AmpliPhi Biosciences Corp
Form 10-K
April 15, 2015

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended December 31, 2014

Commission File Number 000-23930

AMPLIPHI BIOSCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

Washington	**91-1549568**
(State or other jurisdiction of incorporation and organization)	(I.R.S. Employer Identification No.)

4870 Sadler Road, Suite 300

Glen Allen, Virginia 23060

(Address of principal executive offices, including zip code)

(804) 205-5069

(Registrant's telephone number)

Securities registered pursuant to Section 12(b) of the Act:
None

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, par value $0.01 per share
(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ¨ No x

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

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 definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes ¨ No x

As of April 10, 2015, the aggregate market value of voting stock held by non-affiliates of the Registrant, based on the closing price of the Common Stock on June 30, 2014 (the last business day of the Registrant's most recently completed second quarter) as reported on the OTCQB, was approximately $62,219,991. Shares of Common Stock held by each officer and director and by each person who owns 10% or more of the outstanding Common Stock have been excluded from this computation in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of April 10, 2015, the Registrant had outstanding 277,946,973 shares of Common Stock.

Documents incorporated by reference: Portions of the Registrant's proxy statement to be filed pursuant to Regulation 14A within 120 days after Registrant's fiscal year end of December 31, 2014 are incorporated herein by reference into Items 10, 11, 12, 13 and 14 of Part III of this annual report.

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AMPLIPHI BIOSCIENCES CORPORATION

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report and certain information incorporated herein by reference contain forward-looking statements, which are provided under the "safe harbor" protection of the Private Securities Litigation Reform Act of 1995. 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 regarding:

- *our ability to manufacture, or otherwise secure the manufacture of, sufficient amounts of our product candidates for our preclinical studies and clinical trials;*
- *our clinical development plans, including planned clinical trials;*
- *our research and development plans, including our plans to initiate at least one new clinical study in 2015;*
- *our ability to select combinations of phages to formulate our product candidates;*
- *the safety and efficacy of our product candidates;*
- *the anticipated regulatory pathways for our product candidates;*
- *our ability to successfully complete preclinical and clinical development of, and obtain regulatory approval of our product candidates and commercialize any approved products on our expected timeframes or at all;*
- *the content and timing of submissions to and decisions made by the FDA and other regulatory agencies;*
- *our ability to leverage the experience of our management team;*
- *our ability to attract and keep management and other key personnel;*
- *the capacities and performance of our suppliers, manufacturers, contract research organizations, or CROs, and other third parties over whom we have limited control;*
- *the actions of our competitors and success of competing drugs that are or may become available;*
- *our expectations with respect to future growth and investments in our infrastructure, and our ability to effectively manage any such growth;*
- *the size and potential growth of the markets for any of our product candidates, and our ability to capture share in or impact the size of those markets;*
- *the benefits of our 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 operating losses, derivative liabilities, cash flows, expected uses of anticipated cash flow, funding requirements and market risk;*
- *our expectations regarding future planned expenditures;*
- *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;*
- *our ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection of any of our products and product candidates; and*
- *our ability to operate our business without infringing the intellectual property rights of others.*

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 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 Annual Report 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.

This Annual Report on Form 10-K includes trademarks and registered trademarks of AmpliPhi Biosciences Corporation. Products or service names of other companies mentioned in this Annual Report on Form 10-K may be trademarks or registered trademarks of their respective owners.

As used in this Annual Report, 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.

PART I

Item 1. BUSINESS.

Company History

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

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

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

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.

Company Overview

We are a biotechnology company focused on the discovery, development and commercialization of novel phage therapeutics. Our proprietary pipeline is based on the use of bacteriophages, a family of viruses that infect only bacteria. Phages have powerful and highly selective mechanisms of action that permit them to target and kill specific bacterial pathogens, including the so-called multi-drug-resistant 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, which we refer to as Intrexon, directed towards the research, development and commercialization of new bacteriophage-based therapies to target specific antibiotic-resistant infections, including for use in the treatment of bacterial infections associated with acute and chronic wounds, the treatment of acute and chronic *P. aeruginosa* lung infections, and the treatment of infections of *C. difficile*.

In April 2013, we entered into a collaboration agreement, which we refer to as the April Collaboration Agreement, and on September 5, 2013, we entered into a license agreement, which we refer to as the Leicester License Agreement, with the University of Leicester to develop a phage therapy that targets and kills all toxin types of *C. difficile* . Pursuant to the Leicester License Agreement, we may be obligated to pay the University of Leicester a percentage royalty in the single digits and an aggregate of up to £575,000 in milestone payments. We also entered into a collaboration agreement on August 1, 2013, which we refer to as the August Collaboration Agreement, with the University of Leicester and the University of Glasgow, whereby the University of Glasgow carried out certain animal model development work. Pursuant to the August Collaboration Agreement, we were obligated to pay up to a total of approximately £205,000 for services provided. This agreement was extended for a period to expire January 22, 2015. Pursuant to the extended agreement, we were obligated to pay approximately £39,000.

In June 2013, we entered a Collaborative Research and Development Agreement with the United States Army Medical Research and Materiel Command 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.

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.*

The Need for New Anti-Infective Therapies

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

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

Product Candidates

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

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

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

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

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

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

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

In collaboration with Institut Pasteur (Paris, France) and Brompton Clinic, Imperial College (London, United Kingdom), we have demonstrated in the preclinical studies described below that phages can effectively treat infections in animal models of acute *P. aeruginosa* lung infections. The graphic below shows the three groups from a study conducted at the Institute Pasteur. Each group consisted of eight mice. Group 1 was treated with Placebo, or PBS, Group 2 was treated with an antibiotic (note the model was optimized for this antibiotic) and Group 3 was treated with an AmpliPhi phage mix. The colored regions, measured by light, intensity, or luminescence, demonstrate where the *P.*

aeruginosa infection is active and the bacteria are actively replicating. By the 24th hour, the surviving untreated animals (Group 1) are sacrificed as the infection has spread and in some cases has already proved lethal whereas the two treatment groups (Group 2, antibiotic and Group 3, phage) demonstrate effective reduction of the active infection.

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Average luminescence for each group is shown below:

Bacterial counts and the number of bacteriophage infection units detected by assay, or phage titers, were measured in these animals after 24 hours, and the results demonstrated that our phage mix effectively lowered the bacterial counts, or CFU, in the mouse lung to levels comparable to antibiotic treatment (PBS vs. antibiotic, p=0.0003; PBS vs. bacteriophage, p=0.0003). Furthermore, it was evident that phage replicated to high levels in the infected lung. These results are shown in the graphics below.

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In a separate *in vivo* study of acute *P. aeruginosa* infection of the mouse lung conducted at the Brompton Clinic, results demonstrated that our phage mix reduced CFU levels upon simultaneous intranasal administration (six mice in each of the treatment and control groups) and also when administered 24 hours post-bacterial infection (seven mice in the treatment group and eight mice in the control group) using Pa01, a standard strain of *P. aeruginosa*. These results are depicted in the graphics below.

Importantly, a preclinical study conducted at the Institut Pasteur in mice (12 mice in each of the treatment and control groups) demonstrated the ability of our phage mix to reach the lung within two hours of being delivered by oral administration. The phage levels increased between two and six hours post-treatment, and the results were statistically significant (p-value <0.001). A p-value is a statistical measure of the probability that the difference in two values could have occurred by chance. The smaller the p-value, the greater the confidence that the results are significant. These results demonstrate that when orally administered in mice, phages not only reached the lungs but were also able to infect and multiply in target bacteria.

We were granted an advisory meeting with United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) in the first quarter of 2014 to discuss our plans and intent to move the CF program into additional preclinical testing in preparation for a Phase 1/2 study in CF patients. We also sought advice and comment that our planned Chemistry Manufacturing and Controls (CMC) plans were acceptable to the MHRA. The MHRA concurred with our approach and plans as presented, including a first in man dose ranging clinical study in CF patients. Subject to the availability of adequate financing, we expect to continue product selection and formulation work. Upon final product selection, we plan to manufacture the AmpliPhage-001 product in our facility in Ljubljana, Slovenia.

We believe that successful proof of concept in this lung indication could lead to other acute and chronic lung infection markets, such as Ventilator Associated Bacterial Pneumonia (VABP) and Chronic Obstructive Pulmonary Disease (COPD). The bacteria we are currently targeting are predominant pathogens in both of these indications.

AmpliPhage-004: Gastrointestinal (GI) Infection Caused by *C. difficile Infection (CDI)*

From 2000 through 2007, deaths in the United States from *C. difficile* infection increased over 400%. Over 90% of such deaths occur in hospitalized or confined patients over the age of 65. Global Data estimates that the major European Union and United States markets for CDI therapies grew to more than $314 million in 2011 and they are expected to grow to more than $500 million by 2019.

According to the Centers for Disease Control, almost 250,000 people each year require hospitalization for *C. difficile* infections, and at least 14,000 people die each year in the United States from *C. difficile* infections. From 2000 through 2007, deaths in the United States from *C. difficile* infections increased over 400%. We are actively working with researchers at the University of Leicester and the University of Glasgow to develop a phage therapy that targets and kills all toxin types of *C. difficile* . We believe that orally delivered phages are well suited to treat CDI. Within this collaboration, researchers at the University of Leicester have discovered phages that have been shown to be effective against clinically-relevant strains of *C. difficile* isolated from around the world. Since current therapies against *C. difficile* are considered less than optimal, we believe that there is a significant market opportunity for our product in treating this disease.

Prior Clinical Development

In 2010, the Company’s wholly owned subsidiary, Biocontrol, reported a double-blind placebo-controlled, randomized Phase 1/2 clinical trial targeting chronic ear infections (otitis) caused by antibiotic-resistant *P. aeruginosa*. This was the first, and to date, we believe the only, regulated efficacy trial of bacteriophage therapy in humans that has been reported. Results were reported demonstrating decreasing levels of *P. aeruginosa* in the ear and improvement of clinical condition with a single input dose of 2.4 nanograms of bacteriophage preparation. While this was a small trial (n=24), changes from baseline at the end of the trial in the test group (n=12) were statistically significant for both clinical condition (p=0.001) and bacterial load (p=0.016). No significant changes were seen in the control group (n=12) compared to baseline at the end of the trial. Difference between test and control groups was statistically significant by analysis by covariance (ANCOVA) on day 21 for bacterial count (p=0.0365). These results will need to be validated in larger well-controlled trials.

Anti-Infective Therapeutics Market

The market opportunity for antibiotics is extremely large, with the market estimated to reach $40.3 billion in annual sales globally in 2015.

Almost one in every five deaths worldwide occurs as a result of infection and, according to the World Health Organization, or WHO, many bacterial infections will become difficult or impossible to cure as the efficacy of current antibiotic drugs wanes. Despite the advances in antimicrobial and vaccine development, infectious diseases still remain as the third-leading cause of death in the United States and the second-leading cause of death worldwide.

The number of new antibiotics approved by the FDA and other global regulatory authorities has declined consistently over the last two decades. According to the Infectious Diseases Society of America, as of early 2013, only two new antibiotics have been approved by the FDA since 2009 and only seven new antibiotics targeting multi-drug-resistant Gram-negative bacilli were in either Phase 2 or Phase 3 trials. This dramatic decrease in productivity is evidenced by only two classes of antibiotics oxazolidinones and cyclic lipopeptides having been developed and launched in the last 30 years. At the same time, the evolution of antibiotic-resistant bacteria has led to an increasing number of infections for which there are no current treatments available.

Hospital-acquired (nosocomial) infections are a major healthcare problem throughout the world, affecting developed countries as well as resource-poor countries. The WHO reports that hospital-acquired infections are among the major causes of death and increased morbidity among hospitalized patients and estimates that more than 1.4 million people per year worldwide suffer from infectious complications from a hospital stay.

A recent Centers for Disease Control report also cites that in the United States, between 5 and 10% of all patients admitted to a hospital will be affected by a hospital-acquired infection during their stay, typically requiring extended stays and additional care. There is also a significant risk of death from such infections. In the United States, the Centers for Disease Control estimates that approximately 99,000 people die from hospital-acquired infections each year. The Cystic Fibrosis Foundation estimates that *P. aeruginosa* accounts for 10% of all hospital-acquired infections.

Infections also occur in connection with cystic fibrosis (CF), which is a genetic disease affecting primarily Caucasians of northern European descent. According to the Cystic Fibrosis Foundation, there are approximately 50,000 cases of CF in North America and Europe. *P. aeruginosa* opportunistically infects the mucous membranes, primarily the lungs, of CF patients and quickly grows out of control, resulting in pneumonia. *P. aeruginosa* infections are notoriously resistant to known antibiotics, and treatment may be further complicated by the formation of biofilms. Biofilms are organized structures of microorganisms growing on solid surfaces (such as lung tissue) and often limit access of antibiotics to the covered tissues. Since phages attack bacteria in a manner independent of chemical antibiotic resistance mechanisms and can infect bacteria growing in biofilms, we believe that *P. aeruginosa* infection among CF patients represents a compelling indication to pursue. The availability of *Pseudomonas* — specific phages along with validated animal models of *P. aeruginosa* lung infections has contributed to the development of our bacteriophage program in CF.

Compounding the above situations is the alarming and continuing rise in the prevalence of antibiotic-resistant bacterial infections. This, coupled with the lack of new antibiotics in current discovery and development pipelines, has generated a significant clinical management problem worldwide, leading to increases in morbidity and mortality due to these antibiotic-resistant bacteria as well as increases in healthcare costs.

The first of these antibiotic-resistant infections to reach epidemic proportions was caused by the Gram-positive bacterium *S. aureus*. *S. aureus* resistance to a broad range of antibiotics has necessitated the use of expensive and potentially toxic “drugs of last resort”, most notably vancomycin. Antibiotic-resistant forms of *S. aureus* , usually termed MRSA (methicillin-resistant *S. aureus*), VISA (vancomycin-intermediate *S. aureus*), or VRSA (vancomycin-resistant *S. aureus*), can be extremely challenging to treat. Although several antibiotics targeting *S. aureus* have been developed, rapidly developing bacterial resistance has been noted for all of these including linezolid, daptomycin and tigecycline. On the basis of historical evidence, resistance to these existing products is likely to increase over time, and this picture is further complicated by the reduced efficacy of conventional antibiotics against *Staphylococcus* biofilms.

Typically *S. aureus* infection causes a variety of suppurative (pus-forming) infections and toxinoses in humans. It causes superficial skin lesions such as boils, styes and furuncles; more serious infections such as pneumonia, mastitis, phlebitis, meningitis and urinary tract infections; and deep-seated infections, such as osteomyelitis and endocarditis. *S. aureus* is the leading cause of wound infections, in particular, hospital-acquired (nosocomial) infection of surgical wounds and infections associated with indwelling medical devices. *S. aureus* is the leading pathogen in healthcare-associated infections in the United States as a whole, accounting for 30.4% of surgical site infections (SSI), and 15.6% of such infections overall.

Anti-Infective Treatments with Bacteriophages

Background

The dramatic rise in antibiotic resistance, the appearance of an increasing number of new “superbugs” and the lack of new antibiotics in the pipeline has prompted calls to action from many of the world’s major health bodies such as the Centers for Disease Control and the WHO, who warn of an “antibiotic cliff” and a “post-antibiotic era.” In 2009, the European Antimicrobial Resistance Surveillance System, or EARSS, concluded that “the loss of effective antimicrobial therapy increasingly threaten[s] the delivery of crucial health services in hospitals and in the community.” This conclusion was reinforced by The Antimicrobial Availability Task Force, or AATF, of the Infectious Diseases Society of America, or IDSA, and the European Centre for Disease Prevention and Control, or ECDC, in conjunction with the European Medicine Agency, or EMA. Clearly, there is a pressing need to find alternative antibacterial therapies.

Bacteriophage therapy has the potential to be an alternative method of treating bacterial infection. Phages are ubiquitous environmental viruses that grow only within bacteria. The name “bacteriophage” translates as “eaters of bacteria” and reflects the fact that as they grow, phages kill the bacterial host by multiplying inside and then bursting through the cell membrane in order to release the next generation of phages. Phages can differ substantially in morphology and each phage is active against a specific range of a given bacterial species. Phages were first discovered in 1915 at the Institut Pasteur and were shown to kill bacteria taken from patients suffering from dysentery. Furthermore, it was noted that phage numbers rose as patients recovered from infection, suggesting a direct association.

Life Cycle of a Bacteriophage

Until the discovery of effective antibiotics, phages were used as an effective means of combating bacterial infection. When broad-spectrum antibiotics came into common use in the early 1940s, phages were considered unnecessary, with antibiotics being seen for many years as the answer to bacterial disease. This attitude persisted until the development of the wide-ranging, and in some cases total, resistance to antibiotics seen within the last 10 years.

It is now clear that bacteria can adapt to resist chemical antibiotics. In addition, there is now strong pressure to limit the use of antibiotics for human and veterinary use. There is a real need for different approaches to the control of antibiotic-resistant bacterial infections. In the light of current knowledge, it is apparent that early work with phages was hindered by poor understanding of the biology of phages, leading to exaggerated claims that damaged the reputation of phage therapy. Several companies in the 1920s and 1930s began to produce and market bacteriophage preparations. Unfortunately, these were often marketed with promises of efficacy against diseases that are now known to have nothing to do with bacteria, and many preparations themselves failed to actually contain bacteriophages. These conditions made bacteriophage subject to understandable skepticism. Now, with the far greater understanding of phages and their function that is now available, it is possible to identify the bacteria that are causing disease and then target them with highly specific phages that will kill only those bacteria.

Phages have the potential to provide both an alternative to, and a synergistic approach with, antibiotic therapy. Since they use entirely different mechanisms of action, phages are unaffected by resistance to conventional antibiotics. Phage containing certain enzymes also have the ability to disrupt bacterial biofilms, thus potentiating the effect of chemical antibiotics when used in combination with them.

In fact, the ability to isolate and develop phages for any of a broad range of bacterial targets, combined with their ability to disrupt bacterial biofilms, suggests strong potential for this approach in the control of bacterial infections. Published literature indicates that phages have the potential to be used as topical agents for the control of bacterial

infection, and that such use is compatible with the approaches that have been shown to be effective in the treatment of wound injuries.

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Bacteriophage therapy for the treatment of bacterial infections has been in constant use since 1917. Most of the research on phage-based therapy was conducted in the former Soviet Union prior to and immediately after World War II. While the West primarily focused resources into the development of chemical antibiotics, physicians and researchers in the Soviet Union were mass-producing phages and demonstrating their efficacy against a wide range of bacterial infections affecting the GI tract (dysentery), wounds (surgical and combat), skin (boils) and bone (osteomyelitis). While these studies are compelling, most lacked appropriate control group design or lacked control groups completely. 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.

Despite numerous encouraging case studies, bacteriophage treatment was never adopted by Western medicine due to a lack of robust scientific evidence generated through systematically planned, controlled and regulated clinical trials. Recently, however, an increasing number of papers, reviews and books appearing on bacteriophage therapy indicate an increasing appetite among the scientific community and healthcare industry for developing bacteriophage therapy as part of mainstream medicine. Current biomedical technology is vastly superior to that available during the early days of bacteriophage therapy and our understanding of phage biology and the mechanisms of phage-bacterial host interaction have improved, along with advances in knowledge concerning bacterial infection. Although our knowledge of the biology, genetics and bactericidal efficacy of bacteriophages *in vitro* is impressive, less is known about their pharmacokinetic behavior *in vivo* , in particular in human subjects. To date very few human clinical trials have been conducted to modern standards in either the United States or Europe. In 2009, a U.S. Phase 1 clinical trial carried out at the Southwestern Regional Wound Care Center in venous ulcers using a mixture or “cocktail” of phages which individually attack different species of bacteria (*S. aureus*, *P. aeruginosa* and *E. coli*) was reported. The results of this trial showed this multi-bacteriophage preparation to be safe in trial subjects.

These trials, alongside published reports of less well-conducted studies, suggest that phage therapy shows promise for treating infectious diseases caused by antibiotic-resistant bacteria. One, conducted by the Polish Academy of Sciences, started in 2005 and is treating a broad range of infections and clinical conditions associated with antibiotic-refractory infections. This work derives from a phage therapy clinic that has operated at this location. A second is the European Union-sponsored “Phagoburn” Phase 1/2 clinical trial, which is being conducted at multiple centers in France, Belgium and Switzerland. The project has been under way since June 2013, using a large phage mix for treatment of burn wounds infected with *E. coli* and *P. aeruginosa* .

Our Strategy

Our strategy is to use techniques of modern biotechnology and current state-of-the-art practices for drug development in concert with existing regulatory guidance to develop a pipeline of bacteriophage products that will destroy bacterial pathogens such as MRSA, which are resistant to chemical antibiotics. Our business strategy will apply state-of-the-art techniques in molecular biology and in clinical trial design to build upon the long successful history of using phages therapeutically to treat and cure infections.

In collaboration with the U.S. Army, we plan to initiate a clinical trial that will support the development of a treatment for *S. aureus* infections for wound and skin infections. Additionally, subject to the availability of adequate financing, we expect to continue product selection and formulation work for AmpliPhage-001, and following final product selection, in conjunction with leading Centers of Excellence in the UK, we would expect to conduct a Phase 1/2 study using AmpliPhage-001 to treat CF patients with *P. aeruginosa* lung infections. Through our collaboration agreement with the University of Leicester, we are also continuing to develop AmpiPhage-004 to treat patients suffering from serious gastrointestinal infections caused by *C. difficile*.

Acquisitions

In January 2011, we completed the acquisition of Biocontrol, with the goal of developing their phage therapy programs using funding from the sale of our legacy gene therapy assets. Under the terms of our acquisition of Biocontrol, we issued 22,817,198 shares of our common stock to the shareholders of Biocontrol with a total fair value of approximately $8.6 million as of January 6, 2011, resulting in Biocontrol's former shareholders owning approximately 50% of our outstanding equity securities at the time. As a condition to closing the acquisition, Biocontrol raised approximately £200,000 (US$310,000) in working capital for use by us.

In November 2012, we acquired 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, collectively referred to as the SPH Agreements, in exchange for up to 40,000,000 shares of our common stock.

In connection with our acquisition of SPH, we entered into certain other arrangements, including the repayment under a Loan Repayment Deed (as amended) of a $770,000 loan originally made by Cellabs Pty Ltd, or Cellabs, an Australian company affiliated with Dr. Smithyman, to SPH, a consulting agreement with Dr. Smithyman and the payment of $3,017 per month to Cellabs for our laboratory space in Australia. Under the terms of the Loan Repayment Deed, the loan from Cellabs to SPH was to be repaid and fully satisfied partly in cash and partly by issuing 2,000,000 shares of our common stock to Cellabs. As of December 31, 2014, $350,000 has been paid by us to Cellabs and all 2,000,000 shares have been issued. We paid the remaining balance of $200,000 under the terms of the Loan Repayment Deed in December 2013. The SPH acquisition also included several phage therapy projects which had reached the pre-clinical or animal study stage, including the Brompton Hospital CF study, the Adelaide University MRSA chronic rhinosinusitis study and the University of Leicester *C. difficile* project. We believe that acquisition of SPH brings substantial phage scientific expertise and know-how to the Company sufficient to develop, manufacture and commercialize phage-based therapeutics. Under the terms of the consulting agreement with Dr. Smithyman, we were obligated to pay a fee of $10,000 per month to Dr. Smithyman, who provided management consulting services as an independent contractor for a term of 12 months ending October 2013. Between the acquisitions of Biocontrol and SPH, we believe that we are the leading therapeutically focused phage company in the world.

Strategic Alliances and Research Agreements

As discussed below, we have established collaborations with Intrexon, the U.S. Army and the University of Leicester, which provide us with access to the considerable scientific, developmental, and regulatory capabilities of our collaborators. We believe that our collaborations contribute to our ability to rapidly advance our product candidates, build our product platform and concurrently progress a wide range of discovery and development programs.

Exclusive Channel Collaboration with Intrexon

On March 29, 2013, we entered into the Exclusive Channel Collaboration with Intrexon that governs a collaboration arrangement in which AmpliPhi uses Intrexon’s technologies directed towards the research, development and commercialization of new bacteriophage-based therapies to target specific antibiotic-resistant infections. We believe that combining the broadest and most advanced synthetic biology platform with our world-leading phage capabilities will lead to the development of innovative second-generation phage products. The Exclusive Channel Collaboration establishes committees comprised of representatives of the Company and Intrexon that govern activities related to the bacteriophage programs in the areas of project establishment and prioritization, as well as budgets and their approval, chemistry, manufacturing and controls, clinical and regulatory matters, commercialization efforts and intellectual property.

Intrexon is a publicly held biotechnology company focused on the industrial engineering of synthetic biology. According to Intrexon, their advanced bioindustrial engineering platform enables Better DNA ™ technology by combining DNA control systems with corresponding advancements in modular transgene design, assembly and optimization to enable unprecedented control over the function and output of living cells.

Under the terms of the Exclusive Channel Collaboration, the Company will receive an exclusive, worldwide license to utilize Intrexon's proprietary technology and expertise for the standardized design and production of genetically modified bacteriophages, which we refer to collectively as the Bacteriophage Program. The Exclusive Channel Collaboration seeks to develop bacteriophage-containing human therapeutics 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* , which we collectively refer to as AmpliPhi Products. The Exclusive Channel Collaboration grants the Company a worldwide license to use patents and other intellectual property of Intrexon in connection with the research, development, use, importing, manufacture, sale and offer for sale of AmpliPhi Products. Such license is exclusive with respect to any clinical development, selling, offering for sale or other commercialization of AmpliPhi Products, and otherwise is non-exclusive. Subject to limited exceptions, we may not sublicense the rights to Intrexon's technology without Intrexon's written consent.

Under the Exclusive Channel Collaboration, and subject to certain exceptions, we are responsible for, among other things, the performance of the Bacteriophage Program, including development, commercialization and certain aspects of manufacturing AmpliPhi Products. Intrexon is responsible for the costs of establishing manufacturing capabilities and facilities, subject to certain exceptions, for the bulk manufacture of products developed under the Bacteriophage Program, certain other aspects of manufacturing and costs of basic-stage research with respect to Intrexon Channel Technology and Intrexon materials, i.e., platform improvements and costs of filing, prosecution and maintenance of Intrexon's patents.

Subject to certain expense allocations and other offsets provided in the Exclusive Channel Collaboration, AmpliPhi has agreed to pay Intrexon on a quarterly basis tiered royalties on net sales derived in that quarter from the sale of AmpliPhi Products, which are based on or incorporate Intrexon's technology, calculated on a product-by-product basis. If AmpliPhi sublicenses a product developed under the collaboration with Intrexon, AmpliPhi has likewise agreed to pay Intrexon on a quarterly basis a certain percentage of revenues received from the sublicensee. Pursuant to the Exclusive Channel Collaboration, Intrexon received 24,000,000 shares of our common stock as an upfront technology access fee. We may also pay Intrexon up to $7.5 million in aggregate milestone payments for each product, payable either in cash or equity upon the achievement of certain events. Intrexon is also entitled to tiered royalties as a percentage in the upper-single digits of the net product sales of a product developed under the Exclusive Channel Collaboration. No milestones have been achieved under the Exclusive Channel Collaboration through December 31, 2014.

The Exclusive Channel Collaboration is effective until terminated by either Intrexon or AmpliPhi. Intrexon may terminate the Exclusive Channel Collaboration if AmpliPhi fails to use diligent efforts to develop and commercialize AmpliPhi Products or if AmpliPhi elects not to pursue the development of an AmpliPhi Program identified by Intrexon that is a "Superior Therapy" as defined in the Exclusive Channel Collaboration. AmpliPhi has the right to terminate the Exclusive Channel Collaboration upon 90 days' written notice to Intrexon at any time.

Upon termination of the Exclusive Channel Collaboration, AmpliPhi may continue to develop and commercialize any AmpliPhi Product that, at the time of termination:

- is being commercialized by the Company;
- has received regulatory approval;
- is a subject of an application for regulatory approval that is pending before the applicable regulatory authority; or
- is the subject of an ongoing Phase 2 or completed Phase 3 clinical trial in the field.

AmpliPhi's obligation to pay royalties described above with respect to these "retained" products will survive termination of the Exclusive Channel Collaboration.

The Company incurred expenses for services under the Exclusive Channel Collaboration of $862,000 and $440,000 for the years ended December 31, 2014 and 2013, respectively.

Global R&D Agreement with U.S. Army

In June 2013, we entered a Collaborative Research and Development Agreement with the United States Army Medical Research and Materiel Command and the Walter Reed Army Institute of Research. The Collaborative Research and Development Agreement will focus on developing bacteriophage therapeutics to treat at least three types of infections: *S. aureus*, *E. coli* and *P. aeruginosa*. The increasing prevalence of antibiotic-resistant bacteria poses a serious threat to public health and military personnel and is a major problem in hospitals and clinics around the world. The initial indication will be wounds and skin infections from *S. aureus* , which is the leading pathogen in healthcare-associated infections in the United States as a whole, accounting for 30.4% of surgical site infections.

In connection with our Collaborative Research and Development Agreement with the U.S. Army, we submitted a Pre-Investigational New Drug Application briefing package to the FDA to obtain their feedback on our Chemistry, Manufacturing and Controls (CMC) program and plans for our first human study with our lead product, AmpliPhage-002 (*S. aureus*). The FDA endorsed our plan for progressing bacteriophage therapy to the clinic, specifically agreeing to our platform's manufacturing process, product specifications and the absence of any need of non-clinical toxicology to initiate our first Phase 1 study.

We plan to conduct our Phase 1 study at the Walter Reed Army Institute of Research and to conduct further clinical trials at various sites throughout the world. 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.

We will retain global regulatory ownership and commercial rights to all products developed by us under the agreement. United States Army Medical Research and Materiel Command will gain access rights to any products developed. We also have the rights to exclusively license any intellectual property developed by United States Army Medical Research and Materiel Command under the collaboration on terms to be agreed upon.

The Collaborative Research and Development Agreement expires in June 2018 and can be terminated by either United States Army Medical Research and Materiel Command or AmpliPhi upon 60 days' written notice to the other party at any time.

University of Leicester Development Agreements

In April and September 2013, we entered into a collaboration agreement and license agreement, respectively, with the University of Leicester to develop a phage therapy that targets and kills all toxin types of *C. difficile*. 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.

Under these agreements, which we refer to collectively as the Leicester Development Agreements, we are funding the University of Leicester to carry out *in vitro* and the University of Glasgow to carry out animal model development work on the University of Leicester's development of a bacteriophage therapeutic to resolve *C. difficile* infections and we are licensing related patents, materials and know-how from the University of Leicester. Under the Leicester Development Agreements, the University of Leicester will provide the bacteriophage and act as overall project coordinator for the development work. All rights, title and interest to any intellectual property developed under the Leicester Development Agreements belong to us. Under the Leicester License Agreement, we have exclusive rights to certain background intellectual property of the University of Leicester, for which we will pay the University of Leicester royalties based on product sales and make certain milestone payments based on product development.

The collaboration agreement expires on November 12, 2015 and is terminable by either party upon (a) material breach by the other party, subject to a 90-day cure period, (b) the inability of the principal investigator to continue the collaboration or (c) our bankruptcy or winding up of our operations.

The license agreement expires on the later of the expiration of the licensed patents or September 5, 2028, and is terminable by us at any time upon 60 days' notice, by the University of Leicester (a) if we legally challenge the validity or ownership of any of the licensed patents, (b) if we fail to pay the fees, milestones or royalties due under the license agreement or (c) if we fail to make substantial commercial process and agree with Leicester that we will be unable to do so. The license agreement is also terminable by either party upon the material breach by the other party (subject to a 30-day cure period) or upon the other party's bankruptcy or insolvency.

Sale of Assets to Celladon Corporation

On June 27, 2012, we entered into an asset purchase agreement and amended and restated license agreement, or license agreement, with Celladon Corporation, or Celladon, where we sold and transferred all of our rights and interest in our gene therapy business, subject to certain limitations relating to rights contained in our license agreements with the University of Pennsylvania and Genzyme Corporation. Pursuant to our license agreement with the University of Pennsylvania, or UPenn, we may be obligated to make certain royalty and license payments to UPenn as a result of Celladon's (or its affiliate's or licensee's) use of certain technology licensed under our license agreement with Celladon. Pursuant to the license agreement with Celladon, Celladon has agreed to comply with certain terms of the UPenn license agreement and to reimburse us for any payments that come due under the UPenn license agreement. In each of June 2014 and May 2013, we received sublicense maintenance fees from Celladon in the amount of $0.31 million. Celladon's obligation to pay us these sublicense maintenance fees continues until the earlier of Celladon's termination of the agreement (which it may elect to do at any time upon thirty days' notice to us) or expiration of the patents related to the licensed technology.

Intellectual Property

General

Our goal is to obtain, maintain and enforce patent protection for our product candidates, formulations, processes, methods and any other proprietary technologies, preserve our trade secrets and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our current product candidates and any future product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the United States and abroad. However, patent protection may not afford us with complete protection against competitors who seek to circumvent our patents.

We also depend upon the skills, knowledge, experience and know-how of our management and research and development personnel, as well as that of our advisors, consultants and other contractors. To help protect our proprietary know-how, which is not patentable, and for inventions for which patents may be difficult to enforce, we currently and will in the future rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all of our employees, consultants, advisors and other contractors to enter into confidentiality agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

We hold or have exclusive license rights to five U.S. patents and four foreign patents, expiring on various dates between 2024 and 2029. These patents relate to the therapeutic uses of bacteriophages, bacteriophage compositions, the sequential use of bacteriophages in combination with conventional antibiotics, genetic sequence variations, biofilm disrupting agents, methods to reduce antibiotic resistance, and methods to design therapeutic combination panels of bacteriophage.

US 7758856 and national patents within the EU deriving from PCT WO2004062677; Bacteriophage for the treatment of bacterial biofilms

Under an existing license from the United Kingdom Secretary of State for the Department of Health (DoH), we have exclusive rights to develop and exploit technologies relating to the use of bacteriophages combined with biofilm-disrupting agents in treating biofilm infections. The patent specifies agents able to facilitate the penetration of biofilms, and their combination with therapeutic bacteriophage preparations. The priority date for these patents is January 10, 2003 and the date of U.S. grant is July 20, 2010. The date of expiration is December 5, 2026 in the United States (noting Patent Term Adjustment, PTA, by the United States Patent and Trademark Office, or USPTO). The patent is also granted in the European Union (France, Germany, Netherlands, Switzerland/Liechtenstein and the United Kingdom). The date of expiration is January 12, 2024 in the European Union. Pursuant to this license agreement, we may be required to pay the United Kingdom DoH aggregate milestone payments of up to £10,000 per product and single-digit royalties. The agreement, which may be terminated by the DoH upon our default, continues until the earlier of such termination or the expiry of the DoH’s rights in the licensed intellectual property.

US 7807149, US 8105579, US 8388946, continuation application and national filings deriving from PCT WO2005009451; Bacteriophage containing therapeutic agents

Through our wholly owned subsidiary, Biocontrol Ltd, we have three granted U.S. patents and a pending continuation application filed. The granted patents relate to therapeutic, sequential use of bacteriophages in combination with conventional antibiotics, to bacteriophage compositions, and to the uses of bacteriophages. The filed continuation application relates to genetic sequence variation around the protected agents. The earliest priority date for these patents is July 23, 2003. Dates of U.S. grant are October 5, 2010, January 31, 2012 and March 5, 2013. The dates of expiry for the granted patents are March 18, 2027 (noting PTA by the USPTO), July 23, 2024 and July 23, 2024 in the United States. The national application in Australia was granted as AU 2004258731 on June 10, 2010, with July 23, 2024 as the date of expiry. Examination in other jurisdictions is proceeding: for example, in the EU, claims for bacteriophage compositions are approaching allowance; and divisional application (EP2570130) granted on 26 November 2014 with claims directed at therapeutic and non-therapeutic applications of bacteriophage. Patent term expiry in Europe is 23 July 2024.

US 8475787, continuation application and national filings deriving from PCT WO2008110840; Beneficial effects of bacteriophage treatment

Through our wholly owned subsidiary, Biocontrol Ltd, we have one granted U.S. patent, and a pending continuation application filed. The granted patent relates to bacteriophage-induced induction of antibiotic sensitivity for *P. aeruginosa*. The priority date for these patents is March 9, 2007. The date of U.S. grant is July 2, 2013 and the date of expiry for the granted patent is March 21, 2029 (noting PTA by the USPTO). The continuation application has been filed relating to other bacterial species. The national application in Australia was granted as AU 2008224651 on December 19, 2013, with March 7, 2028 as the date of expiry. National applications are under examination in other jurisdictions.

PCT WO2013/16464 (United Kingdom priority filing 1207910.9); Therapeutic bacteriophage compositions

Through our wholly owned subsidiary, Biocontrol Ltd, we have a PCT application relating to the design of effective combinations of bacteriophages. The earliest priority date for this application is May 4, 2012. The PCT application published on November 7, 2013, and national phase applications are currently progressing in the US, Canada, Europe, Japan, and Australia.

Our success in preserving market exclusivity for our product candidates relies on patent protection, including extensions to this where appropriate, and on data exclusivity relating to an approved biologic. This may be extended by orphan drug and/or pediatric use protection where appropriate. Once any regulatory period of data exclusivity

expires, depending on the status of our patent coverage, we may not be able to prevent others from marketing and selling biosimilar versions of our product candidates. We are also dependent upon the diligence of our appointed agents in national jurisdictions, acting for and on behalf of the Company, which manage the prosecution of pending domestic and foreign patent applications and maintain granted domestic and foreign patents.

Competition

We operate in highly competitive segments of the biotechnology and biopharmaceutical markets. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions all seeking to develop novel treatment modalities for bacterial disease. Many of our competitors have significantly greater financial, product development, manufacturing and marketing resources than we do. Large pharmaceutical companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. In addition, many universities and private and public research institutes are active in antibacterial research, some in direct competition with us. We also may compete with these organizations to recruit scientists and clinical development personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Manufacturing and Supply

The manufacturing process for our bacteriophage product is currently under development. We have developed our own manufacturing capabilities at a wholly owned facility in Ljubljana, Slovenia. Our facility must comply with applicable cGMP regulations, which require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. Pharmaceutical product manufacturers and other entities involved in the manufacture and distribution of approved pharmaceutical products are required to register their establishments with the FDA, and certain state agencies, including the applicable government agency where the facility is located, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Our facility in Ljubljana, Slovenia is subject to inspection and regulation by JAZMP, the Slovenian agency that regulates and supervises pharmaceutical products in Slovenia. 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 Drug Product cGMP certification by JAZMP to manufacture AmpliPhage-002; however, there can be no assurance that we will receive such certification. Accordingly, we must continue to expend time, money and effort in the areas of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved New Drug Application/Biologics License Application, or BLA, including withdrawal of the product from the market. In addition, changes to the manufacturing process generally require prior regulatory approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further regulatory review and approval, including approval by the FDA.

Commercialization and Marketing

We have full worldwide commercial rights to all of our phage-based products to treat drug-resistant bacterial infections, including our lead programs: AmpliPhage-001 for the treatment of CF patients with *P. aeruginosa* lung infections; AmpliPhage-002, for the treatment of antibiotic-resistant *S. aureus* (MRSA) infections; and AmpliPhage-004 for the treatment of *C. difficile* infections. We believe we can maximize the value of our company by retaining substantial global commercialization rights to these product candidates and, where appropriate, entering into partnerships to develop and commercialize our other product candidates. We plan to build a successful commercial enterprise using a sales team in the United States and possibly other major markets and with partners in other territories.

We have not yet established a sales, marketing or product distribution infrastructure because our lead candidates are still in early clinical development. We generally expect to retain commercialization and co-commercialization rights in the United States for all of our product candidates for which we receive marketing approvals. Subject to receiving marketing approvals, we intend to explore building the necessary marketing and sales infrastructure to market and sell our current product candidates. We also intend to explore the use of a variety of distribution agreements and commercial partnerships in those territories where we do not establish a sales force for any of our product candidates that obtain marketing approval.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing.

United States Product Development Process

In the United States, the FDA regulates biological products under the Federal Food, Drug and Cosmetic Act, or FDCA, and the Public Health Service Act, or the PHS Act, and related regulations. Biological products are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process or approval process, or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a biological product may be marketed in the United States generally includes the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to good laboratory practice requirements, or GLP, or other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin in the United States;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices, or GCPs, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use or uses;
- submission to the FDA of a Biologics License Application (BLA) for a new biological product;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with the FDA's cGMP regulations, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;
- potential FDA audit of the nonclinical study sites and clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval, or licensure, of the Biologics License Application which must occur before a biological product can be marketed or sold.

The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources even when approvals are inherently uncertain.

The strategies, nature, and technologies of bacteriophage products are different from the conventional antibiotic therapy products. From the regulatory requirements established to ensure the safety, efficacy and quality of bacteriophage preparations, there are several major points to consider during the development, manufacturing, characterization, preclinical study and clinical study of bacteriophage. The major issues include:

- bacteriophage preparation design (single agent versus phage mixes and wild-type phage versus genetically engineered phage);
- proof of concept in development of bacteriophage products;
- selectivity of bacteriophage replication and targeting to specific species of bacteria;
- relevant animal models in preclinical studies; and
- clinical safety.

Before testing any compounds with potential therapeutic value in humans, the biological product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product biology, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the biological product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLP. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the Investigational New Drug Application. The Investigational New Drug Application automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the Investigational New Drug Application on a clinical hold within that 30-day time period. In such a case, the Investigational New Drug Application sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time

before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be certain that submission of an Investigational New Drug Application will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such clinical trial.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by the sponsor. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject inclusion and exclusion criteria and the parameters to be used to monitor subject safety. Each protocol must be submitted to the FDA if conducted under an IND. Clinical trials must be conducted in accordance with GCP requirements. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, or ethics committee if conducted outside of the U.S., at or servicing each institution at which the clinical trial will be conducted. An IRB or ethics committee is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB or ethics committee also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. We intend to use third-party CROs to administer and conduct our planned clinical trials and will rely upon such CROs, as well as medical institutions, clinical investigators and consultants, to conduct our trials in accordance with our clinical protocols and to play a significant role in the subsequent collection and analysis of data from these trials. The failure by any of such third parties to meet expected timelines, adhere to our protocols or meet regulatory standards could adversely impact the subject product development program and we remain legally responsible for compliance with applicable laws and regulations governing the conduct of these clinical trials.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The biological product is initially introduced into healthy human subjects and tested primarily for safety and dosage tolerance. Absorption, metabolism, distribution and excretion may also be tested.
- Phase 2: The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- Phase 3: Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA and other regulatory authorities for approval of a marketing application.

Post-approval studies, or Phase 4 clinical trials, may be requested by the FDA as a condition of approval and are conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written Investigational New Drug Application safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests that there may be a significant risk for human subjects. The FDA or the sponsor or, if used, its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB or ethics committee can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB’s or ethics committee’s requirements or if the pharmaceutical product has been associated with unexpected serious harm to

patients. Suspension of a clinical study due to safety risks attributed to the investigational product will result in termination of the study and possibly others that are underway.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents or other impurities with the use of biological products, the PHS Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency, and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

United States Review and Approval Processes

In order to obtain approval to market a biological product in the United States, a Biologics License Application must be submitted to the FDA that provides data establishing to the FDA's satisfaction the safety and effectiveness of the investigational biological product for the proposed indication. The application includes all data available from nonclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's manufacture and composition, and proposed labeling, among other things. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the Biologics License Application for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each Biologics License Application must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's fee schedule, effective through September 30, 2014, the user fee for an application requiring clinical data, such that the biological product candidate does not undergo unacceptable deterioration over its shelf life as a BLA, is $2,169,100. PDUFA also imposes an annual product fee for biologics ($104,060), and an annual establishment fee ($554,600) on facilities used to manufacture prescription biologics. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication

The FDA has 60 days from its receipt of a Biologics License Application to determine whether the application will be accepted for filing based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. The FDA may refuse to file any Biologics License Application that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the Biologics License Application must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. After the Biologics License Application submission is accepted for filing, the FDA reviews the Biologics License Application to determine, among other things, whether the proposed product is safe and effective for its intended use, has an acceptable purity profile, and whether the product is being manufactured in accordance with GMP regulations to assure and preserve the product's identity, safety, strength, quality, potency, and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA may ultimately decide that the New Drug Application/Biologics License Application does not satisfy the criteria for approval. If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling.

Special FDA Expedited Review and Approval Programs

The FDA has various programs, including fast track designation, accelerated approval and priority review, that are intended to expedite the process for the development and FDA review of drugs that are intended for the treatment of serious or life threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs and biological products to patients earlier than under standard FDA review procedures.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life threatening disease or condition and demonstrates the potential to address an unmet medical need, or if the drug or biological product qualifies as a qualified infectious disease product under the recently enacted Generating Antibiotic Incentives Now, or GAIN Act. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. We intend to request fast track designation for our product candidates if applicable.

Specifically, new drugs and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biological may request the FDA to designate the drug or biologic as a Fast Track product at any time during the clinical development of the product. Unique to a Fast Track product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments.

As a condition of approval, the FDA may require a sponsor of a drug or biological product receiving accelerated approval perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug or biological product may be subject to accelerated withdrawal procedures. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Moreover, under the provisions of the new Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 2012, a sponsor can request designation of a product candidate as a “breakthrough therapy.” A breakthrough therapy is defined as a drug or biological product that is intended, alone or in combination with one or more other drugs or biological products, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the biological product or drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs or biological products designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy. We intend to request “breakthrough therapy” designation for our product candidates if applicable.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Drug Price Competition and Patent Term Restoration Act of 1984

Under the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Amendments, a portion of a product's patent term that was lost during clinical development and application review by the FDA may be restored. The Hatch-Waxman Amendments also provide for a statutory protection, known as non-patent market exclusivity, against the FDA's acceptance or approval of certain competitor applications.

Patent term restoration can compensate for time lost during product development and the regulatory review process by returning up to five years of patent life for a patent that covers a new product or its use. This period is generally one-half the time between the effective date of an Investigational New Drug Application (falling after issuance of the patent) and the submission date of a New Drug Application, plus the time between the submission date of a Biologics License Application and the approval of that application. Patent term restorations, however, cannot extend the remaining term of a patent beyond a total of 14 years. The application for patent term extension is subject to approval by the United States Patent and Trademark Office in conjunction with the FDA. It takes at least six months to obtain approval of the application for patent term extension. Up to five years of interim one-year extensions are available if a product is still undergoing development or FDA review at the time of the expiration.

A patent term extension is only available when the FDA approves a biological product for the first time. However, we cannot be certain that the PTO and the FDA will agree with our analysis or will grant a patent term extension.

A biological product can obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued “Written Request” for such a study.

An abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009, which was part of the Patient Protection and Affordable Care Act, or PPACA, signed into law on March 23, 2010. This amendment to the PHS Act attempts to minimize duplicative testing. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a biological product is biosimilar to the reference biological product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the product and the reference product may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product. However, complexities associated with the larger, and often more complex, structure of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

A reference biological product is granted twelve years of exclusivity from the time of first licensure of the reference product. On April 10, 2013, President Obama released his proposed budget for fiscal year 2014 and proposed to cut this twelve year period of exclusivity down to seven years. He also proposed to prohibit additional periods of exclusivity for brand biological products due to minor changes in product formulation, a practice often referred to as “evergreening.” The first biological product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitting under the abbreviated approval pathway for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant’s favor of a lawsuit challenging the

biologic's patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period.

FDA Post-Approval Requirements

Maintaining substantial compliance with applicable federal, state, local, and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to GMP. We will rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of any products that we may commercialize. Manufacturers of our products are required to comply with applicable requirements in the GMP regulations, including quality control and quality assurance and maintenance of records and documentation. We cannot be certain that we or our present or future suppliers will be able to comply with the GMP and other FDA regulatory requirements. Other post-approval requirements applicable to biological products include reporting of GMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements. After a Biologics License Application is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products.

Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements, by us or our suppliers, may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products are required to register their facilities with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with GMPs and other laws. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Labeling, Marketing and Promotion

The FDA closely regulates the labeling, marketing and promotion of biological products, including direct-to-consumer advertising, promotional activities involving the internet, and industry-sponsored scientific and educational activities. While doctors are free to prescribe any product approved by the FDA for any use, a company can only make claims relating to safety and efficacy of a biological product that are consistent with FDA approval, and the company is allowed to actively market a biological product only for the particular use and treatment approved by the FDA. In addition, any claims we make for our products in advertising or promotion must be appropriately balanced with important safety information and otherwise be adequately substantiated. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising, injunctions and potential civil and criminal penalties.

Other Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice and state and local governments.

International Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our future products. Our manufacturing facility in Ljubljana, Slovenia is subject to inspection and regulation by JAZMP, the Slovenian agency that regulates and supervises pharmaceutical products in Slovenia. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or a mutual recognition procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The mutual recognition procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

Pricing and Reimbursement

Although none of our product candidates has been commercialized for any indication, if they are approved for marketing, commercial success of our product candidates will depend, in part, upon the availability of coverage and reimbursement from third-party payors at the federal, state and private levels. Government payor programs, including Medicare and Medicaid, private healthcare insurance companies and managed-care plans have attempted to control costs by limiting coverage and the amount of reimbursement for particular drug treatments. The U.S. Congress and state legislatures from time to time propose and adopt initiatives aimed at cost-containment. Ongoing federal and state government initiatives directed at lowering the total cost of healthcare will likely continue to focus on healthcare reform, the cost of prescription drugs and biological products and on the reform of the Medicare and Medicaid payment systems. Examples of how limits on drug coverage and reimbursement in the United States may cause reduced payments for drugs in the future include:

- changing Medicare reimbursement methodologies;
- fluctuating decisions on which drugs to include in formularies;
- revising drug rebate calculations under the Medicaid program; and
- reforming drug importation laws.

Indeed, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Healthcare Reform Act, which was signed into law in March of 2010, substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts drugs and biological products manufacturers. The Healthcare Reform Act includes, among other things, the following measures:

- annual, non-deductible fees on any entity that manufactures or imports certain prescription drugs;
- increases in Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program for both branded and generic drugs;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research;
- new requirements for manufacturers to discount drug prices to eligible patients by 50 percent at the pharmacy level and for mail order services in order for their outpatient drugs to be covered under Medicare Part D; and
- an increase in the number of entities eligible for discounts under the Public Health Service pharmaceutical pricing program.

Additionally, some third-party payors also require pre-approval of coverage for new or innovative drug therapies before they will reimburse healthcare providers who use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and operate profitably.

In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors, including government health administrative authorities, managed care providers, private health insurers and other organizations. Third-party payors are increasingly examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy, and, accordingly, significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Adequate third-party reimbursement may not be available for our products to enable us realize an appropriate return on our investment in research and product development.

Employees

As of April 3, 2015, we had eighteen full-time employees and five part-time employees.

Web Site Access to Company's Reports

Our website address is http://www.ampliphibio.com. Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act are available free of charge through our website as soon as reasonably practicable after they are electronically filed with, or furnished to, the Securities and Exchange Commission, or the SEC. We will also provide the reports in electronic or paper form free of charge upon request. 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 Annual Report on Form 10-K.

Item 1A. 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.

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

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

By mutual agreement of the Board of Directors of the Company and Philip J. Young, Mr. Young stepped down from his role as President and Chief Executive Officer of the Company in September 2014. We are looking to replace Mr. Young with a new Chief Executive Officer, and in the interim, Jeremy Curnock Cook, the Chairman of our Board of Directors, is acting as interim Chief Executive Officer, and Wendy Johnson, a member of our Board of Directors, is acting as interim Chief Operating Officer. If we are unable to find a suitable Chief Executive Officer, we may have difficulty executing our business plans, which could cause delays in the commencement of clinical trials or other business activities. The change in Chief Executive Officer may also make it difficult to retain other personnel and the loss of additional personnel could also have an adverse impact on our business and operations. We are also looking to 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.

In December 2013, we completed a private placement of shares of our common stock, which raised approximately $18.0 million, prior to commissions. In March 2015, we completed a private placement of shares of our common stock and warrants, 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-001for 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.

Our former President and Chief Executive Officer stepped down from his roles as President and Chief Executive Officer in September 2014 and Mr. Curnock Cook, our Chairman, has been serving since then as Interim Chief Executive Officer. We currently have a search underway for a new Chief Executive Officer to replace Mr. Curnock Cook. Our inability to hire a new Chief Executive Officer, along with the loss of the services of 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 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.

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.

Our former President and Chief Executive Officer stepped down from his roles as President and Chief Executive Officer in September 2014 and Mr. Curnock Cook, our Chairman, has been serving since then as Interim Chief Executive Officer. We currently have a search underway for a new Chief Executive Officer to replace Mr. Curnock Cook. Our inability to hire the new Chief Executive Officer, along with the loss of the services of 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 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 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 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

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 expect to utilize U.S. Army human resources and facilities to conduct our planned Phase 1 clinical trial of AmpliPhage-002. Due to recent outbreaks of the Ebola virus, the Army has diverted significant resources to studying this potential epidemic. As a result, the U.S. Army has advised the Company that there may be a delay in initiating the planned Phase 1 AmpliPhage-002 study, which may significantly affect our ability to conduct this clinical trial prior to the fourth quarter of 2015.

Risks Related to Our Intellectual Property

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

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

applications.

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

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

- we might not have been the first to make the inventions covered by each of our pending patent applications and issued patents, and we may have to participate in expensive and protracted interference proceedings to determine priority of invention;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative product candidates to any of our product candidates that fall outside the scope of our patents;

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

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

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

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

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

Our ability to commercialize our product candidates depends on our ability to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. Numerous United States and foreign

patents and patent applications, which are owned by third parties, exist in the general field of anti-infective products or in fields that otherwise may relate to our product candidates. If we are shown to infringe, we could be enjoined from use or sale of the claimed invention if we are unable to prove that the patent is invalid. In addition, because patent applications can take many years to issue, there may be currently pending patent applications, unknown to us, which may later result in issued patents that our product candidates may infringe, or which may trigger an interference proceeding regarding one of our owned or licensed patents or applications. There could also be existing patents of which we are not aware that our product candidates may inadvertently infringe or which may become involved in an interference proceeding.

The biotechnology and pharmaceutical industries are characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. For so long as our product candidates are in clinical trials, we believe our clinical activities fall within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the United States, which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. As our clinical investigational drug product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. While we attempt to ensure that our active clinical investigational drugs and the methods we employ to manufacture them, as well as the methods for their use we intend to promote, do not infringe other parties' patents and other proprietary rights, we cannot be certain they do not, and competitors or other parties may assert that we infringe their proprietary rights in any event.

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

Risks Related to Our Industry

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

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

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

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

In July 2012, the Food and Drug Administration Safety and Innovation Act was passed, which included the Generating Antibiotics Incentives Now Act, or the GAIN Act. The GAIN Act is intended to provide incentives for the

development of new, qualified infectious disease products. These incentives may result in more competition in the market for new antibiotics, and may cause pharmaceutical and biotechnology companies with more resources than we have to shift their efforts towards the development of products that could be competitive with our product candidates.

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

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

- delay or failure to complete our clinical trials;
- withdrawal of clinical trial participants;
- decreased demand for our product candidates;
- injury to our reputation;

- litigation costs;
- substantial monetary awards against us; and
- diversion of management or other resources from key aspects of our operations.

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

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

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

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

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

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

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

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

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

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

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

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

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

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

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

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

Our research and development activities use biological and hazardous materials that are dangerous to human health and safety or the environment. We are subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials and wastes resulting from these materials. We are also subject to regulation by the Occupational Safety and Health Administration, or OSHA, state and federal environmental protection agencies and to regulation under the Toxic Substances Control Act. OSHA, state governments or federal Environmental Protection Agency, or EPA, may adopt regulations that may affect our research and development programs. We are unable to predict whether any agency will adopt any regulations that could have a material adverse effect on our operations. We have incurred, and will continue to incur, capital and operating expenditures and other costs in the ordinary course of our business in complying with these laws and regulations.

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

Risks Related to Our Common Stock

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

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

Price declines in our common stock could also 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 the exercise of convertible securities issued in connection with recent financing transactions.

You may incur substantial dilution as a result of the exercise or conversion of convertible securities issued in connection with recent financing transactions. 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 Redeemable Convertible Preferred Stock. As part of the same transaction, approximately $5.5 million in outstanding convertible notes were converted into shares of Series B Redeemable 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 Redeemable 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 Redeemable 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 Redeemable Convertible Preferred Stock is convertible into 10 shares of common stock and accrues dividends at the rate of 10% per year. Additionally, we issued warrants to purchase an aggregate of up to approximately 25.0 million shares of common stock at an exercise price of $0.14 per share.

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

In addition, in March 2015, we completed a private placement in which we issued 78,787,880 shares of the Company’s common stock at a price per share of $0.165 for an aggregate purchase price of $13 million, and warrants to purchase an aggregate of 19,696,971 shares of common stock which will be exercisable at an exercise price of $0.215 per share. We also issued warrants to purchase an aggregate of 4,727,273 shares of common stock to placement agents in connection with the March 2015 private placement.

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 April 3, 2015, we have outstanding warrants to purchase 63,314,696 shares of our common stock at an average exercise price of $0.19 per share, and outstanding options to purchase 22,034,747 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 April 10, 2015 our officers and directors beneficially owned approximately 10% 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 contain 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, 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 intend to reincorporate in Delaware, we will then be governed by the provisions of Section 203 of the Delaware General Corporation Law. 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.

If we do not complete the reverse stock split or reincorporation, we will have a limited number of authorized shares of common stock.

If we do not complete a reverse stock split or the reincorporation, or we do not otherwise increase the number of shares we are authorized to issue, we will not have an adequate number of shares for the exercise of the outstanding warrants.

The holders of our outstanding warrants may be entitled to cash payments if we do not have adequate authorized shares for the exercise of their warrants. The warrants issued in connection with the March 2015 private placement will be exercisable beginning on the later of (i) the first anniversary of the date of issuance and (ii) the date AmpliPhi effects a reverse stock split or increases the number of authorized shares of common stock, in either case in an amount sufficient to permit the exercise in-full of the warrants issued in this offering. If we effect the reverse stock split or increase the number of shares of authorized common stock before the first anniversary of the issuance of the warrants, the warrants will become exercisable at such time. If we do not effect the reverse stock split or increase the number of authorized shares before the first anniversary, the holders of the warrants will be entitled to an aggregate cash payment of $2,500,000, and such payment could have an adverse effect on our results of operations.

In addition, if we do not increase the number of authorized shares available for issuance, we may not be able to raise additional capital until we increase the number of shares we are authorized to issue.

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

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

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

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

In accordance with NASDAQ or 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 NASDAQ or NYSE MKT rules, and officers will be significantly curtailed.

Compliance with these reporting rules, Sarbanes-Oxley Act and NASDAQ or 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 we are unable to successfully remediate any deficiencies or material weaknesses in our internal controls over financial reporting, we may be unable to maintain compliance with securities law requirements, and our stock price may materially decline.

Our independent registered public accounting firms did not perform an evaluation of our internal control over financial reporting as of December 31, 2014 or December 31, 2013 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, 2014 and identified material weakness in the area of complex and non-routine transactions as further described in Item 9A of this Form 10-K. If we are unable to successfully remediate any significant deficiency or material weakness in our internal control over financial reporting, identify any additional significant deficiencies or material weaknesses that may exist, or satisfy the requirements of the Sarbanes-Oxley Act, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, and our stock price may decline materially as a result.

We may be unable to list our common stock on the NYSE MKT or another major national securities exchange, which may have a material adverse effect on the liquidity and value of our common stock.

Trading in our common stock continues to be conducted on the OTCQB in the over-the-counter market. We intend to apply to be listed on the NYSE MKT or another major national securities exchange. To establish and maintain our listing on the NYSE MKT or another major national securities exchange, we must meet certain requirements with respect to corporate governance, minimum bid price per share, minimum capitalization requirements, and various other matters. If we fail to meet any of the applicable listing standards, we may not qualify for listing on the NYSE MKT or such other major national securities exchange. If our common stock is listed on the NYSE MKT or another major national securities exchange, we cannot assure you that we will be able to continue to meet ongoing listing standards and maintain a listing of our common stock on the NYSE MKT or any other major national securities exchange. Until such time as we qualify for listing on the NYSE MKT or another major national securities exchange, our common stock will continue to be quoted on the OTCQB.

Our inability to be listed on a national securities exchange may limit our opportunities to effectively reach capital markets in the future and may limit our credibility with investors. Those factors could affect our ability to raise capital in the future, which could have a potential deleterious effect on the liquidity and value of 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.

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 cause dilution or 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.

In addition, we anticipate that we will need to raise additional capital to continue operations and support our product development activities. Issuances of additional shares or convertible securities may result in dilution of the percentage ownership of our existing stockholders, and could have an adverse effect on the market price of our common stock.

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

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

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

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

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

Item 1B. UNRESOLVED STAFF COMMENTS.

Not applicable to the Company as a smaller reporting company.

Item 2. PROPERTIES.

Our principal offices occupy approximately 471 square feet of leased office space pursuant to a lease agreement that expires in April 2015 and is located at 4870 Sadler Road, Suite 300, Glen Allen, Virginia 23060. We also lease approximately 708 square feet of lab space in Richmond, Virginia, approximately 5,000 square feet of lab space in Brookvale, Australia, approximately 50 square feet of office space in Bedford, United Kingdom, and approximately 4,000 square feet of laboratory and office space in Ljubljana, Slovenia. We believe our facilities are adequate for our current and near-term needs.

Item 3. LEGAL PROCEEDINGS.

From time to time we are involved in legal proceedings or subject to claims arising in the ordinary course of our business. Although the results of litigation and claims cannot be predicted with certainty, we do not believe we are a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, operating results, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our shares of common stock are quoted on the OTCQB 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 2015		
Period from January 1, 2015 to April 3, 2015	$0.30	$0.18
Fiscal Year 2014		
Fourth Quarter ended December 31, 2014	$0.23	$0.14
Third Quarter ended September 30, 2014	$0.45	$0.22
Second Quarter ended June 30, 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

Holders of Common Stock

As of March 16, 2015, there were 305 holders of record of our common stock. As of such date, the number of shares of our common stock outstanding is 364,657,373 which consists of 277,946,973 shares of common stock outstanding as of March 16, 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 March 16, 2015 (assuming a conversion ratio equal to ten (10) common shares for each share of Series B Redeemable Convertible Preferred Stock).

Dividends

We have never declared or paid any cash dividends or distributions 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.

Securities Authorized for Issuance under Equity Compensation Plans

In October 2012, our board of directors approved and adopted the 2012 Stock Incentive Plan, which we refer to as 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 Stock Incentive Plan, which we refer to as the 2009 Stock Incentive 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 in February 2014. The 2013 Plan replaces the Targeted Genetics Corporation Stock Incentive Plan and the 2012 Stock Incentive Plan.

The following table provides information as of December 31, 2014 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]	914,000	$ 0.36	39,250,000
Equity compensation plans not approved by security holders [2]	21,120,747	$ 0.18	0
Total	22,034,747	$ 0.19	39,250,000

(1) The 2009 Plan and 2013 Plan.

(2) The 2012 Plan.

Recent Sales of Unregistered Securities

On March 10, 2015, we entered into subscription agreements to issue an aggregate amount of 78,787,880 shares of common stock as well as warrants to purchase an aggregate 19,696,971 shares of our common stock for an aggregate purchase price of approximately $13.0 million as part of a private placement. The purchasers of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of such purchasers was an “accredited” investor” under Rule 506 of Regulation D or not a “U.S. person” under Regulation S.

On December 16, 2013, we entered into subscription agreements to issue an aggregate amount of 72,007,000 shares of common stock for an aggregate purchase price of approximately $18.0 million as part of a private placement. The purchasers of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of such purchasers was an “accredited investor” under Rule 506 of Regulation D or not a “U.S. person” under Regulation S.

On June 26, 2013, we completed a private placement of convertible preferred stock and warrants to purchase common stock with gross proceeds of $7.0 million through the sale of shares of our newly-created Series B Redeemable Convertible Preferred Stock. As part of the same transaction, approximately $5.5 million in outstanding convertible notes were converted into shares of Series B Redeemable 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 Redeemable 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 million shares of the Series B Redeemable 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 Redeemable Convertible Preferred Stock is convertible into 10 shares of common stock. Additionally, we issued warrants to purchase an aggregate of up to approximately 25.0 million shares of common stock at an exercise price of $0.14 per share. The offers, sales and issuances of Series B Redeemable Convertible Preferred Stock and warrants to purchase common stock were deemed to be exempt from registration under the Securities Act. The purchasers of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of such purchasers was an “accredited investor” under Rule 506 of Regulation D or not a “U.S. person” under Regulation S.

On March 29, 2013, pursuant to a Stock Issuance Agreement, which we refer to as the Issuance Agreement, we issued 24,000,000 shares of our common stock, or 26.4% of our total outstanding capital stock after such issuance, to Intrexon, then a privately held Virginia corporation, which subsequently became publicly traded, that develops technology intended to provide synthetic control over cellular functions, in consideration of Intrexon's concurrent entry into the Exclusive Channel Collaboration with us to develop new bacteriophage-based therapies to target specific antibiotic-resistant infections. The Issuance Agreement also provides for the potential future issuance by us to Intrexon of shares of our common stock having a fair market value of up to $7,500,000, depending upon the reaching of certain milestones under the Exclusive Channel Collaboration . The issuance of shares of common stock under the Issuance Agreement was deemed to be exempt from registration under the Securities Act as Intrexon was an "accredited investor" under Rule 506 of Regulation D.

Between April 13, 2012 and May 13, 2013, we sold convertible notes to Pendinas Limited in varying principal amounts for an aggregate total of $2,750,000. Additionally, we issued warrants to purchase an aggregate of up to approximately 7.0 million shares of common stock at an exercise price of $0.14 per share. All such convertible notes have been converted as a result of the completion of our private placement of convertible preferred stock, as of July 15, 2013. The offers, sales and issuances of convertible notes and warrants to purchase common stock were deemed to be exempt from registration under the Securities Act. Pendinas Limited was both an “accredited investor” under Rule 506 of Regulation D and not a “U.S. person” under Regulation S.

Between November 23, 2010 and February 1, 2012, we sold convertible notes to a total of 22 different parties in varying principal amounts for an aggregate total of $1,872,462. All such convertible notes have been converted as a result of the completion of our private placement of convertible preferred stock, as of July 15, 2013. The offer, sales and issuances of convertible notes were deemed to be exempt from registration under the Securities Act. Each of the purchasers was either an “accredited investor” under Regulation D or not a “U.S. person” under Regulation S.

In November 2012, under the terms of our acquisition of SPH, we issued 40,000,000 shares of our common. The issuance of common stock was deemed to be exempt from registration under the Securities Act. Each of SPH’s selling stockholders and each of the recipients of such shares was either an “accredited investor” under Regulation D or not a “U.S. person” under Regulation S.

In January 2011, under the terms of our acquisition of Biocontrol, we issued 22,586,073 shares of our common stock to the shareholders of Biocontrol with a total fair value of approximately $8.6 million as of January 6, 2011, resulting in Biocontrol’s former shareholders owning approximately 50% of our outstanding equity securities at the time. The issuance of common stock was deemed to be exempt from registration under the Securities Act. Each of Biocontrol’s former shareholders was not a “U.S. person” under Regulation S.

Item 6. SELECTED FINANCIAL DATA

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND

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 consolidated financial statements and the related notes contained elsewhere in this Annual Report. Some of the information contained in this discussion and analysis are set forth elsewhere in this Annual Report, 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 Annual Report.

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 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 Redeemable 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. In March 2015, we completed a private placement of shares of our common stock, which raised approximately $13 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, 2014, we had a cumulative deficit of $362.0 million. We recorded net income of $23.1 million in 2014 and a net loss of $64.6 million in 2013. 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 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.

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, 2014, we have recorded goodwill of $7.6 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, 2014.

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, 2014, we have recorded IPR&D of $12.4 million related to the 2012 acquisition of SPH's know-how and phage libraries and the 2011 acquisition of Biocontrol's know-how and phage library. In management's opinion, no IPR&D has been impaired as of December 31, 2014.

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, 2014 and 2013 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,			
	2014		2013	
Risk-free interest rate	1.3	%	0.6	%
Expected volatility	160.9	%	172.1	%
Expected term (in years)	4.0		4.0	
Expected dividend yield	0.0	%	0.0	%

Warrant and Preferred Shares Conversion Feature Liability

We account for warrants and the preferred shares conversion feature with anti-dilution (“down-round”) provisions under the guidance of ASC 815, Derivatives and Hedging and Emerging Issue Task Force Statement 07-5: Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock, which require the warrants and the preferred shares conversion feature to be recorded as a liability and adjusted to fair value in each reporting period. We estimate the fair values of these securities using a Monte Carlo valuation model. As a results of the revaluation of these liabilities to fair value at each reporting date, we recorded a gain of $37,219,000 in 2014 and a loss of $(49,330,000) in 2013.

JOBS Act

In April 2012, the JOBS Act was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an “emerging growth company.” As an “emerging growth company,” we are electing not to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision not to take advantage of the extended transition period is irrevocable. In addition, we are in the process of evaluating the benefits of relying on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, if as an “emerging growth company” we choose to rely on such exemptions, we may not be required to, among other things, (i) provide an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding a supplement to the auditor’s report providing additional information about the audit and the financial statements (auditor discussion and analysis) and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer’s compensation to median employee compensation. These exemptions will apply for a period of five years following the completion of our initial public offering or until we no longer meet the requirements of being an “emerging growth company,” whichever is earlier.

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Financial Overview

Revenue

To date, our revenues have come primarily from sub-licensing agreements. We have not generated any revenues 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.

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.

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.

Severance Charge

We incurred a severance charge in 2014 related to the departure of our Chief Executive Officer in September 2014. The charge consists of cash compensation and benefits and non-cash stock-based compensation expense pursuant to his employment agreement with the Company.

Oher Income (Expense)

Gain (loss) on warrant and derivative liabilities represents the change in fair value on revaluation of our warrant and preferred stock conversion liabilities, driven primarily by changes in our common stock price, interest rates and remaining estimated life of these liabilities. Amortization of note discount is related to the amortization of discounts related to the value of warrants issued in conjunction with the notes and which have been amortized over the stated life of the notes. Interest expense consists of interest on our convertible loan notes, which were converted to preferred shares in 2013. Any interest earned on our cash and cash equivalents is not considered significant to our financial statements.

Results of Operations

Comparison of the Years Ended December 31, 2014 and 2013

Revenue

For the years ended December 31, 2014 and 2013, we recognized revenues from sub-licensing agreements of $0.4 million and $0.1 million, respectively.

Research and Development

Research and development expenses were $5.8 million for the year ended December 31, 2014, a decrease of $0.7 million, or 10.9%, compared to $6.5 million for the year ended December 31, 2013. This decrease was attributable to a $3.0 million one-time technology access fee incurred in 2013 to Intrexon. Adjusted for this fee, other research and development expenses rose by $2.3 million, or 65.4%. This increase was due to higher discovery, laboratory, nonclinical testing, research and development collaborations, consulting and clinical development planning expenses for our product candidates, as well as the establishment of our pilot manufacturing operation in Slovenia in 2014.

Research and development expenses are expected to increase in 2015 compared to 2014 as we plan to continue devoting substantial resources to research and development in future periods as we start clinical trials and continue our discovery efforts.

General and Administrative

General and administrative expenses were $6.9 million for the year ended December 31, 2014, up $0.9 million, or 14.2%, compared to $6.0 million for 2013. This increase was due to higher legal, accounting, and staffing expenses incurred to satisfy our obligations as a public company and expenses of $0.6 million to certain shareholders as required by the terms of our registration rights agreement from the December 2013 private placement.

Severance Charge

The Company recorded a severance charge of $1.9 million in the third quarter ended September 30, 2014 related to the departure of its Chief Executive Officer. The charge included both 1) severance-period cash compensation and benefits and 2) stock-based compensation expense related to the acceleration of vested stock options, pursuant to the terms of the executive's employment agreement.

Other Income (Expense)

We recorded a gain of $37.2 million for the year ended December 31, 2014 for the change in fair value on revaluation of our warrant and preferred stock conversion liabilities. This gain was primarily attributable to a decline in the value of our common stock price at year end. For the year ended December 31, 2013, we recorded a loss of $49.3 million related to the change in fair value of these liabilities. This loss was related to an increase in the price of our common stock. We will continue to adjust these liabilities related to the warrants and the preferred stock conversion feature for changes in fair value until 1) the earlier of exercise or expiration of the warrants and 2) the conversion of our Series B Redeemable Convertible Stock into common shares.

Income Taxes

We incurred net operating losses for the years ended December 31, 2014 and 2013 and, accordingly, we did not pay any federal or state income taxes. As of December 31, 2014, we had approximately $178.0 million in U.S., Australian,

Slovenian, and UK gross net operating loss carry-forwards and research tax credit carry-forwards of approximately $3.9 million. The carry-forwards began to expire in 2012. Our gross net operating loss carry-forwards are subject to certain limitations on annual utilization as a result of changes in ownership of the Company, as defined by federal and state tax laws. Our current carry-forwards will begin to expire in 2019.

Net Operating Losses

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

Liquidity and Capital Resources

We have incurred net losses since inception through December 31, 2014 of $362.0 million, of which $315.5 million was incurred as a result of the Company’s prior focus on gene therapy in fiscal years 2010 and earlier. We have not generated any product revenues and do not expect to generate revenue from product candidates in the near term.

We had cash and cash equivalents of $6.6 million and $20.4 million at December 31, 2014 and 2013, respectively.

Net cash used in operating activities for the year ended December 31, 2014 was $12.6 million. We recorded net income for the period of $23.1 million, including a non-cash gain on warrant and derivative liabilities of $37.2 million. Other items included in net cash used in operating activities included non-cash charges related to stock-based compensation expenses, depreciation expenses, and patent amortization expense, which collectively approximated $2.1 million. Decreases in accounts payable and accrued expenses and deferred revenue represented an aggregate $1.0 million use of funds, and partially offset by an increase in accrued severance of $0.6 million. We invested $1.2 million in property and equipment in 2014, primarily related to our new cGMP manufacturing facility in Slovenia.

Net cash used in operating activities for the year ended December 31, 2013 was $6.3 million. We recorded a net loss for the period 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. Other items in uses of funds from operations included non-cash charges related to stock-based compensation expenses ($1.4 million), amortization of note discount ($2.6 million), depreciation expense, and amortization of patents, which collectively totaled $4.9 million. Tax refunds, an increase in accounts payable and accrued expenses, and an increase in accrued interest on notes payable represented an aggregate source of funds totaling $1.3 million.

In March 2015, we raised approximately $13 million in a private placement for our common stock and warrants to purchase common stock.

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

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

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

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

Contractual Obligations and Commitments

In February 2011, the Company entered into an agreement with Virginia Biotechnology Research Partnership Authority for Richmond, Virginia laboratory space. This agreement had a contractual expiration date of February 29, 2012 at which time it converted to a rolling three-month lease. At December 31, 2014, the Company's minimum payment commitment for the Company's Richmond, Virginia laboratory space was $3,237.

In December 2014, the Company entered into an agreement with Nevis Limited and Charter Limited for laboratory space in Bedfordshire, United Kingdom. This agreement has a minimum period of one year and a contractual expiration date of December 2017. At December 31, 2014, the Company's minimum payment commitment for the Company's Bedfordshire laboratory space was $9,300.

In 2014, the Company entered into an amended agreement with Office Suites Plus (now Regus Management Group, LLC) for office space in Glen Allen, Virginia. The agreement expires on April 30, 2015. At December 31, 2014, our minimum payment commitment for the Glen Allen space was $13,348.

In February 2014, the Company entered into an agreement with Avtotehna d.o.o. for manufacturing and research space in Ljubljana-Dobrunje, Slovenia. The lease has a termination date of February 2019, with extension provisions at the option of the Company, and a monthly payment is $3,615. At December 31, 2014, our minimum payment commitment for the Ljubljana space was $180,757. In addition, the Company expended $185,000 for leasehold improvements related to this facility. These costs are being amortized on a straight-line basis over the life of the related lease.

The following is a summary of our long-term contractual cash obligations as of December 31, 2014:

	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Operating lease obligations[1]	$220,000	$41,000	$ —	$179,000	$ —
Collaborative agreements	182,000	182,000	—	—	—
Total	$402,000	$223,000	$ —	$179,000	$ —

(1) Operating lease obligations reflect our obligation to make payments in connection with the lease for our office, manufacturing and laboratory space.

Off-Balance Sheet Arrangements

As of December 31, 2014, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. Therefore, we are not

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

Recent Financings

On March 10, 2015, we entered into subscription agreements to issue an aggregate amount of 78,787,880 shares of common stock as well as warrants to purchase an aggregate 19,696,971 shares of common stock for aggregate proceeds price of approximately $13 million as part of a private placement. The purchasers of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of such purchasers was an “accredited investor” under Rule 506 of Regulation D or not a “U.S. person” under Regulation S.

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

On June 26, 2013, we completed a private placement of convertible preferred stock and warrants to purchase common stock with gross proceeds of $7.0 million through the sale of shares of our newly-created Series B Redeemable Convertible Preferred Stock. As part of the same transaction, approximately $5.5 million in outstanding convertible notes were converted into shares of Series B Redeemable 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 Redeemable Convertible Preferred Stock and warrants to purchase common stock. The financing was led by life-sciences investors RA Capital Management and Third Security, LLC, with participation from BioScience Managers Pty Ltd.

Under the terms of the financing, we issued an aggregate amount of approximately 10.0 million shares of the Series B Redeemable Convertible Preferred Stock for aggregate proceeds of approximately $13.3 million (including the conversion of approximately $6.3 million of outstanding convertible notes). Each share of Series B Redeemable Convertible Preferred Stock is convertible into 10 shares of common stock. Additionally, we issued warrants to purchase an aggregate of up to approximately 30,040,195 shares of common stock at an exercise price of $0.14 per share. As a result of the completion of this private placement, as of July 15, 2013, all previously issued convertible notes have been converted and there are no convertible notes outstanding.

Comparison of the Years Ended December 31, 2013 and 2012

Revenue

For the years ended December 31, 2013 and 2012, we recognized $0.1 million and $0.7 million in revenue, respectively.

Research and Development

Research and development expenses were $6.5 million for the year ended December 31, 2013, compared to $1.5 million for the year ended December 31, 2012. The $5.0 million increase in expenses is due a $3.0 million fee related to technology access fees, as well as increases in discovery, laboratory, nonclinical testing, research and development collaborations, consulting and clinical development planning expenses for our product candidates.

General and Administrative

General and administrative expenses were $6.0 million in 2013 compared to $3.2 million for 2012, representing an increase of $2.8 million, or 87.2%. The increase was due to increase in personnel costs and other costs associated with being a public company.

Other Income (Expenses)

We recorded a loss of $49.3 million for the year ended December 31, 2013 for the change in fair value on revaluation of our warrant and preferred stock derivative liabilities. The loss was attributable to the establishment of the liabilities with our issuance of the Series B redeemable convertible preferred stock and common stock warrants issued in conjunction with 2013 equity issuances, both of which included embedded derivatives due to price protection features, as well as changes in the fair value of the liabilities for the year. We will continue to adjust these liabilities related to the warrants and the preferred stock conversion feature for changes in fair value until 1) the earlier of exercise or expiration of the warrants and 2) the conversion of our Series B Redeemable Convertible Stock into common shares.

We recorded amortization of discount on notes payable of $2.6 million, which included the normal amortization of the notes as well as the write-off of the remaining discount upon conversion to Series B redeemable convertible preferred stock in 2013.

Interest expense in 2013 was $0.2 million, compared to $0.3 million for 2012. The increase was due to lower interest costs in 2013 associated with our convertible loan notes, which were converted to preferred stock during the year.

Income Taxes

We incurred net operating losses for the years ended December 31, 2013 and 2012 and, accordingly, we did not pay any federal or state income taxes. As of December 31, 2013, we had accumulated approximately $170.5 million in U.S., Australian, and UK gross net operating loss carry-forwards and research tax credit carry-forwards of approximately $3.7 million. The carry-forwards began to expire in 2012. Our gross net operating loss carry-forwards are subject to certain limitations on annual utilization as a result of changes in ownership of us, as defined by federal and state tax laws.

Net Operating Losses

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

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

AMPLIPHI BIOSCIENCES CORPORATION

INDEX TO AUDITED CONSOLIDATED FINANCIAL STATEMENTS

AmpliPhi Biosciences Corporation

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of AmpliPhi Biosciences Corporation

We have audited the accompanying consolidated balance sheet of AmpliPhi Biosciences Corporation as of December 31, 2014, and the related consolidated statement of operations, redeemable convertible preferred stock and shareholders' equity (deficit), and cash flows for the year ended December 31, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company’s internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of AmpliPhi Biosciences Corporation at December 31, 2014, and the consolidated results of its operations and its cash flows for the year ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Richmond, Virginia

April 15, 2015

REPORT OF INDEPENDENT REGISTERED PUBLIC

ACCOUNTING FIRM

To the Board of Directors and Stockholders

AmpliPhi Biosciences Corporation

Richmond, VA

We have audited the accompanying consolidated balance sheet of AmpliPhi Biosciences Corporation and Subsidiaries (Company) as of December 31, 2013 and the related statements of operations, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of AmpliPhi Biosciences Corporation and Subsidiaries as of December 31, 2013 and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ PBMares, LLP

Richmond, Virginia

April 15, 2015

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AmpliPhi Biosciences Corporation

Consolidated Balance Sheets

	December 31, 2014	2013
Assets		
Current assets		
Cash and cash equivalents	$6,581,000	$20,355,000
Accounts receivable	100,000	8,000
Prepaid expenses and other current assets	339,000	297,000
Total current assets	7,020,000	20,660,000
Property and equipment, net	1,220,000	145,000
In process research and development	12,446,000	12,446,000
Acquired patents, net	369,000	400,000
Goodwill	7,562,000	7,562,000
Total assets	$28,617,000	$41,213,000
Liabilities, Series B redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities		
Accounts payable and accrued expenses	$1,167,000	$2,147,000
Deferred revenue	244,000	244,000
Accrued severance	457,000	—
Total current liabilities	1,868,000	2,391,000
Preferred B stock conversion liability	12,320,000	40,791,000
Warrant liability	5,826,000	16,871,000
Accrued severance	98,000	—
Deferred tax liability	3,078,000	3,078,000
Total liabilities	23,190,000	63,131,000
Series B redeemable convertible preferred stock $0.01 par value, 10,000,000 shares authorized, 8,671,040 shares issued and outstanding at December 31, 2014 and 8,859,978 shares issued and outstanding at December 31, 2013 (liquidation preference of $14,042,000 and $13,022,000 at December 31, 2014 and December 31, 2013, respectively)	1,990,000	707,000
Stockholders' equity (deficit)		
Common stock, $0.01 par value, 445,000,000 shares authorized, 199,159,093 shares issued and outstanding at December 31, 2014 and 182,535,562 shares issued and outstanding at December 31, 2013	1,992,000	1,825,000
Additional paid-in capital	363,451,000	358,828,000
Paid-in-capital – contingent shares	—	1,837,000
Accumulated deficit	(362,006,000)	(385,115,000)
Total stockholders' equity (deficit)	3,437,000	(22,625,000)
Total liabilities, Series B redeemable convertible preferred stock and stockholders' equity (deficit)	$28,617,000	$41,213,000

The accompanying notes are an integral part of these consolidated financial statements.

AmpliPhi Biosciences Corporation

Consolidated Statements of Operations

	Year Ended December 31,	
	2014	2013
Revenue	$ 409,000	$ 81,000
Operating expenses		
Research and development	5,805,000	6,469,000
General and administrative	6,850,000	5,996,000
Severance charge	1,864,000	—
Total operating expenses	14,519,000	12,465,000
Loss from operations	(14,110,000)	(12,384,000)
Other income (expense)		
Gain (loss) on warrant and derivative liabilities	37,219,000	(49,330,000)
Amortization of note discount	—	(2,636,000)
Interest expense, net	—	(233,000)
Other income (expense), net	37,219,000	(52,199,000)
Net income (loss)	23,109,000	(64,583,000)
Accretion of Series B redeemable convertible preferred stock	(1,285,000)	(618,000)
Net income (loss) attributable to common stockholders	$ 21,824,000	$ (65,201,000)
Net income (loss) per share of common stock – basic	$ 0.12	$ (0.64)
Net income (loss) per share of common stock – diluted	0.07	(0.64)
Weighted average number of shares of common stock outstanding – basic	187,331,969	101,201,753
Weighted average number of shares of	323,604,642	101,201,753

common stock
outstanding – diluted

The accompanying notes are an integral part of these consolidated financial statements.

AmpliPhi Biosciences Corporation

Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders’ Equity (Deficit)

Redeemable Convertible Preferred Stock		Stockholders' Equity (Deficit)				
Series B		Common Stock		Additional Paid-in	Accumulated	Total Stockholders’ Equity
Shares	Amount	Shares	Amount			