumption that we would continue our operations as a going concern. However, as discussed in Note 2 to our consolidated financial statements, we have had recurring losses from operations, negative operating cash flow and an accumulated deficit that raise substantial doubt about our ability to continue as a going concern. Uncertainty concerning our ability to continue as a going concern may hinder our ability to obtain future financing.

In December 2013, we completed a private placement of shares of our common stock, which raised approximately $18 million, prior to commissions. We do not generate any cash from operations and must raise additional funds in

order to continue operating our business. We expect to continue to fund our operations primarily through equity and debt financings in the future. If additional capital is not available, we may not be able to continue to operate our business pursuant to our business plan or we may have to discontinue our operations entirely.

Developing drugs and conducting clinical trials is expensive. Our future funding requirements will depend on many factors, including:

- the costs and timing of our research and development activities;
- the progress and cost of our clinical trials and other research and development activities;
- the cost and timing of securing manufacturing capabilities for our clinical product candidates and commercial products, if any;

Our auditors have expressed substantial doubt about our ability to continueas a going concern and we must raise a

TABLE OF CONTENTS

the terms and timing of any collaborative, licensing, acquisition or other arrangements that we may establish;

the costs and timing of obtaining regulatory approvals;

the costs of filing, prosecuting, defending and enforcing any patent applications, claims, patents and other intellectual property rights; and

the costs of lawsuits involving us or our product candidates.

We will seek additional capital to support our product development activities. We may seek funds through arrangements with collaborators or others that may require us to relinquish rights to the products candidates that we might otherwise seek to develop or commercialize independently. We cannot be certain that we will be able to enter into any such arrangements on reasonable terms, if at all.

We may seek to raise capital through a variety of sources, including:

the public equity market;

private equity financing;

collaborative arrangements;

licensing arrangements; and/or

public or private debt.

Our ability to raise additional funds will depend, in part, on the status of our product development activities and other business operations, as well as factors related to financial, economic, and market conditions, collaboration or license agreement with others and factors related to financial, economic and market conditions, many of which are beyond our control. We cannot be certain that sufficient funds will be available to us when required or on satisfactory terms, if at all. Raising additional capital through the sale of securities could cause significant dilution to our stockholders. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through additional arrangements that may require us to relinquish rights to certain of our products, technologies or potential markets, any of which could delay or require that we curtail or eliminate some or all of our development programs or otherwise have a material adverse effect on our business, financial condition and results of operations. In addition, we may have to delay, reduce the scope of or eliminate some of our research and development, which could delay the time to market for any of our product candidates, if adequate funds are not available.

If we are unable to secure additional financing on a timely basis or on terms favorable to us, we may be required to cease or reduce certain research and development projects, to sell some or all of our technology or assets or to merge all or a portion of our business with another entity. Insufficient funds may require us to delay, scale back, or eliminate some or all of our activities, and if we are unable to obtain additional funding, there is uncertainty regarding our continued existence.

Preclinical studies and Phase 1 or 2 clinical trials of our product candidates may not predict the results of subsequent human clinical trials.

Preclinical studies, including studies of our product candidates in animal models of disease, may not accurately predict the result of human clinical trials of those product candidates. In particular, promising animal studies suggesting the efficacy of prototype phage products in the treatment of bacterial infections, such as *P. aeruginosa* may not predict the ability of these products to treat similar infections in humans. Our phage technology may be found not to be efficacious in treating bacterial infections alone or in combination with other agents, when studied in human clinical trials.

To satisfy FDA or foreign regulatory approval standards for the commercial sale of our product candidates, we must demonstrate in adequate and controlled clinical trials that our product candidates are safe and effective. Success in early clinical trials, including Phase 2 trials, does not ensure that later clinical trials will be successful. Our initial results from Phase 1/2 clinical trials also may not be confirmed by later analysis

Preclinical studies and Phase 1 or 2 clinical trials of our product candidates may not predict the results of 30bseque

TABLE OF CONTENTS

or subsequent larger clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

Our product candidates must undergo rigorous clinical testing, the results of which are uncertain and could substantially delay or prevent us from bringing them to market.

Before we can obtain regulatory approval for a product candidate, we must undertake extensive clinical testing in humans to demonstrate safety and efficacy to the satisfaction of the FDA or other regulatory agencies. Clinical trials of new drug candidates sufficient to obtain regulatory marketing approval are expensive and take years to complete.

We cannot be certain of successfully completing clinical testing within the time frame we have planned, or at all. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent us from receiving regulatory approval or commercializing our product candidates, including the following:

our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing or to abandon programs;

the results obtained in earlier stage clinical testing may not be indicative of results in future clinical trials;

clinical trial results may not meet the level of statistical significance required by the FDA or other regulatory agencies;

enrollment in our clinical trials for our product candidates may be slower than we anticipate, resulting in significant delays and additional expense;

we, or regulators, may suspend or terminate our clinical trials if the participating patients are being exposed to unacceptable health risks; and

the effects of our product candidates on patients may not be the desired effects or may include undesirable side effects or other characteristics that may delay or preclude regulatory approval or limit their commercial use, if approved.

Completion of clinical trials depends, among other things, on our ability to enroll a sufficient number of patients, which is a function of many factors, including:

the therapeutic endpoints chosen for evaluation;

the eligibility criteria defined in the protocol;

the perceived benefit of the investigational drug under study;

the size of the patient population required for analysis of the clinical trial s therapeutic endpoints;

our ability to recruit clinical trial investigators and sites with the appropriate competencies and experience;

our ability to obtain and maintain patient consents; and

competition for patients by clinical trial programs for other treatments.

We may experience difficulties in enrolling patients in our clinical trials, which could increase the costs or affect the timing or outcome of these clinical trials. This is particularly true with respect to diseases with relatively small patient populations.

We must develop manufacturing processes for our lead product candidates and any delay in or our inability to do so would result in delays in our clinical trials and materially and negatively affect our business and results.

We are developing novel manufacturing processes for the production of AmpliPhage-002 for treatment of *S. aureus* (MRSA) infections, AmpliPhage-001 for the treatment of *P. aeruginosa* infections and AmpliPhage-004 for the

treatment of *C. difficile* infections at facilities in Ljubljana, Slovenia. The manufacturing processes

We must develop manufacturing processes for our lead product candidatesand any delay in or our inability to do so

TABLE OF CONTENTS

for our product candidates, and the scale up of such process for clinical trials, is novel, and there can be no assurance that we will be able to complete this work in a timely manner, if at all. Any delay in the development or scale up of these manufacturing processes could delay the start of clinical trials and harm our business. Our facilities in Slovenia must also undergo inspections by JAZMP, the Slovenian agency that rgulates and supervises pharmaceutical products in Slovenia, for compliance with their and the FDA s current good manufacturing practice regulations, or cGMP regulations, before the respective product candidates can be approved for use in clinical trials or commercialization. As a result of an initial inspection, we are taking certain non-critical corrective actions regarding the manufacture of AmpliPhage-002, which we believe will lead to certification by JAZMP to manufacture AmpliPhage-002; however, there can be no assurance that we will receive such certification. We will also be subject to additional inspections for GMP compliance for our other product candidates, and may be subject to additional inspections for AmpliPhage-002. In the event these facilities do not receive a satisfactory cGMP inspection for the manufacture of our product candidates, we may need to fund additional modifications to our manufacturing process, conduct additional validation studies, or find alternative manufacturing facilities, any of which would result in significant cost to us as well as a delay of up to several years in obtaining approval for such product candidate.

Our manufacturing facilities will be subject to ongoing periodic inspection by the European regulatory authorities, including JAZMP, and the FDA for compliance with European and FDA cGMP regulations. Compliance with these regulations and standards is complex and costly, and there can be no assurance that we will be able to comply. Any failure to comply with applicable regulations could result in sanctions being imposed (including fines, injunctions and civil penalties), failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecution.

We have conducted and may in the future conduct clinical trials for our products or product candidates outside the United States and the FDA may not accept data from such trials.

We have conducted and may in the future choose to conduct one or more of our clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of such study data by the FDA is subject to certain conditions. For example, the study must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The study population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical studies conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. In addition, such studies would be subject to the applicable local laws and FDA acceptance of the data would be dependent upon its determination that the studies also complied with all applicable U.S. laws and regulations. There can be no assurance the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept any such data, it would likely result in the need for additional trials, which would be costly and time consuming and delay aspects of our business plan.

We may need to license additional intellectual property rights.

The development and commercialization of phage-based antibacterial agents may require us to obtain rights to intellectual property from third parties. For example, pursuant to our Collaborative Research and Development Agreement, or CRADA, with the United States Army Medical Research and Materiel Command, or USAMRMC and the Walter Reed Army Institute of Research, or WRAIR, we are focusing on developing bacteriophage therapeutics to treat *S. aureus, E. coli* and *P. aeruginosa* infections. To the extent the intellectual property is generated from the

USAMRMC or WRAIR that is used in a commercial product, we may be obligated to make payments such as royalties, licensing fees and milestone payments. We may also determine that it is necessary or advisable to license other intellectual property from third parties. There can be no assurance that such intellectual property rights would be available on commercially reasonable terms, if at all.

We are subject to significant regulatory approval requirements, which could delay, prevent or limit our ability to market our product candidates.

Our research and development activities, preclinical studies, clinical trials and the anticipated manufacturing and marketing of our product candidates are subject to extensive regulation by the FDA and

TABLE OF CONTENTS

other regulatory agencies in the United States and by comparable authorities in Europe and elsewhere. There can be no assurance that our planned manufacturing facilities will satisfy the requirements of the FDA or comparable foreign authorities. We require the approval of the relevant regulatory authorities before we may commence commercial sales of our product candidates in a given market. The regulatory approval process is expensive and time-consuming, and the timing of receipt of regulatory approval is difficult to predict. Our product candidates could require a significantly longer time to gain regulatory approval than expected, or may never gain approval. We cannot be certain that, even after expending substantial time and financial resources, we will obtain regulatory approval for any of our product candidates. A delay or denial of regulatory approval could delay or prevent our ability to generate product revenues and to achieve profitability.

Changes in regulatory approval policies during the development period of any of our product candidates, changes in, or the enactment of, additional regulations or statutes, or changes in regulatory review practices for a submitted product application may cause a delay in obtaining approval or result in the rejection of an application for regulatory approval.

Regulatory approval, if obtained, may be made subject to limitations on the indicated uses for which we may market a product. These limitations could adversely affect our potential product revenues. Regulatory approval may also require costly post-marketing follow-up studies. In addition, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping related to the product will be subject to extensive ongoing regulatory requirements. Furthermore, for any marketed product, its manufacturer and its manufacturing facilities will be subject to continual review and periodic inspections by the FDA or other regulatory authorities. Failure to comply with applicable regulatory requirements may, among other things, result in fines, suspensions of regulatory approvals, product recalls, product seizures, operating restrictions and criminal prosecution.

The FDA and foreign regulatory authorities may impose significant restrictions on the indicated uses and marketing of pharmaceutical products.

FDA rules for pharmaceutical promotion require that a company not promote an unapproved drug or an approved drug for an unapproved use. In addition to FDA requirements, regulatory and law enforcement agencies, such as the United States Department of Health and Human Services Office of Inspector General and the United States Department of Justice, monitor and investigate pharmaceutical sales, marketing and other practices. For example, sales, marketing and scientific/educational grant programs must comply with the Medicare-Medicaid Anti-Fraud and Abuse Act, as amended, the False Claims Act, as amended, and similar state laws. In recent years, actions by companies sales forces and marketing departments have been scrutinized intensely to ensure, among other things, that actions by such groups do not qualify as kickbacks to healthcare professionals. A kickback refers to the provision of any item of value to a healthcare professional or other person in exchange for purchasing, recommending, or referring an individual for an item or service reimbursable by a federal healthcare program. These kickbacks increase the expenses of the federal healthcare program and may result in civil penalties, criminal prosecutions, and exclusion from participation in government programs, any of which would adversely affect our financial condition and business operations. In addition, even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Comparable laws also exist at the state level.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties,

We are subject to significant regulatory approval requirements, which coulddelay, prevent or limit our abili to mark

contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we would market, sell and distribute our products. As a biotechnology company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients rights are and will be applicable to our business. Federal healthcare Anti-Kickback Statute will

Our relationships with customers and third-party payors will be subject toapplicable anti-kickback, fraud and abuse

TABLE OF CONTENTS

constrain our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. Federal civil and criminal false claims laws and civil monetary penalty laws impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

The federal physician sunshine requirements under the Affordable Care Act requires manufacturers of drugs, devices, biologics and medical supplies to report annually to HHS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations. Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws require pharmaceutical companies to comply with the pharmaceutical industry s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We are, and in the future may be, subject to new federal and state requirements to submit information on our open and completed clinical trials to public registries and databases.

In 1997, a public registry of open clinical trials involving drugs intended to treat serious or life-threatening diseases or conditions was established under the Food and Drug Administration Modernization Act, or FDMA, in order to promote public awareness of and access to these clinical trials. Under FDMA, pharmaceutical manufacturers and other

clinical trial sponsors are required to post the general purpose of these clinical trials, as well as the eligibility criteria, location and contact information of the clinical trials. Since the establishment of this registry, there has been significant public debate focused on broadening the types of clinical trials included in this or other registries, as well as providing for public access to clinical trial results. A voluntary coalition of medical journal editors has adopted a resolution to publish results only from those clinical trials that have been registered with a no-cost, publicly accessible database, such as *www.clinicaltrials.gov*. The Pharmaceuticals and Research Manufacturers of America has also issued voluntary principles for its members to make results from certain clinical trials publicly available and has established a

We are, and in the future may be, subject to new federal and state requirements to submit information on our open

TABLE OF CONTENTS

website for this purpose. Other groups have adopted or are considering similar proposals for clinical trial registration and the posting of clinical trial results. The state of Maine has enacted legislation, with penalty provisions, requiring the disclosure of results from clinical trials involving drugs marketed in the state, and similar legislation has been introduced in other states. Federal legislation was introduced in the fall of 2004 to expand *www.clinicaltrials.gov* and to require the inclusion of clinical trial results in this registry. In some states, such as New York, prosecutors have alleged that a lack of disclosure of clinical trial information constitutes fraud, and these allegations have resulted in settlements with pharmaceutical companies that include agreements to post clinical trial results. Our failure to comply with any clinical trial posting requirements could expose us to negative publicity, fines, and other penalties, all of which could materially harm our business.

We do not have a sales force and do not currently have plans to develop one.

The commercial success of any of our product candidates will depend upon the strength of sales and marketing efforts for them. We do not have a sales force and have no experience in sales, marketing or distribution. To successfully commercialize our product candidates, we will need to develop such a capability ourselves or seek assistance from a third party with a large distribution system and a large direct sales force. We may be unable to put such a plan in place. In addition, if we arrange for others to market and sell our products, our revenues will depend upon the efforts of those parties. Such arrangements may not succeed. Even if one or more of our product candidates is approved for marketing, if we fail to establish adequate sales, marketing and distribution capabilities, independently or with others, our business will be materially harmed.

Risks Related to Our Financial Performance and Operations

We have incurred losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future, and our future profitability is uncertain.

We have incurred losses in each year since our inception in 1992. Prior to the merger of Targeted Genetics Corporation with Biocontrol in January 2011, our accumulated deficit was $315.5 million, and Biocontrol had an accumulated deficit of $6.9 million. Since January 2011 and through September 30, 2014, we have incurred an accumulated deficit of $37.9 million, and we expect to incur losses for the foreseeable future. We have devoted, and will continue to devote for the foreseeable future, substantially all of our resources to research and development of our product candidates. For the year ended December 31, 2012, we had an operating loss of $4.3 million and a net loss of $1.1 million. For the year ended December 31, 2013, we had an operating loss and a net loss of $57.7 million. Clinical trials and activities associated with discovery research are costly. We do not expect to generate any revenue from the commercial sales of our product candidates in the near term, and we expect to continue to have significant losses for the foreseeable future.

To attain ongoing profitability, we will need to develop products successfully and market and sell them effectively, or rely on other parties to do so. We cannot predict when we will achieve ongoing profitability, if at all. We have never generated revenue from the commercial sales of our product candidates, and there is no guarantee that we will be able to do so in the future. If we fail to become profitable, or if we are unable to fund our continuing losses, we would be unable to continue our research and development programs.

Our success depends in part on retaining and motivating our personnel.

Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists.

As of October 20, 2014, we had 22 employees. Our success will depend on our ability to retain and motivate remaining personnel and hire additional qualified personnel when required. Competition for qualified personnel in the biotechnology field is intense. We face competition for personnel from other biotechnology and pharmaceutical companies, universities, public and private research institutions and other organizations. We may not be able to attract and retain qualified personnel on acceptable terms given the competition for such personnel. If we are unsuccessful in our retention, motivation and recruitment efforts, we may be unable to execute our business strategy.

TABLE OF CONTENTS

We have determined that a material weakness existed in our system of internal control over financial reporting, which could have had a material impact on our business.

We are required to maintain internal control over financial reporting adequate to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements in accordance with generally accepted accounting principles. In connection with the restatement of our consolidated financial statements for the years ended December 31, 2012 and the quarter ended September 30, 2013, we determined that we had a material weakness as of December 31, 2013, namely that our controls over the evaluation and review of complex and non-routine transactions were not effective.

Due to this material weakness, we have concluded that as of December 31, 2013, our internal control over financial reporting were not effective. Subsequent to December 31, 2013, we have restated our consolidated financial statements as of December 31, 2013 to correct for errors caused by this weakness.

We do not expect that our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system s objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. Over time, controls may become inadequate because changes in conditions or deterioration in the degree of compliance with policies or procedures may occur. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. As a result, we cannot assure you that significant deficiencies or material weaknesses in our internal control over financial reporting will not be identified in the future. A material weakness means a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the registrant s annual or interim financial statements will not be prevented or detected on a timely basis.

Risks Related to Our Dependence on Third Parties

We rely on third parties for aspects of product development.

We rely on third parties such as the University of Leicester and the U.S. Army for certain aspects of product development. We are working with the University of Leicester for research and development of product candidates to treat *C. difficile* infections. We are working with the U.S. Army for research and development of product candidates to treat *S. aureus* infections, and we are working with Intrexon to develop new strains of manufacturing hosts for our phage therapies. Because we rely on third parties to conduct these activities, we have less control over the success of these programs than we would if we were conducting them on our own. Factors beyond our control that could impact the success of these programs include the amount of resources devoted to the programs by the applicable third party, the staffing of those projects by third-party personnel, and the amount of time such personnel devote to our programs compared to other programs. Failure of our third-party collaborators to successfully complete the projects that we are working on with them could result in delays in product development and the need to expend additional resources, increasing our expenses beyond current expectations.

We will rely on third parties to conduct some of our clinical trials, and their failure to perform their obligations in a timely or competent manner may delay development and commercialization of our product candidates.

We expect to use third parties such as clinical research organizations or the U.S. Army to assist in conduct of our clinical trials. There are numerous alternative sources to provide these services. However, we may face delays outside of our control if these parties do not perform their obligations in a timely or competent fashion or if we are forced to change service providers. This risk is heightened for clinical trials conducted outside of the United States, where it may be more difficult to ensure that clinical trials are conducted in compliance with FDA requirements. Any third-party that we hire to conduct clinical trials may also provide services to our competitors, which could compromise the performance of their obligations to us. If we experience significant delays in the progress of our clinical trials and in our plans to file New Drug

TABLE OF CONTENTS

Applications (NDAs), the commercial prospects for product candidates could be harmed and our ability to generate product revenue would be delayed or prevented.

We will rely on the U.S. Army to conduct our Phase 1 clinical trial, and their failure to perform in a timely manner may significantly delay the AmpliPhage-002 clinical program.

Pursuant to our Collaborative Research and Development Agreement, or CRADA, with the United States Army Medical Research and Materiel Command, or USAMRMC and the Walter Reed Army Institute of Research, or WRAIR, we expect to utilize US Army human resources and facilities to conduct our planned Phase 1 clinical trial of AmpliPhage-002. Due to recent outbreaks of the Ebola virus, the Army has diverted significant resources to studying this potential epidemic. As a result, the U.S. Army has advised the Company there may be a delay in initiating the planned Phase 1AmpliPhage-002 study, which may significantly impact our ability to conduct this clinical trial prior to the first half of 2015.

We must manage a geographically dispersed organization.

While we are a small company, we currently have operations in the United States, Australia, United Kingdom and Slovenia. In the future, we may also locate facilities in other locations based on proximity to personnel with the expertise needed to research, develop and manufacture phage-based therapeutics, costs of operations or other factors. Managing our organization across multiple locations and multiple time zones may reduce our efficiency, increase our expenses and increase the risk of operational difficulties in the execution of our plans.

Risks Related to Our Intellectual Property

We are dependent on patents and proprietary technology. If we fail to adequately protect this intellectual property or if we otherwise do not have exclusivity for the marketing of our products, our ability to commercialize products could suffer.

Our commercial success will depend in part on our ability to obtain and maintain patent protection sufficient to prevent others from marketing our product candidates, as well as to defend and enforce these patents against infringement and to operate without infringing the proprietary rights of others. Protection of our product candidates from unauthorized use by third parties will depend on having valid and enforceable patents cover our product candidates or their manufacture or use, or having effective trade secret protection. If our patent applications do not result in issued patents, or if our patents are found to be invalid, we will lose the ability to exclude others from making, using or selling the inventions claimed therein. We have a limited number of patents and pending patent applications.

The patent positions of biotechnology companies can be uncertain and involve complex legal and factual questions. This is due to inconsistent application of policy and changes in policy relating to examination and enforcement of biotechnology patents to date on a global scale. The laws of some countries may not protect intellectual property rights to the same extent as the laws of countries having well-established patent systems, and those countries may lack adequate rules and procedures for defending our intellectual property rights. Also, changes in either patent laws or in interpretations of patent laws may diminish the value of our intellectual property. We are not able to guarantee that all

of our patent applications will result in the issuance of patents and we cannot predict the breadth of claims that may be allowed in our patent applications or in the patent applications we may license from others.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

we might not have been the first to make the inventions covered by each of our pending patent applications and issued patents, and we may have to participate in expensive and protracted interference proceedings to determine priority of invention;

we might not have been the first to file patent applications for these inventions;

others may independently develop similar or alternative product candidates to any of our product candidates that fall outside the scope of our patents;

We are dependent on patents and proprietary technology. If we fail toadequately protect this intellectual property or

TABLE OF CONTENTS

our pending patent applications may not result in issued patents;
our issued patents may not provide a basis for commercially viable products or may not provide us with any competitive advantages or may be challenged by third parties;
others may design around our patent claims to produce competitive products that fall outside the scope of our patents;
we may not develop additional patentable proprietary technologies related to our product candidates; and
we are dependent upon the diligence of our appointed agents in national jurisdictions, acting for and on our behalf, which control the prosecution of pending domestic and foreign patent applications and maintain granted domestic and foreign patents.

An issued patent does not guarantee us the right to practice the patented technology or commercialize the patented product. Third parties may have blocking patents that could be used to prevent us from commercializing our patented products and practicing our patented technology. Our issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit our ability to prevent competitors from marketing the same or related product candidates or could limit the length of the term of patent protection of our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent. Patent term extensions may not be available for these patents.

We rely on trade secrets and other forms of non-patent intellectual property protection. If we are unable to protect our trade secrets, other companies may be able to compete more effectively against us.

We rely on trade secrets to protect certain aspects of our technology, including our proprietary processes for manufacturing and purifying bacteriophages. Trade secrets are difficult to protect, especially in the pharmaceutical industry, where much of the information about a product must be made public during the regulatory approval process. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secret information is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to or may not protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If we are sued for infringing intellectual property rights of third parties or if we are forced to engage in an interference proceeding, it will be costly and time-consuming, and an unfavorable outcome in that litigation or interference would have a material adverse effect on our business.

Our ability to commercialize our product candidates depends on our ability to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. Numerous United States and foreign patents and patent applications, which are owned by third parties, exist in the general field of anti-infective products or in fields that otherwise may relate to our product candidates. If we are shown to infringe, we could be enjoined from use or sale of the claimed invention if we are unable to prove that the patent is invalid. In addition, because patent applications can take many years to issue, there may be currently pending patent applications, unknown to us, which may later result in issued patents that our product candidates may infringe, or which may trigger an interference proceeding regarding one of our owned or licensed patents or applications. There could also be existing patents of which we are not aware that our product candidates may inadvertently infringe or which may become involved in an

interference proceeding.

The biotechnology and pharmaceutical industries are characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. For so long as our product candidates are in clinical trials, we believe our clinical activities fall within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the United States, which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. As our clinical

TABLE OF CONTENTS

investigational drug product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. While we attempt to ensure that our active clinical investigational drugs and the methods we employ to manufacture them, as well as the methods for their use we intend to promote, do not infringe other parties patents and other proprietary rights, we cannot be certain they do not, and competitors or other parties may assert that we infringe their proprietary rights in any event.

We may be exposed to future litigation based on claims that our product candidates, or the methods we employ to manufacture them, or the uses for which we intend to promote them, infringe the intellectual property rights of others. Our ability to manufacture and commercialize our product candidates may depend on our ability to demonstrate that the manufacturing processes we employ and the use of our product candidates do not infringe third-party patents. If third-party patents were found to cover our product candidates or their use or manufacture, we could be required to pay damages or be enjoined and therefore unable to commercialize our product candidates, unless we obtained a license. A license may not be available to us on acceptable terms, if at all.

Risks Related to Our Industry

If our competitors are able to develop and market products that are more effective, safer or more affordable than ours, or obtain marketing approval before we do, our commercial opportunities may be limited.

Competition in the biotechnology and pharmaceutical industries is intense and continues to increase. Some companies that are larger and have significantly more resources than we do are aggressively pursuing antibacterial development programs, including traditional therapies and therapies with novel mechanisms of action. In addition, other companies are developing phage-based products for non-therapeutic uses, and may elect to use their expertise in phage development and manufacturing to try to develop products that would compete with ours.

We also face potential competition from academic institutions, government agencies and private and public research institutions engaged in the discovery and development of drugs and therapies. Many of our competitors have significantly greater financial resources and expertise in research and development, preclinical testing, conducting clinical trials, obtaining regulatory approvals, manufacturing, sales and marketing than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established pharmaceutical companies.

Our competitors may succeed in developing products that are more effective, have fewer side effects and are safer or more affordable than our product candidates, which would render our product candidates less competitive or noncompetitive. These competitors also compete with us to recruit and retain qualified scientific and management personnel, establish clinical trial sites and patient registration for clinical trials, as well as to acquire technologies and technology licenses complementary to our programs or advantageous to our business. Moreover, competitors that are able to achieve patent protection, obtain regulatory approvals and commence commercial sales of their products before we do, and competitors that have already done so, may enjoy a significant competitive advantage.

In July 2012, the Food and Drug Administration Safety and Innovation Act was passed, which included the Generating Antibiotics Incentives Now Act, or the GAIN Act. The GAIN Act is intended to provide incentives for the development of new, qualified infectious disease products. These incentives may result in more competition in the market for new antibiotics, and may cause pharmaceutical and biotechnology companies with more resources than we have to shift their efforts towards the development of products that could be competitive with our product candidates.

There is a substantial risk of product liability claims in our business. If we do not obtain sufficient liability insurance, a product liability claim could result in substantial liabilities.

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and marketing of human therapeutic products. Regardless of merit or eventual outcome, product liability claims may result in:

delay or failure to complete our clinical trials;
withdrawal of clinical trial participants;

TABLE OF CONTENTS

decreased demand for our product candidates;
injury to our reputation;
litigation costs;
substantial monetary awards against us; and
diversion of management or other resources from key aspects of our operations.

If we succeed in marketing products, product liability claims could result in an FDA investigation of the safety or efficacy of our products, our manufacturing processes and facilities or our marketing programs. An FDA investigation could also potentially lead to a recall of our products or more serious enforcement actions, or limitations on the indications, for which they may be used, or suspension or withdrawal of approval.

We have product liability insurance that covers our clinical trials up to a $10 million annual aggregate limit. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates or any other compound that we may develop. However, insurance coverage is expensive and we may not be able to maintain insurance coverage at a reasonable cost or at all, and the insurance coverage that we obtain may not be adequate to cover potential claims or losses.

Even if we receive regulatory approval to market our product candidates, the market may not be receptive to our product candidates upon their commercial introduction, which would negatively affect our ability to achieve profitability.

Our product candidates may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any approved products will depend on a number of factors, including:

the effectiveness of the product;
the prevalence and severity of any side effects;
potential advantages or disadvantages over alternative treatments;
relative convenience and ease of administration;
the strength of marketing and distribution support;
the price of the product, both in absolute terms and relative to alternative treatments; and
sufficient third-party coverage or reimbursement.

If our product candidates receive regulatory approval but do not achieve an adequate level of acceptance by physicians, healthcare payors and patients, we may not generate product revenues sufficient to attain profitability.

If third-party payors do not adequately reimburse patients for any of our product candidates, if approved for marketing, we may not be successful in selling them.

Our ability to commercialize any products successfully will depend in part on the extent to which reimbursement will be available from governmental and other third-party payors, both in the United States and in foreign markets. Even if we succeed in bringing one or more products to the market, the amount reimbursed for our products may be insufficient to allow us to compete effectively and could adversely affect our profitability.

Reimbursement by a governmental and other third-party payor may depend upon a number of factors, including a governmental or other third-party payor s determination that use of a product is:

a covered benefit under its health plan;
safe, effective and medically necessary;
appropriate for the specific patient;

If third-party payors do not adequately reimburse patients for any of ourproduct candidates, if approved for marketin

TABLE OF CONTENTS

cost-effective; and
neither experimental nor investigational.

Obtaining reimbursement approval for a product from each third-party and governmental payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor. We may not be able to provide data sufficient to obtain reimbursement.

Eligibility for coverage does not imply that any drug product will be reimbursed in all cases or at a rate that allows us to make a profit. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not become permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower-cost drugs that are already reimbursed, may be incorporated into existing payments for other products or services and may reflect budgetary constraints and/or Medicare or Medicaid data used to calculate these rates. Net prices for products also may be reduced by mandatory discounts or rebates required by government healthcare programs or by any future relaxation of laws that restrict imports of certain medical products from countries where they may be sold at lower prices than in the United States.

The healthcare industry is experiencing a trend toward containing or reducing costs through various means, including lowering reimbursement rates, limiting therapeutic class coverage and negotiating reduced payment schedules with service providers for drug products. The Medicare Prescription Drug, Improvement and Modernization Act of 2003, or MMA, became law in November 2003 and created a broader prescription drug benefit for Medicare beneficiaries. The MMA also contains provisions intended to reduce or eliminate delays in the introduction of generic drug competition at the end of patent or non-patent market exclusivity. The impact of the MMA on drug prices and new drug utilization over the next several years is unknown. The MMA also made adjustments to the physician fee schedule and the measure by which prescription drugs are presently paid, changing from Average Wholesale Price to Average Sales Price. The effects of these changes are unknown but may include decreased utilization of new medicines in physician prescribing patterns, and further pressure on drug company sponsors to provide discount programs and reimbursement support programs. There have been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services, which may affect reimbursement levels for our future products. In addition, the Centers for Medicare & Medicaid Services frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates and may have sufficient market power to demand significant price reductions.

Foreign governments tend to impose strict price controls, which may adversely affect our future profitability.

In some foreign countries, particularly in the European Union, prescription drug pricing is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our profitability will be negatively affected.

We may incur significant costs complying with environmental laws and regulations, and failure to comply with these laws and regulations could expose us to significant liabilities.

Our research and development activities use biological and hazardous materials that are dangerous to human health and safety or the environment. We are subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials and wastes resulting from these materials. We are also subject to regulation by the Occupational Safety and Health Administration, or OSHA, state and federal environmental protection agencies and to regulation under the Toxic Substances Control Act. OSHA, state governments or federal Environmental Protection Agency, or EPA, may adopt regulations that may affect our research and development programs. We are unable to predict

TABLE OF CONTENTS

whether any agency will adopt any regulations that could have a material adverse effect on our operations. We have incurred, and will continue to incur, capital and operating expenditures and other costs in the ordinary course of our business in complying with these laws and regulations.

Although we believe our safety procedures for handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot entirely eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could significantly exceed our insurance coverage.

Risks Related to Our Common Stock

The price of our common stock has been and may continue to be volatile.

The stock markets in general, the markets for biotechnology stocks and, in particular, the stock price of our common stock, have experienced extreme volatility. Although we intend to apply to be listed on the NYSE MKT, our stock is currently quoted on the OTCQB market. The market for our common shares is characterized by significant price volatility when compared to the shares of larger, more established companies that trade on a national securities exchange and have large public floats, and we expect that our share price will continue to be more volatile than the shares of such larger, more established companies for the indefinite future, even if we are listed on the NYSE MKT. The volatility in our share price is attributable to a number of factors. First, our common shares are, compared to the shares of such larger, more established companies, sporadically and thinly traded. As a consequence of this limited liquidity, the trading of relatively small quantities of shares by our stockholders may disproportionately influence the price of those shares in either direction. The price for our shares could, for example, decline precipitously in the event that a large number of our common shares are sold on the market without commensurate demand. Secondly, we are a speculative or risky investment due to the early stage of our drug development programs and our lack of profits to date, and uncertainty of future market acceptance for our potential products. As a consequence of this enhanced risk, more risk-adverse investors may, under the fear of losing all or most of their investment in the event of negative news or lack of progress, be more inclined to sell their shares on the market more quickly and at greater discounts than would be the case with the stock of a larger, more established company that trades on a national securities exchange and has a large public float. Many of these factors are beyond our control and may decrease the market price of our common shares, regardless of our operating performance. We cannot make any predictions or projections as to what the prevailing market price for our common shares will be at any time, including as to whether our common shares will sustain their current market prices, or as to what effect that the sale of shares or the availability of common shares for sale at any time will have on the prevailing market price.

Price declines in our common stock could result from general market and economic conditions and a variety of other factors, including:

adverse results or delays in our clinical trials;
adverse actions taken by regulatory agencies with respect to our product candidates, clinical trials or the manufacturing processes of our product candidates;
announcements of technological innovations, patents or new products by our competitors;
regulatory developments in the United States and foreign countries;
any lawsuit involving us or our product candidates;
announcements concerning our competitors, or the biotechnology or pharmaceutical industries in general;
developments concerning any strategic alliances or acquisitions we may enter into;
actual or anticipated variations in our operating results;

changes in recommendations by securities analysts or lack of analyst coverage;
deviations in our operating results from the estimates of analysts;

TABLE OF CONTENTS

sales of our common stock by our executive officers, directors and five percent stockholders or sales of substantial amounts of common stock; and

loss of any of our key scientific or management personnel.

In the past, following periods of volatility in the market price of a particular company s securities, litigation has often been brought against that company. Any such lawsuit could consume resources and management time and attention, which could adversely affect our business.

You may incur substantial dilution as a result of future offerings of our securities.

You may incur substantial dilution as a result of future offerings by us of debt or equity securities. Since inception, we have funded our operations primarily through issuances of equity and debt. On June 26, 2013, we completed a private placement of convertible preferred stock and warrants to purchase common stock with gross proceeds of approximately $7.0 million through the sale of shares of our newly-created Series B Convertible Preferred Stock. As part of the same transaction, approximately $5.5 million in outstanding convertible notes were converted into shares of Series B Convertible Preferred Stock and warrants to purchase common stock. On July 15, 2013, we completed a second closing in which we converted approximately $0.8 million of outstanding convertible notes into Series B Convertible Preferred Stock and warrants to purchase common stock. The financing was led by life-sciences investors RA Capital Management and Third Security, LLC, with participation from BioScience Managers Pty Ltd.

Under the terms of the financing, we issued an aggregate amount of approximately 10.0 million shares of Series B Convertible Preferred Stock for an aggregate purchase price of approximately $13.3 million (including the conversion of approximately $6.3 million of outstanding convertible notes). Each share of Series B Convertible Preferred Stock is convertible into 10 shares of common stock and accrues dividends at the rate of 10% per year. Additionally, we issued warrants to purchase an aggregate of up to approximately 25.0 million shares of common stock at an exercise price of $0.14 per share.

In addition, in December 2013, we completed a private placement in which we issued 72,007,000 shares of the Company's common stock at a price per share of $0.25, and, in connection with the private placement, issued warrants to purchase 4,320,420 shares of common stock at an exercise price of $0.25 per share to the placement agents.

A significant number of shares of our common stock are subject to issuance upon exercise of outstanding warrants and options, which upon such exercise would result in dilution to our security holders.

As of October 20, 2014, we have outstanding warrants to purchase 38,890,451 shares of our common stock at an average exercise price of $0.15 per share, and outstanding options to purchase 25,719,000 shares of our common stock at an average exercise price of $0.19 per share. The exercise price and/or the number of shares of common stock issuable upon exercise of the warrants may be adjusted in certain circumstances, including certain issuances of securities at a price equal to or less than the then current exercise price, subdivisions and stock splits, stock dividends, combinations, reorganizations, reclassifications, consolidations, mergers or sales of properties and assets and upon the issuance of certain assets or securities to holders of our common stock, as applicable. Although we cannot determine at this time which of these warrants will ultimately be exercised, it is reasonable to assume that such warrants will be exercised only if the exercise price is below the market price of our common stock. To the extent the warrants are exercised, additional shares of our common stock will be issued that will be eligible for resale in the public market, which will result in dilution to our security holders. The issuance of additional securities could also have an adverse

effect on the market price of our common stock.

If our officers, directors and largest stockholders choose to act together, they may be able to control our management and operations, acting in their best interests and not necessarily those of other stockholders.

As of October 20, 2014, our officers and directors beneficially owned approximately 17.18% of our outstanding common stock. As a result, these stockholders, acting together, may be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders

A significant number of shares of our common stock are subject to issuanceupon exercise of outstanding warrants a

TABLE OF CONTENTS

may not always coincide with the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders.

Our (i) current articles of incorporation and bylaws, (ii) our intended certificate of incorporation and bylaws upon reincorporation in Delaware, (iii) Washington law and, (iv) upon reincorporation, Delaware law contains provisions that could discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management.

Provisions of (i) Washington law, where we are incorporated, (ii) Delaware law, where we intend to reincorporate, (iii) our current articles of incorporation and bylaws and (iv) our intended certificate of incorporation and bylaws upon our reincorporation in Delaware may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace or remove our board of directors. These provisions include:

authorizing the issuance of blank check preferred stock without any need for action by stockholders;
providing for a classified board of directors with staggered terms;
requiring supermajority stockholder voting to effect certain amendments to (i) our current articles of incorporation and bylaws and (ii) our intended certificate of incorporation and bylaws upon reincorporation in Delaware;
eliminating the ability of stockholders to call special meetings of stockholders;
prohibiting stockholder action by written consent; and
establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

In addition, because we are incorporated in Washington, we are governed by the provisions of Chapter 23B.19 of the Washington Business Corporation Act, or the WBCA, which, among other things, restricts the ability of shareholders owning ten percent (10%) or more of our outstanding voting stock from merging or combining with us. Because we are reincorporating in Delaware, we will then be governed by the provisions of Section 203 of the Delaware General Corporation Law, or the DGCL. These provisions may prohibit large stockholders, in particular those owning fifteen percent (15%) or more of our outstanding voting stock, from merging or combining with us. These provisions could discourage potential acquisition attempts and could reduce the price that investors might be willing to pay for shares of our common stock in the future and result in the market price being lower than it would without these provisions.

Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if an offer may be considered beneficial by some shareholders. In addition, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it difficult for shareholders to replace members of our board of directors, which is responsible for appointing the members of our management.

We have never paid dividends on our common stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have never declared or paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future

earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be our stockholders sole source of gain for the foreseeable future.

We have never paid dividends on our common stock, and we do not anticipatepaying any cash dividends in the fore

TABLE OF CONTENTS

Maintaining and improving our financial controls and the requirements of being a public company may strain our resources, divert management s attention and affect our ability to attract and retain qualified board members.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and, if our common stock is listed on an exchange (such as the NYSE MKT), the rules of such exchange. The requirements of these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. The Exchange Act will require, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition.

The Sarbanes-Oxley Act will require, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Ensuring that we have adequate internal financial and accounting controls and procedures in place is a costly and time-consuming effort that needs to be re-evaluated frequently.

We currently do not have an internal audit group, and we may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Implementing any appropriate changes to our internal controls may require specific compliance training for our directors, officers and employees, entail substantial costs to modify our existing accounting systems, and take a significant period of time to complete. Such changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent fraud.

In addition, our independent registered public accounting firm did not perform an evaluation of our internal control over financial reporting as of December 31, 2013, December 31, 2012 or December 31, 2011 in accordance with the provisions of the Sarbanes-Oxley Act because no such evaluation was required. Although not required, our management did review our internal controls for the year ended December 31, 2013 and identified material weakness in the area of complex and non-routine transactions as further described in Item 9A of our Form 10-K/A filed on September 12, 2014. If we are unable to successfully remediate any significant deficiency or material weakness in our internal control over financial reporting, identify any additional significant deficiencies or material weaknesses that may exist, or satisfy the requirements of the Sarbanes-Oxley Act, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, and our stock price may decline materially as a result.

In accordance with NYSE MKT rules, we will be required to maintain a majority independent board of directors. We also expect that the various rules and regulations applicable to public companies will make it more difficult and more expensive for us to maintain directors and officers liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to maintain coverage. If we are unable to maintain adequate directors and officers insurance, our ability to recruit and retain qualified directors, especially those directors who may be deemed independent for purposes of NYSE MKT rules, and officers will be significantly curtailed.

Compliance with these reporting rules, Sarbanes-Oxley Act and NYSE MKT requirements may require us to build out our accounting and finance staff. We may need to expand our accounting and financing staff, and our failure to adequately do so would harm our ability to comply with the requirements listed above.

If securities or industry analysts do not publish research or publish unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We currently have one security analyst and may never obtain additional research coverage by other securities and industry analysts. If no additional securities or industry analysts commence coverage of our company, the trading price for our stock could be negatively

TABLE OF CONTENTS

impacted. If we obtain additional securities or industry analyst coverage and if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

Future sales of our common stock or securities convertible into our common stock may depress our stock price.

Sales of a substantial number of shares of our common stock or securities convertible into our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Moreover, we also intend to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to the lock-up agreements contained in the relevant agreements.

If a large number of shares of our common stock or securities convertible into our common stock are sold in the public market after they become eligible for sale, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

Trading of our stock is restricted by the SEC s penny stock regulations and certain FINRA rules, which may limit a stockholder s ability to buy and sell our common stock.

Our securities are covered by certain penny stock rules, which impose additional sales practice requirements on broker-dealers who sell low-priced securities to persons other than established customers and accredited investors. For transactions covered by these rules, a broker-dealer must make a special suitability determination for the purchaser and have received the purchaser s written consent to the transaction prior to sale, among other things. In addition, the penny stock rules require a broker-dealer, before effecting a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document prepared by the SEC that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer s account. The bid and offer quotations, and the broker-dealer and salesperson compensation information, must be given to the customer orally or in writing before effecting the transaction, and must be given to the customer in writing before or with the customer s confirmation. These rules may affect the ability of broker-dealers and holders to sell our common stock and may negatively impact the level of trading activity for our common stock. To the extent our common stock remains subject to the penny stock regulations, such regulations may discourage investor interest in and adversely affect the market liquidity of our common stock.

The Financial Industry Regulatory Authority, or 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 believes that there is a high probability that speculative low priced securities will not be suitable for at least some customers. FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit

your ability to buy and sell our stock and have an adverse effect on the market for our shares.

We are an emerging growth company and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined under the JOBS Act. For so long as we are an emerging growth company, we intend to take advantage of certain exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act,

Trading of our stock is restricted by the SEC s penny stock regulations andcertain FINRA rules, which may limit

TABLE OF CONTENTS

reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We could be an emerging growth company for up to five years, although we may lose such status earlier, depending on the occurrence of certain events. We will remain an emerging growth company until the earliest to occur of (i) the last day of the fiscal year (a) following the fifth anniversary of our initial public offering, (b) in which we have total annual gross revenue of at least $1.0 billion or (c) in which we are deemed to be a large accelerated filer under the Securities Exchange Act of 1934, which we refer to as the Exchange Act, which means that the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30, and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

We cannot predict if investors will find our common stock less attractive or our company less comparable to certain other public companies because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We are an emerging growth company and we cannot be certain if the reduceddisclosure requirements applicable

TABLE OF CONTENTS

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. The forward-looking statements are contained principally in the sections entitled Prospectus Summary, Risk Factors, Management s Discussion and Analysis of Financial Condition and Results of Operations and Business. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

our ability to manufacture, or otherwise secure the manufacture of, sufficient amounts of our product candidates for our preclinical studies and clinical trials;

our clinical development plans, including planned clinical trials;

our research and development plans, including our plans to initiate at least one new clinical study in 2015;

our ability to select combinations of phages to formulate our product candidates;

the safety and efficacy of our product candidates;

the anticipated regulatory pathways for our product candidates;

our ability to successfully complete preclinical and clinical development of, and obtain regulatory approval of our product candidates and commercialize any approved products on our expected timeframes or at all;

the content and timing of submissions to and decisions made by the FDA and other regulatory agencies;

our ability to leverage the experience of our management team;

our ability to attract and keep management and other key personnel;

the capacities and performance of our suppliers, manufacturers, contract research organizations, or CROs, and other third parties over whom we have limited control;

the actions of our competitors and success of competing drugs that are or may become available;

our expectations with respect to future growth and investments in our infrastructure, and our ability to effectively manage any such growth;

the size and potential growth of the markets for any of our product candidates, and our ability to capture share in or impact the size of those markets;

the benefits of our products and product candidates;

market and industry trends;

the effects of government regulation and regulatory developments, and our ability and the ability of the third parties with whom we engage to comply with applicable regulatory requirements;

our financial performance, including our net revenue, return rates and related estimates, cost of revenue, gross profit and gross margin, operating expenses, utilization of net operating losses, or NOLs, stock-based compensation expense, cash flows, expected uses of anticipated cash flow, funding requirements and market risk;

our expectations regarding future planned expenditures;

our expectations with respect to product pricing;

our ability to effectively remediate any significant deficiencies or material weaknesses in our internal control over financial reporting;

TABLE OF CONTENTS

our ability to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act;

our ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection of any of our products and product candidates;

our ability to operate our business without infringing the intellectual property rights of others; and

our plans to potentially transact business outside the United States.

In some cases, you can identify these statements by terms such as anticipates, believes, could, estimates, expec intends, may, plans, potential, predicts, projects, should, will, would or the negative of those ter expressions. These forward-looking statements reflect our management s beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this prospectus and are subject to risks and uncertainties. We discuss many of these risks in greater detail in the section entitled Risk Factors. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements. The forward-looking statements contained in this prospectus are excluded from the safe harbor protection provided by the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act.

You should read this prospectus and the documents that we reference in this prospectus, and have filed as exhibits to the registration statement of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

TABLE OF CONTENTS

USE OF PROCEEDS

The Selling Stockholders will receive all of the proceeds from the sale of the Shares offered for sale under this prospectus. We will not receive any proceeds from the sale of the Shares by the Selling Stockholders.

SELLING STOCKHOLDERS

This prospectus covers the sale of an aggregate of up to 73,362,164 shares (including 1,355,164 shares underlying the exercise of warrants by certain of the Selling Stockholders) of our Common Stock, $0.01 par value per share, by the Selling Stockholders. See Description of Capital Stock beginning on page 86 for a description of the Common Stock.

Each Selling Stockholder represented to us that it was an accredited investor and that it was acquiring the Common Stock for investment only and not with a view towards, or for resale in connection with, the public sale or distribution thereof in a manner that would violate the Securities Act or any applicable state securities laws.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or share voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options or warrants or pursuant to the conversion of our Series B Convertible Preferred Stock that are either immediately exercisable or convertible or exercisable or convertible within 60 days of October 20, 2014. Shares underlying such options, warrants and Series B Convertible Preferred Stock, however, are only considered outstanding for the purpose of computing the percentage ownership of that person and are not considered outstanding when computing the percentage ownership of any other person.

The following table sets forth certain information regarding the Selling Stockholders, the Shares that may be offered by this prospectus and other shares of Common Stock beneficially owned by them as of October 20, 2014. Selling Stockholders may offer Shares under this prospectus from time to time and may elect to sell none, some or all of the Shares set forth below. As a result, we cannot estimate the number of shares of Common Stock that a Selling Stockholder will beneficially own after termination of sales under this prospectus. However, for the purposes of the table below, we have assumed that, after completion of the offering, none of the Shares covered by this prospectus will be held by the Selling Stockholders. In addition, a Selling Stockholder may have sold, transferred or otherwise disposed of all or a portion of that holder s Shares since the date on which they provided information for this table. We are relying on the Selling Stockholders to notify us of any changes in their beneficial ownership after the date they originally provided this information. See Plan of Distribution beginning on page 30. Unless otherwise disclosed in the footnotes to the table below, except for the ownership of the Common Stock, the Selling Stockholders have not had any material relationship with us within the past three years.

Selling Stockholder[1]	Number of Shares Beneficially Owned Before Offering	Number of Shares Covered by This Prospectus	Number of Shares Beneficially Owned After Offering[2]	Percentage of Shares Beneficially Owned after Offering[3]
Edward Cappabianca[4]	338,791	338,791		

OTA, LLC[5]	1,016,373	1,016,373		
NRM VII Holdings I, LLC[6]	46,785,712[7]	20,000,000	26,785,712[7]	9.78 %
Broadfin Healthcare Master Fund, Ltd	14,000,000	14,000,000		
MSD Credit Opportunity Master Fund, L.P.[8]	8,827,000	8,827,000		
Mintz & Co.	400,000	400,000		
Smokeshire Partners, LLC	1,000,000	1,000,000		
BioMatrix Partners, Ltd.	6,100,000	6,000,000	100,000	*
Perceptive Life Sciences Master Fund Ltd.	3,740,000	3,740,000		
Titan Perc Ltd.	260,000	260,000		
Sphera Global Healthcare Master Fund LP	3,787,200	3,787,200		
HFR HE Sphera Global Healthcare Master Trust	212,800	212,800		
Empery Asset Master, Ltd[9]	1,200,000	1,200,000		

TABLE OF CONTENTS

Selling Stockholder[1]	Number of Shares Beneficially Owned Before Offering	Number of Shares Covered by This Prospectus	Number of Shares Beneficially Owned After Offering[2]	Percentage of Shares Beneficially Owned after Offering[3]
Allen Adler	1,200,000	1,200,000		*
Gerald Pogue & Mai Pogue	315,000	200,000	115,000	
Michael Bego	381,000	300,000	81,000	*
Marcus Pelham-Webb	450,890	360,000	90,890	*
Vinh C. Nguyen & JanMari Williams-Nguyen	100,000	100,000		
Susan K. Rho	362,000	200,000	162,000	*
Hudson Bay Master Fund, Ltd.[10]	1,000,000	1,000,000		
Brio Capital Master Fund Ltd.	1,000,000	1,000,000		
Gemini Master Fund, Ltd.	1,000,000	1,000,000		
Kingsbrook Opportunities Master Fund LP[11]	600,000	600,000		
Baxter F. Phillips III[12]	503,125	300,000	203,125	
Marc Levy	200,000	200,000		
BTG Investments LLC[13]	72,000	72,000		
Griffin Securities, Inc.	1,944,571 [14]	48,000	1,896,571[14]	*
Phillip Asset Management Ltd[15]	14,928,562[16]	6,000,000	8,928,562[16]	3.26 %

(1) If required, information about other selling stockholders, except for any future transferees, pledgees, donees or successors of Selling Stockholders named in this table, will be set forth in a prospectus supplement or amendment to the registration statement of which this prospectus is a part. Additionally, post-effective amendments to the registration statement will, to the extent necessary, be filed to disclose any material changes to the plan of distribution from the description contained in the final prospectus.

(2) This number assumes the sale of all shares offered by this prospectus.

(3) These percentages are based upon 273,869,493 shares of Common Stock outstanding on October 20, 2014.

(4) Consists of shares of common stock underlying a warrant to purchase 338,791 shares of common stock.

(5) Consists of shares of common stock underlying a warrant to purchase 1,016,373 shares of common stock.

(6) Julian P. Kirk, a member of the Company s Board of Directors, is the son of Randal J. Kirk, who controls NRM VII Holdings I, LLC.

(7) Includes 21,428,570 shares of common stock issuable upon conversion of Series B Convertible Preferred Stock (assuming a conversion ratio equal to ten (10) common shares for each share of Series B Convertible Preferred Stock) and shares of common stock underlying a warrant to purchase 5,357,142 shares of common stock.

(8) MSDC Management, L.P. is the investment manager of, and may be deemed to have or share voting and dispositive power over, and/or beneficially own securities owned by, MSD Credit Opportunity Master Fund, L.P. MSDC Management (GP), LLC is the general partner of and may be deemed to have or share voting and dispositive power over, and/or beneficially own securities owned by, MSDC Management, L.P. Each of Glenn R. Fuhrman, John C. Phelan and Marc R. Lisker is manager of MSDC Management (GP), LLC and may be deemed to have or share voting and/or dispositive power over, and beneficially own, the common stock beneficially owned by MSD Management (GP), LLC. Each of Mr. Fuhrman, Mr. Phelan and Mr. Lisker disclaim beneficial ownership of such common stock, except to the extent of the pecuniary interest of such person in such shares. The mailing address for MSD Credit Opportunity Master Fund, L.P. is c/o MSDC Management, L.P., 645 Fifth Avenue, 21 st Floor, New York, NY 10022.

(9) Empery Asset Management LP, referred to as EAM, the authorized agent of Empery Asset Master Ltd, has discretionary authority to vote and dispose of the shares held by EAM and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by EAM. EAM, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares.

TABLE OF CONTENTS

(10) Hudson Bay Capital Management LP, the investment manager of Hudson Bay Master Fund Ltd., has voting and investment power over these securities. Sander Gerber is the managing member of Hudson Bay Capital GP LLC, which is the general partner of Hudson Bay Capital Management LP. Sander Gerber disclaims beneficial ownership over these securities.

(11) Kingsbrook Partners LP, referred to as Kingsbrook Partners, is the investment manager of Kingsbrook Opportunities Master Fund LP, referred to as Kingsbrook Opportunities, and consequently has voting control and investment discretion over securities held by Kingsbrook Opportunities. Kingsbrook Opportunities GP LLC, referred to as Opportunities GP, is the general partner of Kingsbrook Opportunities and may be considered the beneficial owner of any securities deemed to be beneficially owned by Kingsbrook Opportunities. KB GP LLC, referred to as GP LLC, is the general partner of Kingsbrook Partners and may be considered the beneficial owner of any securities deemed to be beneficially owned by Kingsbrook Partners. Ari J. Storch, Adam J. Chill and Scott M. Wallace are the sole managing members of Opportunities GP and GP LLC and as a result may be considered beneficial owners of any securities deemed beneficially owned by Opportunities GP and GP LLC. Each of Kingsbrook Partners, Opportunities GP, GP LLC and Messrs. Storch, Chill and Wallace disclaim beneficial ownership of these securities.

(12) Consists of options to purchase 203,125 shares of common stock and 300,000 shares of common stock purchased by Mr. Phillips in the December 2013 private placement.

(13) Byron Roth and Gordon Roth, as members of the selling stockholder have shared voting and investment power over the shares. The address of the selling stockholder is 888 San Clemente Drive, Suite 400, Newport Beach, CA 92660. The selling stockholder is a registered broker-dealer and acted as the placement agent for the private placement of shares of the Company s common stock that occurred in December 2013.

(14) Consists of shares of common stock underlying warrants to purchase 693,168 shares of common stock.

(15) Phillip Asset Management Ltd holds all shares in its capacity as trustee for Bioscience Managers Pty Ltd. Jeremy Curnock Cook, the Chairman of the Company s Board of Directors, is a Managing Director and holds an ownership interest in Bioscience Managers Pty Ltd.

(16) Includes 7,142,850 shares of common stock issuable upon conversion of Series B Convertible Preferred Stock (assuming a conversion ratio equal to ten (10) common shares for each share of Series B Convertible Preferred Stock) and shares of common stock underlying a warrant to purchase 1,785,712 shares of common stock.

TABLE OF CONTENTS

PLAN OF DISTRIBUTION

The shares of common stock being offered for resale by the Selling Stockholders consist of an aggregate of up to 73,362,164 shares, of which 72,007,000 shares were issued pursuant to a Subscription Agreement, dated as of December 19, 2013, and 1,355,164 shares are underlying the exercise of warrants held by certain of the Selling Stockholders. We will pay any fees and expenses incurred by us incident to the registration of the securities.

Each Selling Stockholder of the securities and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their securities covered hereby on the OTCQB market or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A Selling Stockholder may use any one or more of the following methods when selling securities:

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the securities 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;

in transactions through broker-dealers that agree with the Selling Stockholders to sell a specified number of such securities at a stipulated price per security;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;

a combination of any such methods of sale; or

any other method permitted pursuant to applicable law.

The Selling Stockholders may also sell securities under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the Selling Stockholders may arrange for other broker-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholders (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

In connection with the sale of the securities or interests therein, the Selling Stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The Selling Stockholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The Selling Stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The Selling Stockholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by

them may be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Stockholder has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

TABLE OF CONTENTS

The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of securities of the common stock by the Selling Stockholders or any other person. We will make copies of this prospectus available to the Selling Stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock and currently do not plan to declare cash dividends on shares of our common stock in the foreseeable future. We expect that we will retain all of our available funds and future earnings, if any, for use in the operation and expansion of our business. Subject to the foregoing, the payment of cash dividends in the future, if any, will be at the discretion of our board of directors and will depend upon such factors as earnings levels, capital requirements, restrictions imposed by applicable law, our overall financial condition and any other factors deemed relevant by our board of directors.

DILUTION

We are not offering any shares of our common stock by this prospectus. All shares of the common stock that are being registered are beneficially owned by the Selling Shareholders and either are issued and outstanding or, in the case of the warrants, will be issued and outstanding prior to the effectiveness of this registration statement. Accordingly, the sale of the registered shares will not have a dilutive effect to potential shareholders since the common stock to be sold will already be issued and outstanding.

Our historical net tangible book value as of December 31, 2013 was approximately $18,532,000, or $0.10 per share, based on 182,535,562 shares of common stock outstanding as of December 31, 2013.

TABLE OF CONTENTS

MARKET PRICE OF AND DIVIDENDS ON COMMON STOCK AND RELATED MATTERS

Market Information

Our shares of common stock are quoted on the OTCQB market under the symbol APHB. Our shares were previously quoted under the symbol TGEN. On February 22, 2011, in connection with our name change to AmpliPhi Biosciences Corporation, our quotation symbol was changed to APHB.

The following table sets forth the range of reported high and low closing bid quotations for our common stock for the fiscal quarters indicated. These quotations reflect inter-dealer prices, without retail markup, markdown or commission, and may not represent actual transactions. Consequently, the information provided below may not be indicative of our common stock price under different conditions.

	High	Low
Fiscal Year 2014		
Period from October 1, 2014 to November 13, 2014	$ 0.23	$ 0.07
Third Quarter ended September 30, 2014	$ 0.45	$ 0.22
Second Quarter ended June 30, 2014	$ 0.58	$ 0.38
First Quarter ended March 31, 2014	$ 0.74	$ 0.45
Fiscal Year 2013		
Fourth Quarter ended December 31, 2013	$ 0.59	$ 0.31
Third Quarter ended September 30, 2013	$ 0.71	$ 0.15
Second Quarter ended June 30, 2013	$ 0.20	$ 0.10
First Quarter ended March 31, 2013	$ 0.18	$ 0.11
Fiscal Year 2012		
Fourth Quarter ended December 31, 2012	$ 0.22	$ 0.14
Third Quarter ended September 30, 2012	$ 0.20	$ 0.09
Second Quarter ended June 30, 2012	$ 0.23	$ 0.13
First Quarter ended March 31, 2012	$ 0.24	$ 0.11
Fiscal Year 2011		
Fourth Quarter ended December 31, 2011	$ 0.27	$ 0.14
Third Quarter ended September 30, 2011	$ 0.29	$ 0.20
Second Quarter ended June 30, 2011	$ 0.39	$ 0.25
First Quarter ended March 31, 2011	$ 0.17	$ 0.06

Holders of Common Stock

As of October 20, 2014, there were 296 holders of record of our common stock. As of such date, the number of shares of our common stock outstanding was 273,869,493, which consists of 187,159,093 shares of common stock outstanding as of October 20, 2014, and 86,710,400 shares of common stock issuable upon conversion of all outstanding shares of Series B Convertible Preferred Stock as of October 20, 2014 (assuming a conversion ratio equal to ten (10) common shares for each share of Series B Convertible Preferred Stock).

Dividends

We have never declared or paid any cash dividends or distributions on our capital stock. See Dividend Policy on page 31 for a description of our dividend policy.

Securities Authorized for Issuance under Equity Compensation Plans

In October 2012, our board of directors approved and adopted the 2012 Plan. Under the 2012 Plan, we are authorized to issue up to 35,000,000 shares of our common stock in stock incentive awards to employees, directors and consultants.

In March 2009, our board of directors and shareholders adopted the 2009 Plan. Under the 2009 Plan, we are authorized to issue up to 4,200,000 shares of our common stock in stock incentive awards to employees, directors and consultants.

TABLE OF CONTENTS

In December 2013, our board of directors adopted the 2013 Plan. Under the 2013 Plan, we are authorized to issue up to 39,250,000 shares of our common stock in stock incentive awards to employees, directors and consultants. Our shareholders approved the 2013 Plan on February 11, 2014.

The following table provides information as of December 31, 2013 with respect to our equity compensation plans:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders[1]	166,000	$ 0.90	1,304,760
Equity compensation plans not approved by security holders[2]	25,555,000	$ 0.19	9,322,964
Total	25,721,000	$ 0.19	10,627,724

(1) The 2009 Plan.

(2) The 2012 Plan. Excludes shares of our common stock subject to the 2013 Plan, which was adopted by our board of directors in December 2013 and approved by our shareholders in February 2014.

TABLE OF CONTENTS

MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should read in conjunction with Selected Consolidated Financial Data and the Unaudited Condensed Consolidated Financial Statements and related Notes included in this Form S-1.

This discussion contains forward-looking statements that involve risks and uncertainties. Such statements, which include statements concerning product development plans, the use of bacteriophages to kill bacterial pathogens, future revenue sources, selling and marketing expenses, general and administrative expenses, clinical trial and other research and development expenses, capital resources, capital expenditures, tax credits and carry-forwards, the Company s ability to raise capital through additional financings or borrowings, are subject to risks and uncertainties, including, but not limited to, those discussed below and elsewhere in this Form S-1, Risk Factors, that could cause actual results to differ materially from those projected. The forward-looking statements set forth in this Form S-1 are as of the close of business on November 14, 2014, and we do not intend to update this forward-looking information.

Restatement

As discussed in the Explanatory Note Regarding Restatement and Note 14 to the Consolidated Financial Statements included in this Registration Statement on Form S-1, we are amending and restating our audited consolidated financial statements and related disclosures for the years ended December 31, 2013 and December 31, 2012.

The following discussion and analysis of our financial condition and results of operations incorporates the restated amounts. For this reason, the data set forth in this section may not be comparable to discussion and data in our previously filed Registration Statements on Form 10 or Form S-1 for the fiscal year ended December 31, 2012.

Overview

AmpliPhi Biosciences is a biotechnology company focused on the discovery, development and commercialization of novel phage therapeutics. Our proprietary pipeline is based on the use of bacteriophages, a family of viruses that infect only bacteria. Phages have powerful and highly selective mechanisms of action that permit them to target and kill specific bacterial pathogens, including the so-called multi-drug-resistant (MDR) or Superbug strains.

We are combining our proprietary approach and expertise in identifying, characterizing and developing naturally occurring bacteriophages with that of our collaboration partners in bacteriophage biology, drug engineering, development and manufacturing, to develop second-generation bacteriophage products. We believe that phages represent a promising means to treat bacterial infections, especially those that have developed resistance to current medicines.

Our lead program is AmpliPhage-002, for the treatment of methicillin-resistant *S. aureus* (MRSA) infections. We have two other product candidates in development: AmpliPhage-001 for the treatment of *P. Aeruginosa* lung infections in CF patients and AmpliPhage-004 for the treatment of *C. difficile* infections.

We have incurred net losses since our inception. Our operations to date have been limited to research and development and raising capital. Since November 2010, we have raised approximately $5.6 million through the sale and issuance of convertible notes and warrants to purchase common stock. In June and July of 2013, we completed a private placement of shares of our Series B Convertible Preferred Stock and warrants to purchase common stock, with proceeds to the Company of approximately $7.0 million. At the same time we converted approximately $6.3 million in outstanding convertible notes to Series B Convertible Preferred Stock. In December 2013, we completed a private placement of shares of common stock, with gross proceeds of approximately $18 million, prior to commissions. To date, we have not generated any meaningful revenue and have primarily financed our operations through the sale and issuance of convertible notes and the private placement of our equity securities. As of September 30, 2014, we had an accumulated deficit of $355.3 million. We recorded annual net losses of $57.7 million in 2013 and $1.1 million in 2012. We anticipate that a substantial portion of our capital resources and efforts in the foreseeable future will be focused on completing the development and obtaining regulatory approval of our product candidates.

TABLE OF CONTENTS

We expect our research and development expenses to expand as we increase our development activities and commence clinical trials to pursue regulatory approval for our product candidates. We also expect to incur additional expenses associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses at least for the next several years. We do not expect to generate product revenue unless and until we successfully complete development and obtain marketing approval for at least one of our product candidates.

We currently expect to use our existing cash and cash equivalents for the continued research and development of our product candidates and for working capital and other general corporate purposes.

We may also use a portion of our cash and cash equivalents for the potential acquisition of, or investment in, product candidates, technologies, formulations or companies that complement our business, although we have no current understandings, commitments or agreements to do so. We expect that our current cash and cash equivalents will not be sufficient to enable us to complete all necessary development of any potential product candidates. Accordingly, we will be required to obtain further funding through other public offerings, debt financing, collaboration and licensing arrangements or other sources. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs.

Financial Operations Overview

Comparison of the Nine Months Ended September 30, 2014 and 2013

Revenue

We recognized no revenues for the quarter ended September 30, 2014. For the nine month period ending September 30, 2014, we recognized revenues of $310,000 in revenue from sublicensing arrangements, a decrease from $333,000 for the same period in 2013, as a result of reduced grant revenue.

Research and Development

Research and development expenses were $1.8 million for the quarter ended September 30, 2014, up $0.7 million from the $1.1 million recorded for the quarter ended September 30, 2013. Research and development expenses were $4.7 million for the nine month period ended September 30, 2014, compared to $5.4 million for the nine month period ended September 30, 2013. Research and development costs for the nine month period in 2013 included a $3.0 million non-cash one-time technology access fee which was incurred in April 2013. Adjusted for this one-time item, research and development expense for the nine months of 2014 represented an increase of $2.3 million. The increase in research and development expense for both the three month and nine month periods ended September 30, 2014 were due to an increase in discovery, laboratory, nonclinical testing, research and development collaborations, consulting, and clinical development planning expenses for all of our product candidates.

Adjusted for the one-time non-cash technology access fee incurred in 2013, research and development expenses are expected to increase in 2014 compared to 2013 as we plan to continue investing substantial resources to research and development as we prepare to initiate clinical trials and continue our discovery efforts.

General and Administrative

General and administrative expenses were $1.6 million for the quarter ended September 30, 2014 compared to $1.2 million for the quarter ended September 30, 2013. The $0.4 million increase in general and administrative expense was due primarily to a $0.3 million accrual for payments to certain shareholders as required by the terms of our Series B Preferred Stock Purchase Agreement.

General and administrative expenses were $5.4 million for the nine month period ended September 30, 2014 compared to $4.8 million for the nine month period ended September 30, 2013. This increase of $0.6 million was attributable to the accrual of payments to certain shareholders outlined above and higher legal, accounting, and staffing expenses incurred to satisfy our obligations as a public company. Partially offsetting these cost increases were reduced investment fees resulting from the fees incurred in 2013 for our Series B private placement.

TABLE OF CONTENTS

We currently expect our general and administrative expenses to increase in 2014 compared to 2013 due to additional costs associated with being a public company.

Severance Charge

The Company recorded a severance charge in the quarter ended September 30, 2014 of $1.5 million related to severance-period compensation and benefits and stock-based compensation expense related to the acceleration of vested stock options related to the termination of the Company s Chief Executive Officer during the quarter.

Derivative Liabilities

During the quarter ended September 30, 2014, we recognized a gain on derivative liabilities of $24.3 million related to reductions in the fair value of derivative liabilities for warrants issued in June, July, and December 2013 and the conversion feature of the shares of Series B Preferred Stock issued in June and July 2013. The reduction in fair value was attributable to a decline in the market value of our common stock at September 30, 2014. During the quarter ended September 30, 2013, we recognized a loss on derivative liabilities of $41.5 million for warrants issued in June 2013 and the conversion feature of the shares of Series B Preferred Stock issued in June 2013.

For the nine month period ended September 30, 2014, we recognized a gain on derivative liabilities of $34.0 million compared to $45.6 million loss for the nine month period ended September 30, 2013.

Derivative liabilities are adjusted to fair value each reporting period and are influenced by several factors including the price of the Company s common stock as of the balance sheet date. On September 30, 2014, the price per share of the Company s common stock was $0.22 per share compared to $0.50 per share at December 31, 2013.

Income Taxes

We incurred net operating losses for the years ended December 31, 2013 and 2012 and, accordingly, we did not pay any U. S. federal or state income taxes. As of December 31, 2013, we had accumulated approximately $175.4 million in U.S. and UK operating loss carry-forwards and research tax credit carry-forwards of approximately $3.7 million. The carry-forwards began to expire in 2012. Our net operating loss carry-forwards are subject to certain limitations on annual utilization as a result of changes in ownership of the Company, as defined by federal and state tax laws.

Net Operating Losses

We have not recorded a benefit from our net operating loss or research credit carry-forwards because we believe that it is uncertain that we will have sufficient income from future operations to realize the carry-forwards prior to their expiration. Accordingly, we have established a 100% valuation allowance against the deferred tax asset arising from the carry-forwards.

Liquidity and Capital Resources

We have incurred net losses since inception through September 30, 2014 of $355.3 million, of which $315.5 million was incurred in the Company s prior focus on gene therapy in 2010 and years earlier. We have not generated any product revenues and do not expect to generate revenue from the sale of product candidates in the near term.

We had cash and cash equivalents of $9.8 million and $20.4 million at September 30, 2014 and December 31, 2013, respectively.

Net cash used in operating activities for the nine month period ended September 30, 2014 was $9.4 million. We recorded net income for the nine-month period of $22.8 million, including a non-cash gain on derivative liabilities of $34.0 million. Other items in uses of funds from operations included non-cash charges related to stock-based compensation expense, depreciation expenses, and patent amortization, which collectively totaled $1.7 million. Increases in accounts payable and accrued liabilities increased net cash from operating activities by $0.3 million, partially offset by an increase in receivables and prepaid expenses of $0.1 million.

TABLE OF CONTENTS

Net cash used in operating activities for the nine month period ended September 30, 2013 was $4.9 million. We recorded a net loss of $58.3 for the period, including a non-cash charge on derivative liabilities of $45.6 million. The net impact of these two factors was a use of funds of $12.7 million. Other items in uses of funds from operations included non-cash charges for a technology access, amortization of loan discount, stock-based compensation expense, depreciation expenses, warrant-based investment fees, and a loss on disposal of equipment, which collectively totaled $6.4 million. Net changes in accrued liabilities, receivables and other asset also generated $0.1 million in cash.

Net cash used in investing activities for the nine month period ended September 30, 2014 and September 30, 2013 were $1.1 million and $0.9 million, respectively, due to purchases of equipment.

Net cash provided by financing activities for the nine month period ended September 30, 2013 was $9.0 million due to proceeds from our issuance of shares of Series B Preferred Stock and convertible loan notes. We expect 2014 cash requirements to be in the range of $15.0 million to $17.0 million. We believe that our cash as of September 30, 2014, will be sufficient to fund our projected operating requirements through the first quarter of 2015.

Our total use of cash in the nine month period ended September 30, 2014 was $10.6 million.

We expect to need to raise additional capital or incur indebtedness to continue to fund our future operations. We may seek to raise capital through a variety of sources, including:

the public equity market;
private equity financing;
collaborative arrangements;
licensing arrangements; and/or
public or private debt.

Our ability to raise additional funds will depend on our clinical and regulatory developments, our product development activities, our ability to identify promising in-licensing opportunities and factors related to financial, economic and market conditions, many of which are beyond our control. We cannot be certain that sufficient funds will be available to us when required or on satisfactory terms. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through arrangements that may require us to relinquish rights to certain of our products, technologies or potential markets, any of which could delay or require that we curtail our development programs or otherwise have a material adverse effect on our business, financial condition and results of operations. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in ownership dilution to our existing stockholders.

If we are unable to secure additional financing on a timely basis or on terms favorable to us, we may be required to cease or reduce certain research and development projects, to sell some or all of our technology or assets or to merge all or a portion of our business with another entity. Insufficient funds may require us to delay, scale back or eliminate some or all of our activities, and if we are unable to obtain additional funding, there is uncertainty regarding our continued existence.

Off-Balance Sheet Arrangements

As of September 30, 2014, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. Therefore, we are not

materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

Critical Accounting Policies and Use of Estimates

Our management s discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally

TABLE OF CONTENTS

accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Goodwill

Costs of investments in purchased companies in excess of the underlying fair value of net assets at the date of acquisition are recorded as goodwill and assessed annually for impairment. If considered impaired, goodwill will be written down to fair value and a corresponding impairment loss recognized. As of December 31, 2013, we have recorded goodwill of $4.3 million due to the 2012 acquisition of SPH s knowhow and phage libraries and the 2011 acquisition of Biocontrol s patents and phage library. In management s opinion, no goodwill has been impaired as of December 31, 2013.

In Process Research and Development Costs

In Process Research & Development (IPR&D) assets represent capitalized incomplete research projects that the Company acquired through business combinations. Such assets are initially measured at their acquisition date fair values. The fair value of the research projects is recorded as intangible assets on the consolidated balance sheet rather than expensed regardless of whether these assets have an alternative future use. The amounts capitalized are being accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of research and development efforts associated with the projects. Upon successful completion of each project, the Company will make a determination as to the then remaining useful life of the intangible asset and begin amortization. The Company tests its indefinite-lived intangibles, including IPR&D assets, for impairment at least quarterly. As of December 31, 2013, we have recorded IPR&D of $12.5 million due to the 2012 acquisition of SPH s know-how and phage libraries and the 2011 acquisition of Biocontrol s patents and phage library. In management s opinion, no IPR&D has been impaired as of December 31, 2013.

Stock-Based Compensation Expenses

We account for stock options and restricted stock units related to our Stock Incentive Plans under the provisions of ASC 718, which requires the recognition of the fair value of stock-based compensation. The fair value of stock options and restricted stock units was estimated using a Black-Scholes option valuation model.

This model requires the input of subjective assumptions in implementing ASC 718, including expected dividend, expected life, expected volatility and forfeiture rate of each award, as well as the prevailing risk-free interest rate and the fair value of the underlying common stock on the date of grant. The fair value of equity based awards is amortized over the vesting period of the award, and we have elected to use the straight-line method of amortization. Actual results could differ from our assumptions, which may cause us to record adjustments to increase or decrease compensation expense, in future periods. The assumptions used in the Black-Scholes option valuation model for the years ended December 31, 2013 and 2012 are set forth below.

The following are the assumptions for the periods in which we granted stock options:

Expected Dividend: We do not anticipate any dividends.

Expected Life: The expected life represents the period that we expect our stock-based awards to be outstanding. We determine life based on historical experience and vesting schedules of similar awards.

Expected Volatility: Our expected volatility represents the weighted average historical volatility of the shares of our common stock for the most recent four-year and five-year periods.

TABLE OF CONTENTS

Risk-Free Interest Rate: We base the risk-free interest rate used on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent remaining term. Where the expected term of our stock-based awards does not correspond with the terms for which interest rates are quoted, we perform a straight-line interpolation to determine the rate from the available term maturities.

Forfeiture Rate: We apply an estimated forfeiture rate that is derived from historical forfeited shares. If the actual number of forfeitures differs from our estimates, we may record additional adjustments to compensation expense in future periods.

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fairvalue of the stock option grants were as follows:

	Years Ended December 31,	
	2013	2012
Risk-free interest rate	1.13 %	0.6 %
Expected volatility	160.9 %	172.1 %
Expected term (in years)	4.0	4.0
Expected dividend yield	0.0 %	0.0 %

Warrant and Preferred Shares Conversion Feature Liability

We account for warrants and the preferred shares conversion feature with anti-dilution (down-round) provisions under the guidance of ASC 815, Derivatives and Hedging and Emerging Issue Task Force Statement 07-5: Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity s Own Stock, which require the warrants and the preferred shares conversion feature to be recorded as a liability and adjusted to fair value in each reporting period. We estimate the fair values of these securities using a Monte Carlo valuation model.

Accounting for Income Taxes

Our income tax policy records the estimated future tax effects of temporary differences between the tax basis of assets and liabilities and amounts reported in the accompanying balance sheets, as well as operating loss and tax credit carry-forwards. We have recorded a full valuation allowance to reduce our deferred tax assets, as based on available objective evidence; it is more likely than not that the deferred tax assets will not be realized. In the event that we were to determine that we would be able to realize our deferred tax assets in the future, an adjustment to the deferred tax assets would increase net income in the period such determination was made.

Recent Accounting Pronouncements

None.

JOBS Act

In April 2012, the JOBS Act was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an emerging growth company. As an emerging growth company, we are electing not to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision not to take advantage of the extended transition period is irrevocable. In addition, we

are in the process of evaluating the benefits of relying on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, if as an emerging growth company we choose to rely on such exemptions, we may not be required to, among other things, (i) provide an auditor s attestation report on our system of internal controls over financial reporting pursuant to Section 404, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding a supplement to the auditor s report

TABLE OF CONTENTS

providing additional information about the audit and the financial statements (auditor discussion and analysis) and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer s compensation to median employee compensation. These exemptions will apply for a period of five years following the completion of our initial public offering or until we no longer meet the requirements of being an emerging growth company, whichever is earlier.

Results of Operations

Comparison of the Years Ended December 31, 2013 and 2012

Revenue

For the years ended December 31, 2013 and 2012, we recognized $0.3 million and $0.7 million in revenue, respectively. For the years ended December 31, 2013 and 2012, we earned $0.3 million and $0.6 million of revenue through sublicensing agreements involving our former gene therapy program, respectively. For the year ended December 31, 2012, we also earned $0.1 million in grant revenue.

Research and Development

Research and development expenses were $6.5 million for the year ended December 31, 2013, compared to $1.5 million for the year ended December 31, 2012. The $5.0 million increase in expenses is due to an increase in discovery, laboratory, nonclinical testing, research and development collaborations, consulting and clinical development planning expenses for all of our product candidates.

Research and development expenses are expected to increase in 2014 compared to 2013 as we plan to continue devoting substantial resources to research and development in future periods as we start clinical trials and continue our discovery efforts.

General and Administrative

General and administrative expenses were $6.3 million for 2013, compared to $3.2 million for 2012. The $3.1 million increase is due to $1.0 million in placement agent fees associated with the June 2013 Series B Preferred Shares placement, $0.7 million in higher legal expenses due to preparation to become a public company, and $1.4 million in higher staffing and outside consulting expenses (including non-cash compensation expense related to options granted to Company executives).

We currently expect our general and administrative expenses to increase in 2014 compared to 2013 due to the costs associated with being a public company.

Discontinued Operations

In June 2012, we sold certain assets used in our gene therapy business including process development, quality control, quality assurance, manufacturing and bioanalytical functions for $3.1 million. In addition to this cash consideration, we may receive a long-term royalty of 1.75% on all product sales. This royalty may be completely canceled at any time by a one-time payment of $1.8 million.

Interest Income (Expense)

During 2013 and 2012, we issued $2.0 million and $1.0 million in convertible notes, respectively. Interest expense in 2013 was $0.2 million, compared to $0.3 million for 2012. The decrease was due to conversion of the convertible notes into Series B preferred Shares in June and July 2013 and thus eliminating future interest expense.

Income Taxes

We incurred net operating losses for the years ended December 31, 2013 and 2012 and, accordingly, we did not pay any federal or state income taxes. As of December 31, 2013, we had approximately $175.4 million in U.S. and UK operating loss carry-forwards and research tax credit carry-forwards of approximately $3.7 million. The carry-forwards began to expire in 2012. Our net operating loss carry-forwards are subject to certain limitations on annual utilization as a result of changes in ownership of the Company, as defined by federal and state tax laws.

TABLE OF CONTENTS

Net Operating Losses

We have not recorded a benefit from our net operating loss or research credit carry-forwards because we believe that it is uncertain that we will have sufficient income from future operations to realize the carry-forwards prior to their expiration. Accordingly, we have established a 100% valuation allowance against the deferred tax asset arising from the carry-forwards.

Liquidity and Capital Resources

We have incurred net losses since inception through December 31, 2013 of $378.1 million, of which $315.5 million was incurred by Targeted Genetics prior to its merger with Biocontrol, and $6.9 million of which was incurred by Biocontrol. We have not generated any product revenues and do not expect to generate revenue from the sale of product candidates in the near term.

We had cash of $20.4 million and $0.9 million at December 31, 2013 and 2012, respectively.

Net cash used in operating activities for the years ended December 31, 2013 and 2012 was $6.3 million and $4.3 million, respectively. For the year ended December 31, 2013, cash used in operations was attributable to the net loss for the year after adding back non-cash charges for loss on derivative liabilities, shares issued for technology access fee, amortization of loan discount, fair market value of warrants issued as June and July investment fees, stock-based compensation expense, and depreciation expenses. For the year ended December 31, 2012, cash used in operations was attributable to the net loss for the year after adding back non-cash charges for stock-based compensation expense, depreciation expenses and a loss on disposal of equipment, which were partially offset by a decrease in accrued liabilities and an increase in receivables. Net cash used in investing activities for the year ended December 31, 2013 was $0.1 million due to purchases of equipment. Net cash provided by investing activities for the year ended December 31, 2012 was $3.1 million due to the sale of assets from discontinued operations slightly offset by purchases of property and equipment. Net cash provided by financing activities was $25.9 million for the year ended December 31, 2013, due to the December 2013 private placement, the Series B financing and convertible loan notes. Net cash provided by financing activities was $1.0 million for the year ended December 31, 2012, due to proceeds from convertible notes. We expect 2014 cash requirements to be in the range of $15.0 million to $17.0 million. We believe that our cash as of December 31, 2013, will be sufficient to fund our projected operating requirements into the first quarter of 2015.

We expect to need to raise additional capital or incur indebtedness to continue to fund our future operations. We may seek to raise capital through a variety of sources, including:

the public equity market;
private equity financing;
collaborative arrangements;
licensing arrangements; and/or
public or private debt.

Our ability to raise additional funds will depend on our clinical and regulatory events, our ability to identify promising in-licensing opportunities and factors related to financial, economic and market conditions, many of which are beyond our control. We cannot be certain that sufficient funds will be available to us when required or on satisfactory terms. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through arrangements that may require us to relinquish rights to certain of our products, technologies or potential markets, any of which could delay or require that we curtail our development programs or otherwise have a

material adverse effect on our business, financial condition and results of operations. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in ownership dilution to our existing stockholders.

If we are unable to secure additional financing on a timely basis or on terms favorable to us, we may be required to cease or reduce certain research and development projects, to sell some or all of our technology or assets or to merge all or a portion of our business with another entity. Insufficient funds may require us to

TABLE OF CONTENTS

delay, scale back or eliminate some or all of our activities, and if we are unable to obtain additional funding, there is uncertainty regarding our continued existence.

Contractual Obligations and Commitments

In February 2011, the Company entered into an agreement with Virginia Biotechnology Research Partnership Authority for Richmond, Virginia laboratory space. This agreement has a contractual expiration date of February 29, 2012 at which time it converted to a rolling three-month lease. At September 30, 2014, the Company s minimum payment commitment for the Richmond, Virginia laboratory space was $4,900.

In December 2011, the Company entered into an agreement with Nevis Limited and Charter Limited for laboratory space in Bedfordshire, United Kingdom. This agreement has a minimum period of 3 years and a contractual expiration date of December 8, 2016. At September 30, 2014 the Company s minimum payment commitment for the Bedfordshire laboratory space was $67,600.

In February 2013, we entered into an agreement with Office Suites Plus (now Regus Management Group, LLC) for office space in Glen Allen, Virginia. The agreement has a minimum period of one year ending February 28, 2014. In October 2014, the Company entered an agreement to extend this lease for six months to April 2015, with a monthly cost of $3,340. At September 30, 2014, our minimum payment commitment for the Glen Allen space was $23,380.

In September 2013, we entered into an agreement with PBC Carlsbad, LLC for office space in Carlsbad, California. The agreement has a minimum period of six months ending February 28, 2014, at which time it was extended through August 2014, with a monthly cost of $1,033. The agreement was extended through February 28, 2015, with a monthly cost of $1,033. At September 30, 2014, our minimum payment commitment for the Carlsbad office space was $5,165.

Off-Balance Sheet Arrangements

As of December 31, 2013, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. Therefore, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

Recent Financings

On December 16, 2013, we entered into subscription agreements to issue an aggregate amount of 72,007,000 shares of common stock for an aggregate purchase price of approximately $18 million as part of a private placement. The purchasers of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of such purchasers was an accredited investor under Rule 506 of Regulation D or not a U.S. person under Regulation S.

On June 26, 2013, we completed a private placement of convertible preferred stock and warrants to purchase common stock with gross proceeds of $7.0 million through the sale of shares of our newly-created Series B Convertible Preferred Stock. As part of the same transaction, approximately $5.5 million in outstanding convertible notes were

converted into shares of Series B Convertible Preferred Stock and warrants to purchase common stock. On July 15, 2013, we completed a second closing in which we converted approximately $0.8 million of outstanding convertible notes into Series B Convertible Preferred Stock and warrants to purchase common stock. The financing was led by life-sciences investors RA Capital Management and Third Security, LLC, with participation from BioScience Managers Pty Ltd.

Under the terms of the financing, we issued an aggregate amount of approximately 10.0 million shares of the Series B Convertible Preferred Stock for an aggregate purchase price of approximately $13.3 million (including the conversion of approximately $6.3 million of outstanding convertible notes). Each share of Series B Convertible Preferred Stock is convertible into 10 shares of common stock. Additionally, we issued warrants to purchase an aggregate of up to approximately 25.0 million shares of common stock at an exercise

TABLE OF CONTENTS

price of $0.14 per share. As a result of the completion of this private placement, as of July 15, 2013, all previously issued convertible notes have been converted and there are no convertible notes outstanding.

Comparison of the Years Ended December 31, 2012 and 2011

Revenue

For the years ended December 31, 2012 and 2011, we recognized $0.7 million and $0.1 million in revenue, respectively. For the years ended December 31, 2012 and 2011, we earned $0.6 million and $0.1 million of revenue through sublicensing agreements involving our former gene therapy program.

For the years ended December 31, 2012 and 2011, we also earned $0.1 million and $20,000 in grant revenue, respectively.

Research and Development

Research and development expenses were $1.5 million for the year ended December 31, 2012, compared to $0.7 million for the year ended December 31, 2011. The $0.8 million increase in expenses is due to an increase in consulting and development expenses.

Research and development expenses are expected to increase in 2013 compared to 2012 as we plan to continue devoting substantial resources to research and development in future periods as we start clinical trials and continue our discovery efforts.

General and Administrative

General and administrative expenses were $3.2 million for 2012, compared to $3.3 million for 2011. The $0.1 million decrease is due to lower administrative staffing and facilities expenses, partially offset by higher legal expenses related to the acquisition of SPH.

We currently expect our general and administrative expenses to increase in 2013 compared to 2012 due to the costs associated with preparing this registration statement and being a public company.

Discontinued Operations

In June 2012, we sold certain assets used in our gene therapy business including process development, quality control, quality assurance, manufacturing and bioanalytical functions for $3.1 million. In addition to this cash consideration, we may receive a long-term royalty of 1.75% on all product sales. This royalty may be completely canceled at any time by a one-time payment of $1.8 million.

Tax Refund

As of December 31, 2012, we had a United Kingdom research and development tax refund of $0.1 million (£0.1 million) for the losses in the subsidiary based in the United Kingdom, compared to $0.3 million for 2011. The decrease in the refund was due to reduced staffing in 2012 compared to 2011.

Interest Income (Expense)

Interest expense in 2012 was $0.3 million, compared to $0.1 million for 2011. The increase was due to interest accrued for convertible notes. During 2012 and 2011, we issued $1.0 million and $2.7 million in convertible notes, respectively. Interest on the unpaid principal balance of these notes accrues at the rate of ten percent (10%) per annum.

Income Taxes

We incurred net operating losses for the years ended December 31, 2012 and 2011 and, accordingly, we did not pay any federal or state income taxes. As of December 31, 2012, we had accumulated approximately $170.4 million in U.S. and UK operating loss carry-forwards and research tax credit carry-forwards of approximately $4.3 million. The carry-forwards began to expire in 2012. Our net operating loss carry-forwards are subject to certain limitations on annual utilization as a result of changes in ownership of us, as defined by federal and state tax laws.

TABLE OF CONTENTS

Net Operating Losses

We have not recorded a benefit from our net operating loss or research credit carry-forwards because we believe that it is uncertain that we will have sufficient income from future operations to realize the carry-forwards prior to their expiration. Accordingly, we have established a 100% valuation allowance against the deferred tax asset arising from the carry-forwards.

TABLE OF CONTENTS

BUSINESS

Company History

We were incorporated under the laws of the State of Washington in March 1989 as a wholly owned subsidiary of Immunex Corporation and began operations as an independent company in 1992 as Targeted Genetics Corporation.

In January 2011, we completed the acquisition of Biocontrol Ltd, which we refer to as Biocontrol, an antimicrobial biotechnology company based in the United Kingdom, with the goal of developing their phage therapy programs using funding from the sale of our legacy gene therapy assets. On February 22, 2011, we changed our name to AmpliPhi Biosciences Corporation.

In November 2012, we completed the acquisition of Special Phage Holdings Pty Ltd, a company based in Australia, which we refer to as SPH, pursuant to our offer to acquire all outstanding shares of SPH from its shareholders under the terms of a Shareholder Sale Agreement and a Managers Warranty Deed. SPH was formed in 2004 to address the rapidly escalating problem of antibiotic resistance through the development of a series of bacteriophage-based treatments.We intend to reincorporate as AmpliPhi Biosciences Corporation in the State of Delaware.

Company Overview

We are a biotechnology company focused on the discovery, development and commercialization of novel phage therapeutics. Our proprietary pipeline is based on the use of bacteriophages, a family of viruses that infect only bacteria. Phages have powerful and highly selective mechanisms of action that permit them to target and kill specific bacterial pathogens, including the so-called multi-drug-resistant (MDR) or Superbug strains.

We believe that we are a leading developer of phage-based therapeutics. We are combining our proprietary approach and expertise in identifying, characterizing and developing naturally occurring bacteriophages with that of our collaboration partners in bacteriophage biology, drug engineering, development and manufacturing, to develop second-generation bacteriophage products. We believe that phages represent a promising means to treat bacterial infections, especially those that have developed resistance to current medicines.

The extensive use of antibiotics, since their discovery in the 1940s, has resulted in drug resistance among many disease-causing bacteria. Resistance to antibiotics, according to the Centers for Disease Control (CDC), threatens to reverse the medical advances of the last half-century. Examples of clinically important microbes that are rapidly developing resistance to available antimicrobials include bacteria that cause skin, bone, lung and bloodstream infections (e.g., *S. aureus* and MRSA), pneumonia and lung infections in the community, hospital and cystic fibrosis (e.g., *A. baumanii*, *P. aeruginosa*, and *K. pneumoniae*), meningitis (e.g., *S. pneumonia*), urinary tract and gastrointestinal infections (e.g., *E. coli* and *C. difficile*). As a phage kills bacteria in ways entirely unlike the mechanisms used by antibiotics, MDR bacteria are not resistant to a phage in the same manner. Furthermore, as new resistant bacteria emerge, it should be possible to identify new phages that will still have efficacy.

Our lead program is AmpliPhage-002, for the treatment of *S. aureus* infections (including methicillin-resistant MRSA). We also have two other product candidates in development: AmpliPhage-001 for the treatment of *P. aeruginosa* lung infections in CF patients, and AmpliPhage-004 for the treatment of *C. difficile* infections.

We are developing these phage product candidates using our proprietary discovery and development platform, which is designed for rapid identification, characterization and manufacturing of multiple phage therapies. Each product candidate combines several carefully chosen phages which target a specific disease-causing bacterial pathogen such as MRSA, *P. aeruginosa* and *C. difficile*. We believe that our understanding of unique regulatory and development requirements of bacteriophage biology combined with the scientific expertise of our collaboration partners will enable the rapid advancement of phage treatments through the clinic and eventually to the market.

TABLE OF CONTENTS

In March 2013, we entered into an Exclusive Channel Collaboration (ECC) with Intrexon Corporation, which we refer to as Intrexon, directed towards the research, development and commercialization of new bacteriophage-based therapies to target specific antibiotic-resistant infections, including for use in the treatment of bacterial infections associated with acute and chronic wounds, the treatment of acute and chronic *P. aeruginosa* lung infections, and the treatment of infections of *C. difficile.*

In April 2013, we entered into a collaboration agreement, which we refer to as the April Collaboration Agreement, and on September 5, 2013, we entered into a license agreement, which we refer to as the Leicester License Agreement, with the University of Leicester to develop a phage therapy that targets and kills all toxin types of *C. difficile*. Pursuant to the Leicester License Agreement, we may be obligated to pay the University of Leicester a royalty in the single digits and an aggregate of up to £575,000 in milestone payments. We also entered into a collaboration agreement on August 1, 2013, which we refer to as the August Collaboration Agreement, with the University of Leicester and the University of Glasgow, whereby the University of Glasgow will carry out certain animal model development work. Pursuant to the August Collaboration Agreement, we may be obligated to pay up to a total of approximately £205,000 in milestone payments.

In June 2013, we entered a cooperative research and development agreement (CRADA) with the United States Army Reserve Medical Corps (USAMRMC) and the Walter Reed Army Institute of Research (WRAIR) focusing on developing bacteriophage therapeutics to treat *S. aureus*, *E. coli* and *P. aeruginosa* infections.

In October 2014, we entered into a collaboration agreement, effect as of November 9, 2014, with the University of Leicester to develop phage therapies targeting *C. difficile*.

We plan to initiate a clinical trial in 2015 in collaboration with the U.S. Army that will support the development of a treatment for *S. Aureus* infections for wound and skin infections.

The Need for New Anti-Infective Therapies

The rapid and continuous emergence of antibiotic-resistant bacteria has become a global crisis. While the numbers of novel anti-infective therapies in development are at historically low levels, antibiotic-resistant infections have dramatically increased. The CDC estimates that more than two million people in the United States acquire an antibiotic-resistant infection each year and more than 23,000 of these prove fatal. It is estimated that 50 70% of hospital-acquired infections are resistant to first-line anti-infective therapies. The cumulative annual cost for treating resistant bacterial infections in the United States alone is estimated to be $20 billion, while the global antibiotics market opportunity is estimated to be $40.3 billion by 2015.

The CDC s latest report on the matter, *Antibiotic Resistance Threats in the United States, 2013*, notes that there are potentially catastrophic consequences of inaction and ranks *C. difficile* as belonging to the highest tier of threat, Urgent Threats. Despite the potential market opportunity, only two new antibacterial drug applications were approved between 2010 and 2012 compared to eighteen in the period between 1980 and 1984. One of the primary CDC recommendations is the development of new antibiotics to diversify treatment options.

Product Candidates

AmpliPhage-002: Wound and Skin Infections Caused by *S. aureus*

In conjunction with our CRADA with the USAMRMC, we are developing a phage product that is intended to effectively treat acute and chronic wound and skin infections caused by *S. aureus*, including infections caused by methicillin-resistant (MRSA) strains of the same bacterium. MRSA infections are one of the most common causes of hospital-acquired (nosocomial) infections and Global Data estimates the MRSA market for infections alone was more than $2.7 billion in 2007. This market is forecast to grow to more than $3.5 billion by 2019.

By screening our proprietary library of phage samples against a panel of *S. aureus* bacterium, we have selected a phage product mix that has demonstrated in in vitro studies greater than 85% efficacy with high overlap against a global diversity panel that includes some of the most virulent isolates of *S. aureus*, including MRSA identified by the U.S. Army.

We plan to initiate a clinical trial in 2015 in collaboration with the U.S. Army that will support the development of a treatment for *S. Aureus* infections for wound and skin infections.

TABLE OF CONTENTS

After extensive financial and capability evaluation and a global search we have elected to proceed with cGMP manufacturing at a wholly owned facility that has been constructed in Ljubljana, Slovenia. We have been able to access and hire highly skilled process development and phage manufacturing expertise and believe that we now have control of our proprietary platform from phage identification through final product fill and finish. Our facility inclusive of laboratory and office space is approximately 4,000 sq. ft. and is expected to produce cGMP product for our currently planned and future studies. We believe that this facility should be sufficient to meet our product needs through Phase 3 and initial commercialization. Our current formulation for AmpliPhage -002 is intended for nasal and/or topical delivery via a small spray device. We plan to further formulate our product for delivery to patients with wound and skin infections.

AmpliPhage-001: Lung Infections in Cystic Fibrosis (CF) Patients Caused by *P. aeruginosa*

According to Global Data in April 2013, the market for CF therapeutics was $1.2 billion in 2012 and forecasted to grow to $4.6 billion in 2017, with 65% of this market in the United States. One of our lead programs targets *P. aeruginosa*, the most prevalent bacterial infection that leads to the highest mortality in patients with CF with approximately 440 deaths per year in the United States. To develop our products, we have created a global diversity panel of relevant *P. aeruginosa* clinical isolates from CF clinics around the globe. Clinical isolates are bacteria isolated from patients. This diversity panel has been screened against our phage library that was isolated and characterized according to our proprietary discovery and development platform. We have demonstrated *in vitro* that we are able to effectively kill the targeted bacteria with a mixture of a few phages propagated in carefully selected bacterial