AmpliPhi Biosciences Corp
Form 10-K
March 14, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2017

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

(Exact name of registrant as specified in its charter)

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

3579 Valley Centre Drive, Suite 100

San Diego, California 92130

(Address of principal executive offices, including zip code)

(858) 829-0829

(Registrant's telephone number, including area code)

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

Title of each class	**Name of each exchange on which registered**
Common Stock, par value $0.01 per share	NYSE American

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 x

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

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

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. x

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

As of June 30, 2017, 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, 2017 (the last business day of the Registrant's most recently completed second quarter) as quoted on the NYSE American, was approximately $6,574,000.

As of March 7, 2018, 13,695,824 shares of the Registrant's Common Stock were outstanding.

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AMPLIPHI BIOSCIENCES CORPORATION

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report and certain information incorporated herein by reference contain forward-looking statements, which are provided under the "safe harbor" protection of the Private Securities Litigation Reform Act of 1995. These statements relate to future events, 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,” “inten “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative of those terms, and similar expressio 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 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. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain. Given these uncertainties, you should not place undue reliance on any of the forward-looking statements included in this report. In addition, this report also contains estimates, projections and other information concerning our industry, our business, and the markets for our product candidates, as well as data regarding market research, estimates and forecasts prepared by our management. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information.

This report includes trademarks and registered trademarks of AmpliPhi Biosciences Corporation. Products or service names of other companies mentioned in this report may be trademarks or registered trademarks of their respective owners.

As used in this 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 pioneering the development of therapies for antibiotic-resistant infections using bacteriophage-based technology. Phages have powerful and highly selective mechanisms of action that permit them to bind to 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 the beginning of the modern antibiotics era 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, many of which are included on the World Health Organization Priority Pathogens List published in February 2017, 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., *S. aureus*, *Acinetobacter baumannii*, or *A. baumanii, Pseudomonas aeruginosa*, or *P. aeruginosa,* and *Klebsiella pneumonia*, or *K. pneumoniae*), meningitis (e.g., *Streptococcus pneumonia*, or *S. pneumonia*), urinary tract and gastrointestinal infections (e.g., *P. aeruginosa, E. coli* and *Clostridium difficile*, or *C. difficile*). As phages kill bacteria in ways entirely unlike the mechanisms used by traditional antibiotics, we believe that most multi-drug resistant, or MDR, bacteria will be susceptible to phage therapy. We believe bacteriophage therapeutics could also have the potential for the treatment of inflammatory diseases based on selective modulation of the microbiome and for the treatment of bacterial-driven cancers.

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 in clinical and preclinical development for the treatment of *S. aureus* infections, including MRSA and *P. aeruginosa* infections. We intend to develop these product candidates for the treatment of serious or life-threatening, MDR infections. We also intend to seek to advance our chronic rhinosinusitis, or CRS, program and preclinical CF program through partnerships, arrangements and/or with additional outside funding. In April 2017, the U.S. Food and Drug Administration, or FDA, provided positive feedback on our previously submitted detailed development proposal to commence a Phase 2 trial with our proprietary bacteriophage product candidate AB-SA01 for the treatment of antibiotic-resistant *S. aureus* infections in patients with CRS, which feedback followed

a Type B telephonic meeting held with us on February 21, 2017. In the official minutes from the meeting, the FDA acknowledged that phage therapy is an exciting approach to treatment of multi-drug-resistant organisms and expressed a commitment to addressing the unique regulatory challenges that might arise during product development.

We believe our bacteriophage technology may have unique application in the area of targeted medicine, and in May 2017, we announced a new strategic emphasis on targeted therapies for serious or life-threatening antibiotic-resistant infections. In particular, we believe our bacteriophage technology can be used to develop precisely 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 target 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.

Under existing single-patient expanded access guidelines (also referred to as “compassionate use”), established by U.S. and Australia regulatory agencies, we have begun to provide targeted phage therapies to patients suffering from severe antibiotic-resistant infections who have failed prior antibiotic therapies. We believe this strategic approach will not only provide potential benefit to patients to whom we are able to provide targeted phage therapies, but also provide the clinical and microbiological data from these cases that we expect to support the potential validation of the clinical utility of phage therapy, identify the most promising indications for further clinical development of our AB-SA01 and AB-PA01 product candidates for *S. aureus* and *P. aeruginosa*, define optimal treatment regimens, and inform our future discussions with the FDA and other regulatory agencies in 2018 or later on defining a potential path to market approval. We are initially making targeted phage therapies available under the appropriate expanded access guidelines in the United States and in Australia, where we collaborate with select leading hospitals and key opinion leaders to identify and select eligible patients. We believe that the United States and Australia have a favorable regulatory framework and clinical expertise with respect to treating patients under single-patient expanded access guidelines.

Our emphasis on targeted therapies builds upon our prior successes using tailored bacteriophage therapies under emergency investigational new drug applications to treat individual patients battling life-threatening, MDR bacterial pathogens who had exhausted their treatment options. In March 2016, we collaborated with several academic institutions and a U.S. Navy laboratory to produce a targeted bacteriophage therapy that successfully treated a critically ill, comatose patient with an MDR *A. baumannii* infection. Shortly after phage therapy was initiated, the patient emerged from the coma and continued to improve under an ongoing combination of phage and antibiotic therapies until the infection was cleared. To date, the infection has not returned.

In May 2017, we initiated an expanded access program to provide investigational bacteriophage therapies AB-SA01 and AB-PA01 to patients suffering from serious and life-threatening infections in the United States and Australia.

In January 2018, we announced interim, topline results for the first seven patients treated with our investigational bacteriophage product candidates, AB-SA01 and AB-PA01, under our ongoing single-patient expanded access program. The patients in this program were severely ill and unresponsive to antibiotic treatment at the time of enrollment and were treated under emergency investigational new drug applications in the United States or under the Special Access Scheme in Australia.

Of the seven patients treated, four patients received AB-SA01, administered intravenously, for treatment of *S. aureus* infection, and three patients received AB-PA01, administered intravenously or in some cases by inhalation via nebulizer, for treatment of *P. aeruginosa* infection. The bacteriophage therapy was administered along with the treating physician's choice of best available antibiotic therapy. Treated patients suffered from bacteremia, endocarditis and lung infections, and both AB-SA01 and AB-PA01 were well tolerated in all patients with no treatment-related serious adverse events reported.

Treatment success, defined as complete resolution or significant improvement of baseline signs and symptoms, was reported in six of the seven patients (86%) by physician's assessment. One patient was determined to be a treatment failure due to death, which occurred during surgery after three days of bacteriophage treatment. The treating physician determined that the death was unrelated to treatment with bacteriophage therapy. The 28-day all-cause mortality rate was 14%. No additional deaths occurred within 90 days following initiation of therapy, and patient follow-up is continuing. Based on the APACHE II scores (a validated critical care scoring system predictive of mortality) of the seven patients prior to initiation of bacteriophage therapy, the predicted mortality rate for this patient group was 46%.

In December 2017, we engaged Ladenburg Thalmann & Co. Inc. to assist us in exploring strategic alternatives in an effort to maximize shareholder value. We have not set a timetable for completion of this exploratory process and cannot provide any assurances that the process will result in the consummation of a strategic transaction of any kind, or that we will not abandon the process. We do not intend to discuss or disclose further developments during this process unless and until our board of directors has approved a specific action or we otherwise determine that further disclosure is appropriate.

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 report 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, meaning drug-resistant infections now kill more patients every year than breast cancer. 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, and it is further estimated that by 2050 the cumulative annual cost to global economic output could reach $100 trillion.

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.

We believe bacteriophage technology is uniquely positioned to address the global health threat of antibiotic resistance, due to the ability of bacteriophage to precisely target bacterial infections and work synergistically with antibiotics by re-sensitizing MDR bacterial infections to antibiotics. In addition, we believe there is a significant market opportunity for bacteriophage therapeutics, initially for the treatment of antibiotic-resistant infections, and then potentially as a first-line therapy in combination with antibiotics for the treatment of serious and life-threatening infections such as prosthetic joint infections, bacteremia and pneumonia. Based on our market research, we estimate that annually in the United States over 300,000 patients suffer from serious *S. aureus* infections and over 400,000 patients from serious *P. aeruginosa* infections that can potentially be treated with our therapeutic candidates AB-SA01 and AB-PA01.

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, 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. Overall, AB-SA01 has demonstrated *in vitro* activity against 96% of *S. aureus* clinical isolates collected globally from the United States, Europe and Australia.

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. According to Market Research Future, the global MRSA drugs market is expected to reach $4.3 billion by 2023, and the market is projected to grow at a compounded annual growth rate of approximately 4.4% during the forecast period from 2017 to 2023. 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 product candidate targeting *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.

In 2017, we focused the development of AB-SA01 on intravenous administration for the treatment of patients with serious and life-threatening infections who do not respond to antibiotics. Based on our market research, we believe there is a significant unmet medical need and opportunity for bacteriophage therapy for the treatment of *S. aureus* infections such as bacteremia, endocarditis, cardiac implant infections, and prosthetic joint infections.

In September 2017, we announced the first-in-human intravenous administration of the therapeutic candidate AB-SA01 targeting *S. aureus* under the Special Access Scheme of the Australian Therapeutic Goods Administration. We provided AB-SA01 for a patient suffering from a life-threatening *S. aureus* endocarditis. AB-SA01 was administered intravenously over a two-week duration and was well tolerated.

As part of our expanded access program, in 2017 we provided AB-SA01 to a total of four patients suffering from serious or life-threatening infections that were not responding to antibiotic therapy. The patients suffered from *S. aureus* bacteremia, native valve endocarditis and prosthetic valve endocarditis. A total of 90 doses of AB-SA01 were administered intravenously. The treatment with AB-SA01 was well tolerated, with no treatment-related serious adverse events.

AB-PA01: Infections Caused by P. aeruginosa

We are developing AB-PA01, a product comprised of four phages, for the treatment of *P. aeruginosa* infections. To develop our product candidate, we established a diversity panel of relevant *P. aeruginosa* clinical isolates (bacteria isolated from patients) collected from around the globe. This diversity panel has been screened against our phage libraries, which were 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 the target bacteria. Furthermore, the four components in AB-PA01 were subsequently tested for their ability to infect clinically relevant bacterial isolates from the United States, Europe and Australia and were shown to have similar activity with high complementation, defined as the strains of bacteria targeted by more than one phage in the product. We believe that high complementation is an important factor in preventing bacteria from developing resistance to our phage product candidates. Overall, AB-PA01 has demonstrated *in vitro* activity against 70-80% of *P. aeruginosa* clinical isolates collected globally from the United States, Europe and Australia, including both cystic fibrosis, or CF, and non-CF strains.

We assessed the activity of AB-PA01 phage components in eradicating *in vitro* biofilms formed by *P. aeruginosa* strains isolated across three continents from CRS patients with and without CF. A single dose of our bacteriophages was able to significantly reduce biofilms formed by a range of these isolates, supporting the potential of this product candidate to be a novel treatment for *P. aeruginosa* biofilm infections.

In collaboration with Institut Pasteur (Paris, France) and also with the Brompton Hospital, Imperial College (London, United Kingdom), we have demonstrated 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*.

Based on our market research, we believe there is a significant unmet medical need and opportunity for bacteriophage therapy for the treatment of *P. aeruginosa* infections such as lung infections in patients with CF, hospital- and ventilator-associated pneumonia, bacteremia, complicated urinary tract infections, and complicated intra-abdominal infections.

In August 2017, we announced the first-in-human administration of our therapeutic candidate AB-PA01 targeting *P. aeruginosa* under an Emergency IND allowed by the FDA. We provided AB-PA01 for a patient suffering from a life-threatening multidrug-resistant *P. aeruginosa* lung infection. Multiple doses of AB-PA01 were administered intravenously and by inhalation through a nebulizer and were well tolerated.

As part of our expanded access program, in 2017 we provided AB-PA01 to a total of three patients suffering from serious or life-threatening *P. aeruginosa* infections that were not responding to antibiotic therapy. The patients suffered from lung infection, with a background of CF, lung infection post-transplant, and ventilator-associated pneumonia. Over 500 doses of AB-PA01 were administered intravenously or by inhalation via nebulizer. The treatment with AB-PA01 was well tolerated, with no treatment-related serious adverse events.

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.

In 2016, the CDC reported that in the United States, approximately 4% 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. 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.

In February 2017, the WHO published a Priority Pathogens List. Carbapenem-resistant *P. aeruginosa* is among the Priority 1: Critical pathogens. Methicillin-resistant, vancomycin intermediate and resistant *S. aureus* is among the Priority 2: High pathogens. This underscores the global urgency for developing novel therapeutics against *P. aeruginosa* and *S. aureus*.

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 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 of the Infectious Diseases Society of America and the European Centre for Disease Prevention and Control 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, but are among the most abundant and diverse organisms on the planet. 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.

As discussed in greater detail above, we also plan to use our bacteriophage technology to develop precisely targeted therapies for patients who suffer from serious or life-threatening antibiotic-resistant bacterial infections. 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 around the globe. 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, an *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 product candidate, AB-SA01.

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 collaborated with the Royal Brompton Hospital in London where we 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 intend to continue our expanded access clinical strategy for AB-SA01 and AB-PA01 for the treatment of serious and life-threatening infections in the first half of 2018, treat up to an additional 20 patients in the first half of 2018, present data to the FDA in mid-2018, and potentially initiate a Phase 2 or registrational clinical trial as early as the second half of 2018.

Our development pipeline of product candidates is as follows:

ESKAPE pathogens are *Enterococcus faecium, S. aureus, K. pneumoniae, A. baumannii, P. aeruginosa* and *Enterobacter* species.

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.

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 will remain in 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 contractual obligations with third parties to protect our interests. To this end, we require all of our employees, consultants, advisors and other contractors to enter into agreements with contractual obligations 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, 2017, we owned or had exclusive license rights to a total of 71 patents and applications: seven U.S. patents, five U.S. patent applications, 50 foreign patents, and nine foreign patent applications, expiring on various dates between 2024 and 2036. We believe these patents and applications cover our lead phage-therapeutic programs and use thereof, beneficial effects of bacteriophage treatment, bacteriophage combinations, 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.

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 us. Large pharmaceutical companies have extensive experience in clinical development and obtaining regulatory approval for drug products. 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 development, there is, to our knowledge, one corporate-sponsored clinical trial that was recently completed. A French biotechnology company, Pherecydes Pharma, was 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 was a randomized, multi-center open label study to assess tolerance and efficacy of local treatment with a bacteriophage product candidate. Pherecydes has also announced treatment of patients in France and Belgium under emergency use protocols. Adaptive Phage Therapeutics is also developing custom designed bacteriophage therapies for individual patients. To our knowledge, several biotechnology companies, including Synthetic Genomics, BiomX, Epibiome, Intralytix, iNtRON, PhageLux, EnBiotix, Fixed-Phage, Locus Biosciences, Phagomed, Phi Therapeutics, TechnoPhage and LytPhage, Inc., as well as academic institutions, have earlier stage discovery programs utilizing naturally occurring phages or 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). In 2017, Contrafect initiated a Phase 2 clinical trial of its lysin product candidate in patients with *S. aureus* bacteremia.

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.

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, Biotehnološke 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, and 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 5,300 sq. ft. of laboratory and office space, where we produce cGMP clinical trial supplies in our 40-liter bioreactor 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 intravenous, inhaled, sino-nasal or topical delivery. We may 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.

In 2017, our manufacturing facility successfully completed a periodic regulatory GMP inspection by JAZMP, and our GMP certification was renewed. We believe that we have the world’s only GMP-certified facility dedicated to manufacturing bacteriophage therapeutic candidates for human use.

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-SA01, for the treatment of *S. aureus* infections, and

AB-PA01 for the treatment of *P. aeruginosa* 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 these product candidates.

We have not yet established a sales, marketing or product distribution infrastructure because our lead candidates are still in early clinical development. 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;

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

- submission to the FDA of a Biologics License Application, 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, 2017 and 2016 were $2.9 million and $5.7 million, respectively.

Employees

As of March 7, 2018, we had 31 full-time employees and three part-time employees. Of these 34 full-time and part-time employees, 27 employees were engaged in research and development activities and seven employees were 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 5,300 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.ampliphibio.com*. Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the 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*. 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 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.

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, 2017 includes disclosures and an opinion from our independent registered public accounting firm 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, 2017 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, 2017, we had cash and cash equivalents of $5.1 million, and we have had recurring losses from operations and negative operating cash flows since inception. In January 2018, we completed a registered public offering of common stock, resulting in net proceeds to us of approximately $3.5 million.

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 into the third quarter of 2018, 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;
- manufacturing costs associated with our targeted phage therapies strategy and other research and development activities;
- the terms and timing of any collaborative, licensing, acquisition or other arrangements that we may establish;
- whether and when we receive future Australian tax rebates, if any;

- 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 2018 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 or strategic financings;
- 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, on the success of our product development activities, including our targeted phage therapies strategy and any clinical trials we initiate, 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. 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 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 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 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, 2017, our accumulated deficit was $394.2 million, $78.7 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, 2017 and 2016, we had losses from operations of $16.2 million and $23.4 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 in 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 that receive regulatory approval, and market and sell such products 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 product sales 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;
- 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.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions). Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law.

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.

As of December 31, 2017, we had federal net operating loss carryforwards of approximately $198.1 million, of which $7.3 million will expire in 2018 unless utilized, and the remaining carryforwards will expire in taxable years 2019 through 2037. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various states will conform to the newly enacted federal tax law. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We believe we have experienced ownership changes in the past, including in connection with our November 2016, May 2017 and January 2018 public offerings, and we may experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

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. 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. Material weaknesses in our internal controls have been identified in the past, and we cannot assure you that significant deficiencies or material weaknesses in our internal control over financial reporting will not be identified in the future.

If we are unable to 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.

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 American 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. These expenses will likely increase in the future, particularly after we cease to be an "emerging growth company" if we are also no longer a "smaller reporting company" as a result of additional corporate governance and disclosure requirements under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, and SEC rules and regulations.

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

Results from preclinical studies and Phase 1 or 2 clinical trials of our product candidates or from single-patient expanded access treatments 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. Despite promising data in our completed Phase 1 clinical trials, our phage technology may be found not to be efficacious in treating bacterial infections alone or in combination with other agents, when studied in later-stage clinical trials.

In addition, we have used and plan to continue to use our bacteriophage technology in the area of targeted medicine under single-patient expanded access guidelines, which permit the use of phage therapy outside of clinical trials, beginning in the United States and Australia and then potentially expanding to other countries. Despite prior single-patient expanded access successes, no assurance can be given that we will have similar single-patient expanded access treatment successes in the future. Single-patient expanded access is a term that is used to refer to the use of an investigational drug or therapy outside of a clinical trial to treat a patient with a serious or immediately life-threatening disease or condition who has no comparable or satisfactory alternative treatment options. Regulators

often allow single-patient expanded access on a case-by-case basis for an individual patient or for defined groups of patients with similar treatment needs. In some countries, such as Australia, the treating physician can administer treatment under single-patient expanded access guidelines without pre-approval from the applicable regulatory authority.

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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, or in our single-patient expanded access program does not ensure that later clinical trials will be successful. Our initial results from early stage clinical trials or our single-patient expanded access program 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.

Our single-patient expanded access strategy may not be successful, which in turn could adversely affect our business.

Our targeted phage therapies strategy involves providing phage therapy under single-patient expanded access guidelines to patients outside of clinical trials with antibiotic-resistant infections who have few or no other therapeutic options. We believe this strategic approach will not only provide potential benefit to patients to whom we are able to provide targeted phage therapies under the single-patient expanded access guidelines, but also provide the clinical data from these single-patient expanded access cases that we expect to support the potential validation of the clinical utility of phage therapy and inform our future discussions with the FDA in 2018 or later on defining a potential path to market approval. However, this program is subject to numerous risks and uncertainties, including the following:

- We have not established a cost reimbursement structure or otherwise entered into an arrangement that would at least offset our manufacturing costs for our phage therapies that may be administered to patients under single-patient expanded access guidelines. Increasing demand for our phage therapies in single-patient expanded access cases could result in significant costs to us.

- Responding to single-patient expanded access requests could divert attention of our personnel and use manufacturing resources that could otherwise be deployed in other development program activities.

- Single-patient expanded access treatment data may not establish proof-of-concept, and the FDA or other regulatory authorities may not accept single-patient expanded access data as sufficient clinical validation in support of our regulatory approval efforts, which could materially delay and increase the costs of our product development and commercialization activities.

- Patient access to phage therapy will be provided on an individual basis where physicians will make an application or post-treatment notification to the applicable regulatory authorities on a patient-by-patient basis. This can impose a significant administrative burden on participating physicians, who may be resistant to navigating a process with which they are unfamiliar. We may be unable to identify in a timely manner a sufficient number of patients who are eligible for expanded access emergency treatment and we may be unable to identify in a timely manner a sufficient number of physicians who are interested in providing experimental therapy to such patients, which may limit our ability to provide bacteriophage therapeutics under our expanded access program and to collect data from such cases.

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 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 initial formulations of AB-SA01 for the treatment of *S. aureus* infections and AB-PA01 for the treatment of *P. aeruginosa* infections, there can be no assurance that these initial formulations will be the final formulations of AB-SA01 and AB-PA01 for commercialization if approved. 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.

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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.

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 agency that regulates and supervises pharmaceutical products in Slovenia, for compliance with their and the 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. Despite the positive feedback we received from the FDA in April 2017 regarding our proposal to commence a Phase 2 clinical trial of AB-SA01 in the United States, 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. 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.

Our business and operations might be adversely affected by security breaches, including any cybersecurity incidents.

We depend on the efficient and uninterrupted operation of our computer and communications systems, which we use for, among other things, sensitive company data, including our financial data, intellectual property and other proprietary business information.

While certain of our operations have business continuity and disaster recovery plans and other security measures intended to prevent and minimize the impact of IT-related interruptions, our IT infrastructure and the IT infrastructure of our consultants, contractors and vendors are vulnerable to damage from cyberattacks, computer viruses, unauthorized access, electrical failures and natural disasters or other catastrophic events. We could experience failures in our information systems and computer servers, which could result in an interruption of our normal business operations and require substantial expenditure of financial and administrative resources to remedy. System failures, accidents or security breaches can cause interruptions in our operations and can result in a material disruption of our targeted phage therapies, bacteriophage product candidates and other business operations. The loss of data from completed or future studies or clinical trials could result in delays in our research, development or regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the development of our product candidates could be delayed or otherwise adversely affected.

Even though we believe we carry commercially reasonable business interruption and liability insurance, we might suffer losses as a result of business interruptions that exceed the coverage available under our insurance policies or for which we do not have coverage. For example, we are not insured against terrorist attacks or cyberattacks. Any natural disaster or catastrophic event could have a significant negative impact on our operations and financial results. Moreover, any such event could delay the development of our product candidates.

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 Biologics License Applications, 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 Patent and Trademark Office ("U.S. 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 U.S. 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, U.S. 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 U.S. 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 U.S. 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 U.S. 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-adverse investors may, under the fear of losing all or most of their investment in the event of negative news or lack of progress, be more inclined to sell their shares on the market more quickly and at greater discounts than would be the case with the stock of a larger, more established company that 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 American, 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.

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, 2017, we had outstanding common warrants to purchase an aggregate of 8,531,918 shares of our common stock at a weighted average exercise price of $2.87 per share, and outstanding options to exercise 1,115,865 shares of our common stock at a weighted average exercise price of $3.17 per share. The exercise price and/or the

number of shares of common stock issuable upon exercise of the warrants may be further adjusted in certain circumstances, including certain issuances of securities at a price 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.

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 American. 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 American 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 two 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 $1.07 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.

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.

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 are generally not restricted from issuing additional common stock, including any securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. The market price of our common stock could decline as a result of sales of common stock or securities that are convertible into or exchangeable for, or that represent the right to receive, common stock or the perception that such sales could occur.

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 1st of each year by up to 5% of all shares of our capital stock outstanding as of December 31st 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 1st 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 30,000 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 5,300 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

From time to time, we are a party to certain litigation that is either judged to be not material or that arises in the ordinary course of business. We intend to vigorously defend our interests in these matters. We expect that the resolution of these matters will not have a material adverse effect on our business, financial condition or results of operations. However, due to the uncertainties inherent in litigation, no assurance can be given as to the outcome of these proceedings.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Our common stock is traded on the NYSE American under the symbol "APHB." The following table sets forth the range of high and low sales prices for our common stock for the periods indicated. 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.

On April 24, 2017, we effected a 1-for-10 reverse stock split of our issued and outstanding common stock. The per-share amounts listed in the table below are adjusted for all periods to reflect our 1-for-10 reverse stock split.

Year ended December 31, 2017	**High**	**Low**
Fourth Quarter	$1.65	$0.83
Third Quarter	$1.26	$0.70
Second Quarter	$5.00	$0.67
First Quarter	$6.80	$4.20

Year ended December 31, 2016	**High**	**Low**
Fourth Quarter	$16.90	$3.60
Third Quarter	$21.70	$11.50
Second Quarter	$48.40	$14.50
First Quarter	$54.90	$19.20

Holders of Common Stock

As of March 7, 2018, there were 91 holders of record of our common stock. As of such date, there were 13,695,824 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 pioneering the development of therapies for antibiotic-resistant infections using bacteriophage-based technology. Phages have powerful and highly selective mechanisms of action that permit them to bind to 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 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 in clinical and preclinical development for the treatment of *Staphylococcus aureus,*

or *S. aureus,* infections, including methicillin-resistant *S. aureus*, or MRSA, and *Pseudomonas aeruginosa*, or *P. aeruginosa,* infections. We intend to develop these product candidates for the treatment of serious or life-threatening, multi-drug resistant infections. We also intend to seek to advance our chronic rhinosinusitis, or CRS, program and preclinical cystic fibrosis, or CF, program through partnerships, arrangements and/or with additional outside funding. In April 2017, the U.S. Food and Drug Administration, or FDA, provided positive feedback on our previously submitted detailed development proposal to commence a Phase 2 trial with our proprietary bacteriophage product candidate AB-SA01 for the treatment of antibiotic-resistant *S. aureus* infections in patients with CRS, which feedback followed a Type B telephonic meeting held with us on February 21, 2017. In the official minutes from the meeting, the FDA acknowledged that phage therapy is an exciting approach to treatment of multi-drug-resistant organisms and expressed a commitment to addressing the unique regulatory challenges that might arise during product development.

We believe our bacteriophage technology may have unique application in the area of targeted medicine, and in May 2017, we announced a new strategic emphasis on targeted therapies for serious or life-threatening antibiotic-resistant infections. In particular, we believe our bacteriophage technology can be used to develop precisely 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 target 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.

Under existing single-patient expanded access guidelines (also referred to as “compassionate use”), established by the regulatory agencies, we have begun to provide targeted phage therapies to patients suffering from severe antibiotic-resistant infections who have failed prior antibiotic therapies. We believe this strategic approach will not only provide potential benefit to patients to whom we are able to provide targeted phage therapies, but also provide the clinical and microbiological data from these cases that we expect to support the potential validation of the clinical utility of phage therapy, identify the most promising indications for further clinical development of our AB-SA01 and AB-PA01 product candidates for *S. aureus* and *P. aeruginosa*, define optimal treatment regimens, and inform our future discussions with the FDA and other regulatory agencies in 2018 or later on defining a potential path to market approval. We are initially making targeted phage therapies available under the appropriate expanded access guidelines in the United States and in Australia, where we collaborate with select leading hospitals and key opinion leaders to identify and select eligible patients. We believe that the United States and Australia have a favorable regulatory framework and clinical expertise with respect to treating patients under single-patient expanded access guidelines.

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, 2017, we have received approximately $59.0 million in net proceeds from the issuance of our equity securities and convertible debt securities. As of December 31, 2017, we had an accumulated deficit of $394.2 million, $78.7 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, including through our recently announced targeted phage therapies strategy, and for working capital and other general corporate purposes.

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, strategic financing 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.

On January 12, 2018, we completed a registered public offering of 4,000,000 shares of common stock at an offering price of $1.00 per share, for aggregate gross proceeds of $4.0 million. We received net proceeds from the offering of approximately $3.5 million, after deducting placement agent fees and other offering expenses payable by us.

Results of Operations

Comparison of the Years Ended December 31, 2017 and 2016

Revenue

For the years ended December 31, 2017 and 2016, we recognized revenues related to sub-licensing agreements from our former gene therapy program of $115,000 and $260,000, respectively. The decrease of $145,000 was primarily attributable to the termination of a sublicense agreement in 2016.

Research and Development

Research and development expenses for the year ended December 31, 2017 were $2.9 million compared to $5.7 million for the year ended December 31, 2016. During the third quarter of 2017 and the fourth quarter of 2016, we received tax incentive payments of approximately $2.0 million and $0.9 million, respectively, from the Australian tax authority. Such tax incentive payments were based on eligible research and development expenditures incurred by our Australian subsidiary and were recorded as an offset to research and development expense. For the years ended December 31, 2017 and 2016, research and development expenses, excluding any benefit from tax incentive payments, were $4.9 million and $6.6 million, respectively. The decrease of $1.7 million was primarily related to a $1.1 million decrease in professional and consulting fees resulting from the completion of the CRS Phase 1 clinical trial in 2016, a $0.2 million decrease in professional recruitment fees, approximately $0.4 million of expense recorded in connection with assets acquired from Novolytics Ltd in 2016, as well as decreased clinical expenses. This decrease in research and development expenses was offset by a $0.4 million increase in payroll-related costs.

General and Administrative

General and administrative expenses for the year ended December 31, 2017 were $7.6 million compared to $8.4 million for the year ended December 31, 2016. The $0.8 million decrease was primarily attributable to a $1.3 million decrease in non-cash stock-based compensation and a $0.6 million decrease in legal and other professional fees, offset by a $0.8 million increase in salaries and other payroll-related costs and a $0.5 million non-cash charge in 2017 related to the fair value of 523,210 shares of common stock issued to the shareholders who were party to the Common Stock Issuance Agreement.

Impairment Charges

Impairment charges related to our goodwill and in-process research and development (IPR&D) assets were $5.8 million and $9.5 million for the years ended December 31, 2017 and 2016, respectively. In the second quarter of 2017, we performed an interim IPR&D impairment test and determined that IPR&D assets were impaired, specifically assets related to our Staphylococcal and Pseudomonas programs. Due to this impairment, we recorded an impairment charge of $5.8 million, offset by a related income tax benefit of $1.3 million, in the second quarter of 2017. The IPR&D assets had a remaining book value of $4.7 million after the impairment charge, $2.8 million and $1.9 million for the Staphylococcal and Pseudomonas programs, respectively. We completed our annual test for impairment as of December 31, 2017 and determined that no impairment existed for IPR&D assets as of December 31, 2017.

In 2016 we concluded that our goodwill, with a book value of $7.6 million, was fully impaired. Accordingly, we recorded an impairment charge of $7.6 million, representing the write-off of the entire balance of goodwill. No goodwill remained in 2017. In 2016 we recorded a $2.0 million impairment charge, offset by a related income tax benefit of $0.4 million, for IPR&D assets related to our Pseudomonas program.

See further discussion regarding our tests for impairment of goodwill and IPR&D assets in Note 3 in the Notes to the Consolidated Financial Statements.

Other Income (Expense)

For the year ended December 31, 2017, we recorded a net gain of $2.0 million related to the change in fair value of our derivative liabilities. The net gain was primarily related to the $1.7 million decrease in fair value of our derivative liability for warrants issued in November 2016 which was attributable in part to a decline in our common stock price for the period of measurement.

For the year ended December 31, 2016, we recorded a gain of $4.5 million related to the change in fair value of our derivative liabilities. The gain was related to the $2.4 million change in fair value of our derivative liability for warrants, the $1.5 million change in fair value of our Series B preferred stock derivative liability and the $0.6 million change in fair value of our dilutive financing derivative liability. The change in fair value of these derivative liabilities was primarily related to a decline in our common stock price for the periods of measurement. The $2.4 million change in fair value of our derivative liability for warrants included a change in fair value of $1.5 million related to warrants issued in June 2016 and a change in fair value of $0.9 million related to warrants issued in November 2016.

We incurred a total of $1.5 million in offering costs in connection with our June 2016 and November 2016 public offerings of common stock and warrants: $569,000 of these costs were allocated to the warrants issued in connection with these financings and recorded to other expense in the consolidated statements of operations for the year ended December 31, 2016 and the remaining costs of approximately $1.0 million were recorded as an offset to additional paid-in capital. We incurred approximately $1.2 million in offering costs in connection with our May 2017 public offering of common stock, pre-funded warrants and common warrants and the full amount was recorded as an offset to additional paid-in capital.

Income Taxes

The income tax benefit of $1.3 million for the year ended December 31, 2017 is related to a reduction of the existing deferred tax liability during the second quarter of 2017 as a result of a $5.8 million impairment charge for our IPR&D

assets discussed above. We recorded an income tax benefit of $0.6 million for 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 million impairment charge for our IPR&D assets discussed above, and a $0.2 million income tax benefit as a result of a reduction of deferred tax liability resulting from changes in UK enacted tax rates from 20% to 17% in 2016.

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 $394.2 million as of December 31, 2017, $78.7 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 classification 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 $5.1 million and $5.7 million at December 31, 2017 and 2016, respectively. We made operational changes that have reduced our cash expenditures and supported our strategic emphasis on precisely targeted bacteriophage therapies. In January 2018, we completed a registered public offering of common stock, resulting in net proceeds to us of approximately $3.5 million. We believe our existing cash resources, after taking into account the net proceeds from our January 2018 public offering, will be sufficient to fund our planned operations into the third quarter of 2018. However, we cannot provide assurances that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate.

Operating activities

Net cash used in operating activities for the year ended December 31, 2017 was $9.2 million, as compared to $10.6 million for the year ended December 31, 2016. The decrease of $1.4 million was primarily due to the receipt in 2017 of approximately $2.0 million in tax incentive payments from the Australian tax authority, as compared to $0.9 million received in 2016. These tax incentive payments were recorded as an offset to research and development expense in the consolidated statements of operations.

Investing activities

Net cash used in investing activities was $58,000 and $279,000 for the years ended December 31, 2017 and 2016, respectively, and was primarily attributable to purchases of property and equipment.

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Financing activities

Cash provided by financing activities for the year ended December 31, 2017 was comprised of net proceeds of $9.4 million from the May 2017 underwritten public offering of common stock, pre-funded warrants and common warrants to purchase common stock, after deducting the underwriting discount and commissions and other expenses related to the offering of approximately $1.2 million. Cash provided by financing activities for the year ended December 31, 2016 was comprised of net proceeds of $4.2 million from the June 2016 registered public offering of common stock and warrants to purchase common stock, after deducting placement agent fees and other expenses related to the issuance of $0.8 million, and net proceeds of $3.3 million from the November 2016 underwritten public offering of common stock and warrants to purchase common stock, after deducting the underwriting discount and commissions and other expenses related to the offering of approximately $0.7 million.

Future Capital Requirements

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;
- manufacturing costs associated with our targeted phage therapies strategy and other research and development activities;
- the terms and timing of any collaborative, licensing, acquisition or other arrangements that we may establish;
- whether and when we receive future Australian tax rebates, if any;
- 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 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, if at all.

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

- the public equity market;
- private equity financings;

- collaborative arrangements or strategic financings;
- licensing arrangements; and
- public or private debt.

Any additional fundraising efforts may divert our management team 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, on the success of our product development activities, including our targeted phage therapies strategy and any clinical trials we initiate, 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 accounting principles generally accepted in the United States. 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 related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates and judgments, including those related to intangible assets, stock-based compensation and derivative liabilities. We base our estimates on historical experience, known trends and events, and various other factors that we believe are 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.

In-Process Research and 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 at least annually 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 test our IPR&D assets for impairment as of December 31st of each year or more frequently if indicators of impairment are present. Examples of such indicators of impairment include:

- events or changes in circumstances indicate that the carrying value of such assets may not be recoverable, measured by a comparison of the carrying value of the assets to the estimated undiscounted future cash flows to be generated by the assets:
  - loss of legal ownership or title to the assets;
  - significant changes in our strategic business objectives and utilization of the assets; or
  - the impact of significant negative industry or economic trends.

If a change were to occur in any of the above-mentioned factors or estimates, the likelihood of a material change in our reported results would increase.

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, the 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.

If and when a quantitative analysis of IPR&D assets is required based on the results of the optional qualitative assessment, the estimated fair value of IPR&D assets is calculated based on the income approach, which includes discounting expected future net cash flows associated with the assets to a net present value. 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 our impairment analysis. The estimates we use are consistent with the plans and estimates we use to manage our business. Significant assumptions utilized in our income approach model included the 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.

We completed our annual test for impairment of IPR&D assets as of December 31, 2016 and determined that IPR&D assets of $5.2 million related to our Staphylococcal programs were not impaired. We also determined that IPR&D assets of $7.3 million related to our Pseudomonas program were impaired. An impairment charge of $2.0 million, offset by a related income tax benefit of $0.4 million, was recorded as a component of operating expense in the consolidated statements of operations for the year ended December 31, 2016 and represented the excess of the carrying amount over the fair value. During the second quarter of 2017, we determined there was an indicator of impairment of IPR&D assets and an interim test for impairment was performed. As a result of the test, we recognized an impairment charge of $5.8 million during the second quarter of 2017, offset by a related income tax benefit of $1.3 million, related to our Staphylococcal and Pseudomonas programs. The impairment was due to an increase in our discount rate as compared to previous assessments due to the significant difference between our net assets and our market capitalization of $6.7 million as of June 30, 2017. The significant excess of net asset value over market capitalization as of June 30, 2017 existed following the 1-for-10 reverse stock split completed in April 2017 and the receipt of $10.6 million in gross proceeds from an underwritten public offering in May 2017. The impairment charge was included as a component of operating expense in the consolidated statements of operations for the year ended December 31, 2017. The carrying amount of our Staphylococcal and Pseudomonas programs after the impairment charge was $2.8 million and $1.9 million, respectively. We completed our annual test for impairment as of December 31, 2017 and determined that no impairment existed for IPR&D assets as of December 31, 2017.

Goodwill

Goodwill, which has an indefinite useful life, represents the excess of purchase consideration over fair value of net assets acquired. Goodwill is not subject to amortization and is required to be tested for impairment at least on an annual basis. We determine whether goodwill may be impaired by comparing the carrying value of the 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 the consolidated statements of operations.

Based on the results of our annual impairment test of goodwill as of December 31, 2016, as described in Note 3 in the Notes to Consolidated Financial Statements, an impairment charge of $7.6 million, representing the write-off of the entire balance of goodwill, was recorded as a component of operating expense in the consolidated statements of operations for the year ended December 31, 2016. No goodwill was recorded in 2017.

Stock-Based Compensation

Compensation expense related to stock options granted is measured at the grant date based on the estimated fair value of the award and is recognized on a straight-line basis over the requisite service period. We determine the estimated fair value of each stock option on the date of grant using the Black-Scholes valuation model which uses assumptions regarding a number of complex and subjective variables. The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. Expected volatility is based on the historical volatility of our common stock. The expected term represents the period that we expect our stock options to be outstanding. The expected term assumption is estimated using 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 expected term assumption for stock options granted to parties other than employees or directors is the contractual term of the option award. We have never declared or paid dividends on our common stock and have no plans to do so in the foreseeable future. Forfeitures are recognized as a reduction of stock-based compensation expense as they occur. Changes in these assumptions may lead to variability with respect to the amount of stock compensation expense we recognize related to stock options.

Stock-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.

Warrant and Preferred Shares Conversion and Dilutive Financing Features

We account for warrants and preferred shares conversion and dilutive financing features in accordance with the applicable accounting guidance provided in ASC 815 - *Derivatives and Hedging* as either derivative liabilities or as equity instruments depending on the specific terms of the agreements. Liability-classified instruments are recorded at fair value at each reporting period with any change in fair value recognized as a component of change in fair value of derivative liabilities in the consolidated statements of operations. We estimate the fair value of liability-classified instruments using a Monte Carlo valuation model and a Black-Scholes valuation 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 recognized gains of $2.0 million and $4.5 million for the years ended December 31, 2017 and 2016, respectively, recorded as a component of other income (expense) in the consolidated statements of operations.

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 $1.07 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, 2017, 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

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of AmpliPhi Biosciences Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of AmpliPhi Biosciences Corporation (the Company) as of December 31, 2017 and 2016, the related consolidated statements of operations, redeemable convertible preferred stock and stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2016, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

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 suffered recurring losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's evaluation of the events and conditions and management’s plans regarding 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.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2015.

San Diego, California

March 14, 2018

AmpliPhi Biosciences Corporation

Consolidated Balance Sheets

	December 31, 2017	December 31, 2016
Assets		
Current assets		
Cash and cash equivalents	$ 5,132,000	$ 5,711,000
Prepaid expenses and other current assets	253,000	602,000
Total current assets	5,385,000	6,313,000
Property and equipment, net	816,000	1,072,000
In-process research and development	4,661,000	10,461,000
Acquired patents, net	276,000	307,000
Total assets	$ 11,138,000	$ 18,153,000
Liabilities, Series B redeemable convertible preferred stock and stockholders' equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 1,968,000	$ 2,735,000
Note payable	-	803,000
Total current liabilities	1,968,000	3,538,000
Derivative liabilities	292,000	2,443,000
Deferred tax liability	1,147,000	2,449,000
Total liabilities	3,407,000	8,430,000
Commitments and Contingencies (Note 8)		
Series B redeemable convertible preferred stock $0.01 par value; no shares authorized at December 31, 2017 and 2016; no shares issued and outstanding at December 31, 2017 and 2016	-	-
Stockholders' equity		
Common stock, $0.01 par value; 67,000,000 shares authorized at December 31, 2017 and 2016; 9,498,928 and 1,648,751 shares issued and outstanding at December 31, 2017 and 2016, respectively	95,000	16,000
Additional paid-in capital	401,842,000	391,067,000
Accumulated deficit	(394,206,000)	(381,360,000)
Total stockholders' equity	7,731,000	9,723,000
Total liabilities, Series B redeemable convertible preferred stock and stockholders' equity	$ 11,138,000	$ 18,153,000

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

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AmpliPhi Biosciences Corporation

Consolidated Statements of Operations

	Year Ended December 31,	
	2017	2016
Revenue	$115,000	$260,000
Operating expenses		
Research and development	2,881,000	5,678,000
General and administrative	7,590,000	8,413,000
Impairment charges	5,800,000	9,547,000
Total operating expenses	16,271,000	23,638,000
Loss from operations	(16,156,000)	(23,378,000)
Other income (expense)		
Change in fair value of derivative liabilities	2,010,000	4,538,000
Other income (expense), net	6,000	(554,000)
Total other income, net	2,016,000	3,984,000
Loss before income taxes	(14,140,000)	(19,394,000)
Income tax benefit	1,302,000	556,000
Net loss	(12,838,000)	(18,838,000)
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)
Net loss attributable to common stockholders	$(12,838,000)	$(24,276,000)
Per share information:		
Net loss per share of common stock - basic	$(2.01)	$(24.67)
Weighted average number of shares of common stock outstanding - basic	6,387,425	983,846
Net loss per share of common stock - diluted	$(2.18)	$(24.67)
Weighted average number of shares of common stock outstanding - diluted	6,574,117	983,846

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 Series B		Stockholders' Equity Common Stock				
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balances, December 31, 2015	7,527,853	$11,890,000	588,291	$6,000	$375,230,000	$(362,522,000)	$12,714,000
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)	235,902	2,000	10,627,000	-	10,629,000
Warrants issued for Novolytics assets	-	-	-	-	204,000	-	204,000
Common stock issued in June 2016 financing, net of offering costs and warrants	-	-	212,766	2,000	2,632,000	-	2,634,000
Common stock issued in November 2016 financing, net of offering costs and warrants	-	-	533,500	5,000	680,000	-	685,000

Common stock issued pursuant to anti-dilution rights	-	-	75,020	1,000	1,544,000	-	1,545,000
Common stock issued under the employee stock purchase plan	-	-	3,272	-	13,000	-	13,000
Stock-based compensation	-	-	-	-	1,995,000	-	1,995,000
Net loss	-	-	-	-	-	(18,838,000)	(18,838,000)
Balances, December 31, 2016	-	-	1,648,751	16,000	391,067,000	(381,360,000)	9,723,000
Cumulative effect adjustment from adoption of ASU 2016-09	-	-	-	-	8,000	(8,000)	-
Common stock and pre-funded warrants issued in May 2017 financing, net of offering costs	-	-	7,067,419	71,000	9,282,000	-	9,353,000
Warrants exercised	-	-	226,664	2,000	128,000	-	130,000
Warrant derivative liability reclassified to equity due to exercise of warrants	-	-	-	-	119,000	-	119,000
Dilutive financing derivative liability reclassified to equity upon common stock issued pursuant to anti-dilution rights	-	-	28,684	1,000	21,000	-	22,000
Common stock issued pursuant to anti-dilution rights	-	-	523,210	5,000	514,000	-	519,000
Common stock issued under the employee stock purchase plan	-	-	4,200	-	3,000	-	3,000

Stock-based compensation	-	-	-	-	700,000	-	700,000
Net loss	-	-	-	-	-	(12,838,000)	(12,838,000)
Balances, December 31, 2017	-	$-	9,498,928	$95,000	$401,842,000	$(394,206,000)	$7,731,000

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

AmpliPhi Biosciences Corporation

Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2017	2016
Operating activities:		
Net loss	$(12,838,000)	$(18,838,000)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative liabilities	(2,010,000)	(4,538,000)
Impairment charges	5,800,000	9,547,000
Stock-based compensation	700,000	1,995,000
Deferred taxes	(1,302,000)	(556,000)
Charge for common stock issuance	519,000	-
Costs related to equity offerings	-	569,000
Warrants and other non-cash adjustments, net	22,000	193,000
Depreciation	343,000	338,000
Amortization of patents	31,000	31,000
Changes in operating assets and liabilities:		
Accounts payable and accrued liabilities	(838,000)	406,000
Prepaid expenses, accounts receivable and other current assets	381,000	247,000
Net cash used in operating activities	(9,192,000)	(10,606,000)
Investing activities:		
Purchases of property and equipment	(58,000)	(279,000)
Net cash used in investing activities	(58,000)	(279,000)
Financing activities:		
Costs of Series B redeemable convertible preferred stock conversion to common stock	-	(173,000)
Dividend payments	-	(80,000)
Proceeds from sale of common stock and related warrants, net of offering costs	9,353,000	7,566,000
Proceeds from exercises of warrants	130,000	-
Proceeds from stock issuance under employee stock purchase plan	3,000	13,000
Principal payments on note payable	(815,000)	(100,000)
Net cash provided by financing activities	8,671,000	7,226,000
Net decrease in cash and cash equivalents	(579,000)	(3,659,000)
Cash and cash equivalents, beginning of period	5,711,000	9,370,000
Cash and cash equivalents, end of period	$5,132,000	$5,711,000
Supplemental schedule of non-cash financing activities:		
Accretion of Series B redeemable convertible preferred stock	$-	$1,858,000
Fair value of warrant liability upon issuance	-	4,745,000
Offering costs included in accounts payable	-	69,000
Property and equipment included in accounts payable	39,000	-

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

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AmpliPhi Biosciences Corporation

Notes to Consolidated Financial Statements

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 bind to 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. 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, 2017, the Company had cash and cash equivalents of $5.1 million. On January 12, 2018, the Company completed a registered public offering of common stock resulting in net proceeds to the Company of approximately $3.5 million (see Note 14). Management made operational changes in 2017 that have reduced cash expenditures and supported the Company's strategic emphasis on precisely targeted bacteriophage therapies. Considering the Company's current cash resources, including the net proceeds from the public offering in January 2018, management believes the Company's existing resources will be sufficient to fund the Company's planned operations into the third quarter of 2018. For the foreseeable future, the Company's ability to continue its operations is dependent upon its ability to obtain additional capital.

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 Biotehnološke Raziskave in Razvoj 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 accounting principles generally accepted in the United States ("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.

Property and Equipment

Property and equipment are recorded at cost and depreciated over their estimated useful lives using the straight-line method. 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. Estimated useful lives for property and equipment are as follows:

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

Impairment of Long-Lived Assets

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 estimated discounted future net cash flows arising from the assets or asset groups. No impairment losses have been recorded through December 31, 2017.

In-Process Research and Development

In-process research and development (IPR&D) assets are intangible assets with indefinite lives and are not subject to amortization. The Company's IPR&D assets represent capitalized incomplete research projects that the Company acquired through business combinations. Such assets are initially measured at their acquisition-date fair values and are subject to impairment testing at least annually until completion or abandonment of research and development efforts associated with the projects. Upon successful completion of each project, the Company makes a determination as to the then remaining useful life of the intangible asset and begins amortization. The Company periodically re-evaluates whether continuing to characterize the asset as indefinite-lived is appropriate.

The Company tests IPR&D assets for impairment as of December 31 of each year or more frequently if indicators of impairment are present. 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, the 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.

If and when a quantitative analysis of IPR&D assets is required based on the result of the optional qualitative assessment, the estimated fair value of IPR&D assets is calculated based on the income approach, which includes discounting expected future net cash flows associated with the assets to a net present value. 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 uses 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 timing of clinical studies and regulatory approvals, the probability of success of its 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.

The Company completed its annual test for impairment of IPR&D assets as of December 31, 2016 and determined that IPR&D assets of $5.2 million related to its Staphylococcal programs were not impaired. The Company also determined that IPR&D assets of $7.3 million related to its Pseudomonas program were impaired. An impairment charge of $2.0 million, offset by a related income tax benefit of $0.4 million, was recorded as a component of operating expense in the consolidated statements of operations for the year ended December 31, 2016 and represented the excess of the carrying amount over the fair value. During the second quarter of 2017, the Company determined there was an indicator of impairment of IPR&D assets and an interim test for impairment was performed. As a result of the test, the Company recognized an impairment charge of $5.8 million during the second quarter of 2017, offset by a related income tax benefit of $1.3 million, related to its Staphylococcal and Pseudomonas programs. The impairment was due to an increase in the Company's discount rate as compared to previous assessments due to the significant difference between the Company's net assets and its market capitalization of $6.7 million as of June 30, 2017. The significant excess of net asset value over market capitalization as of June 30, 2017 existed following the 1-for-10 reverse stock split completed in April 2017 and the receipt of $10.6 million in gross proceeds from an underwritten public offering in May 2017. The impairment charge was included as a component of operating expense in the consolidated statements of operations for the year ended December 31, 2017. The carrying amount of the Staphylococcal and Pseudomonas programs after the impairment charge was $2.8 million and $1.9 million, respectively. The Company completed its annual test for impairment as of December 31, 2107 and determined that no impairment existed for IPR&D assets as of December 31, 2017.

Goodwill

Goodwill, which has an indefinite useful life, represents the excess of purchase consideration over fair value of net assets acquired. Goodwill is not subject to amortization and is required to be tested for impairment at least on an annual basis. The Company determines whether goodwill may be impaired by comparing the carrying value of the 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 the Company's consolidated statements of operations.

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 impairment test for goodwill based on the income approach which included discounted cash flows. The Company's discounted future cash flows estimate 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 was 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 fair value as determined in step one of the 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 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, an impairment charge of $7.6 million, representing the write-off of the entire balance of goodwill, was recorded as a component of operating expense in the consolidated statements of operations for the year ended December 31, 2016. No goodwill was recorded in 2017.

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Patent Costs

Patent costs, accounted for as intangible assets with definite lives, were acquired by the Company through business combinations. These patent costs are recorded at fair value and are amortized using the straight-line method over their estimated useful lives. As of December 31, 2017, the gross amount of patent assets was $493,000 with accumulated amortization of $217,000. Annual patent amortization expense for the next five years and thereafter are estimated as follows:

	Patent Amortization
2018	$ 31,000
2019	31,000
2020	31,000
2021	31,000
2022	31,000
Thereafter through December 2026	121,000
Total patent amortization expense	$ 276,000

Stock-Based Compensation

Compensation expense related to stock options granted is measured at the grant date based on the estimated fair value of the award and is recognized on a straight-line basis over the requisite service period. Forfeitures are recognized as a reduction of stock-based compensation expense as they occur. Stock-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.

Accounting for Warrant and Preferred Shares Conversion and Dilutive Financing Features

Warrants and preferred shares conversion and dilutive financing features are accounted for in accordance with the applicable accounting guidance provided in ASC 815 - *Derivatives and Hedging* as either derivative liabilities or as equity instruments depending on the specific terms of the agreements. Liability-classified instruments are recorded at fair value at each reporting period with any change in fair value recognized as a component of change in fair value of derivative liabilities 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 its 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, if any, as deferred revenue.

Research and Development Costs

Research and development expenses are charged to operations as incurred. Research and development expenses include, among other things, salaries, costs of outside collaborators and outside services, allocated facility, occupancy and utility expenses, which are partially offset by the benefit of tax incentive payments for qualified research and development expenditures from the Australian tax authority (“AU Tax Rebates”). The Company does not record AU Tax Rebates until payment is received due to the uncertainty of receipt. The Company received AU Tax Rebates of approximately $2.0 million and $0.9 million during the third quarter of 2017 and fourth quarter of 2016, respectively, and such rebates have been recorded as an offset to research and development expense in the Company’s consolidated statements of operations.

Income Taxes

The Company utilizes 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 differences between the financial statement carrying amounts and the tax basis of existing assets and liabilities and net operating loss and tax credit carryforwards. The effect on deferred taxes of a change in tax rates is recognized in income (expense) in the period that includes the enactment date. The Company evaluates the likelihood that 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.

The Company's 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 tax liabilities involves dealing with uncertainties in the application of complex tax regulations. The Company recognizes 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, 2017 and 2016, the Company had unrecognized tax benefits related to its domestic research tax credits of approximately $2.1 million.

Basic and Diluted Net Loss per Common Share

Basic net loss per common share is computed by dividing the net loss available to common stockholders by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per common share is computed in accordance with the treasury stock method and reflects the potential dilution that would occur if securities or other contracts to issue common stock were exercised or converted to common stock. The calculation of diluted loss per share requires that, to the extent the average market price of the underlying shares for the reporting period exceeds the exercise price of the warrants, and the presumed exercise of such securities are dilutive to net loss per common share for the period, an adjustment to net loss available to common stockholders used in the calculation is required to remove the change in fair value of the warrants from the numerator for the period. Likewise, an adjustment to the denominator is required to reflect the related dilutive shares, if any, under the treasury stock method.

Reverse Stock Split

On April 21, 2017, 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-10 (1:10) reverse stock split of its common stock, par value $0.01 per share, effective April 24, 2017. All common share, warrant, stock option, and per share information in the consolidated financial statements gives retroactive effect to the 1-for-10 reverse stock split that was effected on April 24, 2017. In connection with the reverse stock split, the Company adjusted its authorized common stock, from 670,000,000 to 67,000,000 shares. The par value of its common stock was unchanged at $0.01 per share, post-split. The Company adjusted stockholders' equity to reflect the reverse stock split by reclassifying an amount equal to the par value of the shares eliminated by the split from common stock to additional paid-in capital, resulting in no net impact to stockholders' equity on the consolidated balance sheets.

Reclassification

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

Recent Accounting Pronouncements Not Yet Adopted

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 will adopt this ASU effective January 1, 2018 using the modified retrospective method. During the fourth quarter of 2017, the Company completed its assessment to evaluate the impact of adopting this guidance and determined that the impact of adoption will be immaterial to the consolidated financial statements.

In February 2015, the FASB issued ASU No. 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 plans to adopt this ASU on January 1, 2019 and is in the process of evaluating the impact of adopting the guidance on its consolidated financial statements.

In August 2016, the FASB issued ASU No. 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 No. 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.

In July 2017, the FASB issued ASU No. 2017-11, which amends the FASB Accounting Standards Codification. Part I of ASU No. 2017-11, *Accounting for Certain Financial Instruments with Down Round Features*, changes the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. The guidance is effective for reporting periods beginning after December 15, 2019 and interim periods within those fiscal years. The Company is in the process of evaluating the impact of adopting the guidance on its consolidated financial statements.

Recently Adopted Accounting Standards

In November 2015, the FASB issued ASU No. 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 Company adopted this ASU as of January 1, 2017 and the adoption did not have an impact on the Company's consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation – Stock Compensation, (Topic 718)*. This ASU changes certain aspects of accounting for share-based payments to employees and involves 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. Specifically, ASU 2016-09 requires that all income tax effects of share-based awards be recognized as income tax expense or benefit in the reporting period in which they occur. Additionally, ASU 2016-09 amends existing guidance to allow forfeitures of share-based awards to be recognized as they occur. Previous guidance required that share-based compensation expense include an estimate of forfeitures. The Company adopted this ASU as of January 1, 2017 and elected to account for forfeitures as they occur. The cumulative effect of adoption was made on a modified retrospective basis and resulted in an increase of $8,000 to both additional paid-in capital and accumulated deficit.

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

The guidance regarding fair value measurements prioritizes the inputs used in measuring fair value and establishes a three-tier 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.

Liabilities are classified based on the lowest level of input that is significant to the fair value measurements. The Company has not transferred any liabilities between the classification levels.

The Company estimates fair values of derivative liabilities utilizing Level 3 inputs. The Company uses the Monte Carlo and Black-Scholes valuation models 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 liabilities 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.

The recurring fair value measurements of the Company's derivative liabilities at December 31, 2017 and 2016 consisted of the following:

	Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
December 31, 2017				
Liabilities				
June 2016 offering warrant liability	$ -	$ -	$ 32,000	$32,000
November 2016 offering warrant liability	-	-	260,000	260,000
Total liabilities	$ -	$ -	$ 292,000	$292,000
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

The following table sets forth a summary of changes in the fair value of the Company's derivative liabilities:

	June 2016 Offering Warrant Liability	Dilutive Financing Derivative Liability	November 2016 Offering Warrant Liability	Total Derivative Liabilities
Balance, December 31, 2016	$274,000	$126,000	$ 2,043,000	$2,443,000
Changes in estimated fair value	(242,000)	(104,000)	(1,664,000)	(2,010,000)
Exercised warrants	-	-	(119,000)	(119,000)
Settlement of liability	-	(22,000)	-	(22,000)
Balance, December 31, 2017	$32,000	$-	$ 260,000	$292,000

In connection with an issuance of warrants exercisable for an aggregate of 106,383 shares of common stock in a registered public offering, the Company incurred the June 2016 offering warrant liability (see Note 10). The fair value of the June 2016 offering warrant liability on each 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 categorized within Level 3 of the fair value hierarchy. The assumptions used consisted of the following:

	December 31, 2017	December 31, 2016
Volatility	125 %	118 %

Expected term (years)		3.42		4.42	
Risk-free interest rate		2.01	%	1.80	%
Dividend yield		0.00	%	0.00	%
Exercise price	$	22.50	$	22.50	
Common stock closing price	$	1.01	$	4.40	

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In connection with an issuance of warrants exercisable for an aggregate of 533,500 shares of common stock in an underwritten public offering, the Company incurred the November 2016 offering warrant liability (see Note 10). The fair value of the November 2016 offering warrant liability on each measurement date 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 warrants is categorized within Level 3 of the fair value hierarchy. The assumptions used consisted of the following:

	December 31, 2017		December 31, 2016	
Volatility	107	%	112	%
Expected term (years)	3.89		4.89	
Risk-free interest rate	2.08	%	1.91	%
Dividend yield	0.00	%	0.00	%
Exercise price (1)	$ 0.57		$ 7.50	
Common stock closing price	$ 1.01		$ 4.40	

(1) In connection with the Company's April 2017 1-for-10 reverse stock split, the exercise price of the warrants was adjusted downward to $1.00 per share. In September 2017, the exercise price of the warrants was further adjusted downward to $0.57 per share in connection with the issuance of 523,210 shares of the Company's common stock to the shareholders who were party to the Common Stock Issuance Agreement. The exercise price of the warrants is subject to further adjustment upon future dilutive issuances of the Company's common stock and stock combination events as defined in the warrant agreements (see Note 10).

Dilutive Financing Derivative Liability

The dilutive financing derivative liability was originally recorded on the Company's balance sheet on April 8, 2016 in connection with the Company's entry into a Common Stock Issuance Agreement ("CSIA") with certain former holders of the Company's Series B redeemable convertible preferred stock, pursuant to which the Company was obligated to issue its common stock for no consideration to the shareholders who were party to the CSIA upon dilutive issuances of the Company's common stock (see Note 9). As of December 31, 2016, the maximum number of shares that the Company could issue under the rules of the NYSE American and the terms of the CSIA was 28,684 shares. As of December 31, 2016, the dilutive financing liability was valued at $126,000 based on the closing market price of the Company's common stock of $4.40 per share multiplied by the 28,684 shares available to be issued. On June 27, 2017, the Company and the holders entered into an amendment to the CSIA (the "CSIA Amendment") under which the 28,684 common shares were issued to the holders on June 29, 2017. The CSIA Amendment removed the condition which required the CSIA to be treated as a derivative liability. Accordingly, the fair value of the shares were marked-to-market through June 29, 2017, at $22,000, and then reclassified from a liability to equity.

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,	
	2017	2016
Basic and diluted net loss per common share calculation:		
Net loss	$(12,838,000)	$(18,838,000)
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)
Net loss attributable to common stockholders - basic	(12,838,000)	(24,276,000)
Changes in fair value of November 2016 warrants	(1,524,000)	-
Net loss attributable to common stockholders - diluted	$(14,362,000)	$(24,276,000)
Weighted average common shares outstanding - basic	6,387,425	983,846
Net loss per share of common stock - basic	$(2.01)	$(24.67)
Weighted average common shares outstanding - diluted	6,574,117	983,846
Net loss per share of common stock - diluted	$(2.18)	$(24.67)

The $1,524,000 change in fair value of November 2016 warrants for the year ended December 31, 2017 represented a net gain from reduction in the fair value of the warrants starting in April 2017 when the warrants became in the money from an exercise price downward adjustment made in connection with the Company’s 1-for-10 reverse stock split through December 31, 2017. In September 2017, the exercise price was further adjusted down to $0.57 per share in connection with the issuance of 523,210 shares of common stock to shareholders who were parties to the CSIA (See Note 9). The dilutive effect of the November 2016 warrants on net loss per share of common stock (diluted) reflects these exercise price adjustments. The weighted average number of common shares outstanding for the basic loss per share calculation for the year ended December 31, 2016 included 28,684 shares that the Company was obligated to issue under the provisions of the CSIA as of December 31, 2016.

The following outstanding securities at December 31, 2017 and 2016 have been excluded from the computation of diluted weighted average shares outstanding for the years ended December 31, 2017 and 2016, as they would have been anti-dilutive:

	Year Ended December 31,	
	2017	2016
Options	1,115,865	74,890
Warrants	8,225,087	776,267
Total	9,340,952	851,157

6. Balance Sheet Details

Property and Equipment, net

Property and equipment consisted of the following:

	December 31,	
	2017	2016
Laboratory equipment	$1,727,000	$1,747,000
Office and computer equipment	71,000	69,000
Leasehold improvements	188,000	188,000
	1,986,000	2,004,000
Accumulated depreciation and amortization	(1,170,000)	(932,000)
Property and equipment, net	$816,000	$1,072,000

Depreciation expense totaled $343,000 and $338,000 for the years ended December 31, 2017 and 2016, respectively.

Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consisted of the following:

	December 31,	
	2017	2016
Accounts payable	$578,000	$1,056,000
Accrued compensation	1,050,000	895,000
Other accrued expenses	302,000	746,000
Dividends payable	38,000	38,000
	$1,968,000	$2,735,000

7. Income Taxes

Loss before income taxes consisted of the following components:

	Year Ended December 31,	
	2017	2016
United States	$(6,934,000)	$(6,358,000)
Foreign	(7,206,000)	(13,036,000)
	$(14,140,000)	$(19,394,000)

The benefit from income taxes consisted of the following components:

	Year Ended December 31,	
	2017	2016
Current:		
Federal	$-	$-
State	-	-
Foreign	-	-
	-	-
Deferred:		
Federal	-	-
State	-	-
Foreign	(1,302,000)	(556,000)
	(1,302,000)	(556,000)
Total	$(1,302,000)	$(556,000)

The Company recorded an income tax benefit of $1.3 million for the year ended December 31, 2017 related to a reduction of the existing deferred tax liability during the second quarter of 2017 as a result of a $5.8 million impairment charge to the Company's IPR&D assets. During the year ended December 31, 2016, the Company recorded an income tax benefit of $0.6 million, comprised of a $0.4 million income tax benefit related to a reduction of the existing deferred tax liability from a $2.0 million impairment charge to the Company's IPR&D assets, and a $0.2 million income tax benefit as a result of the reduction of deferred tax liability resulting from changes in UK enacted tax rates from 20% to 17% in 2016.

Significant components of the Company's deferred tax assets and liabilities were as follows:

December 31,

	2017	2016
Deferred tax assets:		
Net operating loss carryforwards	$44,049,000	$67,479,000
Research and development and other tax credits, net	3,109,000	3,109,000
Stock-based compensation	188,000	795,000
Other	165,000	301,000
	47,511,000	71,684,000
Valuation allowance	(47,511,000)	(71,684,000)
Total deferred tax assets	-	-
Deferred tax liabilities:		
In-process research and development	(1,147,000)	(2,449,000)
Total deferred tax liabilities	$(1,147,000)	$(2,449,000)

At December 31, 2017, the Company had federal net operating loss (“NOL”) carryforwards of approximately $198.1 million, of which $7.3 million will expire in 2018 unless utilized, and the remaining carryforwards will expire in taxable years 2019 through 2037. The Company had foreign NOL carryforwards of $9.0 million as of December 31, 2017, $0.6 million of which was generated in 2017. At December 31, 2017, the Company had federal research and development (“R&D”) tax credit carryforwards of approximately $3.1 million, net of a reserve for uncertain tax positions of $2.1 million. The R&D tax credit carryforwards will begin to expire in taxable years 2018 through 2031, unless previously utilized. The NOL and tax credit carryforwards may be further subject to the application of Section 382 of the Internal Revenue Code of 1986 (the “Code”) as discussed further below. 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.

The differences between the Company's effective tax rate and the U.S. federal statutory tax rate were as follows:

	December 31,	
	2017	2016
U.S. federal statutory income tax rate	34.0 %	34.0 %
Adjustments for tax effects of:		
Fair value of derivative liabilities	3.6 %	8.0 %
Foreign rate differential	(4.4)%	(1.5)%
Stock-based compensation	(1.0)%	(0.6)%
State taxes, net of federal benefit	(1.7)%	(3.8)%
Australia refundable R&D tax offset	(2.4)%	(5.2)%
Goodwill impairment	-	(13.2)%
Effect of change in federal tax rate	(184.2)%	-
Change in reserve of uncertain tax positions	-	(10.7)%
Change in valuation allowance	170.9 %	(3.5)%
All other	(5.6)%	(0.6)%
Effective income tax rate	9.2 %	2.9 %

On December 22, 2017, the U.S. Tax Cuts and Jobs Act (the "Tax Reform Act") was signed into law. The Tax Reform Act significantly revised the U.S. corporate income tax regime by, among other things, lowering the U.S. corporate tax rate from 35% to 21% effective January 1, 2018, while also repealing the deduction for domestic production activities, implementing a territorial tax system and imposing a repatriation tax on deemed repatriated earnings of foreign subsidiaries. Shortly after enactment, the SEC staff issued Staff Accounting Bulletin ("SAB") 118, which provides guidance on accounting for the Tax Reform Act's impact. SAB 118 requires that the impact of tax legislation be recognized in the period in which the law was enacted. As a result of the Tax Reform Act, the Company recorded additional tax expense of $26.0 million during the year ended December 31, 2017, however, this amount was fully offset by a valuation allowance and no net income tax expense or benefit was recorded in the consolidated financial statements. This net tax expense of $0 represents a provisional amount and is the Company's current best estimate. The provisional amount incorporates assumptions made based upon the Company's current interpretation of the Tax Reform Act and may change as additional clarification and implementation guidance is received. The Company did not record any deemed repatriation tax on unremitted foreign Earnings and Profits ("E&P") due to the accumulated and projected current deficit in foreign E&P for the year ended December 31, 2017.

Because of the complexity of the new Global Intangible Low-Taxed Income ("GILTI") tax rules, we continue to evaluate this provision of the Tax Reform Act and the application of Accounting Standards Codification 740, "*Income Taxes*." Under U.S. GAAP, the Company is allowed to make an accounting policy choice of either (1) treating taxes due on future U.S. inclusions in taxable income related to GILTI as a current-period expense when incurred (the "period cost method") or (2) factoring such amounts into our measurement of its deferred taxes (the "deferred method"). The Company has not yet adopted an accounting policy with respect to GILTI at December 31, 2017.

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 Company's NOL carryforwards and R&D tax credit carryforwards will expire due to the limitations of Sections 382 and 383 of the Code. As a result, the utilization of the carryforwards may be limited and a portion of the carryforwards may expire unused.

The Company has unrecognized tax benefits of approximately $2.1 million related to its federal R&D tax credits as of December 31, 2017 and 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 2016 due to the fact that NOL carryforwards 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, 2017 and 2016, 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

Under the terms of month-to-month subleases, the Company pays monthly rent of $6,000 for its principal corporate offices in San Diego, California and monthly rent of approximately $4,000 for lab space in Brookvale, Australia. The Company leases lab space in Richmond, Virginia and lab and office space in Ljubljana, Slovenia under operating leases that expire in August 2018 and February 2019, respectively. The operating leases have extension provisions which may be elected at the option of the Company. Rent expense under the Company's leases was $208,000 and $227,000 for the years ended December 31, 2017 and 2016, respectively.

Future minimum annual lease payments under the Company's noncancelable operating leases as of December 31, 2017, are as follows:

	Operating Leases
2018	$ 72,000
2019	7,000
Total minimum lease payments	$ 79,000

Collaborative Agreements

In 2013, the Company entered into a Collaboration Agreement and a License Agreement with the University of Leicester (the "Leicester Agreements"). Under the Leicester Agreements, the Company provided payments to support research on the University of Leicester's development of a bacteriophage therapeutic to resolve *C. difficile* infections and licensed related patents, materials and know-how. During the years ended December 31, 2017 and 2016, the Company recorded $79,000 and $166,000, respectively, in research and development expenses related to the Leicester Agreements. The Company terminated the Leicester Agreements effective in the third quarter of 2017 and the termination was not material to the Company.

Legal Proceedings

From time to time, the Company may be involved in disputes, including litigation, relating to claims arising out of operations in the normal course of business. Any of these claims could subject the Company to costly legal expenses

and, while management generally believes that there is adequate insurance to cover many different types of liabilities, the Company's insurance carriers may deny coverage or policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on the consolidated results of operations and financial position. Additionally, any such claims, whether or not successful, could damage the Company's reputation and business. The Company is currently not a party to any legal proceedings, the adverse outcome of which, in management's opinion, individually or in the aggregate, would have a material adverse effect on our consolidated results of operations or financial position.

9. 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 and par value of $0.01 per share. Holders of the Series B shares were entitled to receive cumulative, cash dividends at the rate of 10% of the Series B stated value. 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.

On April 8, 2016, certain holders of over two-thirds of the Company's then-outstanding shares of the Series B shares elected to automatically convert all outstanding shares of Series B into shares of common stock in accordance with the Company's Amended and Restated Articles of Incorporation (the "Conversion"). The transaction was accounted for based on the difference between the fair value of the consideration transferred to the holders of the preferred stock and the carrying amount of the preferred stock on April 7, 2016. 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 150,556 shares of common stock. From December 31, 2015 to April 7, 2016, the Company had accreted $1,858,000 from additional paid-in capital to Series B shares to adjust the redemption value of the Series B. The December 31, 2017 consolidated balance sheet reflects dividends payable of $38,000 to former holders of the Series B, which are classified as current liabilities.

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. As a result of the Conversion on April 8, 2016, the Series B preferred stock derivative liability balance was extinguished, with the decrease in fair value from January 1, 2016 through April 8, 2016 of $1.5 million recorded as a component of change in fair value of derivative liabilities in the Company's consolidated statements of operations for the year ended December 31, 2016.

Common Stock Issuance Agreement

On April 8, 2016, the Company entered into the Common Stock Issuance Agreement ("CSIA") with certain former holders of the Company's Series B (the "Holders") pursuant to which the Company agreed to issue the Holders an aggregate of 85,346 shares of the Company's common stock. Pursuant to the CSIA, the Company and the Holders also agreed to amend warrants to purchase 31,519 shares of common stock previously issued to the Holders in June 2013 in order to reduce the exercise price of such warrants from $70.00 per share to $40.50 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 certain registration rights under provisions in the CSIA. The transaction was accounted for based on the difference between the fair value of the consideration transferred, which includes the common stock issued and Warrant Amendments, to the Holders of the preferred stock and the carrying amount of the preferred stock on April 7, 2016.

Under the terms of the CSIA, the Company also agreed to issue a formula-based number of shares of its common stock to the Holders for no additional consideration upon completion of one or more bona fide equity financings in which the Company sells shares of its common stock below a specified price (a "Dilutive Issuance") in a transaction that occurs prior to the earlier of June 30, 2018 or such time as the Company has raised, following the date of the CSIA, $10.0 million in the aggregate (the "Price Protection Obligations"). In each of June 2016, November 2016 and May 2017, the Company completed offerings of its common stock that constituted Dilutive Issuances under the CSIA. In 2016 the Company issued 75,020 shares under the Price Protection Obligations in connection with the June 2016 financing. Due in part to limitations on the number of shares issuable to the Holders under the rules of the NYSE American, no additional shares of common stock were issued to the holders in connection with the November 2016 and May 2017 offerings prior to June 2017 as discussed below.

On June 27, 2017, the Company and the Holders entered into the CSIA Amendment to, among other things, terminate the Price Protection Obligations. In consideration for the termination for the Price Protection Obligations and a release of claims by the Holders, the Company agreed to (i) issue to the Holders, within five business days of the Amendment, an aggregate of 28,684 shares of its common stock (the "First Issuance"), which, under the rules of the NYSE American, was the maximum number of shares the Company was permitted to issue to the Holders pursuant to the CSIA without further shareholder approval, and (ii) issue to the Holders in a subsequent closing an aggregate 523,210 shares of common stock (the "Second Issuance"), subject to obtaining shareholder approval of the Second Issuance at the Company's 2017 Annual Meeting of Shareholders and the Company's receipt of a release of claims from the Holders at the time of the Second Issuance. On September 7, 2017 the Company's shareholders approved the Second Issuance. The Company received a release of claims from each of the Holders and issued 523,210 shares of common stock on September 19, 2017. The shares were valued at $519,000 as of September 19, 2017 based on the closing price of the Company's common stock of $0.99 per share at September 19, 2017 multiplied by the 523,210 shares of common stock issued to the Holders. The related charge of $519,000 was included as a component of general and administrative expense in the Company's consolidated statements of operations for the year ended December 31, 2017.

The terms of the CSIA required the delivery of shares in the event of a future dilutive financing. The Company determined this was a conditional forward contract and recorded a diluted financing derivative liability for potential future dilutive financings. The dilutive financing derivative liability was valued at $126,000 as of December 31, 2016 and the decrease in fair value of $611,000, excluding the $1.5 million adjustment for the fair value of the dilutive shares issuable as a result of the June 2016 offering, was recorded as a component of change in fair value of derivative liabilities in the consolidated statements of operations for the year ended December 31, 2016. The CSIA Amendment removed the condition which required the CSIA to be treated as a derivative liability. Accordingly, the fair value of the shares were marked-to-market through June 29, 2017 at $22,000, and the decrease in fair value of $104,000 was recorded as a component of change in fair value of derivative liabilities in the consolidated statements of operations for the year ended December 31, 2017.

10. Capital Stock and Warrants

Registered Public Offering of Common Stock and Warrants

On June 3, 2016, the Company completed a registered public offering of 212,766 shares of its common stock and warrants to purchase 106,383 shares of 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 $23.50 per unit, for aggregate gross proceeds to the Company of $5.0 million. The warrants have an exercise price of $22.50 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.

The Company has classified the warrants as a liability due to certain net cash settlement provisions in the warrant agreement. The derivative liability for the warrants was marked-to-market at $32,000 and $274,000 as of December 31, 2017 and 2016, respectively. The decrease in fair value of $242,000 and $1.5 million was recorded as a component of change in fair value of derivative liabilities in the Company’s consolidated statements of operations for the years ended December 31, 2017 and 2016, respectively (see Note 4).

Underwritten Public Offering of Common Stock and Warrants

On November 22, 2016, the Company completed an underwritten public offering of 533,500 shares of its common stock and warrants to purchase up to an aggregate of 533,500 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 $7.50 per unit, for aggregate gross proceeds to the Company of $4.0 million. The warrants originally had an exercise price of $7.50 per share, are exercisable immediately upon issuance and expire five years following the date of issuance. The Company received net proceeds from the offering of approximately $3.3 million, after deducting underwriting discounts and commissions and other offering expenses payable by the Company. In connection with the Company's April 2017 1-for-10 reverse stock split and a provision in the November 2016 warrants that required reduction of the exercise price following the reverse stock split to the lowest daily volume-weighted average price of the Company's common stock during the 15 trading days immediately following the reverse stock split, the exercise price of the warrants was adjusted to $1.00 per share. In September 2017, the exercise price of the warrants was further adjusted to $0.57 per share in connection with the issuance of 523,210 shares of the Company's common stock to the shareholders who were party to the CSIA, pursuant to a provision in the warrant agreements that required reduction of the exercise price following a dilutive issuance of the Company's common stock. The exercise price of the warrants is subject to further adjustment upon future dilutive issuances and stock combination events as defined in the warrant agreements (see Note 9).

The Company has classified the warrants as a liability primarily because the warrants are not indexed to the Company's common stock due to an exercise price adjustment provision and the Company may be required to pay the warrant holders cash under certain circumstances. The derivative liability for the warrants was marked-to-market at $260,000 and $2.0 million as of December 31, 2017 and 2016, respectively. The decrease in fair value of $886,000 for the year ended December 31, 2016 and the decrease in fair value of $1.7 million for the year ended December 31, 2017, excluding the fair value of warrants reclassified from a liability to additional paid-in capital upon exercise of warrants, was recorded as a component of change in fair value of derivative liabilities in the Company's consolidated statement of operations (see Note 4).

Underwritten Public Offering of Common Stock, Pre-funded Warrants and Warrants

On May 10, 2017, the Company completed an underwritten public offering and sold 2,584,085 shares of its common stock and 4,483,334 pre-funded warrants to purchase common stock in lieu of additional shares of common stock, and common warrants to purchase 8,000,000 shares of common stock. All of the pre-funded warrants were exercised during the year ended December 31, 2017. The combined price to the public for each share of common stock and accompanying common warrant was $1.50. The combined price to the public for each pre-funded warrant and accompanying common warrant was $1.49. Each pre-funded warrant was exercisable for one share of common stock at an exercise price of $0.01 per share. The common warrants are exercisable at a price of $1.50 per share of common stock, and will expire five years from the date of issuance. The Company received net proceeds from the offering of approximately $9.4 million, after deducting $1.2 million in offering costs including the underwriting discount and commissions and other offering expenses payable by the Company. The Company evaluated the pre-funded warrants and common warrants issued in the May 2017 offering and determined that the warrants should be classified as equity

instruments.

Warrants

On January 4, 2016, the Company entered into an Asset Purchase Agreement with Novolytics Limited to purchase certain preclinical materials and intangible assets, including patent rights. In consideration for the assets acquired, the Company paid cash consideration of approximately $205,000 and issued warrants to purchase an aggregate of 17,000 shares of the Company's common stock. During the first quarter of 2016, the Company expensed the total value provided for the acquired assets of $409,000, which included warrants with a fair market value of $204,000, to research and development expense.

During the year ended December 31, 2017, warrants to purchase 226,664 shares of the Company's common stock, which were issued in connection with the November 2016 financing, were exercised for proceeds to the Company of $130,000. There were no warrants exercised during the year ended December 31, 2016. During the year ended December 31, 2017, warrants to purchase 17,683 shares of the Company's common stock, originally issued in 2013 and 2015, were forfeited.

At December 31, 2017, outstanding warrants to purchase shares of common stock, accounted for as equity or liabilities, are as follows:

Shares Underlying Outstanding Warrants	Exercise Price	Expiration Date
19,691	$70.00	February 4 to July 15, 2018
8,640	$82.50	December 23, 2018
8,492	$120.00	December 31, 2018
8,492	$120.00	March 1, 2019
41,872	$107.50	March 16, 2020
31,519	$40.50	March 31, 2021
106,381	$22.50	June 3, 2021
306,831	$0.57	November 22, 2021
8,000,000	$1.50	May 10, 2022
8,531,918		

The weighted average exercise price of outstanding warrants to purchase common stock at December 31, 2017 was $2.87 per share.

11. Stock-based Compensation

In June 2016, the Company's stockholders approved the Company's 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 100,000 new shares were added to the authorized share reserve under the 2016 Plan. Under the 2016 Plan, the number of shares authorized for issuance automatically increases annually beginning January 1, 2017 and through January 1, 2026. On January 1, 2017, the number of shares of common stock authorized for future issuance was automatically increased by 82,440 shares. On September 7, 2017, the Company's stockholders approved an amendment to the 2016 Plan which increased the aggregate number of shares of common stock authorized for issuance by 800,000 shares.

The Company estimates the fair value of stock options with performance and service conditions on the date of grant using the Black-Scholes valuation model. The assumptions used in the Black-Scholes model are presented below:

	Year Ended December 31,	
	2017	2016
Risk-free interest rate	1.27 to 2.36 %	1.22 to 1.63 %
Expected volatility	117 to 144 %	113 to 123 %
Expected term (in years)	2.0 to 9.1	6.0
Expected dividend yield	0 %	0 %

The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. Expected volatility is based on the historical volatility of the Company's common stock. The expected term represents the period that the Company expects its stock options to be outstanding. The expected term assumption is estimated using 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 expected term assumption for stock options granted to parties other than employees or directors is the contractual term of the option award. The Company has never declared or paid dividends on its common stock and has no plans to do so in the foreseeable future. Forfeitures are recognized as a reduction of stock-based compensation expense as they occur.

Stock options issued to non-employees other than directors are accounted for at their estimated fair values using the Black-Scholes valuation model and are re-measured to fair value at each period end until the earlier of the date that performance by the non-employee is complete or a performance commitment has been obtained. The stock-based compensation expense related to the grant of stock options to non-employees was not significant for the years ended December 31, 2017 and 2016.

The table below summarizes the total stock-based compensation expense included in the Company's consolidated statements of operations for the periods presented:

	Year Ended December 31,	
	2017	2016
Research and development	$171,000	$138,000
General and administrative	529,000	1,857,000
Total stock-based compensation	$700,000	$1,995,000

Stock option transactions during the years ended December 31, 2017 and 2016 are presented below:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2015	66,964	$ 86.52	9.29	
Granted	26,419	26.48		
Forfeited/Cancelled	(18,493)	89.95		
Outstanding at December 31, 2016	74,890	64.50	8.65	
Granted	1,070,572	1.22		
Forfeited/Cancelled	(29,597)	87.87		
Outstanding at December 31, 2017	1,115,865	$ 3.17	8.98	$118,000
Vested and expected to vest at December 31, 2017	830,752	$ 3.94	8.71	$90,000
Exercisable at December 31, 2017	136,142	$ 13.18	4.02	$14,000

The aggregate intrinsic value of options at December 31, 2017 is based on the Company's closing stock price on that date of $1.01 per share. As of December 31, 2017, there was $1.1 million of total unrecognized stock-based compensation expense related to unvested stock options and the weighted average period over which this cost is expected to be recognized is approximately 2.6 years.

Employee Stock Purchase Plan (ESPP)

On June 20, 2016, the Company's stockholders approved the Company's 2016 Employee Stock Purchase Plan (the "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 are 12,000, and automatically increase annually as allowed for under the ESPP, beginning January 1, 2017 and through January 1, 2026. On January 1, 2017, the number of shares of common stock authorized for issuance under the ESPP was automatically increased by 16,488 shares.

During the years ended December 31, 2017 and 2016, there were 4,200 and 3,272 common shares issued under the ESPP, respectively. The Company recognized $5,000 and $12,000 in compensation expenses related to the ESPP for the years ended December 31, 2017 and 2016, respectively.

Shares Reserved For Future Issuance

As of December 31, 2017, the Company had reserved shares of its common stock for future issuance as follows:

	Shares Reserved
Stock options outstanding	1,115,865
Employee stock purchase plan	21,016
Available for future grants under the 2016 Plan	4,758
Warrants	8,531,918
Total shares reserved	9,673,557

12. 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 made matching contributions to the 401(k) plan of $12,000 and $0 for the years ended December 31, 2017 and 2016, respectively, and the contributions were recorded to operating expense in the consolidated statements of operations.

13. Related Party

During the year ended December 31, 2017 and 2016, the Company incurred travel reimbursement expenses of $22,000 and $46,000, respectively, payable to Biosciences Managers. Two members of the Company's board of directors serve as managing directors of Biosciences Managers.

During the year ended December 31, 2017, the Company issued 110,772 shares of common stock to One Funds Management Limited as Trustee for Asia Pacific Healthcare Fund II ("One Funds") in connection with the CSIA Amendment (See Note 9). During the year ended December 31, 2016, the Company issued 99,666 shares of common stock to One Funds, 53,000 shares in connection with the CSIA and 46,666 shares in connection with the Company's November 2016 public offering of common stock and warrants to purchase common stock. Two members of the Company's board of directors are affiliated with One Funds.

14. Subsequent Event

On January 12, 2018, the Company completed a registered public offering of 4,000,000 shares of its common stock at an offering price of $1.00 per share, for aggregate gross proceeds of $4.0 million. The Company received net proceeds from the offering of approximately $3.5 million, after deducting placement agent fees and other offering expenses payable by the Company.

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.

As of December 31, 2017, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. 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 concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2017.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. 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 Chief Executive Officer and Chief 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, 2017, 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 Chief Executive Officer and Chief Financial Officer, concluded that, as of December 31, 2017, our internal control over financial reporting was effective based on those criteria.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. We were not required to have, nor have we, engaged our independent registered public accounting firm to perform an audit of internal control over financial reporting pursuant to SEC rules that permit us to provide only management’s report in this Annual Report on Form 10-K.

Remediation of Previously Reported Material Weakness

In our Annual Report on Form 10-K for the year ended December 31, 2015 filed with the SEC on March 30, 2016, we reported the following material weakness in our internal control over financial reporting: “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 and 2014.”

To remediate the material weakness described above, we took corrective steps in 2016, and completed documentation and implementation of new and revised internal controls over financial reporting processes in the area of complex and non-routine transactions. These improvements included 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 above, in 2017 we continued to enhance the design and operating effectiveness of our controls related to complex and non-routine transactions, monitored the operations of our remedial controls and performed testing to determine the operating effectiveness of those controls. After completing testing of the design and operating effectiveness of the new controls, we have concluded that the above identified material weakness has been fully remediated as of December 31, 2017.

Changes in Internal Control Over Financial Reporting.

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief 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. Except for the remediation of the material weakness described above, there were no changes in our internal control over financial reporting during the quarter ended December 31, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

None.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

MANAGEMENT

The following table sets forth information about our executive officers and directors as of March 14, 2018.

Name	Age	Position(s)
Paul C. Grint, M.D.	60	Chief Executive Officer, Director
Steve R. Martin	57	Chief Financial Officer
Igor P. Bilinsky, Ph.D.	45	Chief Operating Officer
Non-Employee Directors		
Jeremy Curnock Cook (2) (3)	68	Chairman of the Board
Louis Drapeau (1) (2) (3)	74	Director
Michael S. Perry, Ph.D. (1) (2) (3)	58	Director
Vijay B. Samant (1)	65	Director
Wendy Johnson	66	Director

(1) Member of the audit committee.
(2) Member of the compensation committee.
(3) Member of the nominating and corporate governance committee.

Executive Officers

Paul C. Grint, M.D. has served as our Chief Executive Officer since May 2017 and as a member of our board of directors since November 2015. Dr. Grint served on the compensation committee of our board of directors until his appointment as our Chief Executive Officer. From June 2015 to May 2017, Dr. Grint served as the President and Chief Executive Officer and on the board of directors of Regulus Therapeutics Inc., a company focused on the discovery and development of microRNA therapeutics, and served as the Chief Medical Officer of Regulus Therapeutics Inc. from June 2014 to June 2015. 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, and as Chief Medical Officer of Kalypsys, Inc., a biopharmaceutical company, from 2006 to 2008. Dr. Grint also previously served in similar executive level positions at Pfizer Inc., IDEC Pharmaceuticals Corporation, and Schering-Plough Corporation. Dr. Grint currently serves on the board of directors of Amplyx Pharmaceuticals, Inc. and of Synedgen, Inc., and 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. The nominating and Corporate Governance Committee and the board of directors believe that Dr. Grint's significant experience in leading biotechnology and pharmaceutical companies, as well his significant experience in drug development and in the biotechnology industry, qualifies him to serve on our board of directors.

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).

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

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. He also serves as a member of the board of directors of Avita Medical Ltd, a publicly traded (ASX:AVH) medical technology company, Adherium Ltd (ASX:ADR), Rex Bionics Pty Ltd, Smart Matrix Ltd and Sea Dragon Ltd (NZX:SEA) as Alternate Director. From 1987 to 2000, Mr. Curnock Cook was a director of Rothschild Asset Management Limited, a corporate and investment advisory company, and was responsible for the Rothschild Bioscience Unit. Mr. Curnock Cook founded the International Biochemicals Group in 1975, which was sold in 1985 to Royal Dutch Shell, where he served as Managing Director until 1987. Mr. Curnock Cook received an M.A. in natural sciences from Trinity College, Dublin. The nominating and Corporate Governance Committee and the board of directors believe that Mr. Curnock Cook's significant experience as a board member of multiple biotechnology companies qualifies him to serve on our board of directors.

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. From February 2007 until April 2017, Mr. Drapeau served as a member of the board of Bio-Rad Laboratories, Inc., a publicly traded pharmaceutical company. Mr. Drapeau currently serves on the board of directors of Avita Medical Ltd, a publicly traded (ASX:AVH) medical technology company, Mr. Drapeau received a B.S. in mechanical engineering and an M.B.A. from Stanford University. The nominating and corporate governance committee and the board of directors believe that Mr. Drapeau's experience with respect to accounting and financial matters qualifies him to serve on our board of directors.

Michael S. Perry, D.V.M., Ph.D. has served as a member of our board of directors since November 2005. Since June 2017 Dr. Perry has served as the Chief Executive Officer of Avita Medical Ltd, a publicly traded (ASX:AVH) medical technology company, and has been a member of the board of directors of Avita Medical since February 2013. Since April of 2017 he has also served as a Managing Director of Bioscience Managers Pty Ltd., a medical sciences fund manager. From January 2016 to April 2017, Dr. Perry served as Senior Vice President and Chief Scientific Officer of Global 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, LLC, 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. (2009 to 2011), a publicly held drug development company, and from 2005 to 2009 Dr. Perry also served as Chief Development Officer of VIA Pharmaceuticals, Inc., a publicly held biotechnology company. 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, he served as President and Chief Executive Officer of Pharsight Corporation, a publicly held software and consulting services firm. From 2000 to 2002, he 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., both wholly-owned subsidiaries of Novartis Pharma. He 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 Program. Dr. Perry has served as Adjunct Professor since November 2013 at the Gates Center for Regenerative Medicine at the University of Colorado School of Medicine, Anschutz Medical Campus and since 2014, he has served as Chair of the Translational Medicine External Advisory Board for the Houston Methodist Research Institute. He has served as a member of the board of directors of Arrowhead Pharmaceuticals since December 2011 and on the board of Gamida Cell Ltd. since May 2017. The nominating and corporate governance Committee and the board of directors believe that Dr. Perry's substantial scientific and medical knowledge, investing experience, and operational and executive experience in the biotechnology and pharmaceutical industries qualifies him to serve on our board of directors

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. The nominating and corporate governance committee and the board of directors believe that Mr. Samant's significant experience leading biopharmaceutical product development companies, as well his significant sales, marketing, operations, and business development expertise within the biotechnology and pharmaceutical industries, qualifies him to serve on our board of directors.

Wendy S. Johnson has served as a member of our board of directors since May 2014. In addition, Ms. Johnson served as our Interim Chief Operating Officer from September 2014 to January 2017. In January 2018, Ms. Johnson joined Reneo Pharmaceuticals, Inc. as Chief Operating Officer. 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. The nominating and corporate governance committee and the board of directors believe that Ms. Johnson's significant experience in pharmaceutical drug development and business development, as well her strong background in microbiology, qualifies her to serve on our board of directors.

Board Composition

Our business and affairs are organized under the direction of our board of directors, which currently consists of six 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 American 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 American.

In February 2018, 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 and Vijay Samant qualify as "independent" directors within the meaning of the NYSE American rules. Our board of directors also concluded that Dr. Grint and Ms. Johnson were not at such time "independent" directors within the meaning of the NYSE American rules given Dr. Grint's position as our Chief Executive Officer and Ms. Johnson's recent position as acting Chief Operating Officer and then as a consultant.

As required under applicable NYSE American 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, Dr. Grint 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 American 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;
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- 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, Louis Drapeau 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 American 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 and 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 American 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 American 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.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors, executive officers and any persons beneficially holding more than 10% of our common stock to report their initial ownership of our common stock and any subsequent changes in

that ownership to the SEC. Our executive officers, directors and greater than 10% stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file.

Specific due dates for these reports have been established and we are required to identify those persons who failed to timely file these reports. To our knowledge, based solely on a review of the copies of such reports furnished to us and written representations from our directors and officers that no other reports were required, during the fiscal year ended December 31, 2017, all of our directors, officers and greater than 10% stockholders complied with the Section 16(a) filing requirements, except for the following:

We issued shares of our common stock to One Funds Management Limited as Trustee for Asia Pacific Healthcare Fund II, or One Funds, and amended the terms of certain warrants held by One Funds, pursuant to the provisions of the CSIA and the subsequent amendment to the CSIA, as described in more detail in this Annual Report under Item 13—Certain Relationships and Related Transactions, and Director Independence—Common Stock Issuance Agreement. In addition, on November 22, 2016, One Funds acquired 46,666 shares of our common and warrants exercisable for 46,666 shares of our common stock, at a combined purchase price of $7.50 per share, in our underwritten public offering. In September 2017, the exercise price of these warrants, as well as all other outstanding warrants issued pursuant to our November 2016 public offering, was automatically reduced to $0.5749 in accordance with the terms of the warrants. Jeremey Curnock Cook, the Chairman of our board of directors, was and is affiliated with One Funds as described in greater detail under Item 13 of this Annual Report, such that he is deemed to beneficially own the shares and warrants held by One Funds. Mr. Cook has not filed a report under Section 16(a) of the Exchange Act to reflect the foregoing transactions or his beneficial ownership of the shares and warrants held by One Funds. In April 2017, Dr. Michael Perry, one of our directors, became affiliated with One Funds as described in greater detail under Item 13 of this Annual Report, such that he may be deemed to beneficially own the shares and warrants held by One Funds. Dr. Perry has not filed a report under Section 16(a) of the Exchange Act reflecting his beneficial ownership of the shares and warrants held by One Funds.

We have adopted a code of ethics for directors, officers (including our principal executive officer, principal financial officer, principal accounting officer and controller) 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.ampliphibio.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.

Item 11. EXECUTIVE COMPENSATION

Executive Compensation

Our named executive officers for the year ended December 31, 2017, which consist of all individuals who served as our principal executive officer during 2017 and our two most highly compensated executive officers other than our principal executive officer who were serving as executive officers as of December 31, 2017 are:

- Dr. Paul Grint, our Chief Executive Officer effective June 1, 2017;
- Steve Martin, our Chief Financial Officer;
- Dr. Igor Bilinsky, our Chief Operating Officer;
- M. Scott Salka, our former Chief Executive Officer during 2017 through May 31, 2017

Summary Compensation Table

The following table provides information regarding the compensation paid during the last two fiscal years to our named executive officers, including our former Chief Executive Officer, for the year ended December 31, 2017.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($) (1)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)		Total ($)
Dr. Paul Grint	2017	277,083	-	154,163	50,000	18,750	(4)	499,996
Chief Executive Officer (2)	2016	-	-	-	-	45,000	(4)	45,000
Steve Martin,	2017	320,000	-	154,072	173,409	-		647,481
Senior VP and Chief Financial Officer	2016	306,667	-	239,801	67,200	1,341		615,009
Dr. Igor Bilinsky,	2017	323,525	-	201,173	183,805	-		708,503
Senior VP and Chief Operating Officer								
Michael Scott Salka,	2017	227,769	-	84,693	144,051	247,917	(5)	704,430
former Chief Executive Officer (3)	2016	425,000	-	-	102,000	988		527,988

In accordance with SEC rules, this column represents the aggregate grant date fair value of the option awards granted during 2017 and 2016 (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 Note 11 to the consolidated financial statements. 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.

Dr. Grint commenced employment with us as Chief Executive Officer in June 2017.

(2)

(3) Mr. Salka terminated employment with us as Chief Executive Officer in May 2017.

(4) Represents board of directors service retainers paid to Dr. Grint for board services provided prior to his commencement of employment.

(5) Represents salary continuation severance benefits paid to Mr. Salka.

Base Salary

The base salaries 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.

Dr. Grint's annual base salary for 2017 was $475,000.

Mr. Martin's annual base salary for 2017 and 2016 was $320,000.

Dr. Bilinsky's annual base salary for 2017 was $350,000.

Mr. Salka's annual base salary for 2017 and 2016 was $425,000.

Annual Bonus

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, Dr. Grint is eligible to receive an annual performance-based bonus for 2017 equal to, at target, 50% of his annual salary based on our achievement of certain performance goals. Mr. Martin is eligible to receive an annual performance-based bonus for 2017 equal to, at target, 35% of his annual salary based on our achievement of certain performance goals. Dr. Bilinsky is eligible to receive an

annual performance-based bonus for 2017 equal to, at target, 40% of his annual salary based on our achievement of certain performance goals.

Annual performance bonus amounts for 2016 and 2017 were based entirely on corporate goals relating to capital raising, management of operating costs, our clinical trial and manufacturing progress, and certain organizational achievements. In January 2018, the compensation committee reviewed the corporate performance goals for Dr. Grint, Mr. Martin and Dr. Bilinsky and also considered other external factors impacting the valuation of the Company. Based on the evaluation of the overall 2017 results by the compensation committee and considering the period of services provided in 2017, the compensation committee awarded the following cash bonus awards. Dr. Grint $50,000, Dr. Bilinsky $65,000 and Mr. Martin $65.000.

2017 Financing Bonus

On April 1, 2017 we amended our offer letter agreements with Mr. Martin, Dr. Blinsky and Mr. Salka in order to provide us with additional near-term operating flexibility by the executives waiving certain severance benefit rights in exchange for stock options and eligibility to receive cash bonuses upon successful completion of near-term financings.

Each of the offer letter amendments provided for a waiver by the applicable named executive officer of the severance benefits such executive would have otherwise been entitled to in connection with a qualifying termination of employment in the event such termination occurred in connection with a wind-down event at any time before the earlier of (i) January 1, 2018 and (ii) such time as the board of directors had determined that our cash and cash equivalents were sufficient to fund (A) our operations for at least the 12 months following such determination and (B) all our potential liabilities under all then-outstanding obligations related to accrued salaries and wages, and potential severance benefit payment obligations.

In consideration for the applicable named executive officers' waiver of the severance benefits rights described above, on April 1, 2017 we granted stock options to these individuals under our 2016 Equity Incentive Plan, or 2016 Plan. Such stock options have a four-year term for exercise from the date of grant, were fully-vested upon grant, and were for the following number of shares: Dr. Bilinsky 176,411 shares, Mr. Martin 161,290 share, and Mr. Salka 214,214 shares.

As further consideration for the severance benefit right waivers, under the terms of the offer letter amendments each of Mr. Martin, Dr. Bilinsky and Mr. Salka was eligible to receive the following bonus payments in connection with the following capital raising milestones if such milestones occurred during their employment with us: (A) if we raised, after April 1, 2017 and on or before May 31, 2017, at least $4,000,000 in aggregate gross proceeds from the sale of our equity securities in one or more financing transactions, the executives would be entitled to receive a lump-sum cash bonus payment in an amount equal to (x) in the case of Mr. Salka, 38.8%, in the case of Dr. Bilinsky, 32%, and in the case of Mr. Martin, 29.2%, multiplied by (y) 3.5% multiplied by (z) the gross proceeds raised by us from such financing transaction(s); and (B) if we raised, after April 1, 2017 and on or before December 31, 2017, at least

$10,000,000 in aggregate gross proceeds from the sale of our equity securities in one or more financing transactions, the executives would be entitled to receive a lump-sum cash bonus payment in an amount equal to (x) in the case of Mr. Salka, 38.8%, in the case of Dr. Bilinsky, 32%, and in the case of Mr. Martin, 29.2%, multiplied by (y) 2% multiplied by (z) the gross proceeds raised by us from such financing transaction(s).

In 2017, we raised $10.6 million in gross proceeds from the sale of our equity securities through our May 2017 public offering. As a result, our board of directors approved the payment of lump-sum cash bonuses to Mr. Martin, Dr. Bilinsky and Mr. Salka in the amounts of $108,409, $118,805 and $144,051, respectively.

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."

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.

Dr. Grint. In June 2017, we entered into an offer letter agreement with Dr. Grint, our Chief Executive Officer. Dr. Grint's employment under the agreement is at will and may be terminated by us or Dr. Grint at any time. Under the terms of the agreement, Dr. Grint is entitled to receive an initial annual base salary of $475,000, an annual target performance bonus of 50% of his annual salary based on our achievement of certain performance objectives and options to purchase 475,189 shares our common stock, which were granted in September 2017.

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.

Dr. Bilinsky. In January 2017, we entered into an offer letter agreement with Dr. Bilinsky, our Senior Vice President and Chief Operating Officer. Dr. Bilinsky's employment under the agreement is at will and may be terminated by us or Dr. Bilinsky at any time. Under the terms of the agreement, Dr. Bilinsky is entitled to receive an initial annual base salary of $350,000, an annual target performance bonus of 40% of his annual salary based on our achievement of certain performance objectives, an option to purchase a number of shares of our common stock equal to 1.5% of the number of shares of common stock outstanding on a fully-diluted basis, which was granted in January 2017, and an additional 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 following the completion of the first financing transaction following the start of employment. The financing transaction was completed in May 2017, at which time the additional stock option was granted.

Mr. Salka. On May 31, 2017, Mr. Salka resigned as our Chief Executive Officer and as a member of our board of directors. In connection with Mr. Salka's resignation as our Chief Executive Officer, we entered into a separation and consulting agreement with Mr. Salka (the "Separation Agreement"). Pursuant to the Consulting Agreement and in exchange for our receipt of an effective release and waiver of claims from Mr. Salka, we agreed to provide Mr. Salka with the following: (i) continued payment of his base salary in effect as of May 31, 2017 for 12 months following his resignation (the "Severance Period"); (ii) payment of COBRA premiums on his behalf, through the earliest of the following: (a) the duration of the Severance Period; (b) the date upon which he becomes eligible for health insurance pursuant to another employer-sponsored group health insurance plan; or (c) the date upon which he becomes ineligible for continued coverage under COBRA; and (iii) a stock option under the 2016 Plan, exercisable for 50,000 shares of our common stock at an exercise price equal to the fair market value on the date of grant, which will vest, subject to certain terms and conditions, at the end of the consulting period described below, and may be exercised for a period of three years following the end of such consulting period. Pursuant to the Separation Agreement, Mr. Salka agreed to provide transition and consulting services to us for a period of up to 90 days following May 31, 2017.

Potential Payments and Benefits upon Termination or Change in Control

Dr. Grint, Dr. Bilinsky and Mr. Martin. Under the terms of the offer letter agreements for each of our three current named executive officers, each named executive officer is entitled to receive 12 months of continued base salary if their employment with us is terminated without cause or if the executive resigns for good reason, and additionally, if such termination or resignation occurs in connection with a change in control, full acceleration of the individuals equity awards, provided that in either case the person provides us with an effective release of claims.

All of our 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."

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Grants of Plan-Based Awards in Fiscal Year End

The following table sets forth certain information with respect to stock option awards granted to our named executive officers, including our former Chief Executive Officer, for the year ended December 31, 2017.

Name	Grant Date	Option Awards: Number of Securities Underlying Options (#)	Exercise Price Per Share of Option Awards ($) (1)	Grant Date Fair Value of Option Awards ($) (2)
Dr. Grint	9/7/2017	285,113	0.91	-
	9/7/2017	190,076	0.91	154,163
Mr. Martin	4/1/2017	16,128	4.30	41,335
	9/7/2017	139,000	0.91	112,737
Dr. Bilinsky	1/30/2017	24,732	4.60	98,099
	4/1/2017	17,641	4.30	45,212
	5/30/2017	87,161	0.74	57,862
Mr. Salka	4/1/2017	21,421	4.30	54,900
	6/7/2017	50,000	0.73	29,793

(1) In accordance with the terms of our 2016 Equity Incentive Plan, the exercise price of each stock option granted was set at the market closing price of our common stock on the date of grant.

(2) In accordance with SEC rules, this column represents the grant date fair value of the option awards computed in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718 for stock-based compensation transactions (ASC 718). Assumptions used in the calculation of these amounts are included in Note 11 to the consolidated financial statements. 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.

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, 2017.

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
Dr. Grint	848	(1)	772	(1)	-		56.50	11/5/2025
	-		-		285,113	(2)	0.91	9/6/2027
	-		190,076	(1)	-		0.91	9/6/2027
	848		190,848					
Mr. Martin	4,791	(1)	5,200	(1)	-		28.50	1/18/2026
	16,128	(3)	-		-		4.30	3/31/2021
	-		139,000	(1)	-		0.91	9/6/2027
	20,919		144,200					
Dr. Bilinsky	-		24,732	(1)	-		4.60	1/30/2027
	17,641	(3)	-		-		4.30	3/31/2021
	-		87,161	(1)	-		0.74	5/30/2027
	17,641		111,893					
Mr. Salka	21,421	(3)	-		-		4.30	3/31/2021
	50,000	(4)	-		-		0.73	8/29/2020
	71,421		-					

(1) Twenty-five percent of the shares vest one year after grant date, with the balance vesting in equal monthly installments thereafter over the next three years, subject to continued service with us.

(2) The shares underlying this option will vest upon achievement of certain performance criteria.

(3) One hundred percent of the shares vested upon grant date of April 1, 2017.

(4) One hundred percent of the shares vested 90 days after the grant date of June 7, 2017.

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 2016 Plan and 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, 2017.

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

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 100,000 new shares were added to the authorized share reserve under the 2016 Plan. On January 1, 2017, and January 1, 2018 pursuant to the terms of the 2016 Plan, the number of shares available for issuance under the 2016 Plan automatically increased by 82,440 and 474,946 shares, respectively. On September 7, 2017, the stockholders approved an amendment to the 2016 Plan which increased the aggregate number of shares of common stock authorized for issuance by 800,000 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. Following the adoption of the 2016 Plan, no further awards have been or will be granted under the 2013 Plan, and all awards granted under the 2013 Plan that are repurchased, forfeited, expire or are cancelled become available for grant under the 2016 Plan in accordance with its terms. However, all stock options granted under the 2013 Plan continue to be governed by the terms of the 2013 Plan. The terms of the stock options granted under the 2013 Plan, including vesting requirements, were determined by our board of directors, subject to the provisions of the 2013 Plan. Options granted under the 2013 Plan generally vest over four years and are exercisable after they have been granted and up to ten years from the date of grant. The exercise price of the incentive stock options must equal at least 100% of the fair market value of our common stock on the date of grant.

Under the terms of the 2013 Plan, upon the effectiveness of a corporate transaction (as such term is defined in the 2013 Plan), all awards granted under the 2013 Plan will terminate unless affirmed by us or assumed by the successor entity. Our board of directors may amend the terms of any outstanding award granted under the 2013 Plan, including to provide for acceleration of vesting, but no such action may adversely affect the holder's rights under an outstanding award without the holder's consent.

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, 2017, there were 21,016 shares available for future issuance under the ESPP. On January 1, 2018, pursuant to the terms of the ESPP, the number of shares available for issuance under the ESPP automatically increased by 94,989 shares.

Non-Employee Director Compensation

The following table and related footnotes show the compensation paid during the year ended December 31, 2017 to our non-employee directors, other than Dr. Grint whose 2017 compensation is set forth above under “Executive Compensation” above.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Jeremy Curnock Cook (2)	70,000	8,673	-	78,673
Louis Drapeau (3)	61,000	8,673	-	69,673
Michael S. Perry, Ph.D. (4)	59,000	8,673	-	67,673
Vijay Samant (5)	46,000	8,673	-	54,673
Wendy S. Johnson (6)	40,000	8,673	-	48,673

(1) In accordance with SEC rules, this column represents the aggregate grant date fair value of the option awards granted during 2017 and 2016 (if any) computed in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718 for stock-based compensation transactions (ASC 718). Assumptions used in the calculation of these amounts are included in Note 11 in the Notes to the Consolidated Financial Statements. 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) As of December 31, 2017, Mr. Cook held stock options for an aggregate of 15,810 shares, of which 3,463 shares were vested and exercisable.

(3) As of December 31, 2017, Mr. Drapeau held stock options for an aggregate of 12,520 shares, of which 630 shares were vested and exercisable.

(4) As of December 31, 2017, Dr. Perry held stock options for an aggregate of 12,640 shares, of which 850 shares were vested and exercisable.

(5) As of December 31, 2017, Mr. Samant held stock options for an aggregate of 12,520 shares, of which 848 shares were vested and exercisable.

(6) As of December 31, 2017, Ms. Johnson held stock options for an aggregate of 17,516 shares, of which 5,386 shares were vested and exercisable.

In September 2015, the board of directors approved a revised compensation structure for our non-employee directors. In 2017, 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 2017, Dr. Grint served on our board of directors both before and following his appointment to the role of Chief Executive Officer. Dr. Grint received compensation totaling $18,750 for his services as a non-employee director and committee member from January 1 through May 31, 2017. In June 2017, Dr. Grint assumed the role of Chief Executive Officer. Once he became an employee, Dr. Grint's compensation became governed solely by the terms of his employment offer letter agreement described above and he did not receive additional cash or equity compensation for serving on our board of directors. All of Dr. Grint's 2017 compensation, including the compensation he received while serving as a non-employee director prior to becoming our Chief Executive Officer, 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 13,695,824 shares of common stock outstanding as of January 31, 2018.

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, 2018, which is 60 days after January 31, 2018. 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 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			
Empery Asset Management, LP (1) 1 Rockefeller Plaza, Suite 1205 New York, New York 10020	1,149,449	8.3	%
Directors and Named Executive Officers			
Paul C. Grint, M.D. (2)	950	*	
Jeremy Curnock Cook (3)	290,170	2.1	%
Louis Drapeau (4)	1,669	*	
Michael S. Perry, Ph.D. (5)	287,197	2.1	%
Vijay B. Samant (6)	950	*	
Wendy S. Johnson (7)	5,525	*	
Steve R. Martin (8)	21,919	*	
Igor P. Bilinsky, Ph.D. (9)	24,857	*	
M. Scott Salka (10)	71,421	*	
All current executive officers and directors as a group (8 persons) (11)	347,159	2.5	%

*Represents beneficial ownership of less than 1%.

(1)Consists of 1,000,000 shares of common stock and warrants exercisable for 149,449 shares of common stock.

(2) Consists of 950 shares of common stock that Dr. Grint has the right to acquire from us within 60 days of January 31, 2018, pursuant to the exercise of stock options.

(3) Consists of (a) 330 shares of common stock, (b) 229,285 shares referenced held by One Fund Management Limited as Trustee for Asia Pacific Healthcare Fund II ("One Funds"), an entity with which Mr. Cook is affiliated, and warrants exercisable for 56,793 shares of common stock, and (c) 3,762 shares of common stock that Mr. Cook has the right to acquire from us within 60 days of January 31, 2018, pursuant to the exercise of stock options.

(4) Consists of 1,000 shares of common stock and 669 shares of common stock that Mr. Drapeau has the right to acquire from us within 60 days of January 31, 2018, pursuant to the exercise of stock options.

(5) Consists of (a) 230 shares of common stock, (b) 229,285 shares referenced held by One Funds, an entity with which Dr. Perry is affiliated, and warrants exercisable for 56,793 shares of common stock, and (c) 889 shares of common stock that Dr. Perry has the right to acquire from us within 60 days of June 30, 2017, pursuant to the exercise of stock options.

(6) Consists of 950 shares of common stock that Mr. Samant has the right to acquire from us within 60 days of January 31, 2018, pursuant to the exercise of stock options.

(7) Consists of 100 shares of common stock and 5,425 shares of common stock that Ms. Johnson has the right to acquire from us within 60 days of January 31, 2018, pursuant to the exercise of stock options.

(8) Consists of 376 shares of common stock and 21,543 shares of common stock that Mr. Martin has the right to acquire from us within 60 days of January 31, 2018, pursuant to the exercise of stock options.

(9) Consists of 24,857 shares of common stock that Dr. Bilinsky has the right to acquire from us within 60 days of January 31, 2018, pursuant to the exercise of stock options.

(10) Consists of 71,421 shares of common stock that Mr. Salka has the right to acquire from us within 60 days of January 31, 2018, pursuant to the exercise of stock options. In May 2017, Mr. Salka resigned as our Chief Executive Officer and as a member of our board of directors.

(11) Includes the shares described in footnotes (2) through (9) above (without duplication of the shares and warrants held by One Funds, an entity with which both Mr. Cook and Dr. Perry are affiliated).

Equity Compensation Plan Information

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

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

In December 2013, our board of directors adopted the 2013 Stock Incentive Plan, or the 2013 Plan. Our stockholders approved the 2013 Plan in February 2014 and an amendment to the plan in August 2015. The 2013 Plan replaced the 2012 Plan. There are no shares of common stock remaining for future awards under the 2013 Plan.

In April 2016, our board of directors adopted our 2016 Equity Incentive Plan, or the 2016 Plan. The 2016 Plan was approved by our stockholders in June 2016. With the approval of the 2016 Plan, the remaining unallocated shares under the 2013 Plan were allocated to the 2016 Plan and an additional 100,000 new shares were added to the authorized share reserve under the 2016 Plan. On January 1, 2017, the number of shares of common stock authorized for future issuance was automatically increased by 82,440 shares. On September 7, 2017, our stockholders approved an amendment to the 2016 Plan which increased the aggregate number of shares of common stock authorized for issuance by 800,000 shares.

The following table provides information as of December 31, 2017 with respect to our equity compensation plans:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
	1,111,655	$ 2.80	4,758

Equity compensation plans approved by security holders (1)			
Equity compensation plans not approved by security holders (2)	4,210	$ 100.00	0
Total	1,115,865	$ 3.17	4,758

(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, 2016 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.”

Exclusive Channel Collaboration

Pursuant to that certain Exclusive Channel Collaboration Agreement, or ECC Agreement, dated as of March 29, 2013, with Intrexon Corporation, 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 CSIA, with certain former holders of our Series B convertible preferred stock, including Pendinas Limited (which owned more than 5% of our common stock on the date of the CSIA) and One Funds Management Limited as Trustee for Asia Pacific Healthcare Fund II, or One Funds. One Funds 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 of and holds an ownership interest in Bioscience Managers Pty Ltd., and as of April 2017, Dr. Michael Perry, one of our directors, is also a Managing Director of 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.

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 $70.00 per share to $40.50 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 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	58,455	$1,504,433
One Funds	17,129	$440,859

The CSIA also contained price protection obligations that required us to issue a formula-based number of shares of our common stock to the holders for no additional consideration upon the completion of certain dilutive financings within a defined period.

In connection with the registered direct public offering that we completed in June 2016, on June 21, 2016 we issued 51,383 and 15,057 shares of common stock to Pendinas Limited and One Funds, respectively, for no additional consideration. Pendinas Limited ceased to be a “related person” following the completion of our May 2017 public offering.

On June 27, 2017, we entered into an amendment to the CSIA, or the Amendment, to, among other things, terminate the price protection obligations contained in the CSIA. In consideration for the termination of such price protection obligations and a release of claims by the stockholders party to the CSIA, on June 29, 2017 we issued an aggregate of 28,684 shares of common stock to the stockholders party to the Amendment, including 5,757 shares to One Funds. Pursuant to the Amendment and following receipt of stockholder approval at our 2017 Annual Meeting of Shareholders, on September 19, 2017 we issued to One Funds an additional 105,015 shares of common stock.

Settlement Agreement

On November 12, 2016, we entered into a settlement agreement with NRM VII Holdings I, LLC, or 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 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. Upon NRM's receipt of the $2.0 million settlement payment described above, our accrued dividends payment obligation to NRM was extinguished.

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 American).

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 shareholders. 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

The following table represents aggregate fees billed to us by Ernst & Young LLP for the fiscal years ended December 31, 2017 and 2016.

	Fiscal Year Ended December 31, 2017	Fiscal Year Ended December 31, 2016
Audit Fees	$ 324,000	$ 493,000
Audit Related Fees	97,000	165,000
Tax Fees	-	-
All Other Fees	-	-
Total	$ 421,000	$ 658,000

Representatives of Ernst & Young LLP attended all of the meetings of the Audit Committee occurring during the years ended December 31, 2017 and 2016.

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 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:

2. *Financial Statement Schedules*. None.

3. *Exhibits.*

Exhibit Number	Description of Document
2.1	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).
2.2	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).
2.3	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).
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	Articles of Amendment to Articles of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed on April 24, 2017).
3.3	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, 3.2 and 3.3.
4.2	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-8 (File No. 333-217563), filed on May 1, 2017).
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).
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	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).
4.15	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).
4.16	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).
4.17	Form of Warrant to Purchase Common Stock issued to purchasers in May 2017 (incorporated by reference to Exhibit 4.18 to the Company's Registration Statement on Form S-1 (File No. 333-217169)).
4.18	Form of Pre-funded Warrant (incorporated by reference to Exhibit 4.19 to the Company's Registration Statement on Form S-1 (File No. 333-217169)).
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, as amended (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K, filed with the SEC on September 11, 2017).

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 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).
10.11+	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).
10.12+	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).
10.13+	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).
10.14+	Amendment to Offer Letter Agreement, dated April 1, 2017, by and between the Company and Igor P. Bilinsky, Ph.D. (incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K, filed with the SEC on April 4, 2017).
10.15+	Amendment to Offer Letter Agreement, dated April 1, 2017, by and between the Company and Steve R. Martin (incorporated by reference to Exhibit 99.3 to the Company's Current Report on Form 8-K, filed with the SEC on April 4, 2017).
10.16+	Separation and Consulting Agreement, dated May 30, 2017, by and between the Registrant and M. Scott Salka (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 14, 2017).
10.17+	Offer Letter, dated June 1, 2017, by and between the Company and Paul C. Grint, M.D. (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 14, 2017).
10.18	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).

10.19	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).
10.20	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).
10.21	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).
10.22*	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).

10.23	Agreement of Lease of Business Premises, dated as of February 21, 2014, by and between Avotehna d.d. and Ampliphi, Biotehnološke 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	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).
10.26	First Amendment to Common Stock Issuance Agreement, dated June 27, 2017, by and among the Company and the persons and entities listed on Exhibit A thereto (incorporated by reference to Exhibit 99.1 to the Current Report on Form 8-K, filed on June 30, 2017).
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.**

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

Date: March 14, 2018 By: /s/ Paul C. Grint, M.D.
Name: Paul C. Grint, M.D.
Title: Chief Executive Officer
(Principal Executive Officer)

SIGNATURES AND POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Paul C. Grint, M.D., 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.

SIGNATURE	**TITLE**	**DATE**
/s/ Paul C. Grint, M.D. Paul C. Grint, M.D.	Chief Executive Officer *(Principal Executive Officer)*	March 14, 2018
/s/ Steve R. Martin Steve R. Martin	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 14, 2018
/s/ Jeremy Curnock Cook Jeremy Curnock Cook	Chairman of the Board of Directors	March 14, 2018
/s/ Louis Drapeau Louis Drapeau	Director	March 14, 2018
/s/ Wendy S. Johnson Wendy S. Johnson	Director	March 14, 2018
/s/ Michael S. Perry, Ph.D. Michael S. Perry, Ph.D.	Director	March 14, 2018
/s/ Vijay B. Samant Vijay B. Samant	Director	March 14, 2018