

AmpliPhi Biosciences Corp  
Form 10-K  
March 27, 2017

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-K**

(Mark One)

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

**For the fiscal year ended December 31, 2016**

**or**

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

**For the transition period from                      to**

**Commission File Number 001-37544**

**AMPLIPHI BIOSCIENCES CORPORATION**

Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

(Exact name of registrant as specified in its charter)

**Washington**

**91-1549568**

(State or other jurisdiction of (I.R.S. Employer Identification No.)  
incorporation and organization)

**3579 Valley Centre Drive, Suite 100**

**San Diego, California 92130**

(Address of principal executive offices, including zip code)

**(858) 800-4868**

(Registrant's telephone number, including area code)

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

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.01 per share	NYSE MKT

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes  No

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

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes

No

Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

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

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

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

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

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

As of June 30, 2016, the aggregate market value of voting stock held by non-affiliates of the Registrant, based on the closing price of the Common Stock on June 30, 2016 (the last business day of the Registrant's most recently completed second quarter) as quoted on the NYSE MKT, was approximately \$16,267,000.

As of March 17, 2017, 16,488,120 shares of the Registrant's Common Stock were outstanding.

**TABLE OF CONTENTS**

**AMPLIPHI BIOSCIENCES CORPORATION**

	Page No.
<b><u>PART I</u></b>	
Item 1. <u>Business</u>	4
Item 1A. <u>Risk Factors</u>	19
Item 1B. <u>Unresolved Staff Comments</u>	36
Item 2. <u>Properties</u>	36
Item 3. <u>Legal Proceedings</u>	36
Item 4. <u>Mine Safety Disclosures</u>	36
<b><u>PART II</u></b>	
Item 5. <u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	36
Item 6. <u>Selected Financial Data</u>	37
Item 7. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	37
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	42
Item 8. <u>Financial Statements and Supplementary Data</u>	42
Item 9. <u>Changes In and Disagreements With Accountants on Accounting and Financial Disclosure</u>	44
Item 9A. <u>Controls and Procedures</u>	44
Item 9B. <u>Other Information</u>	45
<b><u>PART III</u></b>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	46

Item 11.	<u>Executive Compensation</u>	51
Item 12.	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	57
Item 13.	<u>Certain Relationships and Related Transactions and Director Independence</u>	59
Item 14.	<u>Principal Accountant Fees and Services</u>	61
<b><u>PART</u></b>		
<b><u>IV</u></b>		
Item 15.	<u>Exhibits and Financial Statement Schedules</u>	63
	<u>Signatures</u>	64

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report and certain information incorporated herein by reference contain forward-looking statements, which are provided under the “safe harbor” protection of the Private Securities Litigation Reform Act of 1995. These statements relate to future events, results or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or events to be materially different from any future results, performance or events expressed or implied by the forward-looking statements.

Forward-looking statements in this report include, but are not limited to, statements regarding:

- our estimates regarding anticipated operating losses, capital requirements and needs for additional funds;
- our ability to manufacture, or otherwise secure the manufacture of, sufficient amounts of our product candidates for our preclinical studies and clinical trials;
  - our clinical development plans, including planned clinical trials;
  - our research and development plans, including our clinical development plans;
  - our ability to select combinations of phages to formulate our product candidates;
    - the safety and efficacy of our product candidates;
    - the anticipated regulatory pathways for our product candidates;
- our ability to successfully complete preclinical and clinical development of, and obtain regulatory approval of our product candidates and commercialize any approved products on our expected timeframes or at all;
  - the content and timing of submissions to and decisions made by the U.S. Food and Drug Administration, or 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 or other therapies that are or may become available;
- our expectations with respect to future growth and investments in our infrastructure, and our ability to effectively manage any such growth;
- the size and potential growth of the markets for any of our product candidates, and our ability to capture share in or impact the size of those markets;
  - the benefits of our product candidates;
  - market and industry trends;
- the effects of government regulation and regulatory developments, and our ability and the ability of the third parties with whom we engage to comply with applicable regulatory requirements;
- the accuracy of our estimates regarding future expenses, revenues, capital requirements and need for additional financing;
  - our expectations regarding future planned expenditures;
- our ability to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act;
- our expectations regarding the period during which we qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act;
- our ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection of any of our products and product candidates; and

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

In some cases, you can identify these statements by terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative of those terms, and similar expressions. These forward-looking statements reflect our management’s beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this Annual Report and are subject to risks and uncertainties. We discuss many of these risks in greater detail in the section entitled “Risk Factors.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

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

As used in this Annual Report, unless the context requires otherwise, the “Company,” “we,” “us” and “our” refer to AmpliPhi Biosciences Corporation and its wholly owned subsidiaries.

## PART I

### Item 1. BUSINESS

#### Company Overview

We are a biotechnology company focused on the discovery, development and commercialization of novel phage therapeutics. Phage therapeutics use bacteriophages, a family of viruses, to kill pathogenic bacteria. Phages have powerful and highly selective mechanisms of action that permit them to target and kill specific bacteria. We believe that phages represent a promising means to treat bacterial infections, especially those that have developed resistance to current therapies, including the so-called multi-drug-resistant or “superbug” strains of bacteria.

The extensive use of antibiotics since their discovery in the 1940s has resulted in drug resistance among many disease-causing bacteria. According to the U.S. Centers for Disease Control and Prevention, or CDC, resistance to antibiotics threatens to reverse many of the key 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., *Staphylococcus aureus*, or *S. aureus* and methicillin-resistant *S. aureus*, or MRSA), pneumonia and lung infections in both community and hospital settings and cystic fibrosis, or CF, patients (e.g., *A. baumannii*, *P. aeruginosa*, and *K. pneumoniae*), meningitis (e.g., *S. pneumoniae*), urinary tract and gastrointestinal infections (e.g., *E. coli* and *C. difficile*). As phages kill bacteria in ways entirely unlike the mechanisms used by traditional antibiotics, we believe that most multi-drug resistant bacteria will be susceptible to phage therapy. Furthermore, should resistant bacteria emerge or evolve, we believe it will remain possible to identify phages that can effectively kill these resistant bacteria.

Our goal is to be the leading developer of phage therapeutics. We are combining our expertise in the manufacture of drug-quality bacteriophages and our proprietary approach and expertise in identifying, characterizing and developing naturally occurring bacteriophages with that of collaboration partners in bacteriophage biology, synthetic biology and manufacturing, to develop state-of-the-art bacteriophage products. We are developing phage products to combat multi- or pan-drug-resistant bacterial pathogens, leveraging advances in sequencing and molecular biology. We have developed certain phage combinations that we believe maximize efficacy and minimize phage resistance. We currently have product candidates for the treatment of *S. aureus* infections, including MRSA, *P. aeruginosa* infections, and *C. difficile* infections.

Our lead product candidate is AB-SA01, for the treatment of *S. aureus* infections, including MRSA. We also have another product candidate in earlier stage development, AB-PA01 for the treatment of *P. aeruginosa* infections, and an additional discovery program, AB-CD01 for the treatment of *C. difficile* infections.



We are developing our phage product candidates using a proprietary discovery and development platform, which is designed for rapid identification, characterization and manufacturing of multiple phage therapeutics. Each product candidate combines several carefully chosen phages, which target a specific disease-causing bacteria such as *S. aureus*, *P. aeruginosa*, and *C. difficile*. We believe that the combination of our platform, our manufacturing capability, our understanding of the regulatory and development requirements of bacteriophage therapeutics, and the clinical and scientific expertise of our collaboration partners may enable the rapid advancement of phage therapeutics through the clinic and the regulatory approval process.

In November 2015, our Australian subsidiary, AmpliPhi Australia Pty Ltd, entered into a clinical trial research agreement with the University of Adelaide and the Queen Elizabeth Hospital, both in Adelaide, SA, Australia, to conduct a Phase 1 clinical trial titled “A Phase 1 Investigator Initiated Study to Evaluate the Safety, Tolerability and Preliminary Effectiveness of AB-SA01 in Patients with Chronic Rhinosinusitis Associated with *S. aureus* infection”. The University of Adelaide sponsored the clinical trial while we supplied AB-SA01 and controlled the trial protocol. This clinical trial primarily measured the safety and tolerability of AB-SA01 and secondarily examined the presence of *S. aureus* and symptoms assessed by the patient as well as by the physician using standard questionnaires used by physicians to assess treatment efficacy. We enrolled nine patients in the trial, divided into three cohorts. The first cohort received a twice daily dose of AB-SA01 for seven days. The second cohort received the same dose twice daily for 14 days. The third cohort received a higher dose of AB-SA01 twice daily for 14 days. Patients were monitored an additional 30 days following their last day of treatment. In October 2016, we reported topline safety and tolerability results which demonstrated that AB-SA01 was well tolerated with no drug-related serious adverse events. In December 2016, we reported the final results from the Phase 1 trial. AB-SA01 met the trial’s primary endpoints of safety and tolerability and all nine patients enrolled in the study experienced a reduction in the quantity of *S. aureus* infecting their sinuses, with some patients showing complete eradication of the bacterial infection. In February 2017, we held a telephonic meeting with the FDA during which we received positive feedback from the FDA regarding our previously submitted proposal to commence a Phase 2 clinical trial of AB-SA01 in chronic rhinosinusitis, or CRS, patients. We are evaluating whether or when to pursue the initiation of such Phase 2 trial.

In June 2013, we entered into a cooperative research and development agreement, or Research and Development Agreement, with the United States Army Medical Research and Materiel Command focusing on developing bacteriophage therapeutics to treat *S. aureus*, *E. coli* and *P. aeruginosa* infections. In 2016, under this Research and Development Agreement, we completed enrollment of a Phase 1 safety study of AB-SA01 for the treatment of wounds infected with *S. aureus* and we reported safety and tolerability results which demonstrated that AB-SA01 was well tolerated with no drug-related serious adverse events. Overall, treatment with AB-SA01 was well tolerated when administered topically to the intact skin of healthy adults.

### **Personalized Precision Medicine Applications**

We believe our bacteriophage technology may have unique application in the area of personalized medicine. In particular, we believe our bacteriophage technology can be used to develop personalized, targeted therapies for patients who suffer from serious or life-threatening antibiotic-resistant bacterial infections and who have limited or no other satisfactory treatment options. Moreover, we believe our ability to customize phage therapies for antibiotic-resistant infections, combined with the ability of bacteriophage to re-sensitize drug-resistant populations to antibiotics, represents what could be a powerful tool against the growing challenge of antibiotic-resistant infections. We continue to explore opportunities to leverage our bacteriophage technology and customization capabilities.

### **The Need for New Anti-Infective Therapies**

The rapid and continuous emergence of antibiotic-resistant bacteria has become a global crisis. Despite this crisis, the number of novel anti-infective therapies currently in development is at historically-low levels. 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. In a reported filed in September 2016, a Reuters analysis found that nationwide, drug-resistant infections were mentioned as contributing or causing the death of more than 180,000 people. In a report commissioned by the U.K. government and published in May 2016, it is estimated that 700,000 people die yearly from drug-resistant infections worldwide and by 2050 that number could reach 10,000,000. It is estimated that 50% 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.

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." Despite the potential market opportunity, only two New Drug Applications, or NDAs, for antibacterial drugs were approved by the FDA between 2010 and 2012 compared to 18 in the period between 1980 and 1984. One of the primary recommendations of the CDC is the development of new antimicrobials to diversify treatment options.

## Product Candidates

### *AB-SA01: Infections Caused by S. aureus*

By screening our proprietary library of phages, we selected a phage product candidate mix that has demonstrated, in *in vitro* studies, greater than 92% activity against a global diversity panel that includes some of the most virulent isolates of *S. aureus*, including MRSA isolates. The three phage constituents of AB-SA01 were subsequently tested for their ability to infect clinically relevant bacterial isolates collected from around the world and were shown to have similar activity with maximal complementation. Complementation, defined as the percentage of *S. aureus* isolates susceptible to more than one phage, is emphasized in product selection to reduce risk of the emergence of bacterial resistance.

In connection with our Research and Development Agreement with the U.S. Army Medical Research and Materiel Command, we have been developing AB-SA01 to treat acute and chronic infections caused by *S. aureus*, including infections caused by MRSA strains of the same bacterium. MRSA infections are one of the most common causes of hospital-acquired (nosocomial) infections. The CDC estimates that more than 850,000 patients were treated for *S. aureus* infections of the skin or soft tissue in 2013 and, due to failure of first-line treatment, more than 50% of these patients required a second-line treatment and approximately 35% of them required a third-line treatment. Global Data estimates the market for MRSA infection treatments alone was more than \$2.7 billion in 2007. This market is forecasted to grow to more than \$3.5 billion by 2019. We initiated the Phase 1 clinical trial in May 2016 and completed enrollment in July 2016. In December 2016, we reported final results from this Phase 1 trial to evaluate the safety and tolerability of AB-SA01, our proprietary investigational phage cocktail targeting *Staphylococcus aureus* (*S. aureus*) infections. Overall, treatment with AB-SA01 was well tolerated when administered topically to the intact skin of healthy adults.

In December 2015, we initiated a Phase 1 trial at the University of Adelaide Queen Elizabeth Hospital to evaluate the safety and preliminary efficacy of AB-SA01 in CRS patients infected with *S. aureus*. In December 2016, we reported final results from this trial. AB-SA01 met the trial's primary endpoints of safety and tolerability and all nine patients enrolled in the study experienced a reduction in the quantity of *S. aureus* infecting their sinuses, with some patients showing complete eradication of the bacterial infection.

***AB-PA01: Lung Infections in Cystic Fibrosis (CF) Patients Caused by P. aeruginosa***

We are initially developing AB-PA01 for the treatment of *P. aeruginosa*, the most prevalent bacterial infection in cystic fibrosis ("CF") patients, *P. aeruginosa* is the primary cause of lung infection in approximately 80% of CF patients ages 25 to 34, causing an estimated 450 deaths per year in the United States. To develop our product candidates, we have created a global diversity panel of relevant clinical isolates (bacteria isolated from patients) from clinics around the globe. These diversity panels have been screened against our phage libraries, which are isolated and characterized according to our set of proprietary discovery protocols. We have demonstrated, in *in vitro* and *in vivo* studies, that our proprietary phage mix is able to effectively kill targeted bacteria. Furthermore, our phage mixes are selected to exhibit a high degree of overlap, defined as the strains of bacteria targeted by more than one phage in the product. We believe that high overlap is an important factor in preventing bacteria from developing resistance to our phage product candidates.

Similar to work described above for *S. aureus*, we have tested over 400 clinical *P. aeruginosa* clinical isolates. As an example, initial host range testing was performed with a reference panel of 67 CF isolates. AB-PA01 showed an activity of 95.5% (64/67) with 87.5% (56/64) of the positives isolates hit by more than one phage in the mix.

In collaboration with Institut Pasteur (Paris, France) and also with the Brompton Hospital, Imperial College (London, United Kingdom), we have demonstrated in the preclinical studies that phages can effectively treat infections in animal models of acute *P. aeruginosa* lung infections. In one such study, we inoculated eight mice with *P. aeruginosa* and treated them with either PBS (control group), our phage mix, or with an antibiotic.

Bacterial counts and the number of bacteriophage infection units detected by assay, or phage titers, were measured in these animals after 24 hours, and the results demonstrated that our phage mix effectively lowered the bacterial counts, or CFU, in the mouse lung to levels comparable to antibiotic treatment (PBS vs. antibiotic,  $p=0.0003$ ; PBS vs. bacteriophage,  $p=0.0003$ ). A p-value is a statistical measure of the probability that the difference in two values could have occurred by chance. The smaller the p-value, the lower the likelihood is that the difference occurred by chance, or the greater our confidence is that the results are statistically significant. Furthermore, it was evident that phage replicated to high levels in the infected lung.

Another preclinical study conducted at the Institut Pasteur in mice (12 mice in each of the treatment and control groups) demonstrated the ability of our phage mix to reach the lung within two hours of being delivered by oral administration. The phage levels increased between two and six hours post-treatment, and the difference was statistically significant (p-value <0.001). These results demonstrate that when orally administered in mice, phages not only reached the lungs, but were also able to infect and multiply in target bacteria.

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

We were granted an advisory meeting with the MHRA in the first quarter of 2014 to discuss our plans and intend to move the AB-PA01 compound into additional preclinical testing in preparation for a Phase 1/2 clinical trial in CF patients. We also sought advice on the acceptability of CMC plans. The MHRA concurred with our approach and plans as presented, including a first-in-man dose ranging clinical trial in CF patients. We have completed product candidate selection and are currently conducting manufacturing process development and scale-up with the goal of completing production of initial batches in mid-2017.

We have also begun an evaluation of our *P. aeruginosa* phages in preclinical animal models of CRS in collaboration with the University of Adelaide.

If we achieve successful proof of concept studies, we may consider developing this compound for the treatment of other acute and chronic lung infections, such as ventilator associated bacterial pneumonia, or VABP, and chronic obstructive pulmonary disease, or COPD and chronic suppurative otitis media. *P. aeruginosa* is the predominant pathogen in these indications.

### **AB-CD01: Gastrointestinal (GI) Infection Caused by *C. difficile*, or CDI**

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

According to the CDC almost 250,000 people each year require hospitalization for CDI and at least 14,000 people die each year in the United States from CDI. The CDC also estimates that 20 – 40% of CDI recurs with standard antibiotic treatment. We believe that orally delivered phages are well suited to treat CDI. Researchers at the University of Leicester have discovered phages that have been shown to be effective *in vitro* and *in vivo* against clinically-relevant strains of *C. difficile* isolated from around the world. These same researchers have also shown phage cocktails to be effective in preventing *C. difficile* biofilm formation *in vitro*. While current pathogenic strains of *C. difficile* are not yet antibiotic-resistant, the CDC has categorized *C. difficile* as an urgent threat and has stated that CDI requires urgent and aggressive action. We believe that there may be a significant market opportunity for a phage therapy in treating this infection. We have conducted preclinical studies to select and optimize our phage cocktail and manufacturing strains as well as evaluate their efficacy in animal models. Data published in 2016 by our collaborators (Nale et al) in *Frontiers in Microbiology* suggest that the phages significantly reduced *C. difficile* biofilms *in vitro*, and *in vivo* prevented bacterial colonization in a wax model (*G. mellonella*) when phages were used alone or in combination with vancomycin and antibiotic commonly used to treat CDI.

### **Prior Clinical Development**

In 2010, our wholly owned subsidiary, Biocontrol Ltd, reported a double-blind placebo-controlled, randomized Phase 1/2 clinical trial targeting chronic ear infections (otitis) caused by *P. aeruginosa*. To our knowledge, this was the first randomized placebo-controlled efficacy trial of bacteriophage therapy. Results were published 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 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 large, with the market estimated to reach \$44.7 billion in annual sales globally in 2020. 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 PEW Charitable Trusts report, as of December 2016 there were an estimated 40 new antibiotics in clinical development for the U.S. market. Historically, the success rate from Phase 1 to marketing approval is only one in five for infectious disease products. We therefore believe there is a need for new approaches to treat serious bacterial infections. 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-acquired infection during their stay, typically requiring extended stays and additional care. There is also a significant risk of death from such infections. In the United States, the 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.

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, VISA (vancomycin-intermediate *S. aureus*), or VRSA (vancomycin-resistant *S. aureus*), can be extremely challenging to treat. Although several antibiotics targeting *S. aureus* have been developed, rapidly developing bacterial resistance has been noted for all of these including linezolid, daptomycin and tigecycline. On the basis of historical evidence, resistance to these existing products is likely to increase over time, and this picture is further complicated by the reduced efficacy of conventional antibiotics against *Staphylococcus* biofilms.

Typically, *S. aureus* infection causes a variety of suppurative (pus-forming) infections and toxins (lesions) 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, or SSI, and 15.6% of such infections overall.

Infections also occur in patients with 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.

## **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 threatens 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. We therefore believe there is a pressing need to find alternative antibacterial therapies.

Bacteriophage therapy has the potential to be an alternative method of treating bacterial infection. Phages are ubiquitous environmental viruses that grow only within bacteria. The name “bacteriophage” translates as “eaters of bacteria” and reflects the fact that as they grow, phages kill the bacterial host by multiplying inside and then bursting through the cell membrane in order to release the next generation of phages. Phages can differ substantially in



morphology and each phage is active against a specific range of a given bacterial species. Phages were first discovered in 1915 at the Institut Pasteur and were shown to kill bacteria taken from patients suffering from dysentery. Furthermore, it was noted that phage numbers rose as patients recovered from infection, suggesting a direct association.

### ***Life Cycle of a Bacteriophage***

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

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

### **Our Strategy**

Our strategy is to use techniques of modern biotechnology and current state-of-the-art practices for drug development in concert with existing regulatory guidance to develop a pipeline of bacteriophage products that will destroy bacteria such as MRSA, which are resistant to antibiotics. We intend to leverage advances in sequencing and molecular biology to build upon the demonstrated ability of using phages therapeutically to successfully treat bacterial infections. We may also use our bacteriophage technology to develop personalized targeted therapies for patients who suffer from serious or life-threatening antibiotic-resistant bacterial infections and who have few or no other satisfactory treatment options. Our long-term strategy is to become the world leader in treating drug-resistant bacterial infections.

We supplement our internal resources with world-class scientific and medical collaborations throughout the world. For example, through a collaboration with The University of Adelaide in Australia and the University Hospital Ghent in Belgium, we conducted preclinical studies showing the ability of *S. aureus* phage preparations to kill over 140 clinical isolates from CRS patients demonstrating activity of greater than 90%. Furthermore, a *S. aureus* mixture was shown to be safe and efficacious in a preclinical sheep model of CRS. A Phase 1 clinical trial for this program was conducted at the University of Adelaide's Queen Elizabeth Hospital for the treatment of patients suffering from CRS associated with *S. aureus* infection. In December 2016, we reported final results from the Phase 1 trial of AB-SA01 in patients with CRS. AB-SA01 met the trial's primary endpoints of safety and tolerability and all nine patients enrolled in the study experienced a reduction in the quantity of *S. aureus* infecting their sinuses, with some patients showing complete eradication of the bacterial infection. In August 2016, we tested AB-SA01 against 90 *S. aureus* clinical isolates from CRS patients located in Belgium and showed similar activity to isolates obtained from Australian patients, highlighting the diverse geographic activity of our phage cocktail.

In collaboration with the U.S. Army, we completed a Phase 1 safety study under an IND that we believe will support the further development of a treatment for *S. aureus* infections for wound and skin infections. In December 2016, we reported final results from the Phase 1 trial to evaluate the safety and tolerability of AB-SA01. Overall, treatment with AB-SA01 was well tolerated when administered topically to the intact skin of healthy adults.

We collaborate with the Royal Brompton Hospital in London where we have demonstrated that a phage product candidate can survive nebulization, was effective in killing over 83% of recent clinical *P. aeruginosa* isolates, and in preclinical mouse models demonstrated that a phage mixture dose-dependently clears *P. aeruginosa* infection from the lung and reduced inflammation. We have completed selection of the phages for drug product selection for AB-PA01, and we may seek to conduct a Phase 1/2 study using AB-PA01 to treat CF patients with *P. aeruginosa* lung infections

## Acquisitions

In January 2011, we completed the acquisition of Biocontrol Ltd, 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 Ltd, we issued 456,344 shares of our common stock to the shareholders of Biocontrol Ltd 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 Ltd raised approximately £200,000 (US\$310,000) in working capital for use by us.

In November 2012, we completed the acquisition of Special Phage Holdings Pty Ltd, a company based in Australia, which we refer to as SPH, with the goal of combining SPH's research on addressing the rapidly escalating problem of antibiotic resistance through the development of a series of bacteriophage-based treatments into our own development programs. We acquired SPH in exchange for shares of our common stock pursuant to the terms of a Stockholder Sale

Agreement and a Managers Warranty Deed.

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, to SPH, a consulting agreement with Dr. Anthony Smithyman and the payment of \$3,017 per month to Cellabs for our laboratory space in Australia through December 31, 2015. Under the terms of the Loan Repayment Deed, the loan from Cellabs to SPH was repaid and fully satisfied partly in cash and partly by issuing 40,000 shares of our common stock to Cellabs. The SPH acquisition also included several phage therapy projects which had reached the pre-clinical or animal study stage, including the Brompton Hospital CF study and the Adelaide University MRSA CRS study and the University of Leicester *C. difficile* project. We believe that acquisition of SPH brought substantial phage scientific expertise and know-how to the Company.

In January 2016, we entered into an Asset Purchase Agreement, pursuant to which we purchased and received all rights, title and interest to two families of patents. The first patent family is titled “Bacteriophages useful for therapy and prophylaxis of bacterial infections.” This patent has been granted in Australia and China and allowed in Europe with prosecution pending in the United States and other countries. The second patent family is titled “Novel bacteriophages” and the U.S. patent application has been allowed, while prosecution is pending in many other countries. We also received clinical isolates for *S. aureus* which will bolster our libraries of clinically relevant strains. Additionally, we received know-how relating to certain formulation processes. We also have access to all previous dialogue between Novolytics and various regulatory organizations including the MHRA.

In connection with the Novolytics Purchase Agreement, we paid cash to Novolytics to cover expenses incurred in connection with winding up its phage-related business, as well as warrants to the shareholders of Novolytics to purchase up to an aggregate of 170,000 shares of our common stock, each with an exercise price of \$12.00 per share. Pursuant to the terms of the Novolytics Purchase Agreement, we granted certain registration rights covering the resale of the shares of common stock underlying such warrants.

## **Strategic Alliances and Research Agreements**

### ***Global R&D Agreement with U.S. Army***

In June 2013, we entered into a Research and Development Agreement with the U.S. Army Medical Research and Materiel Command. The Research and Development Agreement focuses on developing bacteriophage therapeutics to treat *S. aureus*, *E. coli* and *P. aeruginosa* infections, with the initial therapeutic development focus being 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.

We retain global regulatory ownership and commercial rights to all products developed by us under the Research and Development Agreement. The U.S. Army Medical Research and Materiel Command will have the right to retain a non-exclusive license to use any products developed by or on behalf of the U.S. Government for non-commercial uses. We also have the rights to exclusively license any intellectual property developed by the U.S. Army Medical Research and Materiel Command under the collaboration on terms to be agreed upon.

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

### ***University of Leicester License Agreement***

In September 2013, we entered into a license agreement with the University of Leicester which provides us with exclusive rights to certain patents and materials owned by the University of Leicester, as well as non-exclusive licenses to related know-how, to research, develop, manufacture, use and sell one or more phage therapy products for treating *C. difficile* infection or carriage in humans or animals.

Under the license agreement, we have paid an up-front fee and have agreed to pay the University of Leicester royalties based on product sales and make certain milestone payments based on product development. The license agreement expires on the later of the expiration of the licensed patents or September 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.

***License Agreement with United Kingdom Secretary of State for the Department of Health***

In January 2011, upon completion of our acquisition of Biocontrol Ltd., we assumed a license agreement entered into in March 2007 between Biocontrol Ltd. and the Health Protection Agency, Centre for Emergency Preparedness and Response, to use certain intellectual property rights to develop treatments for bacterial biofilm infections. The agreement was subsequently assigned to the United Kingdom Secretary of State for the Department of Health, or DoH.

Under the license agreement, we have obtained exclusive rights to a patent portfolio related to the use of bacteriophages combined with biofilm-disrupting agents in treating biofilm infections. In consideration for the exclusive license, we may be required to pay to the DoH certain milestone payments in the aggregate of up to £10,000 per product, as well as single digit percentage royalty on net sales of products incorporating licensed intellectual property.

The license agreement shall remain in full force and effect until the expiration of the last patent exclusively licensed under the license agreement. If we default on any milestone or royalty payments, or upon breach by us of certain other terms of the license agreement, the DoH may either terminate the license agreement immediately upon written notice or modify the license to be non-exclusive upon 30 days' written notice.

## 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.

As of December 31, 2016, we owned or had exclusive license rights to a total of 65 patents and applications: five U.S. patents, seven U.S. patent applications, 40 foreign patents, and 13 foreign patent applications, expiring on various dates between 2024 and 2036. These patents and applications cover our lead phage-therapeutic programs and use thereof, the sequential use of bacteriophages in combination with conventional antibiotics, genetic sequence variations, biofilm disrupting agents, methods to reduce antibiotic resistance, methods to design therapeutic combination panels of bacteriophage, disinfection methods using bacteriophages, and bacteriophage mutants having increased bacterial host spectra.

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

Under an existing license from the United Kingdom Secretary of State for the Department of Health (DoH), we have exclusive rights to a patent portfolio related to the use of bacteriophages combined with biofilm-disrupting agents in treating biofilm infections. This portfolio includes one issued patent in the United States and a patent granted in Europe (EP1587520 is validated in France, Germany, Netherlands, Switzerland, Liechtenstein and the United

Kingdom). Claims issued in these patents include those directed to compositions and methods related to agents that are able to facilitate the penetration of biofilms, and their combination with therapeutic bacteriophage preparations. The U.S. patent is expected to expire in December 2026 (absent any extensions). The foreign patents are expected to expire in January 2024 (absent any extensions).

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

Through our wholly owned subsidiary, Biocontrol Ltd, we own three granted U.S. patents and one pending U.S. continuation patent application with claims directed generally to bacteriophage compositions, therapeutic methods of using bacteriophages, and methods of treating bacterial infections by sequentially administering bacteriophages in combination with conventional antibiotics. The pending U.S. continuation application (US 13/757655) relates generally to panels of bacteriophages with different strain specificities for bacterial infections. Corresponding patents have been granted in Australia (AU2004258731), Europe (EP1663265 and EP2570130 — both patents are validated in the United Kingdom, Switzerland, Liechtenstein, Germany, Spain, France, Italy and the Netherlands), Japan (JP5731727 and JP5856556) and Canada (CA2533352). Claims issued in these patents include those directed to therapeutic and non-therapeutic applications of bacteriophage and the sequential use of antibiotics to treat bacterial infections. U.S. patents are expected to expire from July 2024 to March 2027 (absent any extensions). The foreign patents are expected to expire in July 2024 to March 2027 (absent any extensions).

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

Through our wholly owned subsidiary, Biocontrol Ltd, we own one granted U.S. patent (8475787), and one pending continuation application (14/625049). This patent family broadly relates to bacteriophage-induced induction of antibiotic sensitivity in a bacterial target, such as *P. aeruginosa* .. The granted U.S. patent is expected to expire in July 2029 (absent any extensions). Corresponding patents have been granted in Australia (AU2008224651), Europe (EP2136826 — validated in the United Kingdom, Switzerland/Liechtenstein, Germany, Spain, France, Italy and the Netherlands), and Japan (JP5988417 and JP6004543). A related Canadian application (CA2680108) has been allowed and will be officially granted upon the payment of the issuance fee due July 4, 2017. Foreign patents in this family are expected to expire in March 2028 (absent any extensions).

***PCT WO2013/164640 (United Kingdom priority filing 1207910.9); Therapeutic bacteriophage compositions***

Through our wholly owned subsidiary, Biocontrol Ltd, we own a Patent Cooperation Treaty, or PCT, application relating to the design of effective bacteriophage combinations and elimination of antagonistic effects between said bacteriophage. The PCT application published on November 7, 2013, and following International Preliminary Examination a positive patentability opinion issued. National/regional phase applications are currently pending in the U.S. (US14/398384), Canada (CA2871986), Europe (EP2874635), Japan (JP2015/523850), and Australia

(AU2013255583). Patents issuing from this PCT, if any, are expected to expire in May 2032 (absent any extensions).



***PCT WO2009/044163 (United Kingdom priority filing 0719438.4); Anti-bacterial compositions***

Pursuant to the terms of the Asset Purchase Agreement with Novolytics Ltd., we acquired and currently own one U.S. continuation application (14/686315) relating to methods for killing/treating Staphylococcus and MRSA, among other bacteria, using a combined bacteriophage K and bacteriophage P68 composition. A corresponding patent has been granted in Australia (AU2008306626), and China (CN101835384), and Japan (JP6053727), while European application (EP2197284) has been allowed. Related applications are pending in Australia (AU2015264918) and Canada (CA2700646). The granted foreign patents are expected to expire October 2028 (absent any extensions).

***PCT WO2013/068743 (United Kingdom priority filing 1119167.3); Novel bacteriophages***

Pursuant to the terms of the Asset Purchase Agreement with Novolytics Ltd., we acquired and currently own a U.S. patent application (14/356869) relating to Staphylococcus aureus and MRSA therapeutics, and in particular Phage K mutants capable of targeting an increased number of Staphylococcus aureus strains when compared to wild-type Phage K, as well as uses of said mutant. U.S. patent application 14/356869 has been allowed. Related applications are also pending in Australia (AU2012335397), Canada (CA2890450), Japan (JP 2014/533943) and Europe (EP2776559). Any granted patents will expire in November 2033.

***US 15/237496 (converted from United States provisional filing 62/204915); Therapeutic bacteriophage compositions***

We own U.S. patent application 15/237496, which is directed to our AB-SA01 bacteriophage panel, mutants thereof, and methods of treating Staphylococcus aureus infections (including MRSA) comprising the use of same. Corresponding foreign applications are being pursued by way of a parallel PCT application. Any granted US patent is expected to expire in August 2036 (absent extensions). Corresponding foreign applications are being pursued by way of a parallel PCT application.

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 our behalf, 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 infections. 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 development and obtaining regulatory approval for drugs. In addition, many universities and private and public research institutes are active in antibacterial research, some in direct competition with us. We also may compete with these organizations to recruit scientists and clinical development personnel.

There are a handful of small biotechnology companies developing bacteriophage products to treat human diseases. Other than our ongoing clinical trials there is, to our knowledge, one corporate-sponsored clinical trial currently enrolling. A French biotechnology company, Pherecydes Pharma, is acting as clinical trial sponsor of a Phase 1/2 clinical trial in Europe of a phage therapy for the treatment of burn wounds infected with either *E. coli* and *P. aeruginosa*, referred to as PhagoBurn. This clinical trial is a randomized, multi-center open label study to assess tolerance and efficacy of local treatment with a bacteriophage cocktail. A multi-center clinical trial also sponsored by Pherecydes Pharma evaluating a bacteriophage cocktail versus placebo for diabetic foot ulcers, is listed on [clinicaltrials.gov](http://clinicaltrials.gov) as active but not yet enrolling. To our knowledge, a small number of biotechnology companies, including Synthetic Genomics and LytPhage, Inc., as well as academic institutions, have earlier stage discovery programs utilizing synthetic biology approaches to genetically modify bacteriophages to remove or input genes to improve therapeutic properties such as increases to the bacterial host range to infect a larger number of bacterial strains and decrease the need for using multiple phages in a product.

A related approach to treating *Staphylococcus* infections is being pursued by Contrafect Corporation using a bacteriophage lysin (a hydrolytic enzyme produced by bacteriophages) to treat *S. aureus* bacteremia (infection in the blood). Contrafect has recently completed a Phase 1 intravenous single dose escalation study in healthy volunteers.

Our bacteriophage programs may compete with or be synergistic with currently approved antibiotics, and experimental approaches such as novel antibiotics, antimicrobial peptides, antimicrobial vaccines, metals, antisense, monoclonal antibodies and possibly microbiome manipulation. For example, Seres Therapeutics is developing a single-dose capsule (SER-109) consisting of bacterial spores to treat recurrent CDI (*Clostridium difficile* infection). SER-109, or similar products that may be in development by third parties, could prove to be competitive to or used in conjunction with a bacteriophage therapeutic approach.

## **Manufacturing and Supply**

We have developed our own manufacturing capabilities at a facility in Ljubljana, Slovenia that is leased by our wholly owned subsidiary, AmpliPhi, Biotehnoške Raziskave in Razvoj, d.o.o. We believe that our facility complies with applicable cGMP regulations, which require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. Pharmaceutical product manufacturers and other entities involved in the manufacture and distribution of approved pharmaceutical products are required to register their establishments with the FDA, and certain state agencies, including the applicable government agency where the facility is located, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws.

After conducting a global search, we elected to proceed with establishing a wholly owned cGMP compliant manufacturing facility in Ljubljana, Slovenia. Upon final product selection, we plan to manufacture each of our product candidates in this facility. We have been able to access and hire highly skilled process development and phage manufacturing expertise and believe that we have control of our proprietary platform from phage identification through final product fill and finish. Our facility is comprised of approximately 6,000 sq. ft. of laboratory and office space, where we produce cGMP clinical trial supplies for our current and planned clinical trials. We believe this facility will be sufficient to meet our manufacturing needs through initial Phase 3 clinical trials. Our current formulation for AB-SA01 is intended for sinonasal or topical delivery via a nasal wash solution or dressed bandage. We plan to further optimize future formulations of our product candidates.

Our facility in Ljubljana, Slovenia is subject to inspection and regulation by JAZMP, the Slovenian agency that regulates and supervises pharmaceutical products in Slovenia. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved New Drug Application/Biologics License Application, including withdrawal of the product from the market. In addition, changes to the manufacturing process generally require prior regulatory approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further regulatory review and approval, including approval by the FDA.

## **Commercialization and Marketing**

We have full worldwide commercial rights to all of our phage-based product candidates to treat drug-resistant bacterial infections, including our product candidates: AB-PA01 for the treatment of CF patients with *P. aeruginosa* lung infections; AB-SA01, for the treatment of *S. aureus* infections; and AB-CD01 for the prevention or treatment of *C. difficile* infections. We believe we can maximize the value of our company by retaining substantial global commercialization rights to these product candidates and, where appropriate, entering into partnerships to develop and commercialize our other product candidates. We plan to build a successful commercial enterprise using a sales team in

the United States and possibly other major markets and with partners in other territories.

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

### **Government Regulation and Product Approval**

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

#### ***United States Product Development Process***

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

completion of preclinical laboratory tests, animal studies and formulation studies according to good laboratory practice requirements, or GLP, or other applicable regulations;

submission to the FDA of an IND, which must become effective before human clinical trials may begin in the United States;

performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices, or GCPs, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use or uses;

submission to the FDA of a Biologics License Application, or 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 even when approvals are inherently uncertain.

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

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. 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 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 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. Clinical trials must be conducted in accordance with GCP requirements. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, or ethics committee if conducted outside of the U.S., at or servicing each institution at which the clinical trial will be conducted. An IRB or ethics committee is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB or ethics committee also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. We intend to use third-party Clinical Research Organizations, or 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. 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 product candidate 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 product candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product candidate 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 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 suggest 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 trial due to safety risks attributed to the investigational product will result in termination of the trial and possibly others that are underway.

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

### *United States Review and Approval Processes*

In order to obtain approval to market a biological product in the United States, a BLA that provides data establishing to the FDA's satisfaction the safety and effectiveness of the investigational product candidate for the proposed indication must be submitted to the FDA. 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.

Each BLA must be accompanied by a significant user fee. The FDA adjusts the user fees on an annual basis. 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 is accepted for filing, the FDA reviews it 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 cGMP to assure and preserve the product's identity, safety, strength, quality, potency, and purity. The FDA may refer applications for novel product candidates or those 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 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 Generating Antibiotic Incentives Now Act, 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.

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 trials 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 to 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.

A sponsor can also 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.

### ***Patent Term Extension and Biosimilars***

Depending upon the timing, duration and specifics of FDA approval of our drugs, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch Waxman Amendments. The Hatch Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one half the time between the effective date of an IND, and the submission date of an NDA or BLA, plus the time between the submission date of an NDA or BLA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension, and the extension must be applied for prior to expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Pediatric exclusivity is a type of marketing exclusivity available in the U.S. under the Best Pharmaceuticals for Children Act, or BPCA, which provides for an additional six months of marketing exclusivity may be available if a sponsor conducts clinical trials in children in response to a written request from the FDA, or a Written Request. If the Written Request does not include clinical trials in neonates, the FDA is required to include its rationale for not requesting those clinical trials. The FDA may request studies on approved or unapproved indications in separate Written Requests. The issuance of a Written Request does not require the sponsor to undertake the described clinical trials.

### **Biologics Price Competition and Innovation Act of 2009**

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, amended the PHSA to create an abbreviated approval pathway for two types of "generic" biologics — biosimilars and interchangeable biologic products, and provides for a twelve year data exclusivity period for the first approved biological product, or reference product, against which a biosimilar or interchangeable application is evaluated; however if pediatric clinical trials are performed and accepted by the FDA, the twelve year data exclusivity period will be extended for an additional six months. A biosimilar product is defined as one that is highly similar to a reference product notwithstanding minor differences in clinically inactive components and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product. An interchangeable product is a biosimilar product that may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

The biosimilar applicant must demonstrate that the product is biosimilar based on data from (1) analytical studies showing that the biosimilar product is highly similar to the reference product; (2) animal studies (including toxicity);

and (3) one or more clinical trials to demonstrate safety, purity and potency in one or more appropriate conditions of use for which the reference product is approved. In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity and potency.

An application for a biosimilar product may not be submitted until four years after the date on which the reference product was first approved. The first approved interchangeable biologic product will be granted an exclusivity period of up to one year after it is first commercially marketed, but the exclusivity period may be shortened under certain circumstances.

### ***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 new products continues after approval, particularly with respect to cGMP. We will rely on third parties for the production of commercial quantities of any products that we may commercialize. We and third party manufacturers of our products are required to comply with applicable requirements in the cGMPs, 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 cGMP and other FDA requirements. Other post-approval requirements applicable to biological products include reporting of cGMP 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 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 cGMPs 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 drugs and 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 product that are consistent with FDA approval, and the company is allowed to actively market a 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, other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice and state and local governments.

### ***International Regulation***

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

than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or a mutual recognition procedure. The centralized procedure, which is compulsory for medicinal products produced by biotechnology or those medicinal products containing new active substances for specific indications such as the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, viral diseases and designated orphan medicines and optional for other medicines which are highly innovative. Under the centralized procedure, a marketing application is submitted to the European Medicines Agency where it will be evaluated by the Committee for Medicinal Products for Human Use and a favorable opinion typically results in the grant by the European Commission of a single marketing authorization that is valid for all European Union member states within 67 days of receipt of the opinion. The initial marketing authorization is valid for five years, but once renewed is usually valid for an unlimited period.

### ***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 third-party reimbursement from payors at the federal, state and private levels. Third party payors include government healthcare programs, such as Medicare and Medicaid, private health insurers and managed-care plans. We anticipate third party payors will provide reimbursement for our products. However, these third party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost effectiveness of our products. Our product candidates may not be considered cost effective. It is time consuming and expensive for us to seek reimbursement from third party payors. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

We expect that there will continue to be a number of federal and state proposals to implement governmental pricing controls and limit the growth of healthcare costs, including the cost of prescription drugs.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the U.S. and generally tend to be significantly lower.



## **Research and Development Expenses**

Our research and development expenses for the years ended December 31, 2016 and 2015 were \$5.7 million and \$4.0 million, respectively.

## **Employees**

As of March 17, 2017, we had 32 full time employees and one part time employee. Twenty-six of our full time employees are engaged in research and development activities and six full time employees are engaged in finance, legal, human resources, facilities and general management. We have no collective bargaining agreements with our employees, we have not experienced any work stoppages and we believe our relations with our employees are good.

## **Facilities**

Our principal offices occupy approximately 1,000 square feet of leased office space pursuant to a month-to-month sublease, located at 3579 Valley Centre Drive, Suite 100, San Diego, California 92130. We also lease approximately 500 square feet of lab space in Richmond, Virginia, approximately 4,000 square feet of lab space in Brookvale, Australia, and approximately 6,000 square feet of lab and office space in Ljubljana, Slovenia. We believe our facilities are adequate for our current and near-term needs.

## **Corporate Information**

We were incorporated under the laws of the State of Washington in March 1989 as a wholly owned subsidiary of Immunex Corporation and began operations as an independent company in 1992 as Targeted Genetics Corporation. In February 2011, we changed our name to “AmpliPhi Biosciences Corporation.”

Our principal executive offices are located at 3579 Valley Centre Drive, Suite 100, San Diego, California 92130. The telephone number at our principal executive office is (858) 829-0829. Our website address is <http://www.ampliphio.com>. Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, are available free of charge through our website as soon as



reasonably practicable after they are electronically filed with, or furnished to, the Securities and Exchange Commission, or the SEC. We will also provide the reports in electronic or paper form free of charge upon request. The SEC maintains a website that contains our public filings with the SEC and other information regarding the Company, at [www.sec.gov](http://www.sec.gov). These reports and other information concerning the Company may also be accessed at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Our website and the information contained on, or that can be accessed through our website, will not be deemed to be incorporated by reference in, and are not considered part of, this Annual Report on Form 10-K.

We are an "emerging growth company," as defined in the JOBS Act. We will remain an emerging growth company until the earliest to occur of (i) the last day of the fiscal year (a) following the fifth anniversary of our initial public offering conducted after we became a reporting company under the Exchange Act pursuant to our registration statement on Form 10 (File No. 000-23930), (b) in which we have total annual gross revenue of at least \$1.0 billion or (c) in which we are deemed to be a "large accelerated filer" under the Exchange Act, which means that the market value of our common stock that is held by non-affiliates exceeds \$700 million as of June 30<sup>th</sup> of the prior year, and (ii) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

## **Item 1A. RISK FACTORS**

*You should consider carefully the following information about the risks described below, together with the other information contained in this Annual Report and in our other public filings, in evaluating our business. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.*

### **Risks Related to Our Financial Condition and Need for Additional Capital**

*There is substantial doubt about our ability to continue as a going concern, which may affect our ability to obtain future financing and may require us to curtail our operations. We will need to raise additional capital to continue our operations.*

This Annual Report on Form 10-K for the year ended December 31, 2016 includes disclosures and an opinion from our independent outside auditors stating that our recurring losses and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern. Our financial statements as of December 31, 2016 were prepared under the assumption that we will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty. At December 31, 2016, we had cash and cash equivalents of \$5.7 million, and we have had recurring losses from operations and negative operating cash flows since inception.



Our ability to continue as a going concern depends on our ability to raise substantial additional funds through public or private equity offerings, collaborative or licensing arrangements and/or debt financing. In the near term, we expect to continue to fund our operations, if at all, primarily through equity and debt financings in the future. If additional capital is not available to us when needed or on acceptable terms, 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. While we believe that our existing resources will be sufficient to fund our planned operations through mid-April 2017, we cannot provide assurances that our estimates are accurate or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate.

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 seeking 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 need to raise additional capital to support our operations and product development activities in 2017 and beyond. We may seek funds through arrangements with collaborators or others that may require us to relinquish rights to the product 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, or at all.

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

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

Raising additional capital through the sale of securities could cause significant dilution to our stockholders. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Our ability to raise additional funds will depend, in part, the success of our preclinical studies and clinical trials and other product development activities, regulatory events, our ability to identify and enter into in-licensing or other strategic arrangements, and other events or conditions that may affect our value or prospects, as well as factors related to financial, economic and market conditions, many of which are beyond our control. In addition, we believe there is currently substantial doubt about our ability to continue as a concern which hinders our ability to raise additional funds in a timely manner and on favorable terms. There can be no assurances that sufficient funds will be available to us when required or on acceptable terms, if at all.

If we are unable to secure additional funds on a timely basis or on acceptable terms, we may be required to defer, reduce or eliminate significant planned expenditures, restructure, curtail or eliminate some or all of our development programs or other operations, dispose of technology or assets, pursue an acquisition of our company by a third party at a price that may result in a loss on investment for our stockholders, enter into arrangements that may require us to relinquish rights to certain of our product candidates, technologies or potential markets, file for bankruptcy or cease operations altogether. Any of these events could have a material adverse effect on our business, financial condition and results of operations. Moreover, if we are unable to obtain additional funds on a timely basis, there will continue to be substantial doubt about our ability to continue as a going concern and increased risk of insolvency and up to a total loss of investment by our stockholders.

***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. As of December 31, 2016, our accumulated deficit was \$381.4 million, \$65.8 million of which has been accumulated since January of 2011, when we began our focus on bacteriophage development, 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 years ended December 31, 2016 and 2015, we had losses from operations of \$23.4 million and \$10.2 million, respectively. Additional information regarding our results of operations may be found in our consolidated financial statements and in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included Item 7 in this report.

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, our business, financial condition and results of operations may be materially adversely impacted and our stock price could decline.

***We have never generated any revenue from product sales and may never be profitable.***

Our ability to generate meaningful revenue and achieve profitability depends on our ability, and the ability of any third party with which we may partner, to successfully complete the development of, and obtain the regulatory approvals necessary to, commercialize our product candidates. We do not anticipate generating revenues from product sales for the foreseeable future, if ever. If any of our product candidates fail in clinical trials or if any of our product candidates do not gain regulatory approval, or if any of our product candidates, if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our ability to generate future revenues from product sales depends heavily on our success in:

- completing research and preclinical and clinical development of our product candidates;

## Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

· seeking and obtaining regulatory and marketing approvals for product candidates for which we complete clinical trials;

· developing a sustainable, scalable, reproducible, and transferable manufacturing process for our product candidates;

· launching and commercializing product candidates for which we obtain regulatory and marketing approval, either by establishing a sales force, marketing and distribution infrastructure, or by collaborating with a partner;

· obtaining market acceptance of any approved products;

· addressing any competing technological and market developments;

· implementing additional internal systems and infrastructure, as needed;

· identifying and validating new product candidates;

· negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;

· maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and

· attracting, hiring and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product. Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, or other foreign regulatory authorities to perform clinical trials and other studies in addition to those that we currently anticipate. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

***Taxing authorities could reallocate our taxable income among our subsidiaries, which could increase our overall tax liability.***

We are organized in the United States, and we currently have subsidiaries in the United Kingdom, Australia and Slovenia. If we succeed in growing our business, we expect to conduct increased operations through our subsidiaries in various tax jurisdictions pursuant to transfer pricing arrangements between us and our subsidiaries. If two or more affiliated companies are located in different countries, the tax laws or regulations of each country generally will require that transfer prices be the same as those between unrelated companies dealing at arm's length and that appropriate documentation is maintained to support the transfer prices. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable tax authorities.

If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arm's length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

***Our ability to use our net operating tax loss carryforwards and certain other tax attributes may be limited.***

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code. These limitations apply if an "ownership change," as defined by Section 382 of the Code, occurs. If we have experienced an "ownership change" at any time since our formation, we may already be subject to limitations on our ability to utilize our existing net operating losses and other tax attributes to offset taxable income. In addition, future changes in our stock ownership (including in connection with future private or public offerings, as well as changes that may be outside of our control), may trigger an "ownership change" and, consequently, limitations under Sections 382 and 383 of the Code. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other pre-change tax attributes to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. We have not completed a study to assess whether an "ownership change" has occurred or whether there have been multiple "ownership changes" since our formation, due to the complexity and cost associated with such a study, and the fact that there may be additional ownership changes in the future.

***If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate financial statements on a timely basis could be impaired and our public reporting may be unreliable.***

We are required to maintain internal control over financial reporting adequate to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements in accordance with generally accepted accounting principles. In connection with the correction of an immaterial error in the third quarter of 2016, and the restatement of our consolidated financial statements for the second quarter of 2015, we determined that we had a material weakness as of December 31, 2016, namely that our internal control over financial reporting, including control over the evaluation and review of complex and non-routine transactions, was not effective. A material weakness means a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the registrant's annual or interim financial statements will not be prevented or detected on a timely basis.

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

We are taking steps to remediate the material weakness in our internal control over financial reporting, including the addition of and training of qualified personnel to identify and evaluate complex and non-routine transactions and the development of specific procedures, processes and internal controls related to complex and non-routine transactions. However, we cannot assure you that these efforts will remediate our material weakness in a timely manner, or at all, or that we will be able to maintain effective controls and procedures even if we remediate our material weakness. If we are unable to successfully remediate our material weakness, implement and maintain effective controls and procedures, or identify any future material weaknesses, 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 and we may experience a loss of public confidence, which could have an adverse effect on our business, financial condition and the market price of our common stock and other securities.



***We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives.***

As a public company, we incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and the NYSE MKT to implement provisions of the Sarbanes-Oxley Act, imposes significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as “say on pay” and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years following their initial public offering. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than expected and thereby incur unexpected expenses.

We expect the rules and regulations applicable to public companies to result in us continuing to incur substantial legal and financial compliance costs. These costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business.

## **Risks Related to Our Business**

***We are seeking to develop antibacterial agents using bacteriophage technology, a novel approach, which makes it difficult to predict the time and cost of development. No bacteriophage products have been approved in the United States or elsewhere.***

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 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, diminishing the relevance of prior claims of improved cure rates. 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 efficiently conduct the clinical trials required to obtain regulatory approval of our product candidates, 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 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 for 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. Planned clinical trials may not be commenced or completed on schedule, or 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;

- failures in our internal manufacturing operations that result in our inability to consistently and timely produce bacteriophages in sufficient quantities to support our clinical trials;

- the availability of financial resources to commence and complete our planned clinical trials;

- delays in reaching a consensus with clinical investigators on study design;

- delays in reaching a consensus with regulatory agencies on trial design or in obtaining regulatory approval to commence a trial;

- delays in obtaining clinical materials;

- slower than expected patient recruitment for participation in clinical trials;

- failure by clinical trial sites, other third parties, or us to adhere to clinical trial agreements;

- delays in reaching agreement on acceptable clinical trial agreement terms with prospective sites or obtaining institutional review board approval; and

- adverse safety events experienced during our clinical trials.

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

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 product candidate under study;

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

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

- our ability to obtain and maintain patient consents; and

competition for patients from clinical trials 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 have not completed formulation development of any of our product candidates.***

The development of our bacteriophage product candidates requires that we isolate, select and combine a number of bacteriophages that target the desired bacteria for that product candidate. The selection of bacteriophages for any of our product candidates is based on a variety of factors, including without limitation the ability of the selected phages, in combination, to successfully kill the targeted bacteria, the degree of cross-reactivity of the individual phages with the same part of the bacterial targets, the ability of the combined phages to satisfy regulatory requirements, our ability to manufacture sufficient quantities of the phages, intellectual property rights of third parties, and other factors. While we have selected an initial formulation of AB-SA01 for the treatment of *S. aureus* infections, there can be no assurance that this will be the final formulation of AB-SA01 for commercialization. In addition, we have initiated final phage selection for AB-PA01, our *P. aeruginosa* product. AB-CD01, which is our *C. difficile* product, is at an earlier stage. If we are unable to complete formulation development of our product candidates in the time frame that we have anticipated, then our product development timelines, and the regulatory approval of our product candidates, could be delayed.

***Our product candidates must undergo rigorous clinical testing, such clinical testing may fail to demonstrate safety and efficacy and any of our product candidates could cause undesirable side effects, which would substantially delay or prevent regulatory approval or commercialization.***

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;

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

our product candidates may have unintended or undesirable effects on patients that may delay or preclude regulatory approval of our product candidates or limit their commercial use, if approved.

***Results from preclinical studies and Phase 1 or 2 clinical trials of our product candidates may not be predictive of the results of later stage clinical trials.***

Preclinical studies, including studies of our product candidates in animal disease models, 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* and *S. aureus*, 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 1 and Phase 2 trials, does not ensure that later clinical trials will be successful. Our initial results from early stage 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 and most product candidates that commence clinical trials are never approved for commercial sale.

***We must continue to develop manufacturing processes for our product candidates and any delay in or our inability to do so would result in delays in our clinical trials.***

We are developing novel manufacturing processes for our product candidates at our facility in Ljubljana, Slovenia. The manufacturing processes for our product candidates, and the scale up of such processes for clinical trials, is novel, and there can be no assurance that we will be able to complete this work in a timely manner, if at all. Any delay in the

development or scale up of these manufacturing processes could delay the start of clinical trials and harm our business. Our facility in Slovenia must also undergo ongoing inspections by JAZMP, the Slovenian agency that regulates and supervises pharmaceutical products in Slovenia, for compliance with their and the European Medicines Agency's, or EMA's, current good manufacturing practice regulations, or cGMP regulations, before the respective product candidates can be approved for use in clinical trials or commercialization. In the event these facilities do not receive a satisfactory cGMP inspection for the manufacture of our product candidates, we may need to fund additional modifications to our manufacturing process, conduct additional validation studies, or find alternative manufacturing facilities, any of which would result in significant cost to us as well as a delay of up to several years in obtaining approval for such product candidate.

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

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

We completed an investigator-sponsored clinical trial of AB-SA01 at the University of Adelaide in Australia for CRS in December 2016. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of such study data by the FDA is subject to certain conditions. For example, the study must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The study population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical studies conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. In addition, such studies would be subject to the applicable local laws and FDA acceptance of the data would be dependent upon its determination that the studies also complied with all applicable U.S. laws and regulations. There can be no assurance the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept any such data, it would likely result in the need for additional trials, which would be costly and time consuming and delay aspects of our business plan. During a telephonic meeting in February 2017, we received positive feedback from the FDA regarding our previously submitted proposal to proceed with a Phase 2 clinical trial of AB-SA01 for CRS. However, there can be no assurances that the FDA would ultimately support any decision by us to pursue a Phase 2 clinical trial based on data we currently have available.

***We may need to license additional intellectual property rights.***

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

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

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

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

Regulatory approval, if obtained, may be made subject to limitations on the indicated uses for which we may market a product. These limitations could adversely affect our potential product revenues. Regulatory approval may also require costly post-marketing follow-up studies. In addition, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping related to the product will be subject to extensive ongoing regulatory requirements. Furthermore, for any marketed product, its manufacturer and its manufacturing facilities will be subject

to continual review and periodic inspections by the FDA or other regulatory authorities. Failure to comply with applicable regulatory requirements may, among other things, result in fines, suspensions of regulatory approvals, product recalls, product seizures, operating restrictions and criminal prosecution.

*A variety of risks associated with our international operations could materially adversely affect our business.*

In addition to our U.S. operations, we have operations and subsidiaries in the United Kingdom, Australia and Slovenia. We face risks associated with our international operations, including possible unfavorable regulatory, pricing and reimbursement, political, tax and labor conditions, which could harm our business. We are subject to numerous risks associated with international business activities, including:

- compliance with differing or unexpected regulatory requirements for the development, manufacture and, if approved, commercialization of our product candidates;

- difficulties in staffing and managing foreign operations;

- foreign government taxes, regulations and permit requirements;

- U.S. and foreign government tariffs, trade restrictions, price and exchange controls and other regulatory requirements;

- anti-corruption laws, including the Foreign Corrupt Practices Act, or the FCPA;

- economic weakness, including inflation, natural disasters, war, events of terrorism or political instability in particular foreign countries;

- fluctuations in currency exchange rates, which could result in increased operating expenses and reduced revenues, and other obligations related to doing business in another country;



compliance with tax, employment, immigration and labor laws, regulations and restrictions for employees living or traveling abroad;

workforce uncertainty in countries where labor unrest is more common than in the United States;

production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;

changes in diplomatic and trade relationships; and

challenges in enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States.

These and other risks associated with our international operations may materially adversely affect our business, financial condition and results of operations.

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

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

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

Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. As of March 17, 2017, we had 32 full time employees and one part time employee. Our success will depend on our ability to retain and motivate personnel and hire additional qualified personnel when required. Competition for qualified personnel in the biotechnology field is intense. We face competition for personnel from other biotechnology and pharmaceutical companies, universities, public and private

research institutions and other organizations. We also face competition from other more well-funded and well-established businesses and we may also be viewed as a riskier choice from a job stability perspective due to our relative newer status than longer existing biotech and pharmaceutical companies. We may not be able to attract and retain qualified personnel on acceptable terms given the competition for such personnel. If we are unsuccessful in our retention, motivation and recruitment efforts, we may be unable to execute our business strategy.

*We must manage a geographically dispersed organization.*

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

#### **Risks Related to Our Reliance on Third Parties**

*We rely on third parties for aspects of product development.*

We rely on third parties such as the U.S. Army for certain aspects of product development. We have worked with the U.S. Army for research and development of product candidates to treat *S. aureus* infections. 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 our clinical trials, and their failure to perform their obligations in a timely or competent manner may delay development and commercialization of our product candidates.*

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

### **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.

Central provisions of The Leahy-Smith America Invents Act, or the America Invents Act went into effect on September 16, 2012 and on March 16, 2013. The America Invents Act includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are being filed, prosecuted and litigated. For example, the America Invents Act enacted proceedings involving post-issuance patent review procedures, such as inter partes review, or IPR, and post-grant review, that allow third parties to challenge the validity of an issued patent in front of the United States PTO Patent Trial and Appeal Board. Each proceeding has different eligibility criteria and different patentability challenges that can be raised. IPRs permit any person (except a party who has been litigating the patent for more than a year) to challenge the validity of the patent on the grounds that it was anticipated or made obvious by prior art. Patents covering pharmaceutical products have been subject to attack in IPRs from generic drug companies and from hedge funds. If it is within nine months of the issuance of the challenged patent, a third party can petition the United States PTO for post-grant review, which can be based on any invalidity grounds and is not limited to prior art patents or printed publications.

In post-issuance proceedings, United States PTO rules and regulations generally tend to favor patent challengers over patent owners. For example, unlike in district court litigation, claims challenged in post-issuance proceedings are given their broadest reasonable meaning, which increases the chance a claim might be invalidated by prior art or lack support in the patent specification. As another example, unlike in district court litigation, there is no presumption of validity for an issued patent, and thus, a challenger's burden to prove invalidity is by a preponderance of the evidence, as opposed to the heightened clear and convincing evidence standard. As a result of these rules and others, statistics released by the United States PTO show a high percentage of claims being invalidated in post-issuance proceedings. Moreover, with few exceptions, there is no standing requirement to petition the United States PTO for inter partes review or post-grant review. In other words, companies that have not been charged with infringement or that lack commercial interest in the patented subject matter can still petition the United States PTO for review of an issued patent. Thus, even where we have issued patents, our rights under those patents may be challenged and ultimately not provide us with sufficient protection against competitive products or processes.

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 be the first to file patent applications for our inventions;

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

- our pending patent applications may not result in issued patents;

- our issued patents may not provide a basis for commercially viable products or may not provide us with any competitive advantages or may be challenged by third parties;

- others may design around our patent claims to produce competitive products that fall outside the scope of our patents;



- we may not develop additional patentable proprietary technologies related to our product candidates; and

we are dependent upon the diligence of our appointed agents in national jurisdictions, acting for and on our behalf, which control the prosecution of pending domestic and foreign patent applications and maintain granted domestic and foreign patents.

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

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

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

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

Our ability to commercialize our product candidates depends on our ability to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. Numerous United States and foreign patents and patent applications, which are owned by third parties, exist in the general field of anti-infective products or in fields that otherwise may relate to our product candidates. If we are shown to infringe, we could be enjoined

from use or sale of the claimed invention if we are unable to prove that the patent is invalid. In addition, because patent applications can take many years to issue, there may be currently pending patent applications, unknown to us, which may later result in issued patents that our product candidates may infringe, or which may trigger an interference proceeding regarding one of our owned or licensed patents or applications. There could also be existing patents of which we are not aware that our product candidates may inadvertently infringe or which may become involved in an interference proceeding.

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

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

## **Risks Related to Our Industry**

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

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

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

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

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

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

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

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



litigation costs;

substantial monetary awards against us; and

diversion of management or other resources from key aspects of our operations.

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

We have product liability insurance that covers our clinical trials up to a \$10.0 million annual per claim and 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.

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

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

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

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

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

## Risks Related to Our Common Stock

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

The stock markets in general, the markets for biotechnology stocks and, in particular, the stock price of our common stock, have experienced extreme volatility. The market for our common stock 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. The volatility in our share price is attributable to a number of factors. 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 shares of our common stock are sold on the market without commensurate demand. We are also 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 and our ability to continue as a going concern. As a consequence of this enhanced risk, more risk-averse 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 has a large public float and broader stockholder base. Many of these factors are beyond our control and may decrease the market price of our common stock, 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 stock will sustain their current market prices, or as to what effect that the sale of shares or the availability of common stock for sale at any time will have on the prevailing market price.

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

- adverse results or delays in our clinical trials;

- adverse actions taken by regulatory agencies with respect to our product candidates, clinical trials or the manufacturing processes of our product candidates;

- announcements of technological innovations, patents or new products by our competitors;

- regulatory developments in the United States and foreign countries;

- any lawsuit involving us or our product candidates;

- announcements concerning our competitors, or the biotechnology or pharmaceutical industries in general;

- developments concerning any strategic alliances or acquisitions we may enter into;

- actual or anticipated variations in our operating results;

- changes in recommendations by securities analysts or lack of analyst coverage;

- deviations in our operating results from the estimates of analysts;

our inability, or the perception by investors that we will be unable, to continue to meet all applicable requirements for continued listing of our common stock on the NYSE MKT, and the possible delisting of our common stock;

sales of our common stock by our executive officers, directors and principal 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.

***We may be required to issue a significant number of additional shares of common stock for no additional consideration to certain of our stockholders.***

In April 2016 we entered into a Common Stock Issuance Agreement, or CSIA, with certain former holders, or the Holders, of our Series B Preferred Stock. We may be required to issue a significant number of additional shares of common stock for no additional consideration to the Holders. Pursuant to the CSIA, we agreed that if in the future we conduct one or more bona fide equity financings in which we sell shares of our common stock or preferred stock at a price of less than \$4.05 per share, we will issue to the Holders, for no additional consideration, a number of additional shares of common stock, or Additional Shares, based on a specified formula. We refer to such rights of the Holders to receive Additional Shares as the Additional Issuance Rights. Specifically, in the event we conduct such a financing, the Holders will be entitled to receive (absent consideration of any applicable restrictions on the number of shares that can be issued in a non-public offering under NYSE MKT rules and interpretations without stockholder approval) in the aggregate a number of Additional Shares equal to (A) the product of (x) 1,037,053 multiplied by (y) a fraction, the numerator of which is \$4.05 and the denominator of which is the lowest price per share paid by investors in such dilutive financing, or the Effective Price, less (B) 1,037,053 and all Additional Shares issued previously to the Holders pursuant to the Additional Issuance Rights. The foregoing formula will be reduced to the extent the resulting number of shares would exceed 19.99% of the outstanding shares of common stock immediately prior to the applicable financing, and is subject to further reductions related limitations under Section 713(a) of the NYSE MKT Company Guide.

Pursuant to Section 713(a) of the NYSE MKT Company Guide, stockholder approval is generally required prior to the issuance of common stock or common stock equivalents in connection with a transaction other than a public offering involving the sale, issuance, or potential issuance by the issuer of common stock or common stock equivalents equal to 20% or more of the outstanding shares of common stock as of immediately prior to the transaction for less than the greater of book or market value of the stock. At our 2016 annual meeting of stockholders on June 20, 2016, our stockholders approved the issuance by us of up to 1,037,053 Additional Shares, for purposes of Section 713(a) of the NYSE MKT Company Guide, to the extent required to satisfy the Additional Issuance Rights. On June 3, 2016, we completed a registered public offering of common stock and warrants to purchase common stock at a combined price per share and associated warrant of \$2.35. As a result of this offering, we issued to the Holders an aggregate of 750,206 Additional Shares. In November 2016, we completed a registered public offering of common stock and warrants to purchase common stock at a price of \$0.74 per share of common stock and \$0.01 per accompanying warrant. Pursuant to the formula set forth in the CSIA, the Holders may claim that we have an obligation to issue them, in the aggregate, 2,224,078 Additional Shares as a result of the November 2016 public offering. However, under Section 713(a) of the NYSE MKT Company Guide, we are only permitted to issue 286,846 Additional Shares to the Holders without further stockholder approval. As of the date of this report, no Additional Shares have been issued to the Holders in connection with the November 2016 public offering. We may be required to obtain stockholder approval to issue additional shares beyond what we are currently allowed to issue them under Section 713(a) of the NYSE MKT, or provide other forms of consideration to the Holders, as a result of the November 2016 public offering or future financing transactions that we may conduct.

Our inability to comply in full with our obligation under the CSIA to issue shares to the Holders in connection with the closing of the most recent financing or any additional financing that triggers Additional Issuance Rights could have additional adverse consequences, including, without limitation:

the Holders may bring an action against us for breach of contract, or threaten to bring an action against us, either of which could require us to expend significant time and resources to resolve the matter, and we may not be successful;

we may need to seek approval from our stockholders in order to issue Additional Shares to the Holders, which would require us to expend time and resources, and our stockholders may not ultimately approve such issuance; and

we may need to provide other consideration to the Holders to settle potential claims arising from our inability to satisfy our contractual obligations under the CSIA, which could involve:

cash make-whole payments, which in turn would deplete our cash resources faster than we would otherwise anticipate; and

other unfavorable terms that could make it difficult for us to raise financing in the future, which would raise further doubts about our ability to continue as a going concern.

The occurrence of any of the foregoing, or even the potential for them to occur, could result in a material decline in our stock price.

Stockholders will incur dilution of their percentage ownership interest in our common stock to the extent we issue Additional Shares to the Holders pursuant to the Additional Issuance Rights. In addition, because the Additional Shares will be issued for no additional consideration, any such issuance would reduce our net tangible book value per share.

Any issuance or potential issuance of Additional Shares could adversely affect our stock price, make it more difficult for us to raise capital on favorable terms, or at all, and have a material adverse effect on our business, results of operations and financial condition

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

As of December 31, 2016, we had outstanding warrants to purchase an aggregate of 7,751,376 shares of our common stock at a weighted average exercise price of \$2.29 per share, and outstanding options to purchase 748,938 shares of our common stock at a weighted average exercise price of \$6.45 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 when these warrants or options will ultimately be exercised, it is reasonable to assume that such warrants and options will be exercised only if the exercise price is below the market price of our common stock. To the extent any of our outstanding warrants or options are exercised, additional shares of our common stock will be issued that will generally be eligible for resale in the public market (subject to limitations under Rule 144 under the Securities Act for certain of our warrants and with respect to shares held by our affiliates), 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.

***Our principal stockholders and management beneficially own a majority of our stock and will be able to exert significant control over matters subject to stockholder approval.***

As of December 31, 2016, our executive officers, directors, greater than 5% stockholders and their affiliates beneficially owned a majority of our outstanding voting stock. Therefore, these stockholders could have the ability to influence us through this ownership position. These stockholders may be able to significantly affect or, acting together, control matters requiring stockholder approval, including elections of directors, amendments of our organizational documents, and approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

***Provisions of Washington law and our current articles of incorporation and bylaws may discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions of Washington law and our current articles of incorporation and bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace or remove our board of directors. These provisions include:

- authorizing the issuance of “blank check” preferred stock without any need for action by stockholders;
- providing for a classified board of directors with staggered terms;
- requiring supermajority stockholder voting to effect certain amendments to our articles of incorporation and bylaws;
- and





establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

In addition, because we are incorporated in Washington, we are governed by the provisions of Chapter 23B.19 of the Washington Business Corporation Act, which, among other things, restricts the ability of stockholders owning 10% 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 acquirers to negotiate with our board of directors, they would apply even if an offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it difficult for stockholders 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 on our common stock 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 are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules of the NYSE MKT. The requirements of these rules and regulations increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and place strain on our personnel, systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Ensuring that we have adequate internal financial and accounting

controls and procedures in place is a costly and time-consuming effort that needs to be re-evaluated frequently.

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

In accordance with NYSE MKT rules, we are required to maintain a majority independent board of directors. The various rules and regulations applicable to public companies 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 officers and directors will be significantly curtailed.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We currently have three securities analysts and may never obtain additional research coverage by other securities and industry analysts. If no additional securities or industry analysts commence coverage of our company, the trading price for our stock could be negatively impacted. If we obtain additional securities or industry analyst coverage and if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

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

We are an “emerging growth company,” as defined under the JOBS Act. For so long as we are an “emerging growth company,” we intend to take advantage of certain exemptions from reporting requirements that are applicable to other public companies that are not “emerging growth companies” including, but not limited to, compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.



We could be an “emerging growth company” for up to five years, although we may lose such status earlier, depending on the occurrence of certain events. We will remain an “emerging growth company” until the earliest to occur of (i) the last day of the fiscal year (a) following the fifth anniversary of our initial public offering conducted after we became a reporting company under the Exchange Act pursuant to our registration statement on Form 10 (File No. 000-23930), (b) in which we have total annual gross revenue of at least \$1.0 billion or (c) in which we are deemed to be a “large accelerated filer” under the Exchange Act, which means that the market value of our common stock that is held by non-affiliates exceeds \$700 million as of June 30<sup>th</sup> of the prior year, and (ii) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

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

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

***Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to decline.***

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

Certain holders of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by our affiliates as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

***Future sales and issuances of our common stock or rights to purchase common stock by us, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to decline.***

We expect that significant additional capital will be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating as a public company. To the extent we raise additional capital by issuing equity or convertible securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2016 Equity Incentive Plan, or the 2016 Plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares available for future grant under the 2016 Plan will automatically increase on January 1<sup>st</sup> of each year by up to 5% of all shares of our capital stock outstanding as of December 31 of the preceding calendar year, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. In addition, we may grant or provide for the grant of rights to purchase shares of our common stock pursuant to our Employee Stock Purchase Plan, or ESPP. The number of shares of our common stock reserved for issuance under the ESPP will automatically increase on January 1<sup>st</sup> of each calendar year by the lessor of 1% of the total number of shares of our common stock outstanding on December 31st of the preceding calendar year and 300,000 shares, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. Currently, we plan to register the increased number of shares available for issuance under the 2016 Plan and ESPP each year. Increases in the number of shares available for future grant or purchase may result in additional dilution, which could cause our stock price to decline.

#### **Item 1B. UNRESOLVED STAFF COMMENTS**

None.

#### **Item 2. PROPERTIES**

Our principal corporate offices occupy approximately 1,000 square feet of leased office space pursuant to a month-to-month sublease, located at 3579 Valley Centre Drive, Suite 100, San Diego, California 92130. We also lease approximately 500 square feet of lab space in Richmond, Virginia, approximately 4,000 square feet of lab space in Brookvale, Australia, and approximately 6,000 square feet of lab and office space in Ljubljana, Slovenia. We believe our facilities are adequate for our current and near-term needs.

#### **Item 3. LEGAL PROCEEDINGS**

On November 12, 2016, we entered into a settlement agreement with NRM VII Holdings I, LLC (“NRM”) to settle a complaint filed by NRM in April 2016 against us and the members of our board of directors in the Superior Court of California, County of San Diego, alleging that we breached the implied covenant of good faith and fair dealing by entering into an alleged scheme to force NRM to convert its shares of Series B redeemable convertible preferred stock into shares of our common stock. The complaint further alleged that the members of our board of directors who were named as defendants breached their fiduciary duty of good faith and loyalty owed to NRM, as one of our stockholders, by participating in this alleged scheme. Pursuant to the settlement agreement, NRM dismissed the allegation with prejudice upon receipt of a cash payment of \$2.0 million, which was paid to NRM by our insurance carrier in 2016. The settlement agreement contains mutual releases covering all claims that we or our affiliates, or NRM or its affiliates, have or may have against the other party or such other party's affiliates in connection with the allegation or otherwise as of the date of the settlement agreement.

Upon the automatic conversion of NRM's shares of our Series B convertible preferred stock into shares of our common stock on April 8, 2016, we became obligated to pay NRM accrued dividends in the amount of approximately \$914,000, which had been fully accrued and recorded as a liability on the Company's balance sheet. Upon NRM's receipt of the \$2.0 million settlement payment described above, our accrued dividends payment obligation to NRM was extinguished. We have agreed to repay our insurance carrier an aggregate amount equal to the accrued dividends as follows: \$100,000 in December 2016, approximately \$205,000 in January 2017, approximately \$305,000 in July 2017 and a final payment of \$305,000 in October 2017.

#### **Item 4. MINE SAFETY DISCLOSURES**

Not applicable.

## PART II

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

Our shares of common stock have been listed on the NYSE MKT since August 21, 2015 and before that, during the periods presented below, were quoted on the OTCQB. The trading symbol for our common stock is "APHB."

The following table sets forth the range of reported high and low sales prices for our common stock on the NYSE MKT for the periods in the table below from August 21, 2015 through December 31, 2016, and the high and low bid quotations for the periods in the table from January 1, 2015 through August 20, 2015. The 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. All prices prior to August 3, 2015 reflect an adjustment for our 1-for-50 reverse stock split.

Fiscal Year 2016	High	Low
Fourth Quarter ended December 31, 2016	\$1.69	\$0.36
Third Quarter ended September 30, 2016	\$2.17	\$1.15
Second Quarter ended June 30, 2016	\$4.84	\$1.45
First Quarter ended March 31, 2016	\$5.49	\$1.92

Fiscal Year 2015	High	Low
Fourth Quarter ended December 31, 2015	\$8.25	\$3.00
Third Quarter ended September 30, 2015	\$11.70	\$3.95
Second Quarter ended June 30, 2015	\$14.25	\$8.00
First Quarter ended March 31, 2015	\$15.00	\$7.50



## **Holders of Common Stock**

As of March 17, 2017, there were 157 holders of record of our common stock. As of such date, there were 16,488,120 shares of our common stock outstanding.

## **Dividends**

We have never declared or paid any cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

## **Recent Sales of Unregistered Securities**

None.

## **Item 6. SELECTED FINANCIAL DATA**

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

## **Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the consolidated financial statements and the related notes contained elsewhere in this Annual Report. Some of the information contained in this discussion and analysis are set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements." Our actual results may differ substantially from those referred to herein due to a number of factors,

including but not limited to risks described in the section entitled “Risk Factors” and elsewhere in this Annual Report.

## Overview

We are a biotechnology company focused on the discovery, development and commercialization of novel phage therapeutics. Phage therapeutics use bacteriophages, a family of viruses, to kill pathogenic bacteria. Phages have powerful and highly selective mechanisms of action that permit them to target and kill specific bacteria. We believe that phages represent a promising means to treat bacterial infections, especially those that have developed resistance to current therapies including the so-called multi-drug-resistant or “superbug” strains of bacteria.

Our goal is to be the leading developer of phage therapeutics. We are combining our expertise in the manufacture of drug-quality bacteriophages and our proprietary approach and expertise in identifying, characterizing and developing naturally occurring bacteriophages with that of collaboration partners in bacteriophage biology, synthetic biology and manufacturing, to develop state-of-the-art bacteriophage products.

We have generally incurred net losses since our inception and our operations to date have been primarily limited to research and development and raising capital. Since the shift in our focus to novel therapeutics in February 2011 through December 31, 2016, we have received approximately \$51.2 million in net proceeds from the issuance of our equity securities and convertible debt securities. As of December 31, 2016, we had an accumulated deficit of \$381.4 million, \$65.8 million of which has been accumulated since January of 2011, when our company began its focus on bacteriophage development. 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 currently expect to use our existing cash and cash equivalents for the continued research and development of our product candidates and for working capital and other general corporate purposes.

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

We may also use a portion of our existing cash and cash equivalents for the potential acquisition of, or investment in, product candidates, technologies, formulations or companies that complement our business, although we have no current understandings, commitments or agreements to do so. Our existing cash and cash equivalents will not be sufficient to enable us to complete all necessary development of any potential product candidates. Accordingly, we will be required to obtain further funding through one or more other public or private equity offerings, debt financings, collaboration or 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 acceptable terms, we may be required to defer, reduce or eliminate significant planned expenditures, restructure, curtail or eliminate some or all of our development programs or other operations, dispose of assets, enter into arrangements that may require us to relinquish rights to certain of our product candidates, technologies or potential markets, file for bankruptcy or cease operations altogether. Any of these events could have a material adverse effect on our business, financial condition and results of operations and result in a loss of investment by our stockholders.

## **Results of Operations**

### **Comparison of the Years Ended December 31, 2016 and 2015**

#### ***Revenue***

For the years ended December 31, 2016 and 2015, we recognized revenues related to sub-licensing agreements from our former gene therapy program of \$0.3 million and \$0.5 million, respectively. We do not expect to recognize significant sub-license revenue from this program in future periods.

#### ***Research and Development***

Research and development expenses for the year ended December 31, 2016 totaled \$5.7 million compared to \$4.0 million for the year ended December 31, 2015. The increase of \$1.7 million was primarily related to increased personnel costs of approximately \$0.7 million, acquisition of Novolytics assets of approximately \$0.4 million, as well as increased clinical expenses. Research and development expenses were offset by the receipt in 2016 of \$0.9 million in tax rebates from the Australian government for qualified research and development expenditures, as compared to \$0.5 million received in 2015.

#### ***General and Administrative***

General and administrative expenses for the year ended December 31, 2016 were \$8.4 million compared to \$6.7 million for the year ended December 31, 2015. The \$1.7 million increase was primarily attributable to \$1.8 million in compensation expenses, including \$1.5 million of non-cash stock-based compensation, offset by a reduction of \$0.4 million of professional and consulting expenses.

### ***Impairment Charges***

We performed an impairment review of our goodwill and In Process Research & Development (IPR&D) assets, which are indefinite lived intangible assets, as of December 31, 2016. Based on the impairment review, we concluded that our goodwill, with a book value of \$7.6 million, was fully impaired. In addition, we recorded a \$2.0 million impairment charge relating to our IPR&D asset, originally capitalized as a result of the acquisition of Biocontrol's know-how and phage library. This IPR&D asset has a remaining book value of \$5.3 million and continues to be utilized in the development of our treatment of *P. aeruginosa* infections.

### ***Other Income (Expense)***

We recorded gains of \$3.0 million and \$0.6 million for the years ended December 31, 2016 and 2015, respectively, for the change in fair value on revaluation of our warrant and derivative liability. These gains were primarily attributable to a decline in the value of our common stock at December 31, 2016 and December 31, 2015 as compared to the prior year end values. We will continue to adjust this liability until the earlier of exercise or expiration of the warrants and derivative.

For the year ended December 31, 2016 and 2015, we recorded a gain of \$1.5 million and \$9.3 million, respectively, related to the change in fair value of our Series B preferred stock liability. These gains were primarily attributable to a decline in the value of our common stock in 2016 and 2015 compared to the prior year values. Series B preferred stock was fully converted into common stock in April 2016 and as a result, the Series B preferred stock liability was extinguished.

We recorded other expenses of \$0.6 million and \$0.3 million in 2016 and 2015, respectively, which consisted primarily of an allocation of the financing costs for warrants issued with our June 2016 and November 2016 financings, and our March 2015 private placement of common stock.

### ***Income Taxes***

We recorded an income tax benefit of \$0.6 million in the year ended December 31, 2016, comprised of a \$0.4 million income tax benefit related to a reduction of the existing deferred tax liability as a result of a \$2.0 impairment charge for our IPR&D asset discussed above, and a \$0.2 million income tax benefit as a result of reduction of deferred tax liability resulting from changes in UK enacted tax rates from 20% to 17% in 2016.

We incurred net operating losses for the years ended December 31, 2016 and 2015 and accordingly, we did not pay any U.S. federal or state income taxes. At December 31, 2016, the Company had U.S. gross net operating loss carry-forwards, or "NOLs", of approximately \$190.7 million, foreign NOLs of \$8.9 million, \$0.3 million of which was generated in 2016 and domestic research tax credit carry-forwards of approximately \$3.1 million, net of a reserve for uncertain tax positions. The carry-forwards will begin to expire in 2018. Our gross net operating loss carry-forwards are subject to certain limitations on annual utilization as a result of changes in ownership of the Company, as defined by U.S. federal and state tax laws.

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

### **Liquidity, Capital Resources and Financial Condition**

We have prepared the accompanying consolidated financial statements on a going concern basis, which assumes that we will realize our assets and satisfy our liabilities in the normal course of business. However, we have incurred net losses since our inception, had negative operating cash flows and had an accumulated deficit of \$381.4 million as of December 31, 2016, \$65.8 million of which has been accumulated since January of 2011, when we began our focus on bacteriophage development. These circumstances raise substantial doubt about our ability to continue as a going concern. The accompanying financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty concerning our ability to continue as a going concern.

We had cash and cash equivalents of \$5.7 million and \$9.4 million at December 31, 2016 and 2015, respectively.

### *Operating activities*

Net cash used in operating activities for the year ended December 31, 2016 was \$10.6 million. Net loss recorded during the year ended December 31, 2016 was \$18.8 million, inclusive of a \$4.5 million non-cash gain on derivative liabilities and a non-cash impairment charge of \$9.5 million. Net cash used in operating activities for the year ended December 31, 2015 was \$9.8 million. We recorded net loss for year ended December 31, 2015 of \$0.5 million, including a non-cash gain on warrant liability of \$0.6 million, a non-cash gain on Series B preferred stock derivative liability of \$9.3 million. The net increase in cash used in operating activities of \$0.8 million from year 2015 to year 2016 is primarily related to an increase in research and development expenses, compensation costs, professional services costs, as well as the non-cash gain in derivative liability noted above.

*Investing activities*

Net cash used in investing activities was \$0.3 million and \$0.2 million for the years ended December 31, 2016 and December 31, 2015, respectively. Net cash used in investing activities for the year ended December 31, 2016 and 2015 was primarily attributable to the leasehold improvements and the purchase of equipment for our Slovenia manufacturing facility.

*Financing activities*

Cash provided by financing activities for the year ended December 31, 2016 totaled \$7.2 million, and was comprised of the gross proceeds of \$5.0 million from the June 2016 registered direct offering, and \$4.0 million from the November 2016 follow on public offering, less offering costs paid. Cash provided by financing activities for the year ended December 31, 2015 totaled \$12.8 million, and was comprised of the gross proceeds of \$13.0 million from the March 2015 private placement of common stock and warrants to purchase common stock, less \$0.6 million of commissions and other cash expenses related to the issuance. We also received \$0.4 million in proceeds from the exercise of warrants during 2015.

**Future Capital Requirements**

We believe our existing resources are sufficient to fund our planned operations through mid-April 2017. This estimate is based on our current product development timelines, projected staffing expenses, working capital requirements, and capital expenditure plans. Our estimate may ultimately prove incorrect or changed circumstances may result in the depletion of our capital resources more rapidly than we currently anticipate. We will need to raise additional capital to continue to fund our future operations. 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 seeking regulatory approvals;

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

- the costs of lawsuits involving us or our product candidates.

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

- the public equity market;

- private equity financings;

- collaborative arrangements;

- licensing arrangements; and/or

- public or private debt.

Our ability to raise additional funds will depend in part on the success of our preclinical studies and clinical trials and other product development activities, regulatory events, our ability to identify and enter into in-licensing or other strategic arrangements, and other events or conditions that may affect our value or prospects, as well as, 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 acceptable terms. If we are unable to secure additional funds on a timely basis or on acceptable terms we may be required to defer, reduce or eliminate significant planned expenditures, restructure, curtail or eliminate some or all of our development programs or other operations, dispose of technology or assets, pursue an acquisition of our company by a third party at a price that may result in a loss on investment for our stockholders, enter into arrangements that may require us to relinquish rights to certain of our product candidates, technologies or potential markets, file for bankruptcy or cease operations altogether. Any of these events could have a material adverse effect on our business, financial condition and results of operations. Moreover, if we are unable to obtain additional funds on a timely basis, there will be substantial doubt about our ability to continue as a going concern and increased risk of insolvency and loss of investment by our stockholders. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities could result in dilution to our existing stockholders.



## **Critical Accounting Policies and Use of Estimates**

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

### ***Goodwill***

The Company accounts for goodwill in accordance with provisions in ASC 350, Goodwill and Other Intangible Assets, which require that goodwill be tested for impairment at least annually. Goodwill is not amortized, but is reviewed for impairment annually or more frequently if indicators of impairment are present. We determine whether goodwill may be impaired by comparing the carrying value of our single reporting unit, including goodwill, to the fair value of the reporting unit. If the fair value is less than the carrying amount, a more detailed analysis is performed to determine whether goodwill is impaired. The impairment loss, if any, is measured as the excess of the carrying value of the goodwill over the implied fair value of the goodwill and is recorded in our consolidated statements of operations.

The Company estimated the fair value in step one of the goodwill impairment test based on the income approach which included discounted cash flows. The fair value measurements utilized to perform the impairment analysis are categorized within Level 3 of the fair value hierarchy. Significant management judgment is required in the forecast of future operating results that are used in the Company's impairment analysis. The estimates the Company used are consistent with the plans and estimates that it uses to manage its business. Significant assumptions utilized in the Company's income approach model included the probability of success of our research and development programs, timing of commercialization of these programs, as well as anticipated growth rates.

The Company's discounted cash flows required management judgment with respect to forecasted sales, launch of new products, gross margins, selling, general and administrative expenses, and capital expenditures and the selection and use of an appropriate discount rate. For purposes of calculating the discounted cash flows, the Company estimated future revenue based on projected commercialization time, market penetration rate and probabilities of success for each of the research and development programs. Future cash flows were then discounted to present value at a discount

rate of 16.8%. Terminal value is not incorporated in the analysis due to the nature of the pharmaceutical and bioscience products. The Company's market capitalization was also considered in assessing the reasonableness of the Company's fair value as determined in step one of the goodwill impairment test. The Company's assessment resulted in a fair value that was lower than the Company's carrying value of net assets at December 31, 2016.

Based upon step one of the impairment test, the Company determined that its goodwill was impaired and that step two of the test was required to measure the amount of goodwill impairment. As a result of step two, the Company recorded a charge of \$7.6 million, representing the write-off of the entire balance of goodwill, within loss from operations in the statement of operation during the year ended December 31, 2016.

### ***In Process Research and Development***

In Process Research & Development assets represent capitalized incomplete research projects that we acquired through business combinations. Such assets are initially measured at their acquisition date fair values, and accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of research and development efforts associated with the projects. Upon successful completion of each project, we make a determination as to the then remaining useful life of the intangible asset and begin amortization. We periodically re-evaluate whether continuing to characterize the asset as indefinite-lived is appropriate.

We review our indefinite-lived intangibles, including IPR&D assets, for impairment at least annually. The authoritative accounting guidance provides an optional qualitative assessment for any indicators that indefinite-lived intangible assets are impaired. If it is determined that it is more likely than not that the indefinitely-lived intangible assets, including IPR&D, are impaired, fair value of the indefinite-lived intangible assets is compared with the carrying amount and impairment is recorded for any excess of the carrying amount over the fair value of the indefinite-lived intangible assets.

The Company estimated the fair value of our IPR&D assets based on the income approach which included discounting expected net cash flows associated with the assets to a net present value. The fair value measurements utilized to perform the impairment analysis of IPR&D are categorized within Level 3 of the fair value hierarchy. Significant management judgment is required in the forecast of future operating results that are used in the Company's impairment analysis. The estimates the Company used are consistent with the plans and estimates that it uses to manage its business. Significant assumptions utilized in the Company's income approach model included timing of clinical studies and regulatory approvals, the probability of success of our research and development programs, timing of commercialization of these programs, forecasted sales, gross margin, selling, general and administrative expenses, capital expenditures, as well as anticipated growth rates. Management also determined that 16.8% was an appropriate discount rate to estimate the fair value of our IPR&D assets.

As a result of the impairment analysis performed, management concluded that our IPR&D assets of \$5.2 million related to the 2012 acquisition of SPH's know-how and phage libraries which are being utilized in our lead product

candidate for development of a treatment for *S. aureus* infections was not impaired. Our IPR&D assets of \$7.3 million related to the 2011 acquisition of Biocontrol's know-how and phage library, which are being utilized in the development of our treatment of *P. aeruginosa* infections, were impaired. The Company recorded an impairment charge of \$2.0 million, representing the excess of carrying amount over the fair value, within loss from operations for the year ended December 31, 2016.

### *Stock-Based Compensation Expenses*

We use the fair value method to account for share-based payments in accordance with the authoritative guidance for share-based compensation. The fair value of each option award is estimated on the date of grant using a Black-Scholes-Merton option pricing model (Black-Scholes model) that uses assumptions regarding a number of complex and subjective variables, such as expected term and volatility. Changes in these assumptions may lead to variability with respect to the amount of expense we recognize in connection with share-based payments.

### *Warrant and Derivative Liability*

We account for warrants and derivatives under the guidance of ASC 480, Distinguishing Liabilities from Equity, and ASC 815, Derivatives and Hedging, which require that warrants and derivatives classified as liabilities should be recorded at fair value and such fair value updated at each reporting period. We estimate liability classified instruments using a Monte Carlo valuation model and Black Scholes model, which require us to develop assumptions and inputs that have significant impact on such valuations. As a result of the revaluation of these liabilities to fair value at each reporting date, we recorded gains of \$4.5 million and \$9.9 million for the years ended December 31, 2016 and 2015, respectively.

### **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.” We have irrevocably elected 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. As an “emerging growth company” we are not be required to, among other things, (i) provide an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding a supplement to the auditor’s report providing additional information about the audit and the financial statements (auditor discussion and analysis) and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer’s compensation to median employee compensation. These exemptions will apply until the earliest to occur of (i) the last day of the fiscal year (a) following the fifth anniversary of our initial public offering conducted after we became a reporting company under the Exchange Act pursuant to our registration statement on Form 10 (File No. 000-23930), (b) in which we have total annual gross revenue of at least \$1.0 billion or (c) in which we are deemed to be a “large accelerated filer” under the Exchange Act, which means that the market value of our common stock that is held by non-affiliates exceeds \$700

million as of June 30th of the prior year, and (ii) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

### **Off-Balance Sheet Arrangements**

As of December 31, 2016, 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.

### **Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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

### **Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**AMPLIPHI BIOSCIENCES CORPORATION**

**INDEX TO AUDITED CONSOLIDATED FINANCIAL STATEMENTS**

**AmpliPhi Biosciences Corporation**

<u>Report of Independent Registered Public Accounting Firm</u>	F-1
<u>Consolidated Balance Sheets as of December 31, 2016 and 2015</u>	F-2
<u>Consolidated Statements of Operations for the Years Ended December 31, 2016 and 2015</u>	F-3
<u>Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity for the Years Ended December 31, 2016 and 2015</u>	F-4
<u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2016 and 2015</u>	F-5
<u>Notes to Consolidated Financial Statements for the Years Ended December 31, 2016 and 2015</u>	F-6

## **Report of Independent Registered Public Accounting Firm**

### **The Board of Directors and Shareholders of AmpliPhi Biosciences Corporation**

We have audited the accompanying consolidated balance sheets of AmpliPhi Biosciences Corporation as of December 31, 2016 and 2015, and the related consolidated statements of operations, redeemable convertible preferred stock and stockholders' equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of AmpliPhi Biosciences Corporation at December 31, 2016 and 2015, and the consolidated results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has recurring losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

San Diego, California

March 27, 2017

F-1



**AmpliPhi Biosciences Corporation****Consolidated Balance Sheets**

	December 31, 2016	December 31, 2015
Assets		
Current assets		
Cash and cash equivalents	\$ 5,711,000	\$ 9,370,000
Accounts receivable, net	25,000	125,000
Prepaid expenses and other current assets	619,000	521,000
Total current assets	6,355,000	10,016,000
Property and equipment, net	1,072,000	1,131,000
In process research and development	10,461,000	12,446,000
Acquired patents, net	307,000	338,000
Goodwill	-	7,562,000
Total assets	\$ 18,195,000	\$ 31,493,000
Liabilities, Series B redeemable convertible preferred stock and stockholders' equity		
Current liabilities		
Accounts payable and accrued expenses	\$ 1,659,000	\$ 1,044,000
Deferred revenue	-	245,000
Accrued compensation	895,000	728,000
Dividends payable	38,000	368,000
Insurance premium liability	185,000	-
Note payable (Note 8)	803,000	-
Total current liabilities	3,580,000	2,385,000
Derivative liabilities	2,443,000	1,499,000
Deferred tax liability	2,449,000	3,005,000
Total liabilities	8,472,000	6,889,000
Commitments and Contingencies (Note 8)		
Series B redeemable convertible preferred stock		
\$0.01 par value, 9,357,935 shares authorized at December 31, 2016 and 2015, respectively, no shares and 7,527,853 shares issued and outstanding at December 31, 2016 and 2015, respectively (liquidation preference of \$0 and \$13,383,000 at December 31, 2016 and 2015, respectively)	-	11,890,000
Stockholders' equity		
Common stock, \$0.01 par value, 670,000,000 shares authorized at December 31, 2016 and 2015, 16,488,120 and 5,883,503 shares issued and outstanding at December 31, 2016 and 2015, respectively	165,000	59,000

Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

Additional paid-in capital	390,918,000	375,177,000
Accumulated deficit	(381,360,000)	(362,522,000)
Total stockholders' equity	9,723,000	12,714,000
Total liabilities, Series B redeemable convertible preferred stock and stockholders' equity	\$ 18,195,000	\$ 31,493,000

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

F-2

**AmpliPhi Biosciences Corporation****Consolidated Statements of Operations**

	Year Ended December 31,	
	2016	2015
Revenues	\$260,000	\$475,000
Operating expenses		
Research and development	5,678,000	3,992,000
General and administrative	8,413,000	6,710,000
Impairment charges	9,547,000	-
Total operating expenses	23,638,000	10,702,000
Loss from operations	(23,378,000)	(10,227,000)
Other income (expense)		
Change in fair value of derivative liabilities	4,538,000	9,940,000
Other expenses	(554,000 )	(302,000 )
Total other income, net	3,984,000	9,638,000
Loss before income taxes	(19,394,000)	(589,000 )
Income tax benefit	556,000	73,000
Net loss	(18,838,000)	(516,000 )
Excess of fair value of consideration transferred on conversion of Series B redeemable convertible preferred stock	(3,580,000 )	-
Accretion of Series B redeemable convertible preferred stock	(1,858,000 )	(10,278,000)
Net loss attributable to common stockholders	\$(24,276,000)	\$(10,794,000)
Per share information:		
Net loss per share of common stock - basic & diluted	\$(2.47 )	\$(1.99 )
Weighted average number of shares of common stock outstanding - basic & diluted	9,838,455	5,411,204

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

## AmpliPhi Biosciences Corporation

## Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity

	Redeemable Convertible Preferred Stock		Stockholders' Equity		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Series B Shares	Amount	Common Stock Shares	Amount			
Balances, December 31, 2014	8,671,040	\$1,990,000	3,983,182	\$40,000	\$365,403,000	\$(362,006,000)	\$3,437,000
Net loss	-	-	-	-	-	(516,000)	(516,000)
Accretion of dividends on Series B redeemable convertible preferred stock	-	1,307,000	-	-	(1,307,000)	-	(1,307,000)
Accretion to redemption value of Series B redeemable convertible preferred stock	-	8,971,000	-	-	(8,971,000)	-	(8,971,000)
Conversion of Series B redeemable convertible preferred stock to common stock	(1,143,187)	(378,000)	228,637	2,000	1,504,000	-	1,506,000
Common stock issued in March 2015 financing, net of offering costs	-	-	1,575,758	16,000	8,250,000	-	8,266,000
Warrants exercised	-	-	56,645	1,000	1,072,000	-	1,073,000
Warrants reclassified from liabilities	-	-	-	-	5,462,000	-	5,462,000

Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

to equity due to amendment of warrants							
Warrants reclassified from liabilities to equity due to increase in authorized shares	-	-	-	-	3,281,000	-	3,281,000
Exercise of common stock options and other	-	-	39,281	-	-	-	-
Stock-based compensation	-	-	-	-	479,000	-	479,000
Stock-based compensation - severance	-	-	-	-	4,000	-	4,000
Balances, December 31, 2015	7,527,853	11,890,000	5,883,503	59,000	375,177,000	(362,522,000)	12,714,000
Net loss	-	-	-	-	-	(18,838,000 )	(18,838,000)
Accretion of dividends on Series B redeemable convertible preferred stock	-	365,000	-	-	(365,000 )	-	(365,000 )
Accretion to redemption value of Series B redeemable convertible preferred stock	-	1,493,000	-	-	(1,493,000 )	-	(1,493,000 )
Conversion of Series B redeemable convertible preferred stock to common stock	(7,527,853)	(13,748,000)	2,359,025	24,000	10,605,000	-	10,629,000
Warrants issued for Novolytics assets	-	-	-	-	204,000	-	204,000
Common stock issued in June 2016	-	-	2,127,660	21,000	2,613,000	-	2,634,000

financing, net of offering costs and warrants Common stock issued in November 2016	-	-	5,335,000	53,000	632,000	-	685,000
financing, net of offering costs and warrants Common stock issued pursuant to anti-dilution rights	-	-	750,206	7,000	1,538,000	-	1,545,000
Common stock issued under the employee stock purchase plan	-	-	32,726	1,000	12,000	-	13,000
Stock-based compensation	-	-	-	-	1,995,000	-	1,995,000
Balances, December 31, 2016	-	\$-	16,488,120	\$165,000	\$390,918,000	\$(381,360,000)	\$9,723,000

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

**AmpliPhi Biosciences Corporation****Consolidated Statements of Cash Flows**

	Year Ended December 31,	
	2016	2015
Operating activities:		
Net loss	\$(18,838,000)	\$(516,000 )
Adjustments required to reconcile net (loss) income to net cash used in operating activities:		
Change in fair value of derivative and warrant liabilities	(4,538,000 )	(9,940,000 )
Impairment charges	9,547,000	-
Stock-based compensation	1,995,000	483,000
Costs related to equity offerings, and other	756,000	213,000
Deferred taxes	(556,000 )	(73,000 )
Noncash Interest expense	6,000	-
Amortization of patents	31,000	31,000
Depreciation expense	338,000	299,000
Gain on re-valuation of liquidated damages liability	-	(120,000 )
Changes in operating assets and liabilities:		
Accounts receivable, net	100,000	(25,000 )
Accounts payable, accrued expenses, deferred revenue and other	298,000	(123,543 )
Accrued compensation	167,000	172,543
Prepaid expenses and other current assets	105,000	(182,000 )
Net cash used in operating activities	(10,589,000)	(9,781,000 )
Investing activities:		
Purchases of property and equipment	(279,000 )	(210,000 )
Net cash used in investing activities	(279,000 )	(210,000 )
Financing activities:		
Proceeds from warrant exercises	-	396,000
Costs of Series B redeemable convertible preferred stock conversion to common stock	(173,000 )	-
Dividend payments	(80,000 )	-
Proceeds from equity offerings, net	7,566,000	12,384,000
Proceeds from stock issuance under employee stock purchase plan	13,000	-
Principal payment on note payable and other financing liability	(117,000 )	-
Net cash provided by financing activities	7,209,000	12,780,000
Net (decrease) increase in cash and cash equivalents	(3,659,000 )	2,789,000
Cash and cash equivalents, beginning of period	9,370,000	6,581,000
Cash and cash equivalents, end of period	\$5,711,000	\$9,370,000
Supplemental disclosure of non-cash financing activities:		
Accretion of Series B redeemable convertible preferred stock	\$1,858,000	\$10,278,000
Fair value of warrant liability upon issuance	\$4,745,000	\$4,210,000
Unpaid offering costs	\$69,000	\$-

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

F-5



## **AmpliPhi Biosciences Corporation**

### **Notes to Consolidated Financial Statements**

**December 31, 2016 and December 31, 2015**

#### **1. Organization and Description of the Business**

AmpliPhi Biosciences Corporation (the “Company”) was incorporated in the state of Washington in 1989 under the name Targeted Genetics Corporation. In February 2011, Targeted Genetics Corporation changed its name to AmpliPhi Biosciences Corporation. The Company is dedicated to developing novel antibacterial therapies called bacteriophage (phage). Phages are naturally occurring viruses that preferentially target and kill their bacterial targets.

#### **2. Liquidity**

The Company has prepared its consolidated financial statements on a going concern basis, which assumes that the Company will realize its assets and satisfy its liabilities in the normal course of business. However, the Company has incurred net losses since its inception and has negative operating cash flows for the years ended December 31, 2016 and 2015. These circumstances raise substantial doubt about the Company’s ability to continue as a going concern. The accompanying financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty concerning the Company’s ability to continue as a going concern.

As of December 31, 2016, the Company had cash and cash equivalents of \$5.7 million. Management believes that its existing resources will be sufficient to fund its planned operations through mid-April 2017. We plan to raise additional capital to support our operations and product development activities in 2017 and beyond. We may seek to raise capital through a variety of sources, including the public equity market, private equity financings, collaborative arrangements, license arrangements, and/or public or private debt. We cannot be certain that we will be able to enter into any such arrangements on reasonable terms, or at all.

The Company’s ability to raise additional funds will depend, in part, on the success of the Company’s preclinical studies and clinical trials and other product development activities, regulatory events, the Company’s ability to identify and enter into in-licensing or other strategic arrangements, and other events or conditions that may affect the value or prospects of the Company, as well as factors related to financial, economic, and market conditions, many of which are beyond the Company’s control. The Company cannot be certain that sufficient funds will be available to it when required or on acceptable terms, if at all. If adequate funds are not available on a timely basis or on acceptable terms, the Company may be required to defer, reduce or eliminate significant planned expenditures, restructure, curtail or

eliminate some or all of its development programs or other operations, dispose of technology or assets, pursue an acquisition of the Company by a third party at a price that may result in a loss on investment for its stockholders, enter into arrangements that may require the Company to relinquish rights to certain of its product candidates, technologies or potential markets, file for bankruptcy or cease operations altogether. Any of these events could have a material adverse effect on the Company's business, financial condition and results of operations and result in a loss of investment to its stockholders.

### **3. Significant Accounting Policies**

#### ***Basis of Presentation***

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries Biocontrol Limited, AmpliPhi d.o.o., and AmpliPhi Australia Pty Ltd. All significant intercompany accounts and transactions have been eliminated.

#### ***Use of Estimates***

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles ("U.S. GAAP") requires management to make estimates and assumptions that affect the amounts reported in its consolidated financial statements and accompanying notes. On an ongoing basis, management evaluates these estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from management's estimates.

#### ***Cash and Cash Equivalents***

Cash and cash equivalents consist primarily of deposits with commercial banks and financial institutions. Cash equivalents include short-term investments that have a maturity at the time of purchase of three months or less, are readily convertible into cash and have an insignificant level of valuation risk attributable to potential changes in interest rates.

***Accounts Receivable***

Accounts receivable amounts are stated at their face amounts less any allowance for doubtful accounts. Provisions for doubtful accounts are estimated based on assessment of the probable collection from specific customer accounts and other known factors. For the years ended December 31, 2016 and 2015, the provisions for doubtful accounts were immaterial.

***Property and Equipment***

Property and equipment consists of computer and laboratory equipment, software, office equipment, furniture and leasehold improvements and is recorded at cost. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred. Upon disposal, retirement, or sale of an asset, the related cost and accumulated depreciation is removed from the accounts and any resulting gain or loss is included in the results of operations. Property and equipment are depreciated on a straight-line basis over their estimated useful lives. The Company's estimated useful life for property and equipment is as follows:

	<b>Estimated Useful Lives</b>
Laboratory equipment	5 – 10 years
Office and computer equipment	3 – 5 years
Leasehold improvements	Shorter of lease term or useful life

The Company reviews long-lived assets for impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparison of the book values of the assets to future net undiscounted cash flows that the assets or the asset groups are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed their fair value, which is measured based on the projected discounted future net cash flows arising from the assets or asset groups. No impairment losses have been recorded since inception.

***Prepaid Expenses and Other Current Assets***

Prepaid expenses and other current assets consist primarily of prepaid insurance, deferred licensing costs and deposits.

## *Goodwill*

The Company accounts for goodwill in accordance with provisions in Accounting Standards Codification (“ASC”) No. 350, Goodwill and Other Intangible Assets, which require that goodwill be tested for impairment at least annually. Goodwill is not amortized, but is reviewed for impairment annually or more frequently if indicators of impairment are present. We determine whether goodwill may be impaired by comparing the carrying value of our single reporting unit, including goodwill, to the fair value of the reporting unit. If the fair value is less than the carrying amount, a more detailed analysis is performed to determine whether goodwill is impaired. The impairment loss, if any, is measured as the excess of the carrying value of the goodwill over the implied fair value of the goodwill and is recorded in our consolidated statements of operations.

The Company’s accounting policy is to perform the annual impairment assessment of goodwill as of December 31 each year. As of December 31, 2016, the Company had a compressed market capitalization, less than the carrying amount of goodwill. The Company estimated the fair value in step one of the goodwill impairment test based on the income approach which included discounted cash flows. The fair value measurements utilized to perform the impairment analysis are categorized within Level 3 of the fair value hierarchy. Significant management judgment is required in the forecast of future operating results that are used in the Company’s impairment analysis. The estimates the Company used are consistent with the plans and estimates that it uses to manage its business. Significant assumptions utilized in the Company’s income approach model included the probability of success of our research and development programs, timing of commercialization of these programs, as well as anticipated growth rates.

The Company’s discounted cash flows required management judgment with respect to forecasted sales, launch of new products, gross margins, selling, general and administrative expenses, and capital expenditures and the selection and use of an appropriate discount rate. For purposes of calculating the discounted cash flows, the Company estimated future revenue based on projected commercialization time, market penetration rate and probabilities of success for each of the research and development programs. Future cash flows were then discounted to present value at a discount rate of 16.8%. Terminal value is not incorporated in the analysis due to the nature of the pharmaceutical and bioscience products. The Company’s market capitalization was also considered in assessing the reasonableness of the Company’s fair value as determined in step one of the goodwill impairment test. The Company’s assessment resulted in a fair value that was lower than the Company’s carrying value of net assets at December 31, 2016.

Based upon step one of the impairment test, the Company determined that its goodwill was impaired and that step two of the test was required to measure the amount of goodwill impairment. As a result of step two, the Company recorded a charge of \$7.6 million, representing the write-off of the entire balance of goodwill, in the operating section of the statement of operations, for the year ended December 31, 2016.

### ***In Process Research and Development***

In Process Research & Development (IPR&D) assets represent capitalized incomplete research projects that we acquired through business combinations. Such assets are initially measured at their acquisition date fair values, and accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of research and development efforts associated with the projects. Upon successful completion of each project, we make a determination as to the then remaining useful life of the intangible asset and begin amortization. We periodically re-evaluate whether continuing to characterize the asset as indefinite-lived is appropriate.

We review our indefinite-lived intangibles, including IPR&D assets, for impairment at least annually. The authoritative accounting guidance provides an optional qualitative assessment for any indicators that indefinite-lived intangible assets are impaired. If it is determined that it is more likely than not that the indefinitely-lived intangible assets, including IPR&D, are impaired, fair value of the indefinite-lived intangible assets is compared with the carrying amount and impairment is recorded for any excess of the carrying amount over the fair value of the indefinite-lived intangible assets.

The Company estimated the fair value of our IPR&D assets based on the income approach which included discounting expected net cash flows associated with the assets to a net present value. The fair value measurements utilized to perform the impairment analysis of IPR&D are categorized within Level 3 of the fair value hierarchy. Significant management judgment is required in the forecast of future operating results that are used in the Company's impairment analysis. The estimates the Company used are consistent with the plans and estimates that it uses to manage its business. Significant assumptions utilized in the Company's income approach model included timing of clinical studies and regulatory approvals, the probability of success of our research and development programs, timing of commercialization of these programs, forecasted sales, gross margin, selling, general and administrative expenses, capital expenditures, as well as anticipated growth rates. Management also determined that 16.8% was an appropriate discount rate to estimate the fair value of our IPR&D assets.

As a result of the impairment analysis performed, management concluded that our IPR&D assets of \$5.2 million related to the 2012 acquisition of SPH's know-how and phage libraries which are being utilized in our lead product candidate for development of a treatment for *S. aureus* infections was not impaired. Our IPR&D assets of \$7.3 million related to the 2011 acquisition of Biocontrol's know-how and phage library, which are being utilized in the development of our treatment of *P. aeruginosa* infections, were impaired. The Company recorded an impairment charge of \$2.0 million, representing the excess of carrying amount over the fair value, within loss from operations for the year ended December 31, 2016.

### ***Patents***

Patents are recorded at fair value and are amortized using the straight-line method over their estimated useful lives. As of December 31, 2016, the gross amount of our patent assets was \$493,000 with accumulated amortization of \$186,000. Annual patent amortization expense for the next five years and thereafter are estimated as follows:

	Patent Amortization
2017	\$ 31,000
2018	31,000
2019	31,000
2020	31,000
2021	31,000
Thereafter through December 2026	152,000
Total patent amortization expense	\$ 307,000

### ***Stock-Based Compensation***

The Company records compensation expense associated with stock options in accordance with the authoritative guidance for stock-based compensation. The cost of employee services received in exchange for an award of an equity instrument is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense on a straight-line basis, net of estimated forfeitures, over the requisite service period of the award. Share-based compensation expense recognized during the period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period. Share-based compensation expense for an award with a performance condition is recognized when the achievement of such performance condition is determined to be probable. If the outcome of such performance condition is not determined to be probable or is not met, no compensation expense is recognized and any previously recognized compensation expense is reversed. Share-based compensation expense recognition is based on awards ultimately expected to vest and is reduced for estimated forfeitures. The authoritative guidance requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

### ***Warrants, Preferred Shares Conversion Feature and Derivative Liabilities***

The Company accounts for warrants and derivative instruments and preferred shares conversion feature under the applicable accounting guidance which requires the warrant and the preferred share features to be recorded as liabilities and adjusted to fair value at each reporting period. Changes in fair value of warrant and derivative liabilities are recorded as non-operating income or loss in the consolidated statements of operations.

### ***Foreign Currency Translations and Transactions***

The functional currency of our wholly owned subsidiaries is the U.S. dollar.

### ***Revenue Recognition***

The Company generates revenue from sub-licensing agreements from our former gene therapy program. Revenue under technology licenses typically consists of nonrefundable, up-front license fees, technology access fees, royalties on product sales, and various other payments. The Company classifies advance payments received in excess of amounts earned as deferred revenue.

### ***Research and Development Costs***

Research and development costs include salaries, costs of outside collaborators and outside services, allocated facility, occupancy and utility expenses, which are partially offset by the benefit of Australian government tax rebates. The Company expenses research and development costs as incurred.

### ***Income Taxes***

We utilize the asset and liability method of accounting for income taxes. Deferred income taxes are recognized for the future tax consequences of temporary differences using enacted statutory tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Temporary differences include the difference between the financial statement carrying amounts and the tax bases of existing assets and liabilities and operating loss and tax credit carryforwards. The effect on deferred taxes of a change in tax rates is recognized in income in the period that includes the enactment date. We assess the likelihood that our deferred tax assets will be recovered from future taxable income. Valuation allowances are provided if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

Our income tax returns are based on calculations and assumptions that are subject to examination by the Internal Revenue Service and other tax authorities. In addition, the calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax regulations. We recognize liabilities for uncertain tax positions based

on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. As of December 31, 2016 and 2015, the Company has unrecognized tax benefits related to its domestic research tax credits of approximately \$2.1 million and \$2.1 million, respectively.

### ***Basic and Diluted Net (Loss) Income per Common Share***

Basic net (loss) income per common share is computed by dividing the net (loss) income attributable to common stockholders, less the impact under the two-class method of the preferred stockholders' participation rights in the Company's undistributed earnings, by the weighted average number of common shares outstanding during the period, excluding the dilutive effect of preferred stock, warrants to purchase common stock, and stock options.

Diluted net (loss) income per share of common stock is computed by dividing 1) the net (loss) income attributable to common stockholders, adjusted by income (loss) related to potential diluted preferred stock and warrants to purchase shares of our common stock by the sum of 2) the weighted average number of shares of common stock outstanding during the period plus the potential dilutive effects of preferred stock, warrants to purchase common stock, stock options outstanding during the period calculated in accordance with the treasury stock method, and any additional dilutive instruments, although these shares, options and warrants and dilutive instruments are excluded if their effect is anti-dilutive.

### ***Reverse Stock Split***

On August 3, 2015, the Company filed Articles of Amendment to Amended and Restated Articles of Incorporation with the Secretary of State of the State of Washington that effected a 1-for-50 (1:50) reverse stock split of its common stock, par value \$0.01 per share, effective August 7, 2015. On August 3, 2015, the Company also increased its authorized common stock from 445,000,000 to 670,000,000 shares. The par value of its common stock was unchanged at \$0.01 per share, post-split. All warrant, stock option, and per share information in the consolidated financial statements gives retroactive effect to the 1-for-50 reverse stock split that was effected on August 7, 2015.

### ***Reclassification***

Certain prior period amounts have been reclassified to conform to the current period presentation.



F-9

### ***Recent Accounting Pronouncements***

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The ASU creates a single source of revenue guidance for companies in all industries. The new standard provides guidance for all revenue arising from contracts with customers and affects all entities that enter into contracts to provide goods or services to their customers, unless the contracts are within the scope of other accounting standards. It also provides a model for the measurement and recognition of gains and losses on the sale of certain nonfinancial assets. This guidance, as amended, must be adopted using either a full retrospective approach for all periods presented or a modified retrospective approach and will be effective for fiscal years beginning after December 15, 2017 with early adoption permitted. The Company plans to adopt this ASU on January 1, 2018, and is in the process of evaluating the impact of adopting the guidance on its consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, which defines management's responsibility to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures if there is substantial doubt about its ability to continue as a going concern. The pronouncement is effective for annual reporting periods ending after December 15, 2016 with early adoption permitted. The Company adopted this ASU as of December 31, 2016 and conformed its footnote disclosure in accordance with the disclosure requirements under this standard.

In February 2015, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which amends the FASB Accounting Standards Codification and creates Topic 842, "Leases." The new topic supersedes Topic 840, "Leases," and increases transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and requires disclosures of key information about leasing arrangements. The guidance is effective for reporting periods beginning after December 15, 2018. ASU 2016-02 mandates a modified retrospective transition method. The Company has not yet evaluated the potential impact of adopting the guidance on its consolidated financial statements.

In November 2015, the FASB issued ASU 2015-17, *Balance Sheet Classification of Deferred Taxes*. The ASU is part of a simplification initiative aimed at reducing complexity in accounting standards. Current U.S. GAAP requires the deferred taxes for each jurisdiction (or tax-paying component of a jurisdiction) to be presented as a net current asset or liability and net noncurrent asset or liability. To simplify presentation, the new guidance requires that all deferred tax assets and liabilities, along with any related valuation allowance, be classified as noncurrent on the balance sheet. The standard is effective for public entities for annual reporting periods beginning after December 15, 2016, and interim periods therein. Early adoption is permitted. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which amends Accounting Standards Codification (“ASC”) Topic 718, Compensation - Stock Compensation. ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. The Company is in the process of evaluating the potential impact of adopting the guidance on its consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, *Cash Flow Statements, Classification of Certain Cash Receipts and Cash Payments*, which addresses eight specific cash flow classification issues with the objective of reducing diversity in practice. The amendments are effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, *Intangibles – Goodwill and Other, Simplifying the Accounting for Goodwill Impairment*. ASU 2017-04 removes Step 2 of the goodwill impairment test, which requires a hypothetical purchase price allocation. A goodwill impairment will now be the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the carrying amount of goodwill. All other goodwill impairment guidance will remain largely unchanged. Entities will continue to have the option to perform a qualitative assessment to determine if a quantitative impairment test is necessary. This new guidance will be applied prospectively, and is effective for calendar year end companies in 2020. Early adoption is permitted for any impairment tests performed after January 1, 2017. Adoption of this ASU is not expected to have a material impact on the Company's consolidated financial statements.

#### **4. Fair Value of Financial Assets and Liabilities – Derivative Instruments**

ASC Topic 820, *Fair Value Measurement* (ASC 820), establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances.

ASC 820 identifies fair value as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tier fair value hierarchy that distinguishes among the following:

Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access.

Level 2—Valuations based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly.

Level 3—Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

The Company estimates fair values of derivative instruments utilizing Level 3 inputs, which is based on the lowest level of any input that is significant to the fair value measurement. The Company uses the Monte Carlo and Black Scholes valuation technique for derivatives which embodies all of the requisite assumptions (including trading volatility, remaining term to maturity, market price, strike price, risk free rates) necessary to determine fair value of these instruments.

The Company's derivative liabilities are marked-to-market with the changes in fair value recorded as a component of change in fair value of derivative liabilities in the Company's consolidated statements of operations. Estimating fair values of derivative financial instruments, including Level 3 instruments, requires the use of significant and subjective inputs that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. In addition, option-based techniques are volatile and sensitive to changes in our trading market price, the trading market price of various peer companies and other key assumptions. Since derivative financial instruments are initially and subsequently carried at fair value, our income will reflect this sensitivity of internal and external factors.

Items measured at fair value on a recurring basis include common stock warrants, and embedded derivatives related to the Company's redeemable convertible preferred stock, and a dilutive financing derivative liability established on April 8, 2016. During the periods presented, the Company has not changed the manner in which it values liabilities that are measured at fair value using Level 3 inputs. The following fair value hierarchy table presents information about each major category of the Company's financial liabilities measured at fair value on a recurring basis:

	Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
December 31, 2016				
Liabilities				
June 2016 offering warrant liability	\$ -	\$ -	\$ 274,000	\$274,000
Dilutive financing derivative liability	-	-	126,000	126,000
November 2016 offering warrant liability	-	-	2,043,000	2,043,000
Total liabilities	\$ -	\$ -	\$ 2,443,000	\$2,443,000

December 31, 2015

Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

Liabilities

Series B preferred stock derivative liability	\$	-	\$	-	\$ 1,493,000	\$ 1,493,000
2011 Warrant liability		-		-	6,000	6,000
Total liabilities	\$	-	\$	-	\$ 1,499,000	\$ 1,499,000

There were no transfers between Level 1, Level 2 or Level 3 of the fair value hierarchy for the years ended December 31, 2016 and 2015.

The following table sets forth a summary of changes in the fair value of the Company's Series B redeemable convertible preferred stock derivative, warrant liabilities and dilutive financing liability, which represents a recurring measurement that is classified within Level 3 of the fair value hierarchy, wherein fair value is estimated using significant unobservable inputs.

	2011 Warrant Liability	June 2016 Offering Warrant Liability	Series B Preferred Stock Derivative Liability	Dilutive Financing Derivative Liability	November 2016 Offering Warrant Liability
Balance, December 31, 2015	\$ 6,000	\$ -	\$ 1,493,000	\$-	\$ -
Creation of derivative or warrant liability	-	1,816,000	-	2,282,000	2,929,000
Changes in estimated fair value	(6,000 )	(1,542,000 )	(1,493,000 )	(611,000 )	(886,000 )
Payout from liability	-	-	-	(1,545,000)	-
Balance, December 31, 2016	\$ -	\$ 274,000	\$ -	\$ 126,000	\$ 2,043,000

The fair value of the November 2016 offering warrant liability on the date of issuance and on December 31, 2016 was estimated using the Monte Carlo valuation model. This method of valuation involves using inputs such as the fair value of the Company's common stock, stock price volatility, contractual term of the warrants, risk-free interest rates and dividend yields. Due to the nature of these inputs, the valuation of the warrant is considered a Level 3 measurement. The following assumptions were used on November 22, 2016 (issuance date) and December 31, 2016:

	December 31, 2016		November 22, 2016	
Volatility	112	%	116	%
Expected term (years)	4.89		5.00	
Risk-free interest rate	1.91	%	1.77	%
Dividend yield	0.00	%	0.00	%
Exercise price	\$ 0.75		\$ 0.75	
Common stock closing price	\$ 0.44		\$ 0.62	

The fair value of the June 2016 offering warrant liability on the date of issuance and on each re-measurement date was estimated using the Black-Scholes valuation model. This method of valuation involves using inputs such as the fair value of the Company's common stock, stock price volatility, risk-free interest rates and dividend yields. Due to the nature of these inputs, the valuation of the warrants is considered a Level 3 measurement. The following assumptions were used on June 3, 2016 (issuance date) and December 31, 2016:

	December 31, 2016		June 3, 2016	
Volatility	118	%	123	%
Expected term (years)	4.42		5.00	
Risk-free interest rate	1.80	%	1.23	%
Dividend yield	0.00	%	0.00	%
Exercise price	\$ 2.25		\$ 2.25	
Common stock closing price	\$ 0.44		\$ 2.06	

The dilutive financing derivative liability was recorded on the accompanying consolidated balance sheet at its initial value on April 8, 2016 and is marked-to-market at each balance sheet date until the liability is relieved. The fair value of the dilutive financing derivative liability on each measurement date is estimated using the Monte Carlo valuation model. For this liability, the Company develops its own assumptions that do not have observable inputs or available market data to support the fair value. This method of valuation involves using inputs such as the fair value of the Company's common stock, stock price volatility, expected future financings, risk-free interest rates and dividend yields. Due to the nature of these inputs, the valuation of future potential dilutive financings is considered a Level 3 measurement. The following assumptions were used to value the dilutive financing derivative liability from the inception date of April 8, 2016 through September 30, 2016:

Volatility	108 to 121	%
------------	------------	---

Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

Expected term (years), weighted average	1.75 to 2.23	
Risk-free interest rate	0.58 to 0.79	%
Dividend yield	0.00	%
Stock price dilutive limit	\$2.35 to \$4.05	
Common stock closing price	\$1.52 to \$3.68	

From April 8, 2016, the date of the Common Stock Issuance Agreement (“CSIA”) through December 31, 2016, the Company raised capital from issuance of common stock and related warrants for gross proceeds of approximately \$9.0 million that were dilutive in accordance with the provisions of the CSIA agreement. The Company issued 750,206 shares in June 2016 to the parties to the CSIA and the Company became obligated to issue additional common shares to the parties to the CSIA in connection with a financing transaction completed by the Company in November 2016. The maximum number of shares that the Company could issue under the rules of the NYSE MKT and the terms of the CSIA agreement was 286,846 shares as of December 31, 2016. As of the balance sheet date, the dilutive financing liability was valued at \$126,000, based on the closing market price of the Company’s common stock of \$0.44 per share multiplied by the 286,846 shares available to be issued.

The fair value of the Series B preferred stock derivative liability on each measurement date is estimated using the Monte Carlo valuation model. For this liability, the Company developed its own assumptions that do not have observable inputs or available market data to support the fair value. This method of valuation involves using inputs such as the fair value of the Company’s common stock, stock price volatility, the expected term of the Series B redeemable convertible preferred stock, risk-free interest rates and dividend yields. Due to the nature of these inputs, the valuation of the Series B redeemable convertible preferred stock conversion liability is considered a Level 3 measurement. On April 8, 2016, all outstanding Series B preferred stock was converted into common stock, and the remaining Series B preferred stock derivative liability balance of \$91,000 was reversed and recorded as a gain in derivative liability on the Company’s consolidated statements of operations in the second quarter of 2016. The following assumptions were used at December 31, 2015:

Volatility	108 to 117 %
Expected term (years), weighted average	0.50 to 2.50
Risk-free interest rate	0.49 to 1.19 %
Dividend yield	0.00 %
Exercise price	\$7.00
Common stock closing price	\$3.98

## 5. Net Loss per Common Share

The following table sets forth the computation of basic and diluted net loss per common share for the periods indicated:

	Year Ended December 31,	
	2016	2015
Basic and diluted net loss per common share calculation:		
Net loss	\$(18,838,000)	\$(516,000 )
Excess of fair value of consideration transferred on conversion of Series B redeemable convertible preferred stock	(3,580,000 )	-
Accretion of Series B redeemable convertible preferred stock	(1,858,000 )	(10,278,000)
Net loss attributable to common stockholders - basic & diluted	\$(24,276,000)	\$(10,794,000)
Weighted average common shares outstanding - basic & diluted	9,838,455	5,411,204
Net loss per share of common stock - basic & diluted	\$(2.47 )	\$(1.99 )

The weighted average number of common shares outstanding for the basic loss per share calculation for the year ended December 31, 2016 included 286,846 shares that the Company was obligated to issue under the provisions of the CSIA agreement (Note 10 ) as of December 31, 2016.

The following outstanding securities at December 31, 2016 and 2015 have been excluded from the computation of diluted weighted average shares outstanding for the years ended December 31, 2016 and 2015, as they would have been anti-dilutive:

	Year Ended December 31,	
	2016	2015
Options	748,938	669,769
Warrants	7,751,376	656,211
Series B redeemable convertible preferred stock	-	7,527,853



Total	8,500,314	8,853,833
-------	-----------	-----------

F-13

## 6. Property and Equipment

Property and equipment consist of the following:

	December 31,	
	2016	2015
Laboratory equipment	\$1,747,000	\$1,494,000
Office and computer equipment	69,000	53,000
Leasehold improvements	188,000	188,000
Total	2,004,000	1,735,000
Less: accumulated depreciation and amortization	(932,000 )	(604,000 )
Property and equipment, net	\$1,072,000	\$1,131,000

Depreciation expense totaled \$338,000 and \$299,000 for the years ended December 31, 2016 and 2015, respectively.

## 7. Income Taxes

For financial reporting purposes, (loss) income from continuing operations before income taxes includes the following components:

	December 31,	
	2016	2015
United States	\$(6,358,000 )	\$1,818,000
Foreign	(13,036,000)	(2,407,000)
Total	\$(19,394,000)	\$(589,000 )

Our income tax benefit consists of the following components for 2016 and 2015:

	December 31,	
	2016	2015
Current		
Federal	\$-	\$-
State	-	-
Foreign	-	-
	-	-

Deferred	-	-
Federal	-	-
State	-	-
Foreign	(556,000)	(73,000)
	(556,000)	(73,000)
Total	\$(556,000)	\$(73,000)

Significant components of our deferred tax assets and liabilities are as follows:

	December 31,	
	2016	2015
Deferred tax assets/(liabilities)		
Net operating loss carry-forwards	\$67,479,000	\$65,425,000
Research and orphan drug credit carry-forwards	3,109,000	5,181,000
Depreciation and amortization	4,000	(3,000 )
Stock options and other	1,010,000	479,000
Intangible assets	(2,367,000 )	(3,079,000 )
Net deferred tax assets	69,235,000	68,003,000
Valuation allowance for deferred tax assets	(71,684,000)	(71,008,000)
Net deferred tax liabilities	\$(2,449,000 )	\$(3,005,000 )

At December 31, 2016, the Company had U.S. gross net operating loss carry-forwards, or “NOLs”, of approximately \$190.7 million, foreign NOLs of \$8.9 million, \$0.3 million of which was generated in 2016 and domestic research tax credit carry-forwards of approximately \$3.1 million, net of a reserve for uncertain tax positions. The carry-forwards may be further subject to the application of Section 382 of the Internal Revenue Code of 1986 or the “Code”, as discussed further below. The NOL carry-forwards will begin to expire in 2018. The domestic research tax credit carry-forward will begin to expire in 2018. The Company has provided a valuation allowance to offset the deferred tax assets due to the uncertainty of realizing the benefits of the net deferred tax asset.

	December 31,	
	2016	2015
Percent of pre-tax income:		
U.S. federal statutory income tax rate	34.0 %	34.0 %
Warrant liability and preferred stock conversion liability	8.0 %	573.8 %
Difference in foreign vs U.S. statutory rates	(1.5 )%	(21.8 )%
Stock option forfeitures & expirations	(0.6 )%	(138.2)%
State taxes, net of federal benefit	(3.8 )%	- %
Non-deductible stock issuance costs	(1.0 )%	(17.9 )%
Australia Refundable R&D tax offset	(5.2 )%	27.8 %
Effect of tax rate changes	0.3 %	12.4 %
Goodwill Impairment	(13.2)%	- %
Change in reserve of uncertain tax positions	(10.7)%	- %
All other	0.1 %	(2.9 )%
Subtotal	6.4 %	467.2 %
Change in valuation allowance	(3.5 ))%	(454.8)%
Effective income tax rate	2.9 %	12.4 %

We recorded an income tax benefit of \$0.6 million in the year ended December 31, 2016, comprised of a \$0.4 million income tax benefit related to a reduction of the existing deferred tax liability as a result of a \$2.0 impairment charge for our IPR&D asset discussed above, and a \$0.2 million income tax benefit as a result of reduction of deferred tax liability resulting from changes in UK enacted tax rates from 20% to 17% in 2016.

The Company’s past sales and issuances of common and preferred stock have likely resulted in ownership changes as defined by Section 382 of the Code. The Company has not conducted a Section 382 study to date. It is possible that a future analysis may result in the conclusion that a substantial portion, or perhaps substantially all, of the NOLs and credits will expire due to the limitations of Sections 382 and 383 of the Code. As a result, the utilization of the NOLs and tax credits may be limited and a portion of the carry-forwards may expire unused.

The Company has unrecognized tax benefits of approximately \$2.1 million related to its domestic research tax credits as of December 31, 2016. The credits are subject to a valuation allowance and thus, any change to the uncertain tax position reserve would not result in an income tax benefit or expense.

The Company is subject to U.S. federal tax examinations by tax authorities for the years 1998 to 2015 due to the fact that NOLs exist going back to 1998 that may be utilized on a current or future year tax return.

The Company has a policy of recognizing tax related interest and penalties as additional tax expense when incurred. During the years ended December 31, 2016 and 2015, the Company did not recognize any interest or penalties. The Company does not expect its unrecognized tax benefits will change significantly over the next twelve months.

## 8. Commitments and Contingencies

### *Operating Leases*

Rent expense under operating leases was \$227,000 and \$192,000 for the years ended December 31, 2016 and 2015, respectively.

Future minimum lease payments under noncancelable lease agreements as of December 31, 2016, were as follows:

	Operating Leases
2017	\$61,000
2018	38,000
2019	6,000
Total minimum lease payments	\$105,000

The Company entered into an agreement with Virginia Biotechnology Research Partnership Authority for Richmond, Virginia laboratory space. At December 31, 2016, the Company's minimum payment commitment for the Richmond laboratory space was approximately \$14,000.

In June 2015, the Company entered into an agreement with Savills Studley, Inc. for San Diego, California office space. The agreement renews on a monthly basis, until terminated by the Company. At December 31, 2016, the Company's minimum payment commitment for the San Diego office space was approximately \$6,000.

In February 2014, the Company entered into an agreement with Avtotehna d.o.o. for manufacturing and research space in Ljubljana, Slovenia. The lease has a termination date of February 2019, with extension provisions at the option of the Company, and a monthly payment of \$3,128. At December 31, 2016, our minimum payment commitment for the Ljubljana space was approximately \$81,000. In addition, the Company expended \$185,000 in 2014 for leasehold improvements related to this facility. These costs are being amortized on a straight-line basis over the life of the related lease, or the useful life of the asset, whichever is shorter.

### *Legal Proceedings*

On November 12, 2016, we entered into a settlement agreement with NRM VII Holdings I, LLC ("NRM") to settle a complaint filed by NRM in April 2016 against the Company and its members of the board of directors, alleging that the Company breached the implied covenant of good faith and fair dealing by entering into an alleged scheme to force NRM to convert its shares of Series B redeemable convertible preferred stock into shares of our common stock. Pursuant to the settlement agreement, NRM dismissed the allegation with prejudice upon receipt of a cash payment of \$2.0 million, which was paid to NRM by our insurance carrier in November 2016. The settlement agreement contains mutual releases covering all claims that we or our affiliates, or NRM or its affiliates, have or may have against the other party or such other party's affiliates in connection with the allegation or otherwise as of the date of the settlement agreement.

Upon the automatic conversion of NRM's shares of our Series B convertible preferred stock into shares of our common stock on April 8, 2016, we became obligated to pay NRM accrued dividends in the amount of approximately \$914,000. The accrued dividends obligation to NRM was reflected in current liabilities on our consolidated balance sheet at September 30, 2016. Upon NRM's receipt of the \$2.0 million settlement payment described above, our accrued dividends payment obligation to NRM was extinguished. We have agreed to repay our insurance carrier an aggregate amount equal to the accrued dividends, or \$914,000, of which \$100,000 was paid in December 2016, and the remainder of the balance of \$803,000, net of imputed interest, was included in the consolidated balance sheet as of December 31, 2016 as Note Payable, and would be paid as follows: approximately \$205,000 in January 2017, approximately \$305,000 in April 2017 and a final payment of \$305,000 in July 2017. In March 2017, the payment terms of the last two installments of \$305,000 each were modified to be payable in July 2017 and October 2017,

respectively.

## 9. Collaborative and Other Agreements

In June 2013, the Company entered into a Collaborative Research and Development Agreement with the United States Army Medical Research and Materiel Command and the Walter Reed Army Institute of Research. The Collaborative Research and Development Agreement is focused on developing and commercializing bacteriophage therapeutics to treat *S. aureus* infections. During the years ended December 31, 2016 and 2015, the Company recorded no payments to Walter Reed Army Institute of Research under the Collaborative Research and Development Agreement.

In March 2013, the Company entered into an Exclusive Channel Collaboration Agreement with Intrexon Corporation (the "ECC Agreement"). This agreement allowed the Company to utilize Intrexon's synthetic biology platform for the identification, development and production of bacteriophage-containing human therapeutics. The Company paid a one-time technology access fee in 2013 to Intrexon of \$3,000,000 in common stock. Pursuant to the agreement, the Company was required to pay Intrexon, in cash or stock, milestone fees of \$2,500,000 for the initiation and commencement of the first Phase 2 trial and \$5,000,000 upon the first regulatory approval of any product in any major market country. With regard to each product sold by the Company, the Company was required to pay, in cash, tiered royalties on a quarterly basis based on net sales of AmpliPhi Products, calculated on a product-by-product basis. No milestones have been met and no milestone payments have been paid to Intrexon through December 31, 2016. During the year ended December 31, 2016, the Company recorded \$61,000 in expenses under the Exclusive Channel Collaboration Agreement, with cash payments totaling \$117,000. During the year ended December 31, 2015, the Company recorded \$178,000, in expenses under the Exclusive Channel Collaboration Agreement, with cash payments for the year ended December 31, 2015 totaling \$125,000. On April 13, 2016, the Company provided written notice to Intrexon of its election to voluntarily terminate the ECC Agreement. The effective date of the termination was July 12, 2016. As of December 31, 2016, the Company had no liability recorded for amounts due to Intrexon. The Company did not incur any early termination penalties as a result of the termination of the ECC Agreement.

In April 2013, the Company entered into a collaboration agreement with the University of Leicester to develop a phage therapy that targets and kills all toxin types of *C. difficile*. In August 2013, the Company entered into a collaboration agreement with both the University of Leicester and the University of Glasgow to carry out certain animal model development work. Under these agreements, which are referred to collectively as the Leicester Development Agreements, the Company provided payments to the University of Leicester to carry out *in vitro* and to 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. The Company licensed related patents, materials and know-how from the University of Leicester pursuant to a license agreement entered into in September 2013 (the "Leicester License Agreement"). Under the Leicester Development Agreements, the University of Leicester agreed to 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 the Company. Under the Leicester License Agreement, the Company has exclusive rights to certain background intellectual property of the University of Leicester, for which it agreed to pay the University of Leicester royalties based on product sales and make certain milestone payments based on product development. In November 2015 the Company and the University of Leicester entered into a new collaboration agreement in order to renew the parties' collaboration. This collaboration agreement was set to expire on November 12, 2018. In March 2017, the Company provided the 180 days' notice to terminate the collaboration agreement originally entered into in November 2015 with University of Leicester. During the year ended December 31, 2016, the Company recorded \$166,000 in expenses to the University of Leicester under the Leicester Development Agreements, with cash payments totaling \$202,000. During the year ended December 31, 2015, the Company recorded \$265,000 in expenses to the University of Leicester under the Leicester Development Agreements, with cash payments in the amount of \$290,000. During the year ended December 31, 2016, the Company recognized no expenses and made no cash payments to the University of Glasgow under the Leicester Development Agreements. During the year ended December 31, 2015, the Company paid and expensed \$61,000 to the University of Glasgow under the Leicester Development Agreements. In March 2017, the Company provided the 180 days' notice to terminate the collaboration agreement with University of Leicester.

In September 2015, the Company entered into a non-exclusive patent license agreement with Takara Bio Inc. (the Takara Agreement). Under this agreement Takara licensed certain patents from the Company related to AAV1 Vector gene delivery systems, for which the Company is an exclusive licensor with the University of Pennsylvania. The Company received a \$40,000 non-refundable, up-front licensing payment and is entitled to receive royalties from Takara of 12.0% of net license product sales and 6.0% of service revenues associated with the licensed products. The agreement calls for minimum annual royalties of \$15,000 that commenced on February 28, 2016. In addition, the Takara Agreement provides milestone fees to the Company of \$30,000 of the first \$1,000,000 of licensed product revenues by Takara and an additional \$40,000 when cumulative net sales of the licensed product by Takara exceed \$2,000,000. During the year ended December 31, 2016, the Company recognized revenue of \$15,000 under the Takara Agreement. No such revenue was recognized during the year ended December 31, 2015.

## **10. Redeemable Convertible Preferred Stock**

On June 13, 2013, the Company's board of directors approved a resolution designating 9,357,935 shares of Preferred Stock as Series B redeemable convertible preferred stock (Series B) with an initial stated value of \$1.40 per share and par value of \$0.01 per share. As of April 7, 2016, each Series B share was convertible into 0.20 shares of common



stock and was entitled to the number of votes equal to the number of shares of common stock into which such Series B share could be converted. The Series B shares were convertible into common stock by the holder of the shares at any time. The Series B shares were subject to automatic conversion into common stock upon the election of the holders of at least two-thirds of the outstanding Series B shares. In addition, pursuant to the Company's Articles of Incorporation, the Series B shares were automatically convertible into common stock upon the occurrence of an underwritten initial public offering by the Company that satisfied certain conditions. Holders of the Series B shares were entitled to receive cumulative cash dividends at the rate of 10% of the Series B stated value. Such dividends accrued from day-to-day commencing on the original issue date, whether or not earned or declared by the board of directors, and were compounded annually. The Series B shares were redeemable by the Company at any time on or after June 26, 2018, upon the election of the holders of at least two-thirds of the outstanding Series B shares for an amount equal to the original issue price per share plus any accrued and unpaid dividends. Holders of the Series B shares were entitled to a liquidation preference in an amount equal to the Series B stated value of \$1.40 per share plus all accrued and unpaid dividends in the event of a liquidation, dissolution, or winding-up of the Company, or in the event of a merger or acquisition of the Company. In connection with the private placement of Series B shares, the Company recorded a liability for an embedded derivative that required bifurcation under the applicable accounting guidance. The embedded derivative included a redemption feature, multiple dividend features, as well as multiple conversion features with specified anti-dilution adjustments for certain financing transactions involving the issuance of securities at a price below a minimum issuance price of \$7.00 per share.

From December 31, 2015 to April 7, 2016, the Company had accreted \$1,858,000 from additional paid-in capital to Series B redeemable convertible preferred stock to adjust the redemption value of the Series B.

On April 8, 2016, certain holders of over two-thirds of the Company's then outstanding shares of the Series B stock (the "Holders") elected to automatically convert all outstanding shares of Series B into shares of common stock in accordance with Section 4.4.4(b)(ii) of the Company's Amended and Restated Articles of Incorporation (the "Conversion"). As a result of the Conversion, the 7,527,853 shares of Series B outstanding as of immediately prior to the Conversion were converted into an aggregate of 1,505,560 shares of common stock.

On April 8, 2016, the Company entered into the CSIA with the Holders pursuant to which the Company agreed to issue the Holders an aggregate of 853,465 shares of the Company's common stock. Pursuant to the CSIA, the Company and the Holders also agreed to amend the common stock warrants previously issued to the Holders in June 2013 in order to reduce the exercise price of such warrants from \$7.00 per share to \$4.05 per share and extend the expiration date thereof from June 26, 2018 to March 31, 2021 (the "Warrant Amendments"). As consideration for the shares and the Warrant Amendments, the Holders waived their right to receive approximately \$2.2 million in aggregate cash payments to which they were entitled upon the Conversion in respect of accrued dividends on their former shares of Series B. The Holders also waived their registration rights with respect to certain future registration statements that may be filed, and certain future public offerings that may be conducted, by the Company.

The transaction was accounted for based on the difference between the fair value of the consideration transferred, which includes the common stock issued and amendment of the warrants, to the Holders of the preferred stock and the carrying amount of the preferred stock on April 7, 2016.

The terms of the CSIA provided that if, after the date of the CSIA, the Company conducts one or more bona fide equity financings in which it sells shares of common stock or preferred stock at a price less than \$4.05 per share (each, a “dilutive financing”), the Company will be required to issue to the Holders additional shares of common stock based on a specified formula until the obligation expires. The obligation to issue additional shares in the event of any such dilutive financing i) only applies to the lowest priced financing conducted after the date of the CSIA for which shares additional shares have been previously issued, (ii) is subject to a specified 19.99% limitation and (iii) will expire at such time the Company has raised \$10.0 million in gross proceeds from the sale of common stock and/or preferred stock in a bona fide financing or financings or June 30, 2018, whichever occurs first.

On June 3, 2016, the Company completed a registered public offering of shares of common stock and warrants at a combined per share purchase price of \$2.35, resulting in aggregate gross proceeds of \$5.0 million. On November 22, 2016, the Company completed an additional underwritten public offering of common stock and warrants at a combined per share purchase price of \$0.75, for gross proceeds of approximately \$4.0 million. These two offerings qualified as dilutive financings under the terms of the CSIA.

On June 20, 2016, the Company obtained stockholder approval for the issuance of up to 1,037,053 shares of common stock to the Holders to the extent required by the terms of the CSIA in connection with one or more dilutive financings completed subsequent to the agreement date. Subsequent to the June and November 2016 financings and as of December 31, 2016, the maximum number of shares the Company could issue to the Holders pursuant to a future dilutive financing was 286,846 shares under the rules of the NYSE MKT. The Company may be contractually required to issue additional shares for no consideration in excess of the maximum number of shares it is currently permitted to issue. The actual number of shares that the Company may be required to issue to the Holders pursuant to the provisions of the CSIA in connection with the closing of a future dilutive financing will depend on the actual price per share of common stock at that such financing. The Company may not be able to comply with its contractual obligation to issue these additional shares.

The CSIA requires the delivery of shares in the event of a future dilutive financing. The Company determined this was a conditional forward contract and recorded a derivative liability as of April 8, 2016 in the amount of \$2.3 million for potential future dilutive financings. On June 3, 2016, the future financing derivative liability was adjusted by the fair value of the dilutive shares issuable of \$1.5 million as a result of the June offering. The derivative liability was marked-to-market as of December 31, 2016, resulting in a gain of \$611,000 for the year ended December 31, 2016.

The consolidated balance sheet as of December 31, 2016 reflects dividends payable of \$38,000 to former holders of preferred stock, which are classified as current liabilities.

## 11. Warrants

On January 4, 2016, the Company entered into an Asset Purchase Agreement with Novolytics Limited (the “Purchase Agreement”), to purchase certain preclinical materials and intangible assets, including patent rights, from Novolytics, an unrelated third party. In consideration for the assets acquired, the Company paid cash consideration of approximately \$205,000 and issued warrants to purchase an aggregate of 170,000 shares of the Company’s common stock. The warrants have an exercise price of \$12.00 per share and contain certain registration rights. The fair value of the warrants issued was \$204,000, based on a Monte Carlo valuation model and are classified as equity in the consolidated balance sheet as of December 31, 2016. The Company expensed the total value provided for the acquired assets of \$409,000 as in-process research and development as of the acquisition date given there was no alternative future use of the acquired assets due to the early stage nature of the technology and preclinical materials.

On April 8, 2016, the Company modified 315,244 warrants held by the Holders, in accordance with the terms of the CSIA (see Note 10).

On June 3, 2016, the Company issued warrants exercisable for an aggregate of 1,063,830 shares of common stock at an exercise price of \$2.25 per share in connection with the closing of a registered public offering of common stock and warrants (see Note 15).

On November 22, 2016, the Company issued warrants exercisable for an aggregate of 5,335,000 shares of common stock at an exercise price of \$0.75 per share in connection with the closing of a registered public offering of common stock and warrants (see Note 15).

The following table provides a summary of warrants outstanding, issued or expired for the year ended December 31, 2016. Also included are the average exercise price per share and the aggregate proceeds to the Company if exercised as of December 31, 2016:

	\$0.75	\$2.25		\$4.05 - \$8.25		\$10.75 - \$23.00		Totals		Weighted
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Average Exercise Price
Balance, December 31, 2015	-	\$-	-	\$-	694,062	\$5.82	515,587	\$11.39	1,209,649	\$8.19
Issuances	5,335,000	0.75	1,063,830	2.25	-	-	170,000	12.00	6,568,830	1.28
Expiration	-	-	-	-	-	-	(27,103 )	23.00	(27,103 )	23.00
Balance, December 31, 2016	5,335,000	\$0.75	1,063,830	\$2.25	694,062	\$5.82	658,484	\$11.07	7,751,376	\$2.29
Aggregate proceeds if exercised	\$4,001,250		\$2,393,618		\$4,039,441		\$7,289,418		\$17,723,727	

## 12. Stock-based Compensation

In June 2016, the Company's stockholders approved the 2016 Equity Incentive Plan (the 2016 Plan). The 2016 Plan provides for the issuance of incentive awards in the form of non-qualified and incentive stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and performance-based stock awards. The awards may be granted by the Company's board of directors to its employees, directors and officers and to consultants, agents, advisors and independent contractors who provide services to the Company or to a subsidiary of the Company. The exercise price for stock options must not be less than the fair market value of the underlying shares on the date of grant. Stock options expire no later than ten years from the date of grant and generally vest and typically become exercisable over a four-year period following the date of grant. Upon the exercise of stock options, the Company issues the resulting shares from shares reserved for issuance under the 2016 Plan. With the approval of the 2016 Plan, the remaining unallocated shares under the Company's 2013 Stock Incentive Plan were allocated to the 2016 Plan and an additional 1,000,000 new shares were added to the authorized share reserve under the 2016 Plan.

The Company accounts for stock options related to its stock incentive plans under the provisions of ASC 718, Stock Compensation, which requires the recognition of the fair value of stock-based compensation. The Company uses the Monte Carlo valuation model to estimate the fair value of certain stock options with market-based vesting requirements. This method of option pricing involves the use of inputs such as the market value of the Company's common stock, stock price volatility, the period during which the options will be outstanding, the rate of return on

risk-free investments, expected dividend yield for the Company's stock, and certain estimates of future value of the Company's common stock. The fair value of stock options with performance and service conditions was estimated using a Black-Scholes option valuation model. This model requires the input of subjective assumptions in implementing ASC 718, including expected dividend, expected life, expected volatility and forfeiture rate of each award, as well as the prevailing risk-free interest rate and the fair value of the underlying common stock on the date of grant. The fair value of equity-based awards is amortized over the vesting period of the award, and the Company has elected to use the straight-line method of amortization. The assumptions used in the Black-Scholes option valuation model for the years ended December 31, 2016 and 2015 are set forth below.

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

*Expected Dividend* : The Company does not anticipate paying any dividends on its common stock.

*Expected Life* : The expected life represents the period that the Company expects its stock-based awards to be outstanding. The Company's expected life assumption was based on the simplified method set forth in the SEC Staff Accounting Bulletin 110, which is the mid point between the option vesting date and the expiration date. The Company's estimation of the expected life for stock options granted to parties other than employees or directors is the contractual term of the option award.

*Expected Volatility* : The Company's expected volatility represents the weighted average historical volatility of the shares of its common stock for the expected life of the stock options.

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

*Forfeiture Rate* : The Company applies an estimated forfeiture rate of 8% which is derived from historical forfeited shares. If the actual number of forfeitures differs from our estimates, the Company may record additional adjustments to compensation expense in future periods.

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

	Year ended December 31,			
	2016		2015	
Risk-free interest rate	1.22 - 1.63	%	1.55 - 1.78	%
Expected volatility	113 - 123	%	139	%
Expected term (in years)	6.0		6.0 - 10.0	
Expected dividend yield	0	%	0	%

Stock-based compensation expense is reduced by an estimated forfeiture rate derived from historical employee termination behavior. If the actual number of forfeitures differs from the Company's estimates, the Company may record adjustments to increase or decrease compensation expense in future periods.

The estimated grant-date fair value of the Company's stock-based awards is amortized ratably over the awards' service periods. Stock-based compensation expense recognized was as follows:

	Year Ended December 31,	
	2016	2015
Research and development	\$ 138,000	\$ 122,000
General and administrative	1,857,000	361,000
Total stock-based compensation	\$ 1,995,000	\$ 483,000

The following table summarizes stock option activity for the years ended December 31, 2016 and 2015:

	Options Outstanding		Weighted Average Exercise Price	Average Remaining Contractual Term (Years)	Intrinsic Value
	Shares Available For Grant	Shares			
Balance, December 31, 2014	785,000	440,695			
Granted	(596,569 )	596,569			
Exercised	-	(214,815)			
Forfeited/Cancelled	15,000	(152,680)			
Shares authorized	520,000	-			

Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

Balance, December 31, 2015	723,431	669,769	\$ 8.68	9.29	\$ -
Granted	(264,208 )	264,208	2.65	-	-
Exercised	-	-	-	-	-
Forfeited/Cancelled	180,939	(185,039)	9.00	-	-
Shares authorized	1,000,000	-	-	-	-
Balance, December 31, 2016	1,640,162	748,938	\$ 6.45	8.65	\$ -
Vested or expected to vest at December 31, 2016		703,508	\$ 6.57	8.62	\$ -
Exercisable at December 31, 2016		316,107	\$ 8.88	8.20	\$ -

The aggregate intrinsic value of unvested options and options exercisable as of December 31, 2016 was zero, based on the Company's closing stock price of \$0.44 per share and a weighted average exercise price of \$4.68 and \$8.88, respectively. As of December 31, 2016, the Company had 432,831 unvested outstanding options, with a weighted average exercise price of \$4.68 per share and weighted average grant date fair value of \$4.12 per share.

During the year ended December 31, 2016, the Company issued 264,208 common stock options to its employees and an executive with an average exercise price of \$2.65 per share. Included in this amount were 99,919 stock options, with an exercise price of \$2.85 per share, to its Chief Financial Officer, pursuant to his employment agreement dated January 18, 2016.

As of December 31, 2016, there was \$1.4 million of total unrecognized compensation expense related to unvested stock options that will be recognized over the weighted average remaining period of 2.59 years.

***Employee Stock Purchase Plan (ESPP)***

On June 20, 2016, the Company’s stockholders approved the Company’s 2016 Employee Stock Purchase Plan (“ESPP”). The ESPP allows eligible employees to purchase shares of the Company’s common stock on a voluntary basis. The shares are sold to participants at a price equal to the lesser of 85% of the fair market value of the Company’s common stock at the (i) beginning of the offering period, or (ii) end of the six month purchase period. The ESPP provides for four six month purchase periods during each 24 month term. The initial shares provided for under the plan were 120,000, and automatically increase annually as allowed for under the ESPP, beginning January 1, 2017 and through January 1, 2026.

During the year ended December 31, 2016, 32,726 shares were issued under the ESPP and the Company recognized \$12,000 in compensation expenses related to the ESPP.

***Shares Reserved For Future Issuance***

As of December 31, 2016, the Company had reserved shares of its common stock for future issuance as follows:

	Shares Reserved
Stock options outstanding	748,938
Employee stock purchase plan	87,274
Available for future grants under the 2016 Plan	1,640,162
Warrants	7,751,376
Total shares reserved	10,227,750

**13. Employee Retirement Plan**

The Company sponsors an employee retirement plan under Section 401(k) of the Internal Revenue Code of 1986, as amended. All of the Company’s employees who meet minimum eligibility requirements are eligible to participate in the plan. Matching contributions to the 401(k) plan are made for certain eligible employees to meet non-discrimination provisions of the plan. The Company did not make any matching contribution to the 401(k) plan



for the years ended December 31, 2016 and 2015.

#### **14. Related Parties**

Randal J. Kirk, the father of Julian P. Kirk, a former member of our board of directors, directly and through certain affiliates, has voting and dispositive power over a majority of the outstanding capital stock of Intrexon. Randal J. Kirk was also deemed a holder of more than five percent of the shares of our common stock, as described in the section entitled “Security Ownership of Certain Beneficial Owners and Management” in our definitive proxy statement for the 2015 annual meeting of stockholders. In March 2013, the Company entered into an Exclusive Channel Collaboration Agreement with Intrexon Corporation. This agreement allowed the Company to utilize Intrexon’s synthetic biology platform for the identification, development and production of bacteriophage-containing human therapeutics. The Company paid a one-time technology access fee in 2013 to Intrexon of \$3,000,000 in common stock. The Company was required to pay Intrexon, in cash or stock, milestone fees for the initiation and commencement of the first Phase 2 trial of \$2,500,000 and \$5,000,000 upon the first regulatory approval of any product in any major market country. With regard to each product sold by the Company, the Company agreed to pay, in cash, tiered royalties on a quarterly basis based on net sales of AmpliPhi Products, calculated on a product-by-product basis. No milestones have been met and no milestone payments have been paid to Intrexon through December 31, 2016. The Company paid \$117,000 and \$125,000 to Intrexon in 2016 and 2015, respectively, for technical services rendered under the agreement. There was no liability due to Intrexon as of December 31, 2016. The Exclusive Channel Collaboration Agreement with Intrexon was terminated in 2016.

As of December 31, 2016, the Company had a liability of \$10,000 payable to Biosciences Managers, where a member of our board of directors serves at the managing director, and such amount represented reimbursement of travel expenses.

#### **15. Stockholders’ Equity**

On November 22, 2016, the Company completed an underwritten public offering of 5,335,000 shares of its common stock and warrants to purchase up to an aggregate of 5,335,000 shares of common stock. Each share of common stock was sold together with a warrant to purchase one share of common stock at a combined purchase price of \$0.75 per unit, for aggregate gross proceeds to the Company of \$4.0 million. The warrants have an exercise price of \$0.75 per share, were exercisable immediately upon issuance and expire five years following the date of issuance. The Company received net proceeds from the offering of approximately \$3.7 million after deducting placement agent fees and other offering expenses payable by the Company.

Pursuant to an Underwriting Agreement dated November 17, 2016, by and between the Company and Roth Capital Partners, LLC (“Roth”) and Griffin Securities, Inc. (“Griffin”), Roth and Griffin acted as co-placement agents for the offering. The Company agreed to pay an aggregate cash fee for placement agent services equal to 6.0% of the gross proceeds of the offering (the “Placement Agent Fee”), as well as a non-refundable legal reimbursement fee of \$70,000.

The Company evaluated the warrants issued in the offering and determined the warrant instruments should be accounted for as a liability primarily because the warrant is not indexed to the Company’s common stock due to exercise price adjustment provision and the Company may be required to pay the warrant holders cash under certain circumstances. The Company recorded a derivative liability for the estimated fair value of the warrants issued in connection with the offering in the amount of \$2.9 million, based on a valuation using the Monte Carlo valuation model. The remaining balance of \$1.1 million, after deducting the fair value of the warrants, was allocated to the value of the common stock. Offering costs directly allocable to the offering totaled \$0.7 million, including placement agent fees and legal expenses. Of this amount, \$0.3 million was allocable to the warrants and recorded as other expense in the Company’s consolidated statements of operations based on the relative fair value of the warrants to the common stock.

The derivative liability for the warrants was marked-to-market at December 31, 2016, with the decrease in fair value of \$886,000 recorded as a component of change in fair value of derivative liability in the Company’s consolidated statement of operations (see Note 4) for the year ended December 31, 2016.

On May 31, 2016, the Company entered into a Securities Purchase Agreement (the “SPA”) with certain purchasers providing for the sale and issuance in a registered public offering of an aggregate of 2,127,660 shares of the Company’s common stock and warrants to purchase 1,063,830 shares of the Company’s common stock. Each share of common stock was sold together with a warrant to purchase 0.50 of a share of common stock at a combined purchase price of \$2.35 per unit, for aggregate gross proceeds to the Company of \$5.0 million. The offering closed on June 3, 2016. The warrants have an exercise price of \$2.25 per share, were exercisable immediately upon issuance and expire five years following the date of issuance. The Company received net proceeds from the offering of approximately \$4.2 million after deducting placement agent fees and other offering expenses payable by the Company.

Pursuant to a Placement Agent Agreement dated May 31, 2016, by and between the Company and Roth and Griffin, Roth and Griffin acted as co-placement agents for the offering. The Company agreed to pay an aggregate cash fee for placement agent services equal to 7% of the gross proceeds of the offering (the “Placement Agent Fee”), as well as a non-refundable legal reimbursement fee of \$75,000.

The Company evaluated the warrants issued in the offering and determined the warrant instruments do not qualify for the scope exception in ASC 815, Stock Compensation, due to certain net cash settlement provisions in the warrant agreement. The Company recorded a derivative liability for the estimated fair value of the warrants issued in

connection with the offering in the amount of \$1.8 million (based on a Black-Scholes Option Pricing Model assuming no dividend yield, volatility of 123%, and a risk-free interest rate of 1.23%). The remaining balance of \$3.2 million, after deducting the fair value of the warrants, was allocated to the value of the common stock. Offering costs directly allocable to the offering totaled \$0.8 million, including placement agent fees and legal expenses. Of this amount, \$0.2 million was allocable to the warrants and recorded as other expense in the Company's consolidated statement of operations for the year ended December 31, 2016 based on the relative fair value of the warrants to the common stock.

The derivative liability for the warrants was marked-to-market at December 31, 2016, with the decrease in fair value of \$1.5 million recorded as a component of change in fair value of derivative liability in the Company's statement of operations (see Note 4) for the year ended December 31, 2016.

On March 16, 2015, the Company issued and sold 1,575,758 shares of common stock in a private placement at a price of \$8.25 per share, for aggregate proceeds of \$13.0 million. In conjunction with this private placement, the Company issued warrants to purchase an aggregate of 393,939 shares of common stock at an exercise price of \$10.75 per share to the purchasers of the common stock. The Company paid \$0.8 million in fees to its placement agents, along with the issuance of warrants to purchase an aggregate of 94,545 shares of common stock at an exercise price of \$10.75 per share. The Company initially valued these warrants as liability instruments and recorded a liability of \$4.2 million as of March 16, 2015. In the first quarter of 2015, the Company recorded \$0.2 million of other expenses representing the portion of the initial warrant value of the placement agent warrants related to the initial fair value of the warrants issued to the purchasers of the common stock. The remainder of the initial fair value of the warrants of \$4.0 million was treated as a reduction of additional paid-in-capital. In addition, \$0.2 million of the fees paid to its placement agent were recorded as other expenses for the year ended December 31, 2015 as they also represented issuance costs related to the initial fair value of the warrants issued to the purchasers of the common stock. The derived value associated with these warrants was reclassified from liabilities to equity in the third quarter of 2015 in connection with the increase in the authorized number of common shares.

## **16. Quarterly Financial Data (Unaudited)**

The following tables summarize the unaudited quarterly statements of operations for the Company for the years ended December 31, 2016 and 2015. The tables include all necessary adjustments, consisting only of normal recurring adjustments necessary in the opinion of management for a fair statement of the results for interim periods.

Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

As discussed in Note 3 of the Form 10-Q filed for the quarter ended September 30, 2016, the Company corrected an immaterial error in the condensed consolidated financial statements for the three months ended September 30, 2016.

2016	Quarter Ended (Unaudited)			
	March 31,	June 30,	September 30,	December 31,
Revenue	\$ 106,000	\$ 103,000	\$ 29,000	\$ 22,000
Total operating expenses	4,624,000	3,692,000	3,436,000	11,886,000
Loss from operations	(4,518,000)	(3,589,000)	(3,407,000)	(11,864,000)
Other income (expense), net	1,406,000	(262,000)	1,032,000	1,808,000
Net loss	(3,112,000)	(3,851,000)	(2,375,000)	(9,500,000)
Accretion of Series B redeemable convertible preferred stock	(1,725,000)	(133,000)	-	-
Excess of fair value of consideration transferred on conversion of Series B redeemable convertible preferred stock	-	(2,366,000)	(1,214,000)	-
Net loss attributable to common stockholders	(4,837,000)	(6,350,000)	(3,589,000)	(9,500,000)
Net loss per share of common stock				
Basic	(0.82)	(0.73)	(0.32)	(0.70)
Diluted	(0.82)	(0.78)	(0.32)	(0.76)

2015	Quarter Ended (Unaudited)			
	March 31,	June 30,	September 30,	December 31,
Revenue	\$ 102,000	\$ 102,000	\$ 143,000	\$ 128,000
Total operating expenses	2,369,000	2,694,000	2,571,000	3,068,000
Loss from operations	(2,267,000)	(2,592,000)	(2,428,000)	(2,940,000)
Other income (expense), net	(12,226,000)	13,361,000	7,867,000	636,000
Income tax benefit	-	-	-	73,000
Net (loss) income	(14,493,000)	10,769,000	5,439,000	(2,231,000)
Accretion of Series B redeemable convertible preferred stock	(338,000)	(1,828,000)	(7,163,000)	(949,000)
Net (loss) income attributable to common stockholders	(14,831,000)	8,941,000	(1,724,000)	(3,180,000)
Net (loss) income per share of common stock				
Basic	(3.49)	1.27	(0.30)	(0.54)
Diluted	(3.49)	(0.33)	(0.30)	(0.54)

## **PART III**

### **Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

### **Item 9A. CONTROLS AND PROCEDURES**

#### **Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this report. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer, have concluded that our disclosure controls and procedures were not effective at the reasonable assurance level as of the end of the period covered by this report due to the presence of a material weakness in internal control over financial reporting. This conclusion was based on the material weakness identified in our internal control over financial reporting, as described below.

A material weakness is defined as “a deficiency, or a combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company’s annual or interim financial statements will not be prevented or detected on a timely basis.”

In light of the material weakness described below, we performed additional analysis and other procedures to ensure that our consolidated financial statements included in this Annual Report on Form 10-K were prepared in accordance with generally accepted accounting principles in the United States (“GAAP”). Notwithstanding the existence of the material weakness in internal control over financial reporting, we believe that our consolidated balance sheets as of December 31, 2016 and 2015 and the related consolidated statements of operations, redeemable convertible preferred stock and stockholders’ equity, and cash flows for the years ended December 31, 2016 and 2015 included in this Annual Report on Form 10-K fairly present, in all material respects, the Company’s financial condition, results of operations and cash flows for the periods presented therein in conformity with GAAP.

### ***Management’s Report on Internal Control Over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for our company. Internal control over financial reporting is defined in Exchange Act Rules 13a-15(f) and 15(d) -15(f) as a process designed by, or under the supervision of, our principal executive and principal financial officer to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles.

Because of inherent limitations, internal controls over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

As of December 31, 2016, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013). In adopting the 2013 Framework, management assessed the applicability of the principles within each component of internal control and determined whether or not they have been adequately addressed within the current system of internal control and adequately documented. Based on this assessment, management, under the supervision and with the participation of our principal executive officer and principal financial officer, identified a material weakness in our internal control over financial reporting and concluded that, as of December 31, 2016, our internal control over financial reporting was not effective at the reasonable assurance level based on those criteria.

As of December 31, 2015, the Company disclosed the following material weakness within its 2015 Form 10-K: “We concluded that we did not maintain adequate and effective internal control in the area of complex and non-routine transactions and in the application of Accounting Standards Codification No. 260, “Earnings Per Share,” or ASC 260, as of December 31, 2015.” Although we have implemented certain aspects of its remediation plan, we do not believe that the applicable remedial controls have operated for a sufficient period of time or number of occurrences to allow for sufficient testing to determine the controls’ operating effectiveness nor do we believe its remediation plan has been fully implemented. Accordingly, the identified prior year material weakness remained outstanding as of December 31, 2016.

***Changes in Internal Control Over Financial Reporting.***

An evaluation was also performed under the supervision and with the participation of our management, including our principal executive officer and our principal financial officer, of any changes in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting, other than as disclosed below.

***Remediation Actions to Date***

During 2016, we implemented certain improvements to our internal control and financial reporting processes to address the material weakness we identified in our internal control over financial reporting in 2016 and 2015 in the area of complex and non-routine transactions. These improvements include the following:

- appointed an experienced Chief Financial Officer in January 2016 with significant experience in public company reporting and complex transactions;
- engaged consultants with experience in the review of unique and complex accounting topics, who consulted with management on complex transactions and reporting;
- designed and implemented additional training programs for relevant personnel and developed specific review procedures regarding the review of complex and non-routine transactions; and
- implemented standardized financial control and reporting processes.

In addition to these remedial actions described below, we continue to enhance the design and operating effectiveness of our controls related to complex and non-routine transactions and ASC 260.

The remediation actions are monitored by the Audit Committee of our Board of Directors.

**Item 9B. OTHER INFORMATION**

None.



**PART III****Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

We have adopted a code of ethics for directors, officers (including our principal executive officer, principal financial officer and principal accounting officer) and employees, known as the Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website at <http://www.ampliphio.com> under the Corporate Governance section of our Investor Relations page. We will promptly disclose on our website (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals that is required to be disclosed pursuant to SEC rules and regulations, the name of such person who is granted the waiver and the date of the waiver.

**MANAGEMENT**

The following table sets forth information about our executive officers and directors.

<b>Name</b>	<b>Age</b>	<b>Position(s)</b>
M. Scott Salka	55	Chief Executive Officer, Director
Igor P. Bilinsky	44	Chief Operating Officer
Steve R. Martin	56	Chief Financial Officer

**Non-Employee Directors**

Jeremy Curnock Cook <sup>(2)</sup> <sup>(3)</sup>	67	Chairman of the Board
Louis Drapeau <sup>(1)</sup> <sup>(3)</sup>	73	Director
Michael S. Perry, Ph.D. <sup>(1)</sup> <sup>(2)</sup> <sup>(3)</sup>	57	Director
Vijay B. Samant <sup>(1)</sup>	64	Director
Paul C. Grint, M.D. <sup>(2)</sup>	59	Director
Wendy Johnson	65	Director

(1)

Member of the audit committee.

(2)

Member of the compensation committee.

(3)

Member of the nominating and corporate governance committee.

## Executive Officers

**M. Scott Salka** has served as our Chief Executive Officer and a member of our board of directors since May 18, 2015. Mr. Salka served as the Chief Executive Officer of Aspyrian Therapeutics Inc., a company focused on developing near-infrared photoimmunotherapy therapies, from March 2010 to May 2015. Prior to that, Mr. Salka served as the Chief Executive Officer of Ambit Biosciences Corporation, a publicly traded company that developed a novel platform for discovering small molecule drugs for oncology, autoimmune and inflammatory diseases, that was acquired by Daiichi Sankyo in 2014. During Mr. Salka's tenure at Ambit, he was responsible for transforming the company from a service contract business to a fully-capable drug discovery and development enterprise. Prior to joining Ambit in 2001, Mr. Salka served as the President and Chief executive officer of two privately-held genomics companies, Arcaris, Inc. and 454 Corporation that was sold to Roche in 2007. He also previously co-founded one of the first commercial genomics companies, Sequana Therapeutics, Inc., a pioneer in the effort to commercialize the international Human Genome Project. From February 2012 to March 2014, Mr. Salka served on the board of directors of Sorrento Therapeutics, Inc. and since 2009, Mr. Salka has served on the board of directors of San Diego State University College of Business Administration. He received his M.B.A. from Carnegie Mellon University and his B.S. in finance from San Diego State University.

**Igor P. Bilinsky, Ph.D.** has served as our Senior Vice President, Chief Operating Officer, since January 30, 2017. Dr. Bilinsky previously served as Senior Vice President, Research Operations and General Manager, Immuno-Oncology of Ignyta, Inc. from February 2016 to January 2017, and before that served as Ignyta's General Manager, Immuno-Oncology and Senior Vice President, Special Operations since September 2015. Prior to joining Ignyta, Dr. Bilinsky was Senior Vice President, Corporate Development at Vical Incorporated, a position he held since 2010. Dr. Bilinsky was previously Vice President, Business Development and Special Operations at Halozyme Therapeutics from 2008 to 2010, after joining Halozyme in 2007 as Executive Director, Corporate Development and Special Operations. From 2005 to 2007, Dr. Bilinsky was Chief Executive Officer of Androclus Therapeutics, a privately-held biotechnology company developing novel therapeutics for autoimmune and inflammatory diseases. He joined Androclus in 2004 as Chief Operating Officer. From 1999 to 2004, Dr. Bilinsky served in positions of increasing responsibility as a management consultant, project leader and ultimately as principal in the healthcare practice of the Boston Consulting Group, where he advised companies in the biotechnology, pharmaceutical and life science industries on business strategy, operational performance and mergers and acquisitions. Prior to joining the Boston Consulting Group, Dr. Bilinsky worked in research positions at Symyx Technologies and the Massachusetts Institute of Technology ("MIT") Lincoln Laboratory. Dr. Bilinsky received his B.S. degree in physics from the Moscow Institute of Physics and Technology and his Ph.D. degree in physics from MIT.

**Steve R. Martin** has served as our Chief Financial Officer since January 2016. Mr. Martin served as Senior Vice President and Chief Financial Officer of Applied Proteomics, Inc., a molecular diagnostics company, from December 2014 to August 2015. From June 2011 to December 2014, Mr. Martin served as Senior Vice President and Chief Financial Officer of Apricus Biosciences, Inc., a publicly traded pharmaceutical company, and served as the Interim Chief Executive Officer of Apricus from November 2012 through March 2013. From 2008 to January 2011, Mr. Martin served as Senior Vice President and Chief Financial Officer of BakBone Software, a publicly traded software company. During his final 10 months with BakBone until the company's acquisition in January 2011, Mr. Martin also served as BakBone's Interim Chief Executive Officer. From 2005 to 2007, Mr. Martin served as Chief Financial Officer of Stratagene Corporation, a publicly traded research products and clinical diagnostics company. Mr. Martin's previous experience also includes serving as Controller with Gen-Probe Incorporated, a publicly traded molecular diagnostics company, as well as 10 years with Deloitte & Touche LLP, a public accounting firm. Mr. Martin holds a B.S. degree from San Diego State University and is a certified public accountant (inactive).

### **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. From September 2014 to May 2015, he served as our Interim Chief Executive Officer. 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. He also serves as a member of the board of directors of the following public companies: Avita Medical Ltd, Adherium Ltd, Phylogica Ltd and Rex Bionics PLC. Mr. Curnock Cook serves as a member of the board of directors on the following private companies: Smart Matrix Ltd and Avena Ltd. Mr. Curnock Cook received an M.A. in natural sciences from Trinity College, Dublin.

**Louis Drapeau** has served as a member of our board of directors since March 2011. Since October 2007 through February 2016, Mr. Drapeau has served in various management positions of InSite Vision, a traded ophthalmology drug development company that was acquired in October 2015, including Vice President and Chief Financial Officer and Chief Executive Officer from November 2008 to December 2010. 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. Since February 2007, Mr. Drapeau has served as a member of the board of Bio-Rad Laboratories, Inc., a publicly traded medical equipment company. Mr. Drapeau has also been a board member of Avita Medical, a public listed global medical technology trading on the Australian Stock Exchange and the OTC market, since January 2015. Mr. Drapeau received a B.S. in mechanical engineering and an M.B.A. from Stanford University.

**Michael S. Perry, D.V.M., Ph.D.** has served as a member of our board of directors since November 2005. Since January of 2016 Dr. Perry has served as Senior Vice President and Chief Scientific Officer of Business Development and Licensing for Novartis AG. From September 2014 to January 2016 he served as Chief Scientific Officer for the Cell and Gene Therapy Unit of Novartis Pharmaceuticals Corporation and from October 2012 to September 2014, he served as Global Head of Stem Cell Therapy and Vice President of the Integrated Hospital Care Franchise for Novartis Pharmaceuticals Corporation. Prior to rejoining Novartis in October 2012, he was a Venture Partner with Bay City Capital, a venture capital firm, from 2005 to September 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. Dr. Perry also previously served as Chief Development Officer of VIA Pharmaceuticals, Inc., a 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's BioScience Division (now Baxalta). From 1997 to 2000, Dr. Perry served as President and Chief Executive Officer of SyStemix Inc. and Genetic Therapy Inc., two wholly-owned subsidiaries of Novartis Pharma. Dr. Perry served as Vice President of Regulatory Affairs for Novartis from 1994 to 1997. Prior to 1994, Dr. Perry held various management positions with Syntex Corporation (now Roche), Schering-Plough Corporation (now Merck) and BioResearch Laboratories, Inc. Dr. Perry received a Doctor of Veterinary Medicine (DVM), a Ph.D. in biomedical science-pharmacology specialty and an Honours B.Sc. in physics from the University of Guelph in Ontario, Canada. He is also a graduate of the Harvard Business School International Management Forum. Dr. Perry has served as Adjunct Professor in the Gates Center for Regenerative Medicine at the University of Colorado School of Medicine, Anschutz Medical Campus since November 2013. He has served as a member of the board of directors of Arrowhead Research Corporation since December 2011 and as a member of the board of directors of Avita Medical Ltd since February 2013.

**Vijay B. Samant** has served as a member of our board of directors since November 2015. Since November 2000, Mr. Samant has served as President and Chief Executive Officer of Vical, Inc., a developer of biopharmaceutical products for the prevention and treatment of chronic life-threatening infectious diseases. Prior to joining Vical, he had 23 years of diverse U.S. and international sales, marketing, operations, and business development experience with Merck. From 1998 to 2000, he was Chief Operating Officer of the Merck Vaccine Division. From 1990 to 1998, he served in the Merck Manufacturing Division as Vice President of Vaccine Operations, Vice President of Business Affairs and Executive Director of Materials Management. Mr. Samant holds a master's degree in management studies from the Sloan School of Management at the Massachusetts Institute of Technology, a master's degree in chemical engineering from Columbia University, and a bachelor's degree in chemical engineering from the University of Bombay, University Department of Chemical Technology. Mr. Samant has been a member of the board of directors of Vical since 2000, and was a member of the board of directors of Raptor Pharmaceutical Corporation from 2011 to 2014, and was a member of the board of directors for BioMarin Pharmaceutical Inc. from 2002 to 2004. Mr. Samant was a Director of the Aeras Global TB Vaccine Foundation from 2001 to 2010, a member of the Board of Trustees for the National Foundation for Infectious Diseases from 2003 to 2012, and a member of the Board of Trustees for the International Vaccine Institute in Seoul, Korea from 2008 to 2012.

**Paul C. Grint, M.D.** has served as a member of our board of directors since November 2015. Since June 2015, Dr. Grint has served as President and Chief Executive Officer of Regulus Therapeutics Inc., a company focused on the discovery and development of microRNA therapeutics. From June 2014 until his appointment as President and Chief Executive Officer, Dr. Grint served as Regulus Therapeutics' Chief Medical Officer. From February 2011 to June 2014, Dr. Grint served as the President of Cerexa, Inc., a wholly-owned subsidiary of Forest Laboratories, Inc., a pharmaceutical company, where he was responsible for the oversight of anti-infective product development. Before that, Dr. Grint served as Senior Vice President of Research at Forest Research Institute, Inc., the scientific development subsidiary of Forest Laboratories, Inc., from January 2009 to February 2011, as Chief Medical Officer of Kalypsys, Inc., a biopharmaceutical company, from 2006 to 2008, and as Senior Vice President and Chief Medical Officer of Zephyr Sciences, Inc., a biopharmaceutical company, during 2006. Dr. Grint also previously served in similar executive level positions at Pfizer Inc., IDEC Pharmaceuticals Corporation, and Schering-Plough Corporation. Dr. Grint has served on the board of directors of Amplyx Pharmaceuticals since May 2016, and he also has served on the board of directors of Regulus Therapeutics Inc since 2015. Dr. Grint has also served on the board of directors of Synedgen, a privately-held bio-pharmaceutical company, since December 2014. In addition, Dr. Grint served on the board of directors of Illumina Inc. from April 2005 to May 2013. Dr. Grint received a B.S. in Medical Science from St. Mary's Hospital in London and his medical degree from St. Bartholomew's Hospital Medical College at the University of London. Dr. Grint is a Fellow of the Royal College of Pathologists, a member of numerous professional and medical societies, and the author or co-author of over 50 scientific publications.

**Wendy S. Johnson** has served as our Interim Chief Operating Officer since September 2014, and previously served as our Interim Chief Operating Officer from September 2014 to January 2017. From 2005 to January 2014, Ms. Johnson served as a venture partner at ProQuest Investments, a venture capital firm. From 2006 to January 2014, Ms. Johnson served as the President and Chief Executive Officer of Aires Pharmaceuticals, a ProQuest portfolio company. Prior to joining ProQuest, she served as Senior Vice President, Corporate Development, at Salmedix Inc., and she held senior business and corporate development positions at WomenFirst Healthcare, Prizm Pharmaceuticals (Selective Genetics Inc.), Cytel Corp., Synbiotics Corp., and Murex Corp. (Cambridge U.K.). Additionally, Ms. Johnson served as Assistant Director with the Center for Devices and Radiological Health at the U.S. Food and Drug Administration.

Ms. Johnson received an M.B.A. from Loyola University, an M.S. in clinical microbiology from the Hahnemann Medical School and a B.S. in microbiology from the University of Maryland.

## **Board Composition**

Our business and affairs are organized under the direction of our board of directors, which currently consists of eight members. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and on an ad hoc basis as required.

Under the listing requirements and rules of the NYSE MKT for smaller reporting companies transferring from other markets, independent directors must compose at least 50% of a listed company's board of directors within a one-year period following such company's initial listing with the NYSE MKT.

In February 2017, 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 Jeremy Curnock Cook, Louis Drapeau, Michael Perry, Vijay Samant and Paul Grint qualify as "independent" directors within the meaning of the NYSE MKT rules. Our board of directors also concluded that M. Scott Salka and Wendy Johnson were not at such time "independent" directors within the meaning of the NYSE MKT rules given Mr. Salka's position as our Chief Executive Officer and Ms. Johnson's consulting relationship with our company.

As required under applicable NYSE MKT rules, we anticipate that our independent directors will meet in regularly scheduled executive sessions at which only independent directors are present.

Our amended and restated bylaws provide that the board of directors will consist of not less than one nor more than nine members, as fixed from time to time by a resolution of the board of directors. The authorized size of our board of directors is currently eight members. Our directors serve under a classified board structure, with each director serving for a three-year term of office. Directors are divided into three classes with one class standing for election every year at our annual meeting of stockholders. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election.



The classification of the board of directors may have the effect of delaying or preventing changes in control of our company. We expect that additional directorships resulting from an increase in the number of directors, if any, will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors.

### **Board Leadership Structure**

Our board of directors has a chairman, Jeremy Curnock Cook, who has authority, among other things, to call and preside over board meetings, to set meeting agendas and to determine materials to be distributed to the board of directors. Accordingly, the chairman has substantial ability to shape the work of the board of directors. We have a separate chair for each committee of our board of directors. As a general policy, our board of directors believes that separation of the positions of Chairman and Chief Executive Officer reinforces the independence of the board of directors from management, creates an environment that encourages objective oversight of management's performance and enhances the effectiveness of the board of directors as a whole. As such, Mr. Salka serves as our Chief Executive Officer while Mr. Cook serves as our Chairman of the board of directors but is not an officer. We expect and intend the positions of Chairman of the Board of Directors and Chief Executive Officer to continue to be held by separate individuals in the future.

### **Role of the Board in Risk Oversight**

The audit committee of our board of directors is primarily responsible for overseeing our financial risk management processes on behalf of our board of directors. Going forward, we expect that the audit committee will receive reports from management at least quarterly regarding our assessment of risks. In addition, the audit committee reports regularly to our board of directors, which also considers our risk profile. The audit committee and our board of directors focus on the most significant risks we face and our general risk management strategies. While our board of directors oversees our risk management, management is responsible for day-to-day risk management processes. Our board of directors expects management to consider risk and risk management in each business decision, to proactively develop and monitor risk management strategies and processes for day-to-day activities and to effectively implement risk management strategies adopted by the audit committee and our board of directors. We believe this division of responsibilities is the most effective approach for addressing the risks we face and that our board of directors leadership structure, which also emphasizes the independence of our board of directors in its oversight of its business and affairs, supports this approach.

### **Board Committees**



Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee.

### *Audit Committee*

Our audit committee consists of Louis Drapeau, Michael S. Perry and Vijay Samant. Our board of directors has determined that each of the members of our audit committee satisfies the NYSE MKT listing requirements and SEC independence requirements. Mr. Drapeau serves as the chair of our audit committee. The functions of this committee include, among other things:

- evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors and to present the committee's conclusion to our board of directors;
- reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non-audit services;
- monitoring the rotation of partners of our independent auditors on our audit engagement team as required by law; prior to engagement of any independent auditor, and at least annually thereafter, reviewing relationships that may reasonably be thought to bear on their independence, and assessing and otherwise taking the appropriate action to oversee the independence of our independent auditor;
- reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," and discussing the statements and reports with our independent auditors and management;
- reviewing with our independent auditors and management significant issues that arise regarding accounting principles and financial statement presentation and matters concerning the scope, adequacy and effectiveness of our internal control over financial reporting;
- reviewing with management and our auditors any earnings announcements and other public announcements regarding material developments;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding internal accounting controls, accounting or auditing matters and other matters;
  - preparing the report that the SEC requires in our annual proxy statement;
- reviewing and providing oversight of any related-person transactions in accordance with our related-person transactions policy and reviewing and monitoring compliance with legal and regulatory responsibilities, including our code of business conduct and ethics;
  - reviewing on a periodic basis our investment policy; and
- reviewing and evaluating on an annual basis its own performance, including its compliance with its charter.

Our board of directors has determined that Mr. Drapeau qualifies as an audit committee financial expert within the meaning of SEC regulations. In making this determination, our board has considered Mr. Drapeau's formal education and previous and current experience in financial roles. Both our independent registered public accounting firm and management periodically meet privately with our audit committee.

### *Compensation Committee*

Our compensation committee consists of Jeremy Curnock Cook, Paul C. Grint and Michael S. Perry. Dr. Perry serves as the chair of our compensation committee. Our board of directors has determined that each of the members of our compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is an outside director, as defined pursuant to Section 162(m) of the Code, and satisfies the NYSE MKT listing independence requirements. The functions of this committee include, among other things:

- reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) our overall compensation strategy and policies;
- reviewing and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) the compensation and other terms of employment of our executive officers;
- reviewing and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) performance goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;
- evaluating risks associated with our compensation policies and practices and assessing whether risks arising from our compensation policies and practices for our employees are reasonably likely to have a material adverse effect on us;
- reviewing making recommendations to the full board of directors regarding the type and amount of compensation to be paid or awarded to our non-employee board members;
- establishing policies with respect to votes by our stockholders to approve executive compensation as required by Section 14A of the Exchange Act and determining our recommendations regarding the frequency of advisory votes on executive compensation, to the extent required by law;
- reviewing and assessing the independence of compensation consultants, legal counsel and other advisors as required by Section 10C of the Exchange Act;
- administering our equity incentive plans;
- establishing policies with respect to equity compensation arrangements;
- reviewing the competitiveness of our executive compensation programs and evaluating the effectiveness of our compensation policy and strategy in achieving expected benefits to us;
- reviewing and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) the terms of any employment agreements, severance arrangements, change-of-control protections and any other compensatory arrangements for our executive officers;
- reviewing the adequacy of its charter on a periodic basis;

reviewing with management and approving our disclosures, if any, under the caption “Compensation Discussion and Analysis” and related tables in our periodic reports or proxy statements to be filed with the SEC;

- preparing the report that the SEC requires in our annual proxy statement; and
- reviewing and assessing on an annual basis its own performance.

### *Nominating and Corporate Governance Committee*

Our nominating and corporate governance committee consists of Jeremy Curnock Cook, Louis Drapeau and Michael S. Perry. Our board of directors has determined that each of the members of this committee satisfies the NYSE MKT listing independence requirements. Mr. Curnock Cook serves as the chair of our nominating and corporate governance committee. The functions of this committee include, among other things:

identifying, reviewing and evaluating candidates to serve on our board of directors consistent with criteria approved by our board of directors;

- evaluating director performance on management and the board and applicable committees of the board and determining whether continued service on our board is appropriate;

- evaluating, nominating and recommending individuals for membership on our board of directors;

- evaluating nominations by stockholders of candidates for election to our board of directors;

- considering and assessing the independence of members of our board of directors;

developing a set of corporate governance policies and principles, periodically reviewing and assessing these policies and principles and their application and recommending to our board of directors any changes to such policies and principles;

- reviewing the adequacy of its charter on an annual basis; and

- annually evaluating the performance of the nominating and corporate governance committee.

We believe that the composition and functioning of our nominating and corporate governance committee complies with all applicable requirements of the Sarbanes-Oxley Act, and all applicable SEC and NYSE MKT listing requirements. We intend to comply with future requirements to the extent they become applicable to us.

### **Limitation of Liability and Indemnification**

Sections 23B.08.510 and 23B.08.570 of the Washington Business Corporation Act authorize Washington corporations to indemnify directors and officers under certain circumstances against expenses (including legal expenses) and liabilities incurred in legal proceedings in which they are involved by reason of being a director or officer, as applicable. Section 23B.08.560 of the Washington Business Corporation Act authorizes a corporation, if authorized by its articles of incorporation or by a provision in the corporation's bylaws approved by its stockholders, to indemnify or agree to indemnify a director made a party to a proceeding, or obligate itself to advance or reimburse expenses incurred in a proceeding, without regard to the limitations imposed by Sections 23B.08.510 through 23B.08.550; provided that no such indemnity shall indemnify any director from or on account of (a) acts or omissions of the director finally adjudged to be intentional misconduct or a knowing violation of law, (b) conduct of the director finally adjudged to be in violation of Section 23B.08.310 of the Washington Business Corporation Act (which section relates to unlawful distributions) or (c) any transaction with respect to which it was finally adjudged that such director personally received a benefit in money, property or services to which the director was not legally entitled.

Article 11 of our current articles of incorporation, provides that, to the fullest extent that the Washington Business Corporation Act permits the limitation or elimination of the liability of a director, a director shall not be liable to us or our stockholders for monetary damages for conduct as a director. Section 10 of our amended and restated bylaws requires us to indemnify every present or former director or officer against expenses, liabilities and losses incurred in connection with serving as a director or officer, as applicable, and to advance expenses of such director or officer incurred in defending any proceeding covered by the indemnity.

We maintain a policy of directors' and officers' liability insurance that insures the directors and officers against the cost of defense, settlement or payment of a judgment under certain circumstances. We have also entered into indemnification agreements with our executive officers and directors that provide for the indemnification of directors and executive officers to the fullest extent permitted by the Washington Business Corporation Act against expenses reasonably incurred by such persons in any threatened, pending or completed action, suit, investigation or proceeding in connection with their service as (i) a director or officer or (ii) a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans, at our request. In addition, the indemnification agreements we are obligated to advance expenses pursuant to the indemnification agreements under certain circumstances and the agreements also provide for procedural protections, including a determination by a reviewing party as to whether the indemnitee is permitted to be indemnified under applicable law. In addition, we have agreed that we will be the indemnitor of first resort should the indemnitee have rights to indemnification provided by other persons.

The limitation of liability and indemnification provisions in our articles of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

We believe that these provisions in our articles of incorporation and amended and restated bylaws and our indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

At present, there is no pending litigation or proceeding involving any of our directors or executive officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

**Item 11. EXECUTIVE  
COMPENSATION**

**Executive Compensation**

Our named executive officers for the year ended December 31, 2016, which consist of all individuals who served as our principal executive officer during 2016 and our two most highly compensated executive officers other than our principal executive officer who were serving as executive officers as of December 31, 2016 are:

M. Scott Salka, our Chief Executive Officer;  
Steve Martin, our Chief Financial Officer;  
Wendy S. Johnson, our former Interim Chief Operating Officer.

In January 2017, Dr. Igor Bilinsky commenced employment with us as our Senior Vice President, Chief Operating Officer. Although Dr. Bilinsky is not one of our named executive officers for the year ended December 31, 2016, we have included information regarding Dr. Bilinsky's compensation in this report in order to provide a more current summary of our executive compensation program.

**Summary Compensation Table**

The following table provides information regarding the compensation paid during the last two fiscal years to our named executive officers for the year ended December 31, 2016.

Name and Principal Position	Year	Salary	Bonus	Option Awards <sup>(1)</sup>	Non-Equity Incentive Plan Compensation	All Other Compensation	Total
Michael Scott Salka, Chief Executive Officer <sup>(2)</sup>	2016	\$425,000	\$0	\$0	\$ 102,000	(3) \$ 988	\$527,988
	2015	\$264,263	\$0	\$3,469,919	\$ 85,000	\$ 364	\$3,819,546
Steve Martin, Senior VP and Chief Financial Officer <sup>(4)</sup>	2016	\$306,667	\$0	\$239,801	\$ 67,200	(3) \$ 1,341	\$615,009
Wendy S. Johnson, Interim Chief Operating Officer and Director <sup>(5)</sup>	2016	\$300,000	\$00	\$0	\$ 250,000	\$ 40,000	(6) \$590,000
	2015	\$270,000	\$25,000	\$289,373	\$ 0	\$ 30,000	(6) \$614,373

In accordance with SEC rules, this column represents the aggregate grant date fair value of the option awards granted during 2016 and 2015 (if any) computed in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718 for stock-based compensation transactions (ASC 718).

(1) Assumptions used in the calculation of these amounts are included in the notes to our audited financial statements incorporated herein by reference. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options.

(2) Mr. Salka commenced employment with us as Chief Executive Officer in May 2015.

(3) Non-Equity Incentive Plan Compensation for 2016 for Mr. Salka and Mr. Martin was approved by the board of directors as to amount and has not been paid. The amounts are expected to be paid no earlier than after completion of the next financing transaction and no later than March 15, 2018.

(4) Mr. Martin commenced employment with us as Chief Financial Officer in January 2016.

(5) Ms. Johnson served as our Interim Chief Operating Officer until Dr. Bilinsky's appointment in January 2017.

(6) Represents board of directors service retainers paid to Ms. Johnson.

**Base Salary**

The base salary or consulting compensation of our named executive officers, as applicable, is generally determined and approved by our Board of Directors, based on the recommendation of the Compensation Committee.

Mr. Salka's annual base salary for 2015 and 2016 was \$425,000.

Mr. Martin's annual base salary for 2016 was \$320,000.

Ms. Johnson was paid monthly consulting fees for her service as our Interim Chief Operating Officer during 2015 and 2016. Ms. Johnson was compensated at a rate of \$20,000 per month for her consulting services as Interim Chief Operating Officer from January 1, 2015 until June 30, 2015, which rate was increased to \$25,000 per month effective on July 1, 2015 and remained as such during 2016.

### **Bonus Opportunity**

In addition to base salaries, certain of our named executive officers are eligible to receive annual performance-based cash bonuses, which are designed to provide appropriate incentives to our executives to achieve defined annual corporate goals and to reward our executives for individual achievement towards these goals. The performance-based bonus a named executive officer may be eligible to receive is generally based on the extent to which we achieve the specified corporate goals that our Board of Directors or Compensation Committee establishes. After the end of the year, typically in February or March, the Board of Directors and/or Compensation Committee reviews our performance against the established corporate goals and approves the extent to which we achieved such goals. In addition, we may award a named executive officer a discretionary cash or equity bonus, if our Board of Directors or Compensation Committee determines appropriate based on the circumstances.

The Board of Directors and/or Compensation Committee generally will consider each executive officer's individual contributions towards reaching our corporate goals and may also establish specific individual goals for our executive officers as it determines appropriate. There is no minimum bonus percentage or amount established for the named executive officers and, as a result, the bonus amounts vary based on corporate and individual performance, as applicable. Under the terms of his offer letter agreement described below, Mr. Salka is eligible to receive an annual performance-based bonus for 2016 equal to, at target, 40% of his annual salary based on our achievement of certain performance goals. Under the terms of her consulting agreement described below, Ms. Johnson is eligible to receive up to \$250,000 in cash bonus payments for 2016 upon achievement of specific goals relating to dosing of the first patient in the first clinical trial utilizing our drug product, the successful regulatory filing in the United States related to one of our clinical trials and the issuance of a final report related to on-going clinical trials utilizing our drug product. Mr. Martin is eligible to receive an annual performance-based bonus for 2016 equal to, at target, 35% of his annual salary based on our achievement of certain performance goals.

Mr. Salka's and Mr. Martin's 2016 bonus was based entirely on corporate goals relating to capital raising, management of operating costs, our clinical trial and manufacturing progress, and certain organizational achievements.

In February 2017, the Compensation Committee reviewed the corporate performance goals for Mr. Salka and Mr. Martin and determined that on an overall basis, we had achieved 60% of such goals for 2016, based on the evaluation of the results by the Compensation Committee and considering the importance of each goal to our company. The Compensation Committee assessed the goals established for Ms. Johnson's bonus throughout the fiscal year and determined that she had met the goals established for 2016.

### **Equity-Based Awards**

Our equity-based incentive awards are designed to align our interests with those of our employees and consultants, including our named executive officers. Our Board of Directors or our Compensation Committee approves equity grants. Vesting of equity awards is generally tied to continuous service with us and serves as an additional retention measure. Our executives may be awarded an initial new hire grant upon commencement of service and may receive additional grants, as the Board of Directors or Compensation Committee determines appropriate, in order to incentivize and/or reward such executives.

We have traditionally granted stock options to our named executive officers under our equity incentive plans, the terms of which are described below under "—Equity Benefit Plans."



On January 18, 2016, in accordance with Mr. Martin's offer letter agreement, we granted Mr. Martin an option to purchase 99,919 shares of our common stock with an exercise price of \$2.85 per share. Twenty-five percent of the shares underlying this option vested on January 18, 2017, with the balance vesting in equal monthly installments thereafter over the next three years, subject to Mr. Martin's continued service with us.

### **Agreements with our Named Executive Officers**

Below are descriptions of our employment and consulting agreements with our named executive officers governing the terms of their service with us. For a discussion of the severance pay and other benefits that may be provided in connection with a termination of service and/or a change in control under the arrangements with our named executive officers, please see "—Potential Payments and Benefits upon Termination or Change in Control" below.

*Mr. Salka.* In April 2015, we entered into an offer letter agreement with Mr. Salka, our Chief Executive Officer. Mr. Salka's employment under the agreement is at will and may be terminated at any time by us or Mr. Salka. Under the terms of the agreement, Mr. Salka is entitled to receive an initial annual base salary of \$425,000, an annual target performance bonus of 40% of his annual salary based on our achievement of certain performance objectives and an option to purchase a number of shares of our common stock under our 2013 Plan equal to 4% of the number of shares of common stock outstanding on a fully-diluted basis, which was granted in August 2015 and is described above under "—Equity-Based Awards".

*Ms. Johnson.* We entered into an agreement with Ms. Johnson in September 2014 which provided for Ms. Johnson's services as an independent contractor on an interim basis as our Chief Operating Officer. In September 2015, we entered into a consulting agreement with Ms. Johnson, which superseded her prior agreement, effective July 1, 2015. Under the terms of her consulting agreement, including amendments, Ms. Johnson is entitled to receive monthly compensation of \$25,000 for consulting services of at least 120 hours per month, cash bonus payments up to an aggregate of \$300,000 upon the achievement of certain Company milestones and an option to purchase a number of shares of our common stock under our 2013 Plan equal to 0.5% of the number of shares of common stock outstanding on a fully-diluted basis, which was granted in September 2015. In February 2017, upon termination of her prior consulting agreement, we entered into a new consulting agreement with Ms. Johnson, pursuant to which Ms. Johnson has agreed to provide consulting services to us in the areas of clinical, regulatory, manufacturing and other operating activities as deemed necessary by the Company's Chief Executive Officer and Chief Operating Officer. Ms. Johnson is entitled to receive cash compensation in the amount of \$25,000 for services performed over an initial service period that extends for 60 days following the date of the consulting agreement. After the initial 60-day service period, Ms. Johnson may provide additional services to us on a project-by-project basis in exchange for compensation at a rate of \$400 per hour. The consulting agreement replaces Ms. Johnson's former September 2015 consulting agreement with us.

*Mr. Martin.* In January 2016, we entered into an offer letter agreement with Mr. Martin, our Senior Vice President and Chief Financial Officer. Mr. Martin's employment under the agreement is at will and may be terminated by us or Mr. Martin at any time. Under the terms of the agreement, Mr. Martin is entitled to receive an initial annual base salary of \$320,000, an annual target performance bonus of 35% of his annual salary based on our achievement of certain performance objectives and an option to purchase a number of shares of our common stock equal to 1% of the number of shares of common stock outstanding on a fully-diluted basis, which was granted in January 2016 and is described above under "—Equity-Based Awards".

### **Agreements with our Chief Operating Officer**

In January 2017, we entered into an offer letter agreement with Dr. Bilinsky. We agreed to provide Dr. Bilinsky with the following compensation: (i) annual base salary of \$350,000; and (ii) eligibility to receive an annual performance-based bonus, with an initial target bonus of 40% of his base salary. Pursuant to his offer letter, in January 2017 Dr. Bilinsky was also granted an option to purchase 247,322 shares of the Company's common stock at an exercise price of \$0.46 per share, and is expected to be granted an additional stock option exercisable for 1% of our total outstanding shares of common stock following the completion of our next financing transaction. Twenty-five percent of the shares subject to the option granted in January 2017 vest on the one-year anniversary of Dr. Bilinsky's commencement of employment with us and the remainder vests in 36 equal monthly installments thereafter, subject to Dr. Bilinsky's continued service with us. The additional stock option, if granted, is expected to have the same vesting schedule.

### **Potential Payments and Benefits upon Termination or Change in Control**

*Mr. Salka.* Under the terms of his offer letter agreement, as amended, Mr. Salka is entitled to receive 12 months of continued base salary if his employment with us is terminated without cause or if he resigns for good reason, and additionally, if such termination or resignation occurs in connection with a change in control, full acceleration of his equity awards, provided that in either case Mr. Salka executes an effective release of claims against us.

*Mr. Martin.* Under the terms of his offer letter agreement, Mr. Martin is entitled to receive 12 months of continued base salary if his employment with us is terminated without cause or if he resigns for good reason, and additionally, if such termination or resignation occurs in connection with a change in control, full acceleration of his equity awards, provided that in either case Mr. Martin executes an effective release of claims against us.

*Dr. Bilinsky.* Under the terms of his offer letter agreement, if Dr. Bilinsky is entitled to receive 12 months of continued base salary if his employment with us is terminated without cause or if he resigns for good reason, and

additionally, if such termination or resignation occurs in connection with a change in control, full acceleration of his equity awards, provided that in either case Dr. Bilinsky executes an effective release of claims against us.

All of the named executive officers hold stock options under our equity incentive plans that were granted subject to the general terms of our equity incentive plans and form of stock option agreements. A description of the termination and change in control provisions in such equity incentive plans and stock options granted thereunder is provided below under “—Equity Benefit Plans” and the specific vesting terms of each named executive officer’s stock options are described below under “—Outstanding Equity Awards at Fiscal Year End.”

### 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, 2016.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards:		
			Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price (\$)	Option Expiration Date
Mr. Salka	185,979	80,498	(1) 0	\$ 9.45	8/5/2025
Mr. Martin	0	99,919	(2) 99,919	\$ 2.85	1/17/2026
Ms. Johnson	49,965	0	0	\$ 7.46	9/8/2025
	2,167	4,333	(3) 0	\$ 6.38	9/21/2025
	0	0	9,700	(4) \$ 6.38	9/21/2025

- 133,239 of the shares vest over a four year period commencing on May 18, 2015 (with 25% vesting on the one-year anniversary of the commencement of Mr. Salka's employment and the balance vesting in monthly installments thereafter), subject to Mr. Salka's continued service with us, and 133,238 of the option grant vest upon satisfaction of certain business goals relating to human clinical trial milestones for our phage products.
- (1)
- (2) Twenty-five percent of the shares underlying this option vested on January 18, 2017, with the balance vesting in equal monthly installments thereafter over the next three years, subject to Mr. Martin's continued service with us.
- (3) The shares underlying this option vest on an equal monthly basis over a four-year period commencing on August 3, 2015. This option was granted to Ms. Johnson for her services as a non-employee director.
- (4) The shares underlying this option will vest on the date that the market price of our common stock reaches \$25.00 per share before the option expires. This option was granted to Ms. Johnson for her services as a non-employee director.

All of the stock options held by our named executive officers listed in the table above were granted under and subject to the terms of our 2013 Stock Incentive Plan, the terms of which are described below under "—Equity Benefit Plans".

### **Option Exercises and Stock Vested**

Our named executive officers did not exercise any stock option awards during the year ended December 31, 2016.

### **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 Benefit Plans**

### ***2016 Equity Incentive Plan***

Our 2016 Equity Incentive Plan, or the 2016 Plan, was approved by our Board of Directors in April 2016 and subsequently approved by our stockholders in June 2016. The plan provides for the issuance of incentive awards in the form of non-qualified and incentive stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and performance-based stock awards. The awards may be granted by the Company's Board of Directors to its employees, including officers, non-employee directors and consultants who provide services to the Company or to a subsidiary of the Company. The exercise price for stock options must not be less than the fair market value of the underlying shares on the date of grant. Stock options expire no later than ten years from the date of grant and generally vest and typically become exercisable over a four-year period following the date of grant. Upon the exercise of stock options, the Company issues the resulting shares from shares reserved for issuance under the 2016 Plan. With the approval of the 2016 Plan, the remaining unallocated shares under the Company's 2013 Stock Incentive Plan were allocated to the 2016 Plan and an additional 1,000,000 new shares were added to the authorized share reserve under the 2016 Plan. On January 1, 2017, pursuant to the terms of the 2016 Plan, the number of shares available for issuance under the 2016 Plan automatically increased by 824,406 shares.

### ***2013 Stock Incentive Plan***

Our 2013 Stock Incentive Plan, or the 2013 Plan, was first approved by our Board of Directors in December 2013 and approved by our stockholders in February 2014, and subsequently amended by our Board of Directors and stockholders effective in August 2015. With the approval of the 2016 Plan, we will not issue any further awards under the 2013 Plan. We have included this description of the 2013 Plan in order to provide information regarding the material terms of the awards we granted to our named executive officers during the years ended December 31, 2015 and December 31, 2016. As of December 31, 2016, there were outstanding stock options to purchase 663,838 shares of our common stock under the 2013 Plan.

The 2013 Plan permitted the granting of stock options (both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify), stock appreciation rights, restricted stock, restricted stock units, dividend equivalent rights, and cash-based awards. The exercise price of each stock option was determined by our plan administrator to be at no less than 100% of the fair market value of our common stock on the date of grant or, in the case of an incentive stock option granted to a 10% owner, no less than 110% of the fair market value of our common stock on the date of grant. The term of each stock option was fixed by the plan administrator and may not exceed 10 years from the date of grant. The plan administrator determines at what time or times each option may be exercised.

Under the terms of the 2013 Plan, an option may be exercised following the cessation of a participant's service with us only to the extent provided in the applicable option agreement. If a participant's service relationship with us or any of our affiliates ceases for any reason other than disability or death, the participant may generally exercise any vested options for a period of three months following the cessation of service. If a participant's service relationship with us or any of our affiliates ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested options for a period of 12 months. In no event may an option be exercised beyond the expiration of its term.

Under the terms of the 2013 Plan, upon the effectiveness of a corporate transaction (as such term is defined in the 2013 Plan) in the event that all awards are not affirmed by us or assumed by the successor entity, all awards granted under the 2013 Plan shall terminate. In addition, in connection with a corporate transaction or change in control (as such term is defined in the 2013 Plan) the plan administrator may provide the full or partial automatic vesting and exercisability of one or more outstanding unvested awards under the 2013 Plan and the release from restrictions on transfer or forfeiture rights of such awards in connection with such transaction, on such terms and conditions as the plan administrator may specify.

Our Board of Directors may amend the 2013 Plan at any time; no further grants will be made under the 2013 Plan as of the effectiveness of our 2016 Plan, but outstanding awards granted under the 2013 Plan continue to be governed by its terms. The plan administrator may amend the terms of any outstanding award granted under the 2013 Plan, but no such action may adversely affect the holder's rights under an outstanding award without the holder's consent. Certain amendments to the 2013 Plan require the approval of our stockholders.

### ***Employee Stock Purchase Plan***

Additional long-term equity incentives are provided through our 2016 Employee Stock Purchase Plan (the "ESPP"), which became effective in connection with our 2016 Annual Meeting of Shareholders in May 2016. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of section 423 of the Code. Our Board of Directors has delegated its authority to administer the ESPP to our Compensation Committee. Under the ESPP, all of our regular employees (including our Named Executive Officers) may participate and may contribute, normally through payroll deductions, up to 15% of their earnings for the purchase of our common stock. The ESPP is implemented through a series of offerings of purchase rights to eligible employees. Under the ESPP, we may specify offerings with a duration of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which our common stock will be purchased for employees participating in the offering. Unless otherwise determined by our Compensation Committee, shares are purchased for accounts of employees participating in the ESPP at a price per share equal to the lower of (a) 85% of the fair market value of our common stock on the first date of an offering or (b) 85% of the fair market value of our common stock on the date of purchase. As of December 31, 2016, there were 87,274 shares available for future issuance under the ESPP. On January 1, 2017, pursuant to the terms of the ESPP, the number of shares available for issuance under the ESPP automatically increased by 164,881 shares.

**Non-Employee Director Compensation**

The following table and related footnotes show the compensation paid during the year ended December 31, 2016 to our non-employee directors, other than Ms. Johnson whose 2016 compensation is set forth above under “Executive Compensation” above. We did not grant any equity awards to our non-employee directors during the year ended December 31, 2016.

Name	Fees Earned or Paid in	
	Cash	Total
Jeremy Curnock Cook <sup>(1)</sup>	\$ 70,000	\$70,000
Louis Drapeau <sup>(2)</sup>	\$ 58,000	\$58,000
Michael S. Perry, Ph.D. <sup>(3)</sup>	\$ 59,000	\$59,000
Vijay Samant <sup>(4)</sup>	\$ 46,000	\$46,000
Paul C. Grint <sup>(5)</sup>	\$ 45,000	\$45,000
Julian Kirk <sup>(6)</sup>	\$ 11,667	\$11,667

(1) As of December 31, 2016, Mr. Cook held stock options for an aggregate of 49,100 shares, of which 25,077 shares were vested and exercisable.

(2) As of December 31, 2016, Mr. Drapeau held stock options for an aggregate of 16,200 shares, of which 4,567 shares were vested and exercisable.

(3) As of December 31, 2016, Mr. Perry held stock options for an aggregate of 17,400 shares, of which 6,767 shares were vested and exercisable.

(4) As of December 31, 2016, Mr. Samant held stock options for an aggregate of 16,200 shares, of which 4,388 shares were vested and exercisable.

(5) As of December 31, 2016, Mr. Grint held stock options for an aggregate of 16,200 shares, of which 4,388 shares were vested and exercisable.

(6) Mr. Kirk resigned from our Board of Directors in April 2016. As of December 31, 2016, Mr. Kirk did not have any outstanding or vested stock options.

In September 2015, the Board of Directors approved a revised compensation structure for our non-employee directors. In 2016, the chairman of the Board received an annual cash retainer of \$60,000 and each other non-employee director received an annual cash retainer of \$40,000. For the Audit Committee, the committee chair received an additional annual cash retainer of \$15,000 and each member received an additional annual cash retainer of \$6,000. For the Compensation Committee, the committee chair received an additional annual cash retainer of \$10,000 and each member received an additional annual cash retainer of \$5,000. For the Nominating and Corporate Governance Committee, the committee chair received an additional annual cash retainer of \$5,000 and each member received an additional annual cash retainer of \$3,000.

During 2016, Mr. Salka and Ms. Johnson served on our Board of Directors. As an employee, Mr. Salka did not receive cash or equity compensation for his services as a director during 2016. Ms. Johnson received a retainer of \$40,000 for her services as a director during 2016. As named executive officers, the compensation of each of Mr. Salka and Ms. Johnson is reflected in the Summary Compensation Table above.

**Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The following table sets forth information regarding beneficial ownership of our capital stock by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all of our current executive officers and directors as a group.

The percentage ownership information in the table below is based on 16,488,120 shares of common stock outstanding as of January 31, 2017.

Information with respect to beneficial ownership provided in the table below is based upon information supplied by officers, directors and principal shareholders and Schedules 13D and 13G and Form 4 filed with the SEC. 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 shared 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 on or before April 1, 2017, which is 60 days after January 31, 2017. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown



Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

as beneficially owned by them, subject to applicable community property laws.

Except as otherwise noted below, the address for each person or entity listed in the table is c/o AmpliPhi Biosciences Corporation, 3579 Valley Centre Drive, Suite 100, San Diego, California 92130.

Beneficial Owner	Beneficial Ownership Number of Shares	Percent of Total
5% or Greater Shareholders		
Sabby Management, LLC <sup>(1)</sup> 10 Mountainview Road, Suite 205 Upper Saddle River, NJ 07458	3,006,757	16.7 %
Pendinas Limited <sup>(2)</sup> Ballacarrick, Poolvaish Road Isle of Man, IM9 4PJ	2,144,742	12.7 %
Heights Capital Management, Inc. <sup>(3)</sup> 101 California Street, Suite 3250 San Francisco, CA 94111	2,012,650	11.4 %
Phillip Asset Management Limited <sup>(4)</sup> Level 12, 15 William Street Melbourne VIC Australia	1,753,109	10.3 %
Hudson Bay Capital Management <sup>(5)</sup> 777 Third Avenue, 30 <sup>th</sup> Floor New York, NY 10017	1,140,909	6.5 %
Directors and Named Executive Officers		
M. Scott Salka <sup>(6)</sup>	205,506	1.2 %
Jeremy Curnock Cook <sup>(7)</sup>	1,784,484	10.4 %
Louis Drapeau <sup>(8)</sup>	14,973	*
Michael S. Perry, Ph.D. <sup>(9)</sup>	9,473	*
Vijay B. Samant <sup>(10)</sup>	5,400	*
Paul C. Grint, M.D. <sup>(11)</sup>	5,400	*
Wendy Johnson <sup>(12)</sup>	53,538	*
Steven R. Martin <sup>(13)</sup>	32,903	*
<b>All current executive officers and directors as a group (nine persons)<sup>(14)</sup></b>	<b>2,111,677</b>	<b>12.1 %</b>

\*Represents beneficial ownership of less than 1%.

Consists of (a) 1,440,369 shares of common stock held by Sabby Healthcare Master Fund, Ltd., which we refer to as Sabby Healthcare, (b) 1,310,638 shares of common stock issuable upon exercise of warrants held by Sabby Healthcare, (c) 78,445 shares of common stock held by Sabby Volatility Warrant Master Fund, Ltd., which we refer to as Sabby Volatility, and (d) 177,305 shares of common stock issuable upon exercise of warrants held Sabby Volatility. Sabby Management, LLC serves as the investment manager of Sabby Healthcare and Sabby Volatility, and has shared voting and investment power over the shares beneficially owned by Sabby Healthcare (1) and Sabby Volatility listed in the foregoing clauses (a)-(d). Shares held by Sabby Healthcare and Sabby Volatility may be deemed to be indirectly beneficially owned (as defined under Rule 13d-3 promulgated under the Exchange Act) by Sabby Management, LLC. Sabby Management, LLC disclaims beneficial ownership of such shares, except to the extent of any pecuniary interest therein. Hal Mintz is the Manager of Sabby Management, LLC. 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. Mintz. Mr. Mintz disclaims beneficial ownership of such shares, except to the extent of any pecuniary interest therein.

(2) Includes 336,044 shares of common stock issuable upon exercise of warrants.

Consists of (a) 879,316 shares of common stock held by CVI Investments, Inc., which we refer to as CVI Investments, and (b) 1,133,334 shares of common stock issuable upon exercise of warrants held by CVI (3) Investments. Heights Capital Management, Inc., which serves as the investment manager to CVI Investments, may be deemed to be the beneficial owner of all shares owned by CVI Investments. Heights Capital Management, Inc. disclaims beneficial ownership of such shares, except to the extent of any pecuniary interest therein.

Consists of (a) 1,185,145 shares of common stock held by One Fund Management Limited as Trustee for Asia Pacific Healthcare Fund II, which is also known as Phillip Asset Management Limited as Trustee for Asia Pacific (4) Healthcare Fund II ("Phillip Asset Management") and (b) 567,964 shares of common stock issuable upon exercise of warrants held by Phillip Asset Management. Phillip Asset Management holds all securities in its capacity as trustee for Bioscience Managers Pty Ltd. Jeremy Curnock Cook, the Chairman of the Company's Board of Directors, is a Managing Director and holds an ownership interest in Bioscience Managers Pty Ltd.

Consists of 1,140,909 shares of common stock issuable upon exercise of warrants held by Hudson Bay Master Fund Ltd., which we refer to as Hudson Bay Master. Excludes 354,610 shares of common stock issuable upon exercise of warrants held by Hudson Bay Master that are subject to a limitation, pursuant to which Hudson Bay Master cannot exercise any of such securities if Hudson Bay Master would beneficially own, after any such (5) exercise, more than 4.99% of the outstanding shares of our outstanding common stock. Hudson Bay Capital Management, L.P. is the investment manager of Hudson Bay Master and may be deemed to be the beneficial owner of all shares beneficially owned by Hudson Bay Master. Sander Gerber serves as the managing member of Hudson Bay Capital GP LLC, which is the general partner of Hudson Bay Capital Management, L.P. Mr. Gerber disclaims beneficial ownership of these securities.

- (6) Includes 194,306 shares of common stock that Mr. Salka has the right to acquire from us within 60 days of January 31, 2017, pursuant to the exercise of stock options.
- (7) Includes the shares referenced in Footnote 4 above and 28,075 shares of common stock that Mr. Cook has the right to acquire from us within 60 days of January 31, 2017, pursuant to the exercise of stock options.
- (8) Includes 4,973 shares of common stock that Mr. Drapeau has the right to acquire from us within 60 days of January 31, 2017, pursuant to the exercise of stock options.
- (9) Includes 7,173 shares of common stock that Dr. Perry has the right to acquire from us within 60 days of January 31, 2017, pursuant to the exercise of stock options.
- (10) Includes 5,400 shares of common stock that Mr. Samant has the right to acquire from us within 60 days of January 31, 2017, pursuant to the exercise of stock options.
- (11) Includes 5,400 shares of common stock that Dr. Grint has the right to acquire from us within 60 days of January 31, 2017, pursuant to the exercise of stock options.

(12) Includes 52,538 shares of common stock that Ms. Johnson has the right to acquire from us within 60 days of January 31, 2017, pursuant to the exercise of stock options.

(13) Includes 29,143 shares of common stock that Mr. Martin has the right to acquire from us within 60 days of January 31, 2017, pursuant to the exercise of stock options.

(14) Consists of (a) 1,216,705 shares of common stock, (b) 567,964 shares of common stock issuable upon exercise of warrants, and (c) 327,008 shares of common stock pursuant to the exercise of stock options exercisable within 60 days of January 31, 2017.

### **Equity Compensation Plan Information**

In March 2009, our board of directors and stockholders adopted the 2009 Stock Incentive Plan, which we refer to as the 2009 Stock Incentive Plan. There are no shares of common stock remaining for future awards under the 2009 Stock Incentive Plan.

In October 2012, our board of directors approved and adopted the 2012 Stock Incentive Plan, which we refer to as the 2012 Plan. There are no shares of common stock remaining for future awards under the 2012 Stock Incentive Plan.

In December 2013, our board of directors adopted the 2013 Stock Incentive Plan, or the 2013 Plan. Under the 2013 Plan, we are authorized to issue up to 1,320,000 shares of our common stock in stock option and other stock incentive awards to employees, directors and consultants. Our stockholders approved the 2013 Plan in February 2014 and an amendment to the plan in August 2015. The 2013 Plan replaces the 2012 Stock Incentive Plan.

In June 2016, the Company's stockholders approved the 2016 Equity Incentive Plan (the 2016 Plan). With the approval of the 2016 Plan, the remaining unallocated shares under the Company's 2013 Stock Incentive Plan were allocated to the 2016 Plan and an additional 1,000,000 new shares were added to the authorized share reserve under the 2016 Plan.

The following table provides information as of December 31, 2016 with respect to our equity compensation plans:

Number of

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average price of outstanding options, warrants and rights (b)	securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a) (c)
Equity compensation plans approved by security holders <sup>(1)</sup>	706,838	\$ 6.24	1,640,162
Equity compensation plans not approved by security holders <sup>(2)</sup>	42,100	\$ 10.00	-
Total	748,938	\$ 6.45	1,640,162

(1)

The 2009 Plan, 2013 Plan and 2016 Plan.

(2)

The 2012 Plan.

**Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The following includes a summary of transactions since January 1, 2014 to which we have been a party, in which the amount involved in the transaction exceeded the lesser of \$120,000 or one percent of the average of our total assets at year end for the last two completed fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described in the sections above entitled “Executive Compensation” and “Non-Employee Director Compensation.”

## **Sale of Common Stock**

In March 2015, in connection with a private placement of our common stock, we sold an aggregate of 68,455 shares and 17,113 shares underlying warrants to One Fund Management Limited as Trustee for Asia Pacific Healthcare Fund II, which is also known as Phillip Asset Management Limited as Trustee for Asia Pacific Healthcare Fund II, or Phillip Asset Management. Jeremy Curnock Cook, our then-interim Chief Executive Officer and the current chairman of our board of directors, is a Managing Director and holds an ownership interest in Bioscience Managers Pty Ltd. Phillip Asset Management Limited is 100% owned by Phillip Capital Holdings Ltd., an Australian stockbroker. Phillip Asset Management holds all shares in its capacity as trustee for Bioscience Managers Pty Ltd.

In addition, in connection with the March 2015 private placement, we sold an aggregate of 278,788 shares and 69,697 shares underlying warrants to Intrexon Corporation. Intrexon was affiliated with Randal J. Kirk, one of our principal stockholders and also the father of a former member of our board of directors, Julian P. Kirk. In connection with the March 2015 private placement, we entered into a registration rights agreement with Intrexon and certain other purchasers in the private placement, pursuant to which we registered for resale on Form S-1 (File No. 333-203454) 824,848 shares of common stock (on a post-August 2015 reverse split basis) held or issuable upon exercise of warrants by Intrexon. We also granted Intrexon certain piggyback registration rights.

## **Exclusive Channel Collaboration**

Pursuant to that certain Exclusive Channel Collaboration Agreement, dated as of March 29, 2013, with Intrexon Corporation, which we refer to as the ECC Agreement, we agreed to pay Intrexon Corporation royalties as a percentage in the upper-single digits of the net product sales of a product developed under the collaboration, and up to \$7.5 million in aggregate milestone payments for each product developed. Intrexon Corporation owned more than 5% of our common stock at the time of the transaction. On April 13, 2016, we provided written notice to Intrexon Corporation of our election to voluntarily terminate the ECC Agreement. The effective date of termination was July 12, 2016.

## **Common Stock Issuance Agreement**

On April 8, 2016, we entered into a Common Stock Issuance Agreement, or the CSIA, with certain former holders of our Series B convertible preferred stock, including Pendas Limited and One Funds. Pursuant to the CSIA, we issued shares of our common stock to such holders, and amended certain warrants to purchase common stock issued to such holders in the private placement of Series B convertible preferred stock in June 2013 and/or July 2013, in order to reduce the exercise price of such warrants from \$7.00 per share to \$4.05 per share and extend the expiration date

thereof from June 26, 2018 to March 31, 2021. As consideration for the transactions described above, such holders waived their right to receive approximately \$2.2 million in aggregate cash payments to which they were entitled upon the conversion of all outstanding shares of Series B redeemable convertible preferred stock into shares of common stock on April 8, 2016, in respect of accrued dividends on their former shares of Series B convertible preferred stock. Such holders also waived their registration rights with respect to certain future registration statements that may be filed, and certain future public offerings that may be conducted, by us.

The table below summarizes the shares issued to Pendinas Limited and One Funds and the accrued dividends waived by such parties:

Related Person	Shares Issued	Accrued Dividends Waived
Pendinas Limited	584,556	\$1,504,433
One Funds	171,298	\$440,859

Pursuant to the terms of the CSIA and in connection with the registered direct public offering that we completed in June 2016, on June 21, 2016 we issued 513,837 and 150,576 shares of common stock to Pendinas Limited and One Funds, respectively, for no additional consideration. We may be required to issue additional shares to Pendinas and One Funds pursuant to the CSIA.

### **Settlement Agreement**

On November 12, 2016, we entered into a settlement agreement with NRM. See “ — Legal Proceedings” for more information.

### **Employment Agreements**

We have entered into compensatory arrangements with our executive officers, as more fully described in the section above entitled “Executive Compensation.”

### **Stock Options Granted to Executive Officers and Directors**

We have granted stock options to our executive officers and directors, as more fully described in the sections above entitled “Executive Compensation” and “Non-Employee Director Compensation.”

### **Indemnification Agreements**

We have entered, and intend to continue to enter, into separate indemnification agreements with each of our directors and executive officers, as described in the sections above entitled “Executive Compensation” and “Non-Employee Director Compensation.”

### **Policies and Procedures for Transactions with Related Persons**

We have adopted a written related-person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration and oversight of “related-person transactions.” For purposes of our policy only, a “related-person transaction” is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any “related person” are participants involving an amount that exceeds \$120,000 (or such lower threshold as may be applicable to us from time to time pursuant to the rules and regulations of the SEC or the NYSE MKT).

Transactions involving compensation for services provided to us by an employee, consultant or director are not considered related-person transactions under this policy. A related person is any executive officer, director or a holder of more than five percent of our common stock, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, where a transaction has been identified as a related-person transaction, management must present information regarding the proposed related-person transaction to our audit committee (or, where review by our audit committee would be inappropriate, to another independent body of our board of directors) for approval. The presentation must include a description of, among other things, the material facts, the direct and indirect interests of the related persons, the benefits of the transaction to us and whether any alternative transactions are available. To identify related-person transactions in advance, we rely on information supplied by our executive officers, directors and certain significant stockholders. In considering related-person transactions, our audit committee or other independent body of our board of directors takes into account the relevant available facts and circumstances including,



but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated; the terms of the transaction;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties.

In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval.

#### **Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

We engaged Ernst & Young LLP as our independent accountant as of January 20, 2015. Prior to such date in 2015 and during the year ended December 31, 2014, PBMares, LLP served as our independent registered public accounting firm.

The following table represents aggregate fees billed to us for the fiscal years ended December 31, 2016 and December 31, 2015 by Ernst & Young LLP, our current principal accountant.

	Fiscal Year Ended December 31, 2016	Fiscal Year Ended December 31, 2015
Audit Fees	\$448,595	\$510,988
Audit Related Fees	165,000	22,600
Tax Fees	0	0
All Other Fees	0	0
Total	\$613,595	\$533,588

The total audit fees billed to us by PBMares LLP, our former principal accountant, for the fiscal years ended December 31, 2016 and 2015 was \$0 and \$51,551, respectively. There were no audit related fees or tax fees or any other fees from PBMares, LLP for the fiscal years ended December 31, 2016 and 2015.

Representatives of Ernst & Young LLP attended all of the meetings of the Audit Committee occurring after January 20, 2015. Representatives of PBMares, LLP attended all of the meetings of the Audit Committee during the period commencing on January 1, 2014 and ending on January 20, 2015.

The Audit Committee approves in advance the engagement and fees of the independent registered public accounting firm for all audit services and non-audit services, based upon independence, qualifications and, if applicable, performance. The Audit Committee may form and delegate to subcommittees of one or more members of the Audit Committee the authority to grant pre-approvals for audit and permitted non-audit services, up to specific amounts. All audit services provided by Ernst & Young LLP and PBMares, LLP for the periods presented were pre-approved by the Audit Committee.

**PART IV**

**Item 15. EXHIBITS**

1. *Financial Statements.* We have filed the following documents as part of this Annual Report:

	<b>Page</b>
Report of Independent Registered Public Accounting Firm	F-1
Consolidated Balance Sheets	F-2
Consolidated Statements of Operations	F-3
Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity	F-4
Consolidated Statements of Cash Flows	F-5
Notes to Consolidated Financial Statements	F-6

2. *Financial Statement Schedules.* None.

3. *Exhibits.* For a list of exhibits filed with this Annual Report on Form 10-K, refer to the Exhibit Index appearing immediately following the signature pages to this Annual Report.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

### AMPLIPHI BIOSCIENCES CORPORATION

By: /s/ Michael Scott Salka

Name: Michael Scott Salka

Title: Chief Executive Officer

(Principal Executive Officer)

By: /s/ Steve R. Martin

Name: Steve R. Martin

Title: Chief Financial Officer

(Principal Financial and Accounting Officer)

Date: March 27, 2017

**SIGNATURES AND POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Michael Scott Salka and Steve R. Martin, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that such attorneys-in-fact and agents or any of them, or his or her or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

<b>SIGNATURE</b>	<b>TITLE</b>	<b>DATE</b>
/s/ Michael Scott Salka Michael Scott Salka	Chief Executive Officer <i>(Principal Executive Officer)</i>	March 27, 2017
/s/ Steve R. Martin Steve R. Martin	Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	March 27, 2017
/s/ Jeremy Curnock Cook Jeremy Curnock Cook	Chairman of the Board of Directors	March 27, 2017
/s/ Louis Drapeau Louis Drapeau	Director	March 27, 2017
/s/ Paul C. Grint, M.D. Paul C. Grint, M.D.	Director	March 27, 2017
/s/ Wendy S. Johnson Wendy S. Johnson	Director	March 27, 2017
/s/ Michael S. Perry, Ph.D. Michael S. Perry, Ph.D.	Director	March 27, 2017
/s/ Vijay B. Samant Vijay B. Samant	Director	March 27, 2017



**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description of Document</b>
3.1	Amended and Restated Articles of Incorporation of the Company, as amended (incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on November 16, 2015).
3.2	Amended and Restated Bylaws of the Company, as amended (incorporated by reference to Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on November 16, 2015).
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form 10, as amended (File No. 000-23930), filed with the SEC on December 16, 2013).
4.3	Form of Warrant to Purchase Shares of Common Stock issued to purchasers in June 2013, July 2013 and December 2013 in connection with private placements (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form 10, as amended (File No. 000-23930), filed with the SEC on December 16, 2013).
4.4	Subscription Agreement to Purchase Series B Preferred Stock and Common Stock Warrants, dated June 26, 2013 (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form 10, as amended (File No. 000-23930), filed with the SEC on December 16, 2013).
4.5	Registration Rights Agreement, dated December 16, 2013, by and among the Company and certain purchasers of the Company's Common Stock (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form 10, as amended (File No. 000-23930), filed with the SEC on December 16, 2013).
4.6	Subscription Agreement to Purchase Common Stock and Warrants, dated December 16, 2013 (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form 10, as amended (File No. 000-23930), filed with the SEC on December 16, 2013).
4.7	Subscription Agreement to Purchase Common Stock and Warrants, dated March 10, 2015 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on March 19, 2015).
4.8	Form of Common Stock Warrant issued to purchasers in March 2015 private placement (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on March 19, 2015).
4.9	Registration Rights Agreement, dated March 10, 2015, by and among the Company and certain purchasers of the Company's Common Stock (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed with the SEC on March 19, 2015).

Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

- 4.10 Form of Amendment to Warrants to Purchase Shares of Common Stock issued to purchasers in June 2013, July 2013 and December 2013 in connection with private placements (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on May 15, 2015).
- 4.11 Form of Warrant to Purchase Shares of Common Stock issued in connection with the Company's acquisition of Biocontrol Ltd in December 2011 (incorporated by reference to Exhibit 4.11 to the Company's Annual Report on Form 10-K, filed with the SEC on March 30, 2016).
- 4.12 Form of Warrant to Purchase Shares of Common Stock issued in connection with the issuance of convertible notes of the Company in February 2013, March 2013, April 2013 and May 2013 (incorporated by reference to Exhibit 4.12 to the Company's Annual Report on Form 10-K, filed with the SEC on March 30, 2016).
- 4.13 Form of Warrant to Purchase Shares of Common Stock issued in connection with the Company's acquisition of certain assets of Novolytics Limited in February 2016 (incorporated by reference to Exhibit 4.13 to the Company's Annual Report on Form 10-K, filed with the SEC on March 30, 2016).
- 4.14 Common Stock Issuance Agreement, dated April 8, 2016, by and among the Company and the persons and entities listed on Exhibit A thereto (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on April 8, 2016)
- 4.15 Form of Warrant to Purchase Common Stock issued to purchasers in May 2016 registered direct offering (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on June 1, 2016).



- 4.16 Form of Securities Purchase Agreement (incorporated by reference to Exhibit 99.3 to the Company's Current Report on Form 8-K, filed with the SEC on June 1, 2016).
- 4.17 Form of Warrant to Purchase Common Stock issued to purchasers in November 2016 registered direct offering (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on November 17, 2016).
- 10.1+ Targeted Genetics Corporation 2009 Stock Incentive Plan (incorporated by reference to Exhibit 10.12 to the Company's Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
- 10.2+ AmpliPhi Biosciences Corporation 2012 Stock Incentive Plan (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
- 10.3+ Form of Stock Option Agreement under AmpliPhi Biosciences Corporation 2012 Stock Incentive Plan (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
- 10.4+ AmpliPhi Biosciences Corporation 2013 Stock Incentive Plan (incorporated by reference to Exhibit 10.21 to the Company's Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
- 10.5+ Form of Grant Notice and Stock Option Agreement under AmpliPhi Biosciences Corporation 2013 Stock Incentive Plan (incorporated by reference to Exhibit 10.16 to the Company's Annual Report on Form 10-K, filed with the SEC on March 30, 2016).
- 10.6+ AmpliPhi Biosciences Corporation 2016 Equity Incentive Plan (incorporated by reference to Exhibit 99.1 to the Company's Registration Statement on Form S-8, filed with the SEC on June 22, 2016).
- 10.7+ Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the AmpliPhi Biosciences Corporation 2016 Equity Incentive Plan (incorporated by reference to Exhibit 99.2 to the Company's Registration Statement on Form S-8, filed with the SEC on June 22, 2016).
- 10.8+ AmpliPhi Biosciences Corporation 2016 Employee Stock Purchase Plan (incorporated by reference to Exhibit 99.3 to the Company's Registration Statement on Form S-8, filed with the SEC on June 22, 2016).
- 10.9+ Form of Indemnity Agreement with the Company's Directors and Executive Officers (incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K, filed with the SEC on January 19, 2016)
- 10.10+ Offer Letter, dated as of April 28, 2015, by and between the Company and M. Scott Salka (incorporated by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K, filed with the SEC on March 30, 2016).
- 10.11+ Offer Letter, dated as of January 18, 2016, by and between the Company and Steve R. Martin (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K, filed with the SEC on January 19, 2016).

Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

- 10.12+ Offer Letter, dated as of January 27, 2017, by and between the Company and Igor P. Bilinsky, Ph.D (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K, filed with the SEC on February 2, 2017).
- 10.13+ Consulting Agreement, dated as of February 1, 2017, by and between the Company and Wendy S. Johnson (incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K, filed with the SEC on February 2, 2017).
- 10.14 Loan Repayment Deed, dated September 28, 2012, by and among the Company, Cellabs Pty Ltd and Special Phage Holdings Pty Ltd. (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form 10, as amended (File No. 000-23930), filed with the SEC on December 16, 2013).
- 10.15 Stock Issuance Agreement, dated as of March 29, 2013, by and between the Company and Intrexon Corporation (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form 10, as amended (File No. 000-23930), filed with the SEC on December 16, 2013).
- 10.16\* License, dated as of September 5, 2013, by and between the Company and the University of Leicester (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form 10, as amended (File No. 000-23930), filed with the SEC on December 16, 2013).
- 10.17 Cooperative Research and Development Agreement, dated as of June 13, 2013, by and between the Company and United States Army Medical Research and Materiel Command (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form 10 , as amended (File No. 000-23930), filed with the SEC on December 16, 2013).
- 10.18 Agreement of Lease, dated as of February 23, 2011, by and between the Company and Virginia Biotechnology Research Partnership Authority (incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form 10, as amended (File No. 000-23930), filed with the SEC on December 16, 2013).

- 10.19 Lease, dated as of December 8, 2011, by and between Biocontrol Limited, Nevis Limited and Charter Limited (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form 10, as amended (File No. 000-23930), filed with the SEC on December 16, 2013).
- 10.20\* License Agreement, dated as of July 3, 2007, by and between the Company and Health Protection Agency, Centre for Emergency Preparedness and Response (incorporated by reference to Exhibit 10.18 to the Company's Registration Statement on Form S-1, as amended (File No. 333-193458), filed with the SEC on January 21, 2014).
- 10.21 Stockholder Sale Agreement, dated as of September 8, 2012, by and among the Company, Anthony Smithyman and Margaret Smithyman, AmpliPhi Australia Pty Ltd, Special Phage Holdings Pty Ltd, and the other parties listed therein (incorporated by reference to Exhibit 10.19 to the Company's Registration Statement on Form S-1, as amended (File No. 333-193458), filed with the SEC on January 21, 2014).
- 10.22 Agreement and Plan of Merger, dated as of November 12, 2010, by and among the Company, Sheffield Acquisition 1, Inc., and Sheffield Acquisition 2, Inc. (incorporated by reference to Exhibit 10.20 to the Company's Registration Statement on Form S-1, as amended (File No. 333-193458), filed with the SEC on January 21, 2014).
- 10.23 Agreement of Lease of Business Premises, dated as of February 21, 2014, by and between Avotehna d.d. and AmpliPhi, Biotehnoške Raziskave in Razvoj, d. o. o. (incorporated by reference to Exhibit 10.22 to the Company's Registration Statement on Form 10, as amended (File No. 000-23930), filed with the SEC on December 16, 2013).
- 10.24 Agreement of Sublease, dated as of April 17, 2015, by and between the Company and Virginia Biotechnology Research Partnership Authority (incorporated by reference to Exhibit 10.26 to the Company's Annual Report on Form 10-K, as amended, filed with the SEC on April 30, 2015)
- 10.25\* Collaboration Agreement, dated as of November 4, 2015, by and between the Company and the University of Leicester (incorporated by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K, filed with the SEC on March 30, 2016).
- 10.26 Asset Purchase Agreement, dated as of January 4, 2016, by and between the Company and Novolytics Limited (incorporated by reference to Exhibit 10.26 to the Company's Annual Report on Form 10-K, filed with the SEC on March 30, 2016).
- 10.27 Placement Agency Agreement, dated as of May 31, 2016, by and among the Company, Roth Capital Partners, LLC and Griffin Securities, Inc. (incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K, filed with the SEC on June 1, 2016)
- 10.28 Settlement Agreement, dated as of November 12, 2016, by and between the Company and NRM VII Holdings I, LLC (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K, filed with the SEC on November 14, 2016)
- 21.1 Subsidiaries of the Company.
- 23.1 Consent of Ernst & Young LLP, independent registered public accounting firm.

- 24.1 Power of Attorney (contained on the signature page).
- 31.1 Certification of Chief Executive Officer Pursuant to Rule 13a-14(a)/15d-14(a).
- 31.2 Certification of Chief Financial Officer Pursuant to Rule 13a-14(a)/15d-14(a).
- 32.1 Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350.
- 32.2 Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350.
- 101.INS XBRL Instance Document
- 101.SCH XBRL Taxonomy Extension Schema Document
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document
- 101.DEF XBRL Taxonomy Extension Definition Linkbase Document
- 101.LAB XBRL Taxonomy Extension Label Linkbase Document
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

**+ Indicates management contract or compensatory plan or arrangement.**

**\* Indicates confidential treatment has been requested.**