AmpliPhi Biosciences Corp
Form 10-12G
December 16, 2013

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

FORM 10

GENERAL FORM FOR REGISTRATION OF SECURITIES

Pursuant to Section 12(b) or (g) of the Securities Exchange Act of 1934

AMPLIPHI BIOSCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

Washington (prior to reincorporation)
Delaware (after reincorporation)

(State of other jurisdiction of incorporation)

91-1549568

(I.R.S. Employer Identification No.)

4870 Sadler Road, Suite 300
Glen Allen, Virginia 23060

(Address of principal executive offices) (Zip Code)

(804) 205-5069

(Registrant s telephone number, including area code)

Securities to be registered pursuant to Section 12(b) of the Act:

Title of each class to be so registered	Name of each exchange on which each class is to be registered
None	Not applicable

Securities to be registered pursuant to Section 12(g) of the Act:

Common Stock, par value $0.01 per share

(Title of class)

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

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

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

our clinical development plans, including planned clinical trials;

our research and development plans;

the safety and efficacy of our products and product candidates;

the anticipated regulatory pathways for our product candidates;

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

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

our ability to leverage the experience of our management team;

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

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

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

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

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

the benefits of our products and product candidates;

market and industry trends;

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

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

our expectations regarding future planned expenditures;

our expectations with respect to product pricing;

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

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

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

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

our plans to potentially transact business outside the United States.

In some cases, you can identify these statements by terms such as anticipates, believes, could, estimates, expec intends, may, plans, potential, predicts, projects, should, will, would or the negative of those ter expressions. These forward-looking statements reflect our management s beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this registration statement 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.

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

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

Item 1. Business.

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 connection with the registration of our shares, we intend to reincorporate as AmpliPhi Biosciences Corporation in the State of Delaware.

Implications of Being an Emerging Growth Company

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until the earliest of (1) the last day of the first fiscal year (a) following the fifth anniversary of the completion of 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, which means the market value of our common stock that is held by non-affiliates exceeded $700.0 million as of the prior June 30th; or (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. We refer to the Jumpstart Our Business Startups Act of 2012 herein as the JOBS Act and references herein to emerging growth company shall have the meaning associated with it in the JOBS Act.

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

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

reduced disclosure about our executive compensation arrangements;

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

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

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

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

As used in this registration statement, unless the context requires otherwise, the Company, we, us and our refer t 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.

Background

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

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

The extensive use of antibiotics, since their discovery in the 1940s, has resulted in drug resistance among many disease-causing bacteria. Resistance to antibiotics, according to the Centers for Disease Control (CDC), threatens to reverse the medical advances of the last half-century. Examples of clinically important microbes that are rapidly developing resistance to available antimicrobials include bacteria that cause skin, bone, lung and bloodstream infections (e.g., *S. aureus* and MRSA), pneumonia and lung infections in the community, hospital and cystic fibrosis

(e.g., *A. baumanii*, *P. aeruginosa*, and *K. pneumoniae*), meningitis (e.g., *S. pneumonia*), urinary tract and gastrointestinal infections (e.g., *E. coli* and *C. difficile*). As a phage kills bacteria in ways entirely unlike the mechanisms used by antibiotics, MDR bacteria are not resistant to a phage in the same manner. Furthermore, as new resistant bacteria emerge, it should be possible to identify new phages that will still have efficacy.

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

We plan to develop our phage product candidates using our proprietary discovery and development platform, which allows for rapid identification, characterization and manufacturing of multiple phage therapies. Each product candidate combines several carefully selected phages specific for a particular disease-causing bacterial pathogen. We believe that our understanding of bacteriophage biology combined with the clinical and technical expertise of our collaboration partners will enable the rapid advancement of phage treatments to the clinic and eventually the market.

In March 2013, we entered into the Exclusive Channel Collaboration, or ECC, with 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*. We also entered into a collaboration agreement on August 1, 2013, which we refer to as the August Collaboration Agreement, with the University of Leicester and the University of Glasgow, whereby the University of Glasgow will carry out certain animal model development work.

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

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

The Need for New Anti-Infective Therapies

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

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

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Product Candidates

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. 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 up to 100% of 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 complementation, defined as the number of bacteria targeted by more than one phage in the product. High complementation is an important factor in preventing bacteria from developing resistance to our phage products.

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In collaboration with Institut Pasteur (Paris, France) and Brompton Clinic, Imperial College (London, United Kingdom), we have demonstrated in multiple preclinical studies 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. 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 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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Bacterial counts and phage titers were measured in these animals, 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. Furthermore, it was evident that phage replicated to high levels in the infected lung. These results are shown in the graphics below.

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 administration and also when administered 24 hours post-bacterial infection. These results are depicted in the graphics below.

Importantly, a preclinical study conducted at the Institut Pasteur in mice demonstrated the ability of our phage mix to reach the lung within two hours of being delivered by oral administration. The phage levels increased significantly between two and six hours post-treatment demonstrating that when orally administered, phages not only reached the lungs but were also able to infect and multiply in target bacteria.

We plan to consult with the MHRA in the first quarter of 2014 and intend to move the CF program into additional preclinical testing in preparation for a Phase 1/2 study. Initially, we aim to prove that our phage mix can be safely administered to healthy volunteers and CF patients while demonstrating a decrease in bacterial counts, thus setting the stage for later-stage trials. We plan to manufacture the AmpliPhage-001 product as further described below.

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

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

Using the same strategy outlined above for product development of AmpliPhage-001, we have selected a phage product mix that has greater than 85% efficacy with high complementation against a global diversity panel that includes some of the most virulent isolates of *S. aureus* identified by the U.S. Army.

We plan to initiate a Phase 1 study of AmpliPhage-002 in 2014 to demonstrate the safety of AmpliPhage-002 when administered to healthy normal volunteers colonized by *S. aureus*. If that study is successful, we then intend to conduct a Phase 2 study in *S. aureus* for wound and skin infections.

We are currently working with the U.S. Army bioprocessing facility to manufacture cGMP AmpliPhage-002, formulated for nasal delivery. We plan to further formulate our product for delivery to patients with wound and skin infections.

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.

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. Positive 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.

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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 CDC 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-aquired 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 CDC 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.

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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 CDC 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 Lytic Phage

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. 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.

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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. They 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.

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 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 the body of less well-conducted studies, suggest that phage therapy shows promise for treating infectious diseases caused by antibiotic-resistant bacteria.

Our Strategy

Our strategy is to use techniques of modern biotechnology and current state-of-the-art practices for drug development 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.

We plan to conduct Phase 1 studies in 2014 and also Phase 2 studies if the Phase 1 studies are successful. Initially, in collaboration with the U.S. Army, we plan to study the safety and tolerability of our phage product (AmpliPhage-002)

developed for treating *S. aureus* (MRSA) infections in a Phase 1 study and then in a Phase 2 study of wounds and skin infections. Additionally, in conjunction with leading Centers of Excellence in the UK and Australia, we plan to conduct a Phase 1/2 study using AmpliPhage-001 to treat CF patients with *P. aeruginosa* lung infections. Longer term, we plan to build upon our preclinical data and conduct studies in patients suffering from serious gastrointestinal infections caused by *C. difficile*.

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Recent 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 to 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. 20,000,000 of those shares were issued directly to the selling stockholders of SPH upon the closing of the acquisition, and the remaining 20,000,000 shares were issued and held in escrow. Of the escrow shares, 8,000,000 shares, referred to as Claims Shares, were subject to claims by us for breaches of representations by the selling stockholders of certain individual representations and certain additional representations made with respect to SPH itself and its operations by Dr. Anthony Smithyman and Mrs. Margaret Smithyman, the two largest shareholders of SPH, referred to as the Managers. The Claims Shares were released from escrow in November 2013, 12 months following the closing of the acquisition. The remaining 12,000,000 shares held in escrow, referred to as Contingent Shares, are to be released to the Managers upon the meeting (within 24 months of the closing) of three clinical and developmental milestones relating to SPH s phage therapy projects. At the satisfaction of each of those milestones, one third of the Contingent Shares will be released to the Managers. If, within 24 months of the closing, any of those milestones has not been met, as a result of our failure to use best endeavors to cause such milestones to occur or as a result of a natural and unavoidable catastrophe that prevents the milestone from occurring, the unsatisfied milestone will be deemed satisfied and we will be required to release the applicable number of Contingent Shares to the Managers. Contingent Shares relating to milestones that have not been released to the Managers as of the 24th month following the acquisition, and that are not subject to claim by the Managers that such milestone was met or is otherwise due, will be returned to us. The Contingent Shares are also subject to claims for breaches of the representations being made by the Managers to the extent that the Claims Shares are insufficient to satisfy our claims under the terms of the SPH Agreements. Further, the Managers are not eligible to retain any dividends or other distributions by us that are allocable to unreleased Contingent Shares and have designated our President and Chairman of the Board, and each of them, as proxies to vote unreleased Contingent Shares.

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 September 30, 2013, $150,000 has been paid by us to Cellabs and all 2,000,000 shares have been issued. Under the terms of the Loan Repayment Deed, we are obligated to pay an additional $200,000. These remaining payments are to be paid out of proceeds we receive in connection with certain commercial transactions we may enter into, and if we have not repaid the remaining obligation to Cellabs by the end of the 18th month following the closing of our acquisition of SPH, we will be obligated to pay any remaining amounts in $10,000 monthly installments thereafter. The SPH acquisition also included several phage therapy projects which had reached the pre-clinical or animal study stage, including the Bromptom 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 an initial term of twelve (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.

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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 ECC 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 ECC 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 ECC, 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 ECC 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 ECC 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 ECC, 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 ECC, 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. In addition, in partial consideration for each party s execution and delivery of the ECC, we entered into a Stock Issuance Agreement with Intrexon.

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The ECC is effective until terminated by either Intrexon or AmpliPhi. Intrexon may terminate the ECC 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 ECC. AmpliPhi has the right to terminate the ECC upon 90 days written notice to Intrexon at any time.

Upon termination of the ECC, 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 ECC.

Global R&D Agreement with U.S. Army

In June 2013, we entered a CRADA with the USAMRMC and the WRAIR. The CRADA will focus on developing and commercializing 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 CRADA with the U.S. Army, we submitted a Pre-IND 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 manufacture our initial phage product in collaboration with the Walter Reed Bioprocessing facility in Bethesda, Maryland and, in collaboration with the U.S. Army, will conduct clinical trials at various sites throughout the world. We plan to initiate a Phase 1 feasibility and safety study in phage treatment of *S. aureus* infections in the second half of 2014 followed by a Phase 2 study of *S. aureus* infections.

We will retain global regulatory ownership and commercial rights to all products developed by us under the agreement. USAMRMC will gain access rights to any products developed. We also have the rights to exclusively license any intellectual property developed by USAMRMC under the collaboration on terms to be agreed upon. WRAIR will be responsible for cGMP production of the lead *S. aureus* product, AmpliPhage-002 for Phase 1 and 2 clinical trials at its bioproduction facility.

The CRADA expires in June 2018 and can be terminated by either USAMRMC or AmpliPhi upon 60 days written notice to the other party at any time.

University of Leicester Development Agreements

On April 24, 2013, we entered into the April Collaboration Agreement and on September 5, 2013, we entered into the Leicester License Agreement with the University of Leicester to develop a phage therapy that targets and kills all toxin types of *C. difficile*. We also entered into the August Collaboration Agreement with the University of Leicester and the University of Glasgow, whereby the University of Glasgow will carry out certain animal model development work.

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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 April Collaboration Agreement expires on November 12, 2014 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 August Collaboration Agreement expires on October 22, 2014 and is terminable under the same conditions as the April Collaboration Agreement.

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.

Grants

Engineering and Physical Sciences Research Council (EPSRC) Grant: Encapsulated Phage for Treatment of Burns and Wound Site Infections

Through its wholly owned subsidiary, Biocontrol, the Company benefits from a United Kingdom grant awarded jointly to the University of Bath, the Frenchay Hospital, and Biocontrol. The grant runs for four years from June 2011. The awarding body is the Engineering and Physical Sciences Research Council. The total amount awarded is £0.6 million (US$0.9 million), of which £63,000 (US$0.1 million) is allocated to fund work at Biocontrol, along with staff paid from the grant, which is administered by the University of Bath. At present all staff are based at the University of Bath.

Technology Strategy Board Grant: Development of Instrumental and Bioinformatic Pipelines to Accelerate Commercial Applications of Metagenomics Approaches

Through its wholly owned subsidiary, Biocontrol, the Company benefits from a United Kingdom grant awarded jointly to Unilever PLC, the University of Glasgow, the University of Liverpool, Skalene Limited, and Biocontrol. The grant runs for three years from September 2011. The grant-awarding body is the Technology Strategy Board. The total amount awarded is £2.3 million (US$3.5 million as of June 30, 2013), of which up to £0.3 million (US$0.4 million as of June 30, 2013) is to be used at Biocontrol.

European Union Consortium Grant

The Company is also in the process of closing down a European Union consortium grant and returning £45,481 (US$70,496) of a £69,353 (US$0.1 million) advance, the remainder of which has been spent on work carried out prior to closure.

Legacy Programs

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

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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.

Under the terms of the Celladon asset sale and license agreement, we retained certain liabilities, including obligations to indemnify against charges of infringement of certain intellectual property pursuant to our asset purchase agreement with Genzyme Corporation, our license agreement with Amsterdam Molecular Therapeutics B.V. and our collaboration and license agreement dated January 1, 2005 with the International AIDS Vaccine Initiative, the Children s Research Institute and the Children s Hospital of Philadelphia.

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. and 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 and methods to reduce antibiotic resistance.

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 Health Protection Agency, 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 (extended 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.

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, we have three granted U.S. patents and a further 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 priority dates for these patents are July 23, 2003 and May 14, 2004. Dates of U.S. grant are October 5, 2010,

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January 31, 2012 and March 5, 2013. The dates of expiry for the granted patents are March 18, 2027 (extended 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 February 9, 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 a divisional application has been submitted for therapy claims although there is no assurance that claims or applications will ultimately be granted.

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

Through our wholly owned subsidiary, Biocontrol, we have one granted U.S. patent, with a 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 (extended 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 August 7, 2013, with March 7, 2028 as the date of expiry. National applications are under examination in other jurisdictions.

United Kingdom filing 1207910.9; Therapeutic bacteriophage compositions

Through our wholly owned subsidiary, Biocontrol, we have a United Kingdom patent application relating to the design of effective combinations of bacteriophages. The priority date for this application is May 4, 2012. The application has now progressed to the PCT stage (as yet unpublished).

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 cancer 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 are optimizing a manufacturing platform that will allow us to prepare therapeutic phages to cGMP regulations, in a cost-effective manner. Preclinical studies with Institut Pasteur and other centers of academic excellence have been conducted. We have evaluated phage efficacy when given at different doses via different routes of administration. We are establishing banks of relevant clinical bacterial isolates for ongoing phage sensitivity testing. We currently depend on third-party contract manufacturers for all of our required raw materials, active pharmaceutical ingredients, or API, and finished products for our preclinical and clinical trials. Manufacturers of our products are required to 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

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agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers 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 NDA/Biologics License Application, or BLA, including withdrawal of the product from the market. In addition, changes to the manufacturing process 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.

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 expect to commence commercialization activities by building a focused sales and marketing organization in the United States to sell our products. We believe that such an organization will be able to address the community of key specialists in treating the patient populations for which our product candidates are being developed. To achieve global commercialization, we anticipate using 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;
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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 BLA 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 and 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 IND application. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the IND on a clinical hold within that 30-day time period. In such a case, the IND 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 IND 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

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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 IND 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.

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United States Review and Approval Processes

In order to obtain approval to market a biological product in the United States, a BLA 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 BLA 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 BLA 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, 2013, 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 ($554,5600) 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 BLA 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 BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. After the BLA submission is accepted for filing, the FDA reviews the BLA 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 NDA/BLA 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.

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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.

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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 IND (falling after issuance of the patent) and the submission date of an NDA, plus the time between the submission date of a BLA 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.

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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 BLA 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.

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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. 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.

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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 December 6, 2013 we had eight full-time employees and three part-time employees.

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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.

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

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

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

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

To satisfy FDA or foreign regulatory approval standards for the commercial sale of our product candidates, we must demonstrate in adequate and controlled clinical trials that our product candidates are safe and effective. Success in early clinical trials, including Phase 2 trials, does not ensure that later clinical trials will be successful. Our initial results from Phase 1/2 clinical trials also may not be confirmed by later analysis or subsequent larger clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

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

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

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

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

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

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

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

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

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

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

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 product candidates must undergo rigorous clinical testing, the results ofwhich are uncertain and could substant

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our ability to recruit clinical trial investigators and sites with the appropriate competencies and experience;
our ability to obtain and maintain patient consents; and
competition for patients by clinical trial programs for other treatments.

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

We may need to license additional intellectual property rights.

The development and commercialization of phage-based antibacterial agents may require us to obtain rights to intellectual property from third parties. For example, pursuant to our Collaborative Research and Development Agreement, or CRADA, with the United States Army Medical Research and Materiel Command, or USAMRMC and the Walter Reed Army Institute of Research, or WRAIR, we are focusing on developing and commercializing bacteriophage therapeutics to treat *S. aureus, E. coli* and *P. aeruginosa* infections. To the extent the intellectual property is generated from the USAMRMC or WRAIR that is used in a commercial product, we may be obligated to make payments such as royalties, licensing fees and milestone payments. We may also determine that it is necessary or advisable to license other intellectual property from third parties. There can be no assurance that such intellectual property rights would be available on commercially reasonable terms, if at all.

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

Our research and development activities, preclinical studies, clinical trials and the anticipated manufacturing and marketing of our product candidates are subject to extensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in Europe and elsewhere. For example, our research facilities in Colworth, United Kingdom, recently failed an audit by the Health and Safety Executive, Britain s national regulatory for workplace health and safety; as a result of this failure we have elected to reconfigure our research operations. 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.

We are subject to significant regulatory approval requirements, which coulddelay, prevent or limit our abili57 to mark

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

and Clinical Health Act, or HITECH, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

The federal physician sunshine requirements under the Affordable Care Act requires manufacturers of drugs, devices, biologics and medical supplies to report annually to HHS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations. Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving

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

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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 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.

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

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

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

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

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

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

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

Risks Related to Our Financial Performance and Operations

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

We have incurred losses in each year since our inception in 1992. Prior to the merger of Targeted Genetics Corporation with Biocontrol in January 2011, our accumulated deficit was $315.5 million, and Biocontrol had an accumulated deficit of $6.9 million. Since January 2011, we have incurred a cumulative deficit of $14.6 million, and we expect to incur losses for the foreseeable future. We have devoted, and will continue to devote for the foreseeable future, substantially all of our resources to research and development of our product candidates. For the year ended December 31, 2012, we had an operating loss of $0.8 million and a net loss of $1.1 million. For the nine months ended September 30, 2013, we had an operating loss of $9.0 million and a net loss of $9.6 million, of which $3.0 million was due to a non-cash technology access fee paid to Intrexon Corporation, which we refer to as Intrexon. Clinical trials and activities associated with discovery research are costly. We do not expect to generate any revenue from the commercial sales of our product candidates in the near term, and we expect to continue to have significant losses for the foreseeable future.

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

Our success depends in part on retaining and motivating key personnel and, if we fail to do so, it may be more difficult for us to execute our business strategy. As a small organization we are dependent on key employees and may need to hire additional personnel to execute our business strategy successfully.

Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our senior management, particularly our Chief Executive Officer, Philip J. Young and our Global Head of Research, Sandra Morales. The loss of the services of Mr. Young, Ms. Morales or one or more of our other key employees could delay or have an impact on the successful completion of our clinical trials or the development of additional product candidates.

As of December 6, 2013, we had eleven 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.

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

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Risks Related to Our Dependence on Third Parties

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

Through our Collaborative Research and Development Agreement with the United States Army Medical Research and Materiel Command, we are depending on the U.S. Army to develop manufacturing processes for the production of AmpliPhage-002 for treatment of *S. aureus* (MRSA) infections. The manufacturing processes for AmpliPhage-002, and the scale up of such process for clinical trials, is novel, and there can be no assurance the U.S. Army 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. The facilities of the U.S. Army must also undergo an inspection by the FDA for compliance with the FDA s current good manufacturing practice regulations, or cGMP regulations, before the respective product candidates can be approved. 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. In addition, sequestration and other budget constraints of the United States federal budget reduce the resources available to support manufacturing development and manufacturing of our product candidate, which could result in significant development delays and require additional expenditures by us.

We rely on third parties for aspects of product development.

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

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

We expect to use clinical research organizations to assist in conduct of our clinical trials. There are numerous alternative sources to provide these services. However, we may face delays outside of our control if these parties do not perform their obligations in a timely or competent fashion or if we are forced to change service providers. This

risk is heightened for clinical trials conducted outside of the United States, where it may be more difficult to ensure that clinical trials are conducted in compliance with FDA requirements. Any third-party that we hire to conduct clinical trials may also provide services to our competitors, which could compromise the performance of their obligations to us. If we experience significant delays in the progress of our clinical trials and in our plans to file New Drug Applications (NDAs), the commercial prospects for product candidates could be harmed and our ability to generate product revenue would be delayed or prevented.

We must manage a geographically dispersed organization.

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

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operations or other factors. Managing our organization across multiple locations and multiple time zones may reduce our efficiency, increase our expenses and increase the risk of operational difficulties in the execution of our plans.

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

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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.

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

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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.

There is a substantial risk of product liability claims in our business. If we donot obtain sufficient liability insurance, a

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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

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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.

We may incur significant costs complying with environmental laws andregulations, and failure to comply with these

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

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

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

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

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

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

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 September 30, 2013, we have outstanding warrants to purchase 36,780,385 shares of our common stock at an average exercise price of $0.15 per share, and outstanding options to purchase 25,347,052 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 December 6, 2013, our officers and directors beneficially owned approximately 18.24% of our outstanding common stock. As a result, these stockholders, acting together, may be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily

those of other stockholders.

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

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

If our officers, directors and largest stockholders choose to act together, theymay be able to control our manageme

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stockholders to replace or remove our current management by making it more difficult for stockholders to replace or remove our board of directors. These provisions include:

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

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

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

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

We have never declared or paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be our stockholders sole source of gain for the foreseeable future.

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

As a public company, we will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and, if our common stock is listed on the NYSE MKT, the New York Stock Exchange Rules, or NYSE MKT rules. 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.

Maintaining and improving our financial controls and the requirements ofbeing a public company may strain our res

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

In addition, our management and independent registered public accounting firm did not perform an evaluation of our internal control over financial reporting as of December 31, 2012 or December 31, 2011 in accordance with the provisions of the Sarbanes-Oxley Act because no such evaluation was required. Had we and our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, significant deficiencies or material weaknesses may have been identified. If we are unable to successfully remediate any significant deficiency or material weakness in our internal control over financial reporting, identify any additional significant deficiencies or material weaknesses that may exist, or satisfy the requirements of the Sarbanes-Oxley Act, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, and our stock price may decline materially as a result.

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

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

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively impacted. If we obtain securities or industry analyst coverage and if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

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

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

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

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Item 2. Financial Information.

Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

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

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

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

We have incurred net losses since our inception. Our operations to date have been limited to research and development and raising capital. Since November 2010, we have raised approximately $5.6 million through the sale and issuance of convertible notes and warrants to purchase common stock. In June and July of 2013, we completed a private placement of shares of our Series B Convertible Preferred Stock and warrants to purchase common stock, which raised approximately $7.0 million in addition to converting approximately $6.3 million in outstanding convertible notes. 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, 2012, we had a deficit accumulated of $320.4 million. We recorded annual net losses of $1.1 million in 2012 and $3.9 million in 2011. 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. Upon completion of an initial public offering, 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 the net proceeds, together with our existing cash and cash equivalents for the continued research and development of our product candidates and for working capital and other general corporate purposes. We may also use a portion of these proceeds 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.

Financial Operations Overview

Revenue

To date, we have not generated any revenue from the sale of our product candidates and do not expect to generate any revenue from the sale of our product candidates in the near term. In the last two years, we recognized $3.9 million in revenue related to the sale of assets used in our former gene therapy business including patents, process development, quality control, quality assurance, manufacturing and bioanalytical

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functions and licensing revenue. We also received revenue from license agreements and grants from governments and academic institutions. These revenues were used in our new focus, the development of phages.

Research and Development Expenses

Research and development costs consist of the costs associated with our research and discovery activities, conducting clinical trials, manufacturing development efforts and activities related to regulatory filings. Our research and development expenses consist of salaries, non-cash stock-based compensation, costs of outside collaborators and outside services, royalty and license costs and facility, occupancy and utility expenses. We expense research and development costs as incurred. We expect annual research and development expenses will increase significantly in the future as we progress with development. In the last two years, we incurred an aggregate of $2.2 million on research and development expenses, including non-cash stock-based compensation expense.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for our personnel in the executive, finance, patent, accounting and other administrative functions, including non-cash stock-based compensation, as well as consulting costs for functions for which we either do not or only partially staff internally, including public relations, market research and recruiting. Other costs include professional fees for legal and accounting services, insurance and facility costs. In the last two years, we incurred an aggregate of $6.5 million in general and administrative expenses, including non-cash stock-based compensation expense.

Interest Income (Expense)

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

Critical Accounting Policies and Use of Estimates

Our management s discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these 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 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, 2012, we have recorded goodwill of $17.6 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

September 30, 2013.

Stock-Based Compensation Expenses

We account for stock options and restricted stock units related to our Stock Incentive Plans under the provisions of ASC 718-10, 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 ASIC 718-10, 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

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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, 2012 and 2011 and for the nine months ended September 30, 2013 and 2012 are set forth below.

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,		Nine Months Ended September 30,	
	2011[(1)]	2012	2012	2013
Risk-free interest rate		0.6 %		1.1 %
Expected volatility		172.1 %		172.1 %
Expected term (in years)		4.0		4.0
Expected dividend yield		0.0 %		0.0 %

(1) No stock options were granted in the year ended December 31, 2011.

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.

Accounting for Income Taxes

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

Recent Accounting Pronouncements

In September 2011, the FASB issued Accounting Standards Update (ASU) no. 2011-08, Intangibles Goodwill and Other (Topic 350): Testing Goodwill for Impairment that simplifies how public and nonpublic entities test goodwill for impairment. The amendments permit an entity to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test described in FASB Accounting Standards Codification Topic 350. The more-likely-than-not threshold is defined as having a likelihood of more than 50%. The guidance also includes examples of the types of events and circumstances to consider in conducting the qualitative assessment. The amendments will be effective for

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annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. We elected to early adopt this standard and used these new guidelines in assessing goodwill impairment for the consolidated financial statements.

On May 16, 2013, the FASB issued a proposed Accounting Standards Update, Leases (Topic 842): a revision of the 2010 proposed Accounting Standards Update, Leases (Topic 840). The proposal affects operating leases, especially with properties, and requires lessees to recognize assets and liabilities arising from those leases. The draft also proposes changes in accounting for purchase options and contingent rentals, which would affect the measurement of assets and liabilities for capital leases. An entity will be required to recognize all outstanding leases within the scope of the draft as of the date of initial application using a simplified retroactive approach. The exposure draft proposes that lessee and lessors should apply a right-of-use model in accounting for all leases, with few exceptions. An entity has a right to use an asset if it has control over the asset which is fulfilled if one of the three conditions outlined in the document are met. For leases within the scope of the draft, a lessee would recognize a right of use asset representing its right to use and the liability to make lease payments. A lessor would recognize an asset representing its right to receive lease payments using a performance obligation approach or a derecognition approach depending on its exposure to risks. There are numerous disclosures that would also be required such as a reconciliation of the opening and closing balances for the leased asset and liabilities. This proposed guidance could impact all companies that participate in leasing activities. We do not believe this proposed accounting standard will have a significant impact on the Company s future financial reporting.

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 mandatory audit firm rotation or 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.

Results of Operations

Comparison of the Years Ended December 31, 2012 and 2011

Revenue

For the years ended December 31, 2012 and 2011, we recognized $3.8 million and $0.1 million in revenue, respectively. In June 2012, we sold certain assets used in our gene therapy business including process development, quality control, quality assurance, manufacturing and bioanalytical functions for $3.0 million. In addition to this cash consideration, we may receive a long-term royalty of 1.75% on all product sales. This royalty may be completely canceled at any time by a one-time payment of $1.8 million.

In 2006, we granted a non-exclusive, field-restricted, perpetual license to Amsterdam Molecular Therapeutics, or AMT, for the patent rights related to an AAV1 vector gene delivery system in certain

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lipoprotein lipase deficiency conditions. For the years ended December 31, 2012 and 2011, we earned $0.2 million and $0.1 million of revenue under the AMT license, respectively.

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

Research and Development

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

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

General and Administrative

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

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

Tax Refund

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

Interest Income (Expense)

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

Income Taxes

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

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 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, 2012 of $320.4 million, of which $315.5 million was incurred in the Company s prior focus of gene therapy in 2010 and years earlier. We have not generated any product revenues and do not expect to generate revenue from the sale of product candidates in the near term.

We had cash of $0.9 million and $1.1 million at December 31, 2012 and 2011, respectively.

Net cash used in operating activities for the years ended December 31, 2012 and 2011 was $1.1 million and $4.7 million, respectively. For the year ended December 31, 2012, cash used in operations was

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attributable to the net loss for the year after adding back non-cash charges for stock-based compensation expense, depreciation expenses and loss on disposal of equipment, offset by a decrease in accrued liabilities and an increase in receivables. For the year ended December 31, 2011, cash used in operations was attributable to the net loss for the year after adding back non-cash charges for stock-based compensation expense and depreciation expenses, offset by a decrease in accrued liabilities and an increase in receivables. Net cash used in investing activities for the year ended December 31, 2012 was $0.1 million, due to purchases of property and equipment. Net cash used in investing activities for the year ended December 31, 2011 was $0.1 million, due to purchases of property and equipment. Net cash provided by financing activities was $1.0 million for the year ended December 31, 2012, due to proceeds from convertible notes. Net cash provided by financing activities was $2.5 million for the year ended December 31, 2011, due to proceeds from convertible notes. We expect 2013 cash requirements to be in the range of $9.0 million to $10.0 million. We believe that our cash as of December 31, 2012, in addition to convertible loan note revenue received in February through May 2013 and the recent $7.0 million in financing, will be sufficient to fund our projected operating requirements into the first quarter of 2014.

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

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

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

If we are unable to secure additional financing on a timely basis or on terms favorable to us, we may be required to cease or reduce certain research and development projects, to sell some or all of our technology or assets or to merge all or a portion of our business with another entity. Insufficient funds may require us to 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, we entered into an agreement with Virginia Biotechnology Research Partnership Authority for Richmond, Virginia laboratory space. This agreement has a contractual expiration date of February 29, 2012, at which time it converted to a rolling three-month lease. At September 30, 2013, our minimum payment commitment for our Richmond, Virginia laboratory space was $4,800.

In December 2011, we entered into an agreement with Nevis Limited and Charter Limited for laboratory space in Bedfordshire, United Kingdom. This agreement has a minimum period of three years and a contractual expiration date

of December 8, 2016. At September 30, 2013, our minimum payment commitment for the Bedfordshire laboratory space was $0.2 million.

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In February 2013, we entered into an agreement with Office Suites Plus (now Regus Management Group, LLC) for office space in Glen Allen, Virginia. The agreement has a minimum period of one year ending February 28, 2014, with a monthly cost of $2,075. At September 30, 2013, our minimum payment commitment for the Glen Allen space was $10,375.

Off-Balance Sheet Arrangements

As of December 31, 2012, 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.

Comparison of the Nine Months Ended September 30, 2013 and 2012

Revenue

For the nine-month periods ended September 30, 2013 and 2012, we recognized $0.3 million and $3.8 million in revenue, respectively. In May 2013, we received a $0.3 million sublicense fee from Celladon Corporation. In addition to the June 2012 sale of certain assets used in our gene therapy business to Celladon Corporation for $3.5 million, we earned $0.2 million of revenue under the AMT license for the nine-month period ended September 30, 2012. We received $23,000 in grant revenue for the nine-month period ended September 30, 2013 compared to $0.2 million for the nine-month period ended September 30, 2012.

Research and Development

Research and development expenses were $5.4 million for the nine-month period ended September 30, 2013 compared to $0.9 million for the nine-month period ended September 30, 2012. $3.0 million of the $4.5 million increase in expenses was due to a one-time technology access fee to Intrexon as part of the Exclusive Channel Collaboration Agreement, which we refer to as the ECC. The remaining increase is due to the addition of staff and facility expense for our new Australian subsidiary, stock option expense and an increase in consulting expense.

General and Administrative

General and administrative expenses were $4.0 million for the nine-month period ended September 30, 2013 compared to $2.3 million for the nine-month period ended September 30, 2012. The $1.7 million increase was due primarily to $1.2 million in stock option expense and a placement agent commission of $0.3 million for the private placement of convertible preferred stock.

Interest Expense

Interest expense was $0.6 million for the nine-month period ended September 30, 2013, compared to $0.2 million for the nine-month period ended September 20, 2012. The $0.4 million increase was due to the accrual of dividends

payable on Series B Preferred Stock. During the nine-month periods ended September 30, 2013 and 2012, we issued $2.0 million and $1.0 million in convertible notes, respectively. Interest on the unpaid principal balance of these notes accrues at the rate of ten percent (10%) per annum. We also issued $7.0 million in Series B Preferred Stock. Dividends on the stock also accrue at the rate of ten percent (10%) per annum.

Net Cash Used in Operating Activities

For the nine months ended September 30, 2013, net cash flow used in operating activities was $4.8 million, compared to net cash flow provided by operating activities of $0.4 million for the nine months ended September 30, 2012. Net cash flow used in operating activities during the nine months ended September 30, 2013 consisted primarily of a net loss of $9.6 million, increased by $3.0 million for the Intrexon technology access fee paid by stock, $1.2 million for stock option expense, $0.5 million for the receipt of tax refund, $0.2 million for accrued interest on convertible loans and $0.3 million for accrued dividends payable on Series B Preferred Stock. Net cash flow provided by operating activities during the

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nine months ended September 30, 2012, consisted primarily of net income of $0.3 million, increased by $0.1 million for the receipt of an AMT license fee receivable and $0.2 million for accrued interest on convertible notes, and decreased by $0.2 million for accounts payable and accrued liabilities.

Net Cash from Financing Activities

During the nine months ended September 30, 2013, net cash flow provided from financing activities was $8.9 million, compared to net cash flow provided from financing activities of $1.0 million for the nine months ended September 30, 2012. Net cash flow provided from financing activities during the nine months ended September 30, 2013 consisted of $7.0 million received through the Series B Convertible Preferred Stock issuance and $2.0 million received through the issuance of convertible notes. Net cash flow provided from financing activities during the nine months ended September 30, 2012, consisted of $1.0 million received through the issuance of convertible notes.

Recent Financings

On June 26, 2013, we completed a private placement of convertible preferred stock and warrants to purchase common stock with gross proceeds of $7.0 million through the sale of shares of our newly-created Series B Convertible Preferred Stock. As part of the same transaction, approximately $5.5 million in outstanding convertible notes were converted into shares of Series B Convertible Preferred Stock and warrants to purchase common stock. On July 15, 2013, we completed a second closing in which we converted approximately $0.8 million of outstanding convertible notes into Series B Convertible Preferred Stock and warrants to purchase common stock. The financing was led by life-sciences investors RA Capital Management and Third Security, LLC, with participation from BioScience Managers Pty Ltd.

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

On December 16, 2013, we entered into subscription agreements to issue an aggregate amount of approximately 72,003,000 shares of common stock for an aggregate purchase price of approximately $18 million as part of a private placement.

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Item 3. Properties.

Our principal offices occupy approximately 314 square feet of leased office space pursuant to a lease agreement that expires in February 2014 and is located at 4870 Sadler Road, Suite 300, Glen Allen, VA 23060. We also lease approximately 708 square feet of lab space in Richmond (Virginia), approximately 153 square feet of office space in Carlsbad (California), approximately 5,000 square feet of lab space in Brookvale (Australia) and approximately 2,672 square feet of lab space in Bedford (United Kingdom). We believe our facilities are adequate for our current and near-term needs.

Item 4. Security Ownership of Certain Beneficial Owners and Management.

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of December 6, 2013, for:

each person known by us to beneficially own more than 5% of our outstanding shares of common stock,
each of our directors,
each of our named executive officers, and
all such directors, nominees for director and executive officers as a group.

The percentage of ownership depicted below is based on 199,128,285 shares of common stock outstanding on December 6, 2013, which consists of 110,528,505 shares of common stock outstanding as of December 6, 2013, and 88,599,780 share of common stock issuable upon conversion of all outstanding shares of Series B Convertible Preferred Stock as of December 6, 2013 (assuming a conversion ratio equal to ten (10) common shares for each share of Series B Convertible Preferred Stock).

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or share voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options or warrants that are either immediately exercisable or exercisable within 60 days of December 6, 2013. Shares underlying such options and warrants, however, are only considered outstanding for the purpose of computing the percentage ownership of that person and are not considered outstanding when computing the percentage ownership of any other person. We do not know of any arrangements, including any pledge by any person of our securities, the operation of which may at a subsequent date result in a change of control.

Name of Beneficial Owner[1]	Shares Beneficially Owned	Percentage Total Voting Power
5% Stockholders		
Anthony M. Smithyman	26,679,305[2]	13.40%
Randal J. Kirk	50,880,820[3]	25.55%
RA Capital Healthcare Fund, LP	19,892,915[4]	9.99 %[4]
Pendinas Limited	47,486,789[5]	23.85%
Named Executive Officers and Directors		
Philip J. Young	7,777,334 [6]	3.91 %
Kelley A. Wendt	156,250 [7]	*
David Harper, Ph.D.	1,204,352 [8]	*
Jeremy Curnock Cook	300,500 [9]	*
Louis Drapeau	37,500 [10]	*
Michael S. Perry, Ph.D.	166,125 [11]	*

Anthony M. Smithyman	26,679,305[(2)]	13.40%
Julian P. Kirk	0	*
Baxter F. Phillips III	0	*
All officers and directors as a group (8 persons)	36,321,366	18.24%

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* Less than 1%.

(1) Unless otherwise indicated, the address of such stockholder is c/o AmpliPhi Biosciences Corporation, 4870 Sadler Road, Suite 300, Glen Allen, VA 23060.

(2) Includes 12,000,000 shares of common stock held in escrow pending fulfillment of certain contractual terms of the SPH acquisition and options to purchase 15,625 shares of common stock.

(3) Consists of 26,880,820 shares held by NRM VII Holdings I, LLC, which we refer to as NRM VII Holdings (21,523,678 shares of common stock issuable upon conversion of Series B Convertible Preferred Stock and 5,357,142 shares of common stock issuable upon exercise of warrants) and 24,000,000 shares held by Intrexon Corporation. Randal J. Kirk controls NRM VII Holdings. Shares held by this entity may be deemed to be indirectly beneficially owned (as defined under Rule 13d-3 promulgated under the Exchange Act) by Mr. Kirk. Mr. Kirk disclaims beneficial ownership of such shares, except to the extent of any pecuniary interest therein. Randal J. Kirk, directly and through certain affiliates, has voting and dispositive power over a majority of the outstanding capital stock of Intrexon Corporation. Mr. Kirk may therefore be deemed to have voting and dispositive power over the shares of the issuer owned by Intrexon Corporation. Shares held by Intrexon Corporation may be deemed to be indirectly beneficially owned (as defined under Rule 13d-3 promulgated under the Exchange Act) by Mr. Kirk. Mr. Kirk disclaims beneficial ownership of such shares, except to the extent of any pecuniary interest therein.

(4) Includes 15,607,200 shares of common stock issuable upon conversion of Series B Convertible Preferred Stock and 4,285,715 shares of common stock issuable upon exercise of warrants. RA Capital Healthcare Fund, LP holds shares of Series B Convertible Preferred Stock that are convertible into an aggregate of 17,218,946 shares of common stock. However, such stockholder has elected to be subject to a cap under the Company s Articles of Incorporation that prevents it from converting shares of Series B Convertible Preferred Stock to the extent that after giving effect to such conversion, it will own in excess of 9.99% of the shares of the Company s common stock outstanding immediately after giving effect to such conversion. As such, such stockholder s beneficial ownership has been calculated based on 15,607,200 shares of common stock issuable upon conversion of Series B Convertible Preferred Stock, which together with the 4,285,715 shares of common stock issuable upon exercise of warrants, represents 9.99% ownership. The address of such stockholder is 20 Park Plaza, Suite 1200, Boston, MA 02116.

(5) Includes 32,393,750 shares of common stock issuable upon conversion of Series B Convertible Preferred Stock and 15,093,039 shares of common stock issuable upon exercise of warrants. The address of such stockholder is Ballacarrick, Pooilvaaish Road, Isle of Man, IM9 4PJ.

(6) Includes options to purchase 7,777,334 shares of common stock.

(7) Includes options to purchase 156,250 shares of common stock.

(8) Includes options to purchase 375,000 shares of common stock.

(9) Includes options to purchase 235,500 shares of common stock.

(10) Includes options to purchase 37,500 shares of common stock.

(11) Includes options to purchase 121,125 shares of common stock.

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Item 5. Directors and Executive Officers.

The following table sets forth certain information about our executive officers, key employees and directors as of the date of this registration statement.

Name	Age	Position
Philip J. Young	56	President, Chief Executive Officer and Director
Kelley A. Wendt	39	Chief Financial Officer
Baxter F. Phillips III	38	Vice President of Corporate Strategy and Business Development
Jeremy Curnock Cook[1][2][3]	63	Chairman of the Board
Louis Drapeau[1][2][3]	68	Director
Michael S. Perry, Ph.D.[1][2][3]	53	Director
Anthony Smithyman, Ph.D.	64	Director
Julian P. Kirk	39	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the nominating and corporate governance committee.

No events listed in Item 401(f) of Regulation S-K have occurred during the past 10 years that are material to the evaluation of the ability or integrity of any of our directors or executive officers.

The following is a brief biography of the business experience during the past five years (and, in some instances, for prior years) of each director and executive officer of the Company, with each director biography including information regarding the experiences, qualifications, attributes or skills that caused our board of directors to determine that such member of our board of directors should serve as a director as of the date of this registration statement.

Executive Officers

Philip J. Young has served as our President, Chief Executive Officer and Director since November 2011. Mr. Young is a U.S.-based long-time executive in the biopharmaceuticals industry. He is the former President and CEO of Osteologix, Inc., a biopharmaceutical company, which is currently based in Ireland. Prior to joining Osteologix, Mr. Young served as an Executive Vice President and Chief Business Officer for Insmed Inc., a publicly traded biotechnology company, from 2004 2007. Prior to Insmed Inc., Mr. Young held executive positions at Elan Corporation, Neurex Corporation, and Pharmacia Corporation. Mr. Young started his career in the biopharmaceuticals industry at Genentech, Inc. Mr. Young received a B.S. in Sociology with minors in Business and Psychology from James Madison University.

Kelley A. Wendt has served as our Chief Financial Officer since December 2011. Prior to joining AmpliPhi, she served as the Chief Financial Officer for Osteologix, Inc., a global biopharmaceutical company, which is currently based in Ireland. Prior to joining Osteologix, Ms. Wendt served as the Chief Financial Officer for Crop Life America, a global chemical industry trade organization, from 2006 to 2008. She is the former Controller for Sheltering Arms Hospitals, a rehabilitation hospital company with nine facilities across the Richmond, Virginia region. Her pre-executive experience consists of several regional and national public accounting firms, primarily in audit and consulting roles. Ms. Wendt received a B.S. in Business, Accounting, from Wright State University.

Baxter Phillips III has served as our Vice President, Corporate Strategy and Business Development since October 2013. Prior to joining AmpliPhi, Mr. Phillips served as Director, Business Development at Depomed, Inc., a commercially engaged specialty pharmaceutical company developing and commercializing products to treat pain and other central nervous system conditions, from 2011 2013. Prior to Depomed, Mr. Phillips served as Senior Director, Corporate Development at Osteologix, Inc., a global biopharmaceutical company, from 2007 2011. Prior to Osteologix, Mr. Phillips served in a number of senior research, corporate and sales and marketing positions at Insmed Inc., a publically traded biotechnology company, from 1998 2007. Mr. Phillips has a B.S. in Biology from Hampden-Sydney College and an MBA from The Mason School of Business at the College of William and Mary.

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Non-Employee Directors

Jeremy Curnock Cook has served as a member of our board of directors since July 1995 and as chairman of the board of directors since February 1998. Mr. Curnock Cook has served as Chairman of International Bioscience Managers Limited, a corporate and investment advisory firm since 2000, and also currently serves as Managing Director of Bioscience Managers Pty Ltd, a medical sciences fund manager. From 1987 to 2000, Mr. Curnock Cook was a director of Rothschild Asset Management Limited, a corporate and investment advisory company, and was responsible for the Rothschild Bioscience Unit. Mr. Curnock Cook founded the International Biochemicals Group in 1975, which was sold in 1985 to Royal Dutch Shell, where he served as managing director until 1987. Mr. Curnock Cook holds an M.A. in natural sciences from Trinity College, Dublin. He also serves as a member of the board of Avita Medical Ltd, Nexus6 Ltd and SeaDragon Ltd.

Louis Drapeau has served as a member of our board of directors since March 2011. Mr. Drapeau currently serves as Vice President and Chief Financial officer of InSite Vision, an ophthalmology drug development company, a position he has held since October 2007. From November 2008 until December 2010, he was also CEO of InSite Vision. Prior to InSite Vision, he served as Chief Financial Officer, Senior Vice President, Finance, at Nektar Therapeutics, a biopharmaceutical company, from January 2006 to August 2007. Prior to Nektar, he served as Acting Chief Executive Officer from August 2004 to May 2005 and as Senior Vice President and Chief Financial Officer from August 2002 to August 2005 for BioMarin Pharmaceutical Inc. Previously, Mr. Drapeau spent 30 years at Arthur Andersen, including 19 years as an Audit Partner in Arthur Andersen s Northern California Audit and Business Consulting practice, which included 12 years as Managing Partner. Mr. Drapeau received both his undergraduate degree in mechanical engineering and an M.B.A. from Stanford University. He also serves as a member of the board of Bio-Rad Laboratories and InterMune, Inc.

Michael S. Perry, D.V.M., Ph.D. has served as a member of our board of directors since November 2005. Dr. Perry is currently Global Head of Stem Cell Therapy and Vice President of the Integrated Hospital Care Franchise for Novartis Pharmaceuticals Corporation. Prior to joining Novartis in 2012, he was a Venture Partner with Bay City Capital, a venture capital firm, from 2005 to 2012. While serving in this capacity, he concurrently served as President and Chief Medical Officer at Poniard Pharmaceuticals, Inc., a publicly held drug development company, from 2009 to 2011 and also previously served as Chief Development Officer of VIA Pharmaceuticals, Inc., another publicly held biotechnology company, from 2005 to 2009. Dr. Perry served as chairman and Chief Executive Officer of Extropy Pharmaceuticals, Inc., a privately held pediatric specialty pharmaceutical company, from 2003 to 2005. From 2002 to 2003, Dr. Perry served as President and Chief Executive Officer of Pharsight Corporation, a publicly held software and consulting services firm. From 2000 to 2002, Dr. Perry served as Global Head of Research and Development for Baxter Healthcare. From 1997 to 2000, Dr. Perry was President and Chief Executive Officer of both SyStemix Inc. and Genetic Therapy Inc., two wholly owned subsidiaries of Novartis Pharma; he was Vice President of Regulatory Affairs for Novartis from 1994 to 1997. Prior to 1994, Dr. Perry held various management positions with Syntex Corporation, Schering-Plough Corporation and BioResearch Laboratories, Inc. Dr. Perry holds a Doctor of Veterinary Medicine, a Ph.D. in Biomedical Science-CardioPulmonary Pharmacology and a B.S. in Physics from the University of Guelph. He also serves as a member of the board of Arrowhead Research Corporation and of Avita Medical Ltd.

Anthony Smithyman, Ph.D. joined our board of directors in November 2012 following the merger with Special Phage Services Pty Ltd of Sydney, Australia. Born in Malawi, Central Africa, Dr. Smithyman was educated in Scotland and obtained a B.Sc. from the University of St. Andrews, followed by a Ph.D. in Bacteriology and Immunology from Glasgow University. After completing a two-year post-doctoral Fellowship at the Sloan-Kettering Cancer Center in New York in 1978, he joined ICI Pharmaceuticals Ltd in Alderley Edge, Cheshire, England as Laboratory Head in the Immunology Department before moving to Australia in 1982. Dr. Smithyman has been involved with the Australian

biotechnology industry for over 30 years, including as the current Managing Director of Cellabs Pty Ltd., a longstanding Australian biotechnology company. In 2004, Dr. Smithyman established Special Phage Services Pty Ltd to develop novel phage therapeutics for the human health, veterinary and aquaculture industries.

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Julian P. Kirk has served as a member of our board of directors since June 2013. Since its inception, Mr. Kirk has worked with several portfolio companies of Third Security, LLC s managed investment funds and is involved with oversight of Third Security, LLC s internal operations. Since October 2012, he has served on the board of directors of Fibrocell Science, Inc. Since August 2010, he has served on the board of the New River Valley Economic Development Alliance. From October 2006 until December 2011, he served as member of the board of directors of IntelliMat, Inc. and as co-chairman of the board between September 2008 and December 2011. From September 2005 until December 2011, Mr. Kirk served as President of Harvest Pharmaceuticals Inc. Mr. Kirk also served as chairman of the board of managers of ECDS, LLC from June 2008 until March 2010. Mr. Kirk graduated as an Echols Scholar from the University of Virginia.

Item 6. Executive Compensation.

Summary Compensation Table

The following table provides information regarding the compensation paid during the year ended December 31, 2012 to our principal executive officer, and our two most highly compensated executive officers other than our principal executive officer who were serving as executive officers at the end of the last completed fiscal year, who are collectively referred to as named executive officers elsewhere in this registration statement.

Name and Principal Position	Year	Salary	Bonus	Option Awards[1]	All Other Compensation	Total
Philip J. Young President, Chief Executive and Director	2012	$325,000	$	$1,680,000	$	$2,005,000
David Harper, Ph.D. Chief Scientific Officer	2012	$228,672	$	$240,000	$	$468,672
Kelley A. Wendt, Chief Financial Officer[2]	2012	$	$	$100,000	$ 120,247	$220,247

(1) Represents the aggregate grant date fair value computed in accordance with FASB ASC Topic 718.

(2) Ms. Wendt became Chief Financial Officer on January 1, 2013. Prior to this date, Ms. Wendt was engaged as an accounting consultant and all compensation paid during the year ended December 31, 2012 was for her services in that capacity.

Executive Employment Agreement

We entered into an employment agreement with Philip J. Young on October 19, 2011. The employment agreement provides for at-will employment, base salary, incentive bonuses, standard employee benefit plan participation and recommendations for initial stock option grants. The employment agreement was subject to execution of a standard proprietary information and invention agreement and proof of identity and work eligibility in the United States.

Mr. Young is entitled to severance and change in control benefits pursuant to his employment, the terms of which are described below under Potential Payments upon Termination or Change in Control. We believe that these severance and change in control benefits help us from a retention standpoint and they are particularly necessary in an industry, such as ours, where there has been market consolidation. We believe that they help executive officers maintain continued focus and dedication to their assigned duties to maximize shareholder value if there is a change of control. We believe that these severance and change in control benefits are an essential element of our overall executive compensation package.

Pursuant to the terms of his employment agreement, as amended, Mr. Young was granted options to purchase 8,400,000 shares of our common stock on October 23, 2012 and options to purchase 11,600,000 of our common stock on June 25, 2013.

Potential Payments upon Termination or Change in Control

Regardless of the manner in which a named executive officer s employment terminates, the named executive officer is entitled to receive amounts earned during his term of employment, including salary and

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unused vacation pay. In addition, each of our named executive officers that are currently employed by us is entitled to severance and change in control benefits described below.

On October 19, 2011, the Company entered into an employment agreement with Mr. Young, the Company s President, Chief Executive Officer and member of the board of directors, which provides if the Company terminates Mr. Young without cause or he resigns for good reason, he will be entitled to: (i) severance payments on a monthly basis at a rate equal to his base salary then in effect for a period ranging from at least six months up to one year and (ii) accelerated vesting of his stock option shares with respect to the number of shares that would have vested if Mr. Young had remained employed by the Company during the period in which he is to receive severance payments.

If Mr. Young s employment is terminated by the Company, with or without cause, or by Mr. Young for changed circumstances in connection with or following a change in control, he will be entitled to: (i) severance payments on a monthly basis at a rate equal to his base salary then in effect for a period of one year, (ii) accelerated vesting of his stock option shares with respect to the number of shares that would have vested if Mr. Young had remained employed by the Company during the period in which he is to receive severance payments, and (iii) the pro rata portion of any eligible bonus compensation as of the date of termination.

The following table sets forth potential payments payable to our named executive officers upon a termination of employment without cause or resignation for good reason or termination of employment with or without cause or resignation following a change in control. The table below reflects amounts payable to our executive officers assuming their employment was terminated on December 31, 2012 and, if applicable, a change in control also occurred on such date.

	Upon Termination without Cause or Resignation for Good Reason No Change in Control			Upon Termination with or without Cause or Resignation Change in Control		
Name	Cash Severance	Value of Accelerated Vesting[1]	Total	Cash Severance	Value of Accelerated Vesting[1]	Total
Philip J. Young	$1,950,000	$ 420,000	$2,370,000	$3,900,000	$ 420,000	$4,320,000
David Harper, Ph.D.	$	$	$	$	$	$
Kelley A. Wendt	$	$	$	$	$	$

(1) The value of accelerated vesting is equal 2,100,000 stock option shares vesting at $0.20 per share.

Grants of Plan-Based Awards

The following table sets forth certain information regarding grants of plan-based awards to our named executive officers for 2012.

Name	Grant Date	All other option awards: number of securities underlying	Exercise or base price of option awards ($/share)[1]	Grant date fair value of option awards ($)[2]

		options (#)		
Philip J. Young	10/23/2012	8,400,000	$ 0.20	$ 1,680,000
David Harper, Ph.D.	10/23/2012	1,200,000	$ 0.20	$ 240,000
Kelley A. Wendt[3]	10/23/2012	500,000	$ 0.20	$ 100,000

(1) Represents the per share fair market value of our common stock, as determined in good faith by our board of directors on the grant date.

(2) Amounts listed represent the aggregate fair value amount computed as of the grant date of each option and award during 2012 in accordance with FASB ASC Topic 718. Assumptions used in the calculation of these amounts are included in Note 6, Stock Options and Warrants, of the Notes to the Financial Statements. As required by SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. Our named executive officers will only realize compensation to the extent the trading price of our common stock is greater than the exercise price of such stock options.

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(3) Ms. Wendt became Chief Financial Officer on January 1, 2013. Prior to this date, Ms. Wendt was engaged as an accounting consultant and all compensation paid during the year ended December 31, 2012 was for her services in that capacity.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth certain information regarding all outstanding equity awards held by our named executive officers as of December 31, 2012.

Name	Number of Securities Underlying Unexercised Options (# Exercisable)	Number of Securities Underlying Unexercised Options (# Unexercisable)	Option Exercise Price ($)	Option Expiration Date
Philip J. Young[1]		8,400,000	$ 0.20	10/23/2022
David Harper, Ph.D.[2]		1,200,000	$ 0.20	10/23/2022
Kelley A. Wendt[3]		500,000	$ 0.20	10/23/2022

(1) 6.25% of the total shares underlying this option vested and became exercisable on January 23, 2013. 6.25% of the total shares underlying this option vests and becomes exercisable on the first business day of each three (3) month period thereafter, subject to continued service through each vesting date. This option may be subject to accelerated vesting as described above. As of December 6, 2013, 2,100,000 of the total shares underlying this option are vested and exercisable.

(2) 6.25% of the total shares underlying this option vested and became exercisable on January 23, 2013. 6.25% of the total shares underlying this option vests and becomes exercisable on the first business day of each three (3) month period thereafter, subject to continued service through each vesting date. This option may be subject to accelerated vesting as described below. As of December 6, 2013, 300,000 of the total shares underlying this option are vested and exercisable.

(3) 6.25% of the total shares underlying this option vested and became exercisable on January 23, 2013. 6.25% of the total shares underlying this option vests and becomes exercisable on the first business day of each three (3) month period thereafter, subject to continued service through each vesting date. This option may be subject to accelerated vesting as described below. As of December 6, 2013, 125,000 of the total shares underlying this option are vested and exercisable.

Option Exercises and Stock Vested

Our named executive officers did not exercise any stock option awards during the year ended December 31, 2012.

Pension Benefits

None of our named executive officers participate in or have account balances in qualified or non-qualified defined benefit plans sponsored by us.

Non-Qualified Deferred Compensation

None of our named executive officers participate in or have account balances in qualified or non-qualified defined contribution plans or other non-qualified compensation plans sponsored by us.

Equity Incentive Plans

The purpose of all of our equity incentive plans is to promote the long-term success of the Company and the creation of shareholder value by offering key service providers an opportunity to share in such long-term success by acquiring a proprietary interest in the Company and to attract and retain the best available personnel for positions of substantial responsibility, and to provide additional incentive to employees, consultants and directors.

Our equity incentive plans seek to achieve these purposes by providing for discretionary long-term incentive awards in the form of options (which may constitute incentive stock options or nonstatutory stock options), stock appreciation rights, stock grants and stock units. Our equity incentive plans are administered by the board or a committee appointed by the board, which we refer to as the plan administrator and have a term of 10 years from the date they were adopted by the board of directors.

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2009 Targeted Genetics Stock Incentive Plan and 2012 Stock Incentive Plan

Our board of directors and shareholders adopted the 2009 Plan in March 2009. Our board of directors adopted our 2012 Plan in October 2012. As of December 6, 2013, there are 1,304,760 shares of common stock and 9,353,323 shares of common stock remaining for future awards under the 2009 Plan and the 2012 Plan, respectively. We refer to the 2009 Plan and the 2012 Plan together as the Existing Plans.

The number of shares authorized under each of the Existing Plans is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization. The shares we issue under the Existing Plans may be authorized but unissued shares or shares we reacquire. The shares of common stock underlying any equity awards that are forfeited, canceled, repurchased, expired or are otherwise terminated (other than by exercise) under the Existing Plans are currently added back to the shares of common stock available for issuance under the Existing Plans.

The Existing Plans permit us to make grants of incentive stock options to employees and grants of non-qualified stock options and restricted stock to employees, officers, directors and consultants. The Existing Plans are administered by our board of directors. Our board of directors has the authority to select the individuals to whom awards will be granted, to make any combination of awards to participants, to accelerate the exercisability or vesting of any award and to determine the specific terms and conditions of each award, subject to the provisions of the Existing Plans.

The Existing Plans permit the grant of (1) options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Internal Revenue Code of 1986, as amended, or the Code, and (2) options that do not so qualify. The option exercise price of each option will be determined by our board of directors but may not be less than 100% of the fair market value of the common stock on the date of grant. The term of each option will be fixed by our board of directors and may not exceed 10 years from the date of grant. All stock option awards that are granted pursuant to the Existing Plans are covered by an option agreement.

The Existing Plans also permit the award of stock grants, stock appreciation rights and stock units to participants, subject to such terms, conditions and restrictions as our board of directors may determine. All stock grants, stock appreciation rights and stock units that are granted pursuant to the Existing Plans are covered by a written agreement.

The Existing Plans provide that upon the effectiveness of a corporate transaction, as defined in each of the Existing Plans, in the event that all awards are not assumed or continued or substituted by the successor entity, all awards granted under the Existing Plans shall terminate. In addition, in connection with a corporate transaction, the plan administrator may provide the full automatic vesting and exercisability of one or more outstanding unvested awards under the Existing Plans in connection with a corporate transaction, on such terms and conditions as the plan administrator may specify. Furthermore, in connection with a change in control, as defined in each of the Existing Plans, the Existing Plans provide for the full automatic vesting and exercisability of any outstanding unvested awards held by certain key service providers, which under the terms of the Existing Plans, is defined as any employee, director or consultant who has been designated as a key service provider by the plan administrator, in the event that any such awards are not assumed or continued or substituted by the successor entity, or otherwise fully automatically vested by the plan administrator in connection with such change in control.

Our board of directors may amend, alter, suspend or terminate the Existing Plans at any time, subject to stockholder approval where such approval is required by applicable law. Our board of directors may also amend, modify or terminate any outstanding award, provided that no amendment to an award may materially impair any of the rights of a participant under any awards previously granted without his or her written consent. No awards may be granted under the 2009 Plan and 2012 Plan after March 3, 2019 and October 19, 2022, respectively.

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Non-Executive Director Compensation

The following table and related footnotes show the compensation paid during the year ended December 31, 2012 to our non-executive directors.

Name	Fees Earned or Paid in Cash	Option Awards[1]	All Other Compensation	Total
Jeremy Curnock Cook	$ 40,500	$ 88,000 [2]	$	$ 128,500
Louis Drapeau	$ 27,500	$ 24,000 [3]	$	$ 51,500
Anthony Peter Gellert	$ 3,333	$ 10,000 [4]	$	$ 13,333
Michael S. Perry, Ph.D.	$ 26,500	$ 34,000 [5]	$	$ 60,500
Anthony Smithyman, Ph.D.	$ 3,333	$ 10,000 [6]	$	$ 13,333
Caroline A. Williams	$ 29,000	$ 30,000 [7]	$	$ 59,000

(1) Amounts listed represent the aggregate fair value amount computed as of the grant date of each option and award during 2012 in accordance with FASB ASC Topic 718. Assumptions used in the calculation of these amounts are included in Note 6, Stock Options and Warrants, of the Notes to Financial Statements. As required by SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. Our directors will only realize compensation to the extent the trading price of our common stock is greater than the exercise price of such stock options.

(2) On October 23, 2012, stock options exercisable for an aggregate of 440,000 shares of our common stock were granted to Jeremy Curnock Cook with an exercise price of $0.20 per share. As of December 6, 2013, 110,000 shares are vested and exercisable.

(3) On October 23, 2012, stock options exercisable for an aggregate of 120,000 shares of our common stock were granted to Louis Drapeau with an exercise price of $0.20 per share. As of December 6, 2013, 30,000 shares are vested and exercisable.

(4) On October 23, 2012, a stock option exercisable for 50,000 shares of our common stock was granted to Anthony Peter Gellert with an exercise price of $0.20 per share. On June 26, 2013, Mr. Gellert resigned from our Board of Directors. As of June 26, 2013, 6,250 shares are vested and exercisable. Pursuant to the terms of his resignation, vesting will continue until December 31, 2015 as if that was his resignation date, at which time all unvested shares will have vested and will be exercisable pursuant to the standard post-termination exercise terms of the applicable stock option agreements, which will allow the stock options to be exercised for a period of ninety (90) days following December 31, 2015. As of December 6, 2013, 12,500 shares are vested and exercisable.

(5) On October 23, 2012, stock options exercisable for an aggregate of 170,000 shares of our common stock were granted to Michael S. Perry with an exercise price of $0.20 per share. As of December 6, 2013, 42,500 shares are vested and exercisable.

(6) On October 23, 2012, a stock option exercisable for 50,000 shares of our common stock was granted to Anthony Smithyman with an exercise price of $0.20 per share. As of December 6, 2013, 12,500 shares are vested and exercisable.

(7) On October 23, 2012, stock options exercisable for an aggregate of 150,000 shares of our common stock were granted to Caroline A. Williams with an exercise price of $0.20 per share. On June 26, 2013, Ms. Williams resigned from our board of directors. As of June 26, 2013, 18,750 shares are vested and exercisable. Pursuant to the terms of her resignation, vesting will continue until December 31, 2015 as if that was her resignation date, at which time all unvested shares will have vested and will be exercisable pursuant to the standard post-termination exercise terms of the applicable stock option agreements, which will allow the stock options to be exercised for a period of

ninety (90) days following December 31, 2015. As of December 6, 201337,500 shares are vested and exercisable.

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Item 7. Certain Relationships and Related Transactions, and Director Independence.

Transactions with Related Persons

The following is a summary of transactions since January 1, 2012 to which we have been a participant in which the amount involved exceeded or will exceed $120,000, and in which any of our then directors, executive officers or holders of more than 5% of any class of our capital stock at the time of such transaction, or any members of their immediate family, had or will have a direct or indirect material interest, other than compensation arrangements which are described under the sections of this registration statement titled Non-Executive Director Compensation and Executive Compensation.

Sale of Convertible Notes

Since January 1, 2012, we have 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 following table summarizes sales of such convertible notes to Pendinas Limited, which was a holder of more than 5% of our common stock as of the dates of each such transaction:

Related Party	Date	Principal Amount
Pendinas Limited	April 13, 2012	$ 500,000.00
	June 5, 2012	$ 250,000.00
	February 4, 2013	$ 500,000.00
	March 12, 2013	$ 500,000.00
	April 12, 2013	$ 500,000.00
	May 13, 2013	$ 500,000.00

Sale of Series B Convertible Preferred Stock

In June 2013, we sold an aggregate of 9,357,935 shares of our Series B Convertible Preferred Stock and warrants to purchase an aggregate of 23,394,835 shares of our common stock. Pendinas Limited, a holder of more than 5% of our common stock as of the date of such transaction, converted all of its outstanding convertible notes into 3,225,061 shares of Series B Convertible Preferred Stock and a warrant to purchase 8,062,652 shares of our common stock in the transaction.

In connection with our June 2013 private placement of convertible preferred stock, we paid a placement fee to Griffin Securities, Inc. in the amount of $270,000 in cash and warrants to purchase 4,285,714 shares of common stock at an exercise price of $0.14 per share, and to Phillip Capital Ltd in the amount of $60,000 in cash and warrants to purchase 714,285 shares of common stock at an exercise price of $0.14 per share.

The shares of common stock post-conversion pursuant to the June private placement of our Series B Convertible Preferred Stock will be entitled to piggyback rights and S-1 and S-3 registration rights. See the section of this registration statement entitled Item 11. Description of Registrant s Securities to be Registered Registration Rights for additional information.

Director Independence

In October 2013, our board of directors undertook a review of the independence of each director and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. In making this determination, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. As a result of this review, our board of directors determined that Messrs. Jeremy Curnock Cook, Louis Drapeau and Michael Perry qualify as independent directors within the meaning of the rules of the NYSE MKT.

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Item 8. 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.

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Item 9. Market Price of and Dividends on the Registrant s Common Equity and Related Stockholder Matters.

Our shares of common stock are quoted on the Pink Sheets 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 2013		
Period from October 1, 2013 to December 13, 2013	$ 0.59	$ 0.45
Third Quarter ended September 30, 2013	$ 0.71	$ 0.15
Second Quarter ended June 30, 2013	$ 0.20	$ 0.10
First Quarter ended March 31, 2013	$ 0.18	$ 0.11
Fiscal Year 2012		
Fourth Quarter ended December 31, 2012	$ 0.22	$ 0.14
Third Quarter ended September 30, 2012	$ 0.20	$ 0.09
Second Quarter ended June 30, 2012	$ 0.23	$ 0.13
First Quarter ended March 31, 2012	$ 0.24	$ 0.11
Fiscal Year 2011		
Fourth Quarter ended December 31, 2011	$ 0.27	$ 0.14
Third Quarter ended September 30, 2011	$ 0.29	$ 0.20
Second Quarter ended June 30, 2011	$ 0.39	$ 0.25
First Quarter ended March 31, 2011	$ 0.17	$ 0.06

Holders of Common Stock

As of December 6, 2013, there were 299 holders of record of our common stock. As of such date, 10,528,505 shares of common stock were issued and outstanding.

Dividends

We have never declared or paid any cash dividends or distributions on our capital stock. We currently intend to retain our future earnings, if any, to support operations and to finance expansion and we do not anticipate paying any cash dividends on our common stock in the foreseeable future.

Securities Authorized for Issuance under Equity Compensation Plans

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

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