

AmpliPhi Biosciences Corp
Form S-1/A
April 15, 2014

As filed with the Securities and Exchange Commission on April 15, 2014

Registration No. 333-193458

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

**AMENDMENT NO. 2 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)

Philip J. Young
President and 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

Stephen Thau Morrison & Foerster LLP 2000 Pennsylvania Avenue NW Washington, DC 20006 (202) 88721500

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

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

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.

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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 April 15, 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 29 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 _____, 2014.

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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

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 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.

Our lead programs consist of three product candidates: AmpliPhage-001 for the treatment of *P. aeruginosa* lung infections in cystic fibrosis (CF) patients; AmpliPhage-002, for the treatment of methicillin-resistant *S. aureus* (MRSA) infections; and AmpliPhage-004 for the treatment of *C. difficile* infections.

We currently plan to develop 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. We believe that our understanding of bacteriophage biology combined with the clinical and scientific expertise of our collaboration partners will enable the rapid advancement of phage treatments through the clinic and eventually to the market.

We plan to initiate at least one new clinical study in 2014.

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;

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we depend on the U.S. Army for assistance in developing our initial manufacturing processes of our lead product candidates and any disruption of this relationship or the U.S. Army's operations would materially and negatively affect our business; their failure to comply with manufacturing regulations could result in an interruption in the supply of our product candidates;

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 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.

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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.ampliphio.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.

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THE OFFERING

Common stock covered by this prospectus	73,362,164 shares
Common stock outstanding as of March 24, 2014	271,135,342 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 OTC Pink market under the symbol APHB.

The number of shares of our common stock outstanding as of March 24, 2014 is 271,135,342, which consists of 182,535,562 shares of common stock outstanding as of March 24, 2014, and 88,599,780 shares of common stock issuable upon conversion of all outstanding shares of Series B Convertible Preferred Stock as of March 24, 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 \$0.18 per share;

9,353,323 shares of our common stock reserved for future issuance under the 2012 Plan;

166,000 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 \$0.90 per share;

1,304,760 shares of our common stock reserved for future issuance under the 2009 Plan;

40,000,000 shares of common stock reserved for future issuance under our 2013 Stock Incentive Plan, or the 2013 Plan; and

42,746,165 shares of our common stock issuable upon the exercise of outstanding warrants, at a weighted-average exercise price of \$0.16 per share.

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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.

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

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 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:

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

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;

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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 under construction in Ljublyana, Slovenia. The manufacturing processes 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 the European regulatory authorities 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. 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 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

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

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

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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 other regulatory agencies in the United States and by comparable authorities in Europe and elsewhere. For example, our research facilities in Colworth, United Kingdom, recently failed an audit by the Health and Safety Executive, Britain's national regulatory for workplace health and safety; as a result of this failure we have elected to reconfigure our research operations.

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

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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, 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 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

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

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

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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 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.

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

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

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.

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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;
- 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.

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, we have incurred a cumulative

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deficit of \$14.6 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 \$4.2 million and a net loss of \$1.1 million. For the year ended December 31, 2013, we had an operating loss of \$15.0 million and a net loss of \$58.4 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 key personnel and, if we fail to do so, it may be more difficult for us to execute our business strategy. As a small organization we are dependent on key employees and may need to hire additional personnel to execute our business strategy successfully.

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. We are highly dependent upon our senior management, particularly our Chief Executive Officer, Philip J. Young. The loss of the services of Mr. Young or one or more of our other key employees could delay or have an impact on the successful completion of our clinical trials or the development of additional product candidates.

As of March 24, 2014, we had twelve 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.

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 2011 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.

Our success depends in part on retaining and motivating key personnel and, if we fail to do so, it may be more difficult

Due to this material weakness, we have concluded that as of December 31, 2013, our internal control over financial reporting was 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

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

We must manage a geographically dispersed organization.

While we are a small company, we currently have operations in the United States, Australia, the 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.

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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;

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

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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 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

If we are sued for infringing intellectual property rights of third parties or if we are forced to engage in an interference

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.

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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;
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;

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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;
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

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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 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 This Offering and 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 OTC Pink market, on the Limited Information tier. 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

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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;
- 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.

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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 March 24, 2014, we have outstanding warrants to purchase 42,746,165 shares of our common stock at an average exercise price of \$0.16 per share, and outstanding options to purchase 25,721,000 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 March 24, 2014, our officers and directors beneficially owned approximately 13.40% 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 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

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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.

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 will be 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

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

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 weaknesses in the area of complex and non-routine transactions. 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

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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 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.

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

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

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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, 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.

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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 2014;

the safety and efficacy of our products and 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;

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

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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, expects, intends, may, plans, potential, predicts, projects, should, will, would or the negative of those terms and other similar 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.

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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 March 24, 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 March 24, 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 29. 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		

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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⁾	9.88 %
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		

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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	1,381,600	1,200,000	181,600	*
Gerald Pogue & Mai Pogue	200,000	200,000		
Michael Bego	351,000	300,000	51,000	*
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	300,000	300,000		
Marc Levy	200,000	200,000		
BTG Investments LLC ⁽¹²⁾	72,000	72,000		
Griffin Securities, Inc.	1,735,714 ⁽¹³⁾	48,000	1,735,714 ⁽¹³⁾	*
Phillip Asset Management Ltd ⁽¹⁴⁾	14,928,562 ⁽¹⁵⁾	6,000,000	8,928,562 ⁽¹⁵⁾	3.29 %

*

Less than 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 (1) 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 271,135,342 shares of Common Stock outstanding on March 24, 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, 21st

Floor, New York, NY 10022.

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 (9) 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.

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(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) 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.

(13) Consists of shares of common stock underlying warrants to purchase 1,735,714 shares of common stock. 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.

(15) 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.

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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 OTC Pink 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.

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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.

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Our shares of common stock are quoted on the OTC Pink 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 April 1, 2014 to April 14, 2014	\$ 0.58	\$ 0.50
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

Holder of Common Stock

As of March 24, 2014, there were 317 holders of record of our common stock. As of such date, the number of shares of our common stock outstanding was 271,135,342, which consists of 182,535,562 shares of common stock outstanding as of March 24, 2014, and 88,599,780 shares of common stock issuable upon conversion of all outstanding shares of Series B Convertible Preferred Stock as of March 24, 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 30 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.

In December 2013, our board of directors adopted the 2013 Plan. Under the 2013 Plan, we are authorized to issue up to 40,000,000 shares of our common stock in stock incentive awards to employees, directors and consultants. Our shareholders approved the 2013 Plan on February 11, 2014.

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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	9,353,323
Total	25,721,000	\$ 0.20	10,658,083

(1) The 2009 Plan.

(2) The 2012 Plan.

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the financial statements and the related notes contained elsewhere in this registration statement. Some of the information contained in this discussion and analysis or set forth elsewhere in this registration statement, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. See Special Note Regarding Forward-Looking Statements. Our actual results may differ substantially from those referred to herein due to a number of factors, including but not limited to risks described in the section entitled Risk Factors and elsewhere in this registration statement.

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 programs consist of three product candidates: AmpliPhage-001 for the treatment of *P. aeruginosa* lung infections in cystic fibrosis (CF) patients; AmpliPhage-002, for the treatment of methicillin-resistant *S. aureus* (MRSA) infections; 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, which raised approximately \$7.0 million in addition to converting approximately \$6.3 million in outstanding convertible notes. In December 2013, we completed a private placement of shares of our common stock, which raised approximately \$18 million, prior to commissions. To date, we have not generated any 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 December 31, 2013, we had a deficit accumulated of \$387.2 million. We recorded annual net losses of \$58.4 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.

We expect our research and development expenses to increase as we 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 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 these funds 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

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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

Revenue

To date, we have not generated any revenue from the sale of our product candidates and do not expect to generate any revenue from the sale of our product candidates in the near term. In the last two years, we recognized \$1.0 million in revenue related to license agreements and grants from governments and academic institutions. These revenues were used in our new focus, the development of phages.

Research and Development Expenses

Research and development costs consist of the costs associated with our research and discovery activities, conducting clinical trials, manufacturing development efforts and activities related to regulatory filings. Our research and development expenses consist of salaries, non-cash stock-based compensation, costs of outside collaborators and outside services, royalty and license costs and facility, occupancy and utility expenses. We expense research and development costs as incurred. We expect annual research and development expenses will increase significantly in the future as we progress with development. In the last two years, we incurred an aggregate of \$8.0 million on research and development expenses, including non-cash stock-based compensation expense.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for our personnel in the executive, finance, patent, accounting and other administrative functions, including non-cash stock-based compensation, as well as consulting costs for functions for which we either do not or only partially staff internally, including public relations, market research and recruiting. Other costs include professional fees for legal and accounting services, insurance and facility costs. In the last two years, we incurred an aggregate of \$12.0 million in general and administrative expenses, including non-cash stock-based compensation expense.

Interest Income (Expense)

Interest income consists of interest earned on our cash and cash equivalents and is not considered significant to our financial statements. We expect our interest income to increase in the future as we raise further capital to fund our operations.

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 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 know-how 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.

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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 \$12.9 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.

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 fair value of the stock option grants were as follows:

Years Ended
December 31,