AmpliPhi Biosciences Corp
Form 424B3
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Registration No. 333-203454

Prospectus

152,554,535 Shares

Common Stock

This prospectus covers the sale of an aggregate of up to 152,554,535 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 78,787,880 shares of our common stock, which were issued pursuant to a subscription agreement, dated as of March 10, 2015, entered into by us and the selling stockholders listed in this prospectus, and 24,424,244 shares of our common stock underlying warrants, 19,696,971 of which are underlying warrants that were issued pursuant to the subscription agreement and 4,727,273 of which are underlying warrants that were issued to the placement agents in connection with the completion of the March 2015 private placement, as well as 24,000,000 shares previously issued to Intrexon Corporation in connection with the Exclusive Channel Collaboration in March 2013 and 25,342,411 shares previously issued to Dr. Anthony Smithyman and his affiliates in connection with our acquisition of SPH in November 2012.

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

We are an “emerging growth company” as that term is used in the Jumpstart Our Business Startups Act of 2012, as amended, and a “smaller reporting company” as that term is defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, 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 and of Being a Smaller Reporting 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 May 14, 2015.

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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 or additional information. If anyone provides you with different, additional 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 of this prospectus and our financial statements and notes thereto that appear elsewhere in this prospectus. As used in this prospectus, unless the context requires otherwise, the "Company," "we," "us" and "our" refer to AmpliPhi Biosciences Corporation, a Washington corporation, or, where appropriate, Targeted Genetics Corporation or AmpliPhi Biosciences Corporation, a Delaware corporation to be formed in connection with the Company's planned reincorporation.

Our Company

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

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

The extensive use of antibiotics, since their discovery in the 1940s, has resulted in drug resistance among many disease-causing bacteria. Resistance to antibiotics, according to the Centers for Disease Control, threatens to reverse the medical advances of the last half-century. Examples of clinically important microbes that are rapidly developing

resistance to available antimicrobials include bacteria that cause skin, bone, lung and bloodstream infections (e.g., *S. aureus* and MRSA), pneumonia and lung infections in the community, hospital and cystic fibrosis (e.g., *A. baumanii, P. aeruginosa,* and *K. pneumoniae*), meningitis (e.g., *S. pneumonia*), urinary tract and gastrointestinal infections (e.g., *E. coli* and *C. difficile*). As a phage kills bacteria in ways entirely unlike the mechanisms used by antibiotics, multi-drug resistant bacteria are not resistant to a phage in the same manner. Furthermore, as new resistant bacteria emerge, it may be possible to identify new phages that will still have efficacy.

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

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

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

In April and September 2013, we entered into a collaboration agreement and a license agreement, respectively, with the University of Leicester to develop a phage therapy that targets and kills all toxin types of *C. difficile*. Pursuant to the September 2013 license agreement, we may be obligated to pay the University of Leicester a percentage royalty in the single digits and an aggregate of up to £575,000 in milestone payments. We also entered into a related agreement with the University of Leicester and the University of Glasgow, whereby the University of Glasgow carried out certain animal model development work. Total obligations under this agreement were £244,000. In October 2014, we renewed our collaboration agreement, effective as of November 9, 2014, with the University of Leicester to develop phage therapies targeting C. difficile.

In June 2013, we entered a Cooperative Research and Development Agreement with the United States Army Reserve Medical Corps and the Walter Reed Army Institute of Research focusing on developing bacteriophage therapeutics to treat *S. aureus*, *E. coli* and *P. aeruginosa* infections.

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

Our Risks

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

- we are seeking to develop antibacterial agents using bacteriophage technology, which has not resulted in any approved product on the market to date;
- we have incurred losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future, and our future profitability is uncertain;

- we must hire additional members of our senior management team and we must retain and motivate our personnel;

- we must develop commercial-scale manufacturing capabilities or find third party contract manufacturers with the skill and capacity to manufacture our products on a commercial scale;

- 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 previously expressed substantial doubt about our ability to continue as a going concern and we may need to raise additional capital to continue operations.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, which is commonly known as the JOBS Act. 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. References herein to “emerging growth company” shall have the meaning associated with it in the JOBS Act.

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

- only two years of audited consolidated financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Conditions and Results of Operations" disclosure;
- reduced disclosure about our executive compensation arrangements;
- no requirement that we hold non-binding advisory votes on executive compensation or golden parachute arrangements; and
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

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

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

Corporate Information

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

In January 2011, we completed the acquisition of Biocontrol Ltd, 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.

In February 2014, our shareholders approved a plan for us to reincorporate as AmpliPhi Biosciences Corporation in the State of Delaware at such time as is determined by our board of directors. The reincorporation would be effected through a merger of our current Washington entity with a newly formed Delaware entity.

Our principal executive offices are located at 800 East Leigh Street, Suite 209, Richmond, Virginia 23219. The telephone number at our principal executive office is (804) 827-2524. Our website address is *http://www.ampliphibio.com*. Our website and the information contained on, or that can be accessed through, our website will not be deemed to be incorporated by reference in, and are not considered part of, this prospectus. You should not rely on our website or any such information in making your decision whether to purchase our common stock.

THE OFFERING

Common stock covered by this prospectus	**128,130,291 shares and 24,424,244 shares underlying warrants to purchase common stock**
Common stock outstanding as of April 10, 2015	**277,946,973 shares**
Use of proceeds	The selling stockholders will receive all of the proceeds from the sale of the shares and warrants which they offer for sale under this prospectus. We will not receive proceeds from the sale of the shares and warrants 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 or warrants of our common stock.
Dividend policy	We currently intend to retain any future earnings to fund the development activities and operation of our business. Therefore, we do not currently anticipate paying cash dividends on our common stock.
Trading symbol	Our common stock is quoted on the OTCQB market under the symbol “APHB.”

The number of shares of voting securities outstanding as of April 10, 2015 is 364,657,373, which consists of 277,946,973 shares of common stock outstanding as of April 10, 2015, and 86,710,400 shares of common stock issuable upon conversion of all outstanding shares of Series B Redeemable Convertible Preferred Stock as of April 10, 2015 (assuming a conversion ratio equal to ten (10) common shares for each share of Series B Redeemable Convertible Preferred Stock), and does not include the following:

- 21,120,747 shares of our common stock issuable upon the exercise of stock options outstanding under our 2012 Stock Incentive Plan, at a weighted-average exercise price of $0.18 per share;

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

- 750,000 shares of Common Stock issuable upon the exercise of stock options outstanding under our 2013 Stock Incentive Plan, at a weighted-average exercise price of $0.28 per share;

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

- 63,314,696 shares of our common stock issuable upon the exercise of outstanding warrants, at a weighted-average exercise price of $0.18 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;
- 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.

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

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

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

We must hire additional members of our senior management team.

Wendy Johnson, a member of our Board of Directors, is acting as interim Chief Operating Officer. We are looking to appoint a new Chief Operating Officer and add additional members to the Company’s management team, including the possible additions of senior staff to manage key functions in research, clinical and non-clinical development. If we do not hire additional senior management personnel, we may not be able to effectively manage our business and operations.

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, we have had recurring losses from operations, negative operating cash flow and an accumulated deficit of $362 million.

In December 2013, we completed a private placement of shares of our common stock, which raised approximately $18 million, prior to commissions. In March 2015, we completed a private placement of shares of our common stock and warrants to purchase shares of our common stock, which raised approximately $13 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. We believe that we have adequate capital to fund operations through the second quarter of 2016.

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.

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:

- the therapeutic endpoints chosen for evaluation;
- the eligibility criteria defined in the protocol;
- the perceived benefit of the investigational drug under study;
- the size of the patient population required for analysis of the clinical trial's therapeutic endpoints;
- our ability to recruit clinical trial investigators and sites with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents; and
- competition for patients by clinical trial programs for other treatments.

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

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

We are developing novel manufacturing processes for the production of AmpliPhage-002 for treatment of *S. aureus* (MRSA) infections, AmpliPhage-001 for the treatment of *P. aeruginosa* infections and AmpliPhage-004 for the treatment of *C. difficile* infections at facilities in Ljubljana, Slovenia. The manufacturing processes for our product candidates, and the scale up of such processes for clinical trials, is novel, and there can be no assurance that we will be able to complete this work in a timely manner, if at all. Any delay in the development or scale up of these manufacturing processes could delay the start of clinical trials and harm our business. Our facilities in Slovenia must also undergo inspections by JAZMP, the Slovenian agency that regulates and supervises pharmaceutical products in Slovenia, for compliance with their and the FDA's current good manufacturing practice regulations, or cGMP regulations, before the respective product candidates can be approved for use in clinical trials or commercialization. As a result of an initial inspection, we are taking certain non-critical corrective actions regarding the manufacture of AmpliPhage-002, which we believe will lead to certification by JAZMP to manufacture AmpliPhage-002; however, there can be no assurance that we will receive or maintain such certification. We will also be subject to additional inspections for GMP compliance for our other product candidates, and may be subject to additional inspections for AmpliPhage-002. In the event these facilities do not receive a satisfactory cGMP inspection for the manufacture of our product candidates, we may need to fund additional modifications to our manufacturing process, conduct additional validation studies, or find alternative manufacturing facilities, any of which would result in significant cost to us as well as a delay of up to several years in obtaining approval for such product candidate.

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

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

We have conducted and may in the future choose to conduct one or more of our clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of such

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

We may need to license additional intellectual property rights.

The development and commercialization of phage-based antibacterial agents may require us to obtain rights to intellectual property from third parties. For example, pursuant to our Collaborative Research and Development Agreement with the United States Army Medical Research and Materiel Command and the Walter Reed Army Institute of Research, 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 United States Army Medical Research and Materiel Command or Walter Reed Army Institute of Research 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, 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 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. The 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, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

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

other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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

In 1997, a public registry of open clinical trials involving drugs intended to treat serious or life-threatening diseases or conditions was established under the Food and Drug Administration Modernization Act, or FDMA, in order to promote public awareness of and access to these clinical trials. Under FDMA, pharmaceutical manufacturers and other clinical trial sponsors are required to post the general purpose of these clinical trials, as well as the eligibility criteria, location and contact information of the clinical trials. Since the establishment of this registry, there has been significant public debate focused on broadening the types of clinical trials included in this or other registries, as well as providing for public access to clinical trial results. A voluntary coalition of medical journal editors has adopted a resolution to publish results only from those clinical trials that have been registered with a no-cost, publicly accessible database, such as *www.clinicaltrials.gov*. The Pharmaceuticals and Research Manufacturers of America has also issued voluntary principles for its members to make results from certain clinical trials publicly available and has established a 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 success depends in part on attracting, retaining and motivating our personnel.

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

institutions, clinicians and scientists. The loss of the services of 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 April 3, 2015, we had twenty-three 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 also face competition from other more well-funded and well-established businesses and we may also be viewed as a riskier choice from a job stability perspective due to our relative newer status than longer existing biotech and pharmaceutical companies. 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 must manage a geographically dispersed organization.

While we are a small company, we currently have operations in the United States, Australia 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 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 deficit of $46.5 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, 2013, we had an operating loss of $12.4 million and a net loss of $64.6 million, including a non-cash loss on warrant and derivative liabilities of $49.3 million and a non-cash charge of $3.0 million related to common shares issued for a technology access fee. For the year ended December 31, 2014, we had an operating loss of $14.1 million and a net income of $23.1 million, including a non-cash gain on warrant and derivative liabilities of $37.2 million. Additional information regarding our results of operations may be found in our consolidated financial statements and in “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

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.

We may be required to make cash payments to the holders of our Series B Redeemable Convertible Preferred Stock if the holders elect to receive payment for the Series B dividends in cash.

The holders of our shares of Series B Redeemable Convertible Preferred Stock are entitled to receive a cumulative dividend at the rate of 10% per annum, payable in cash at the option of the holders of two-thirds of the shares of Series B Redeemable Convertible Preferred Stock. If such holders elect to receive payment for such dividends in cash, we will have less cash available, which will have a negative effect on our operations and financial results.

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 year ended December 31, 2013 and the quarters ended March 31, 2014, June 30, 2014 and September 30, 2014, we determined that we had a material weakness as of December 31, 2014, namely that our controls over the evaluation and review of complex and non-routine transactions were not effective.

Due to this material weakness, we have concluded that as of December 31, 2014, our internal controls over financial reporting were not effective. Subsequent to December 31, 2014, we have restated our consolidated financial statements as of December 31, 2013, March 31, 2014, June 30, 2014 and September 30, 2014 to correct for errors caused by this weakness.

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

Risks Related to Our Dependence on Third Parties

We rely on third parties for aspects of product development.

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

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

We expect to use third parties, such as clinical research organizations or the U.S. Army, to assist in conducting 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, the commercial prospects for product candidates could be harmed and our ability to generate product revenue would be delayed or prevented.

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