AmpliPhi Biosciences Corp
Form 10-K
March 25, 2019

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, 2018

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 every Interactive Data File required to be submitted 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 such files). Yes x No ¨

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	x	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 29, 2018, 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 29, 2018 (the last business day of the Registrant's most recently completed second quarter) as quoted on the NYSE American, was approximately $18.6 million.

As of March 8, 2019, 32,294,008 shares of the Registrant's Common Stock were outstanding.

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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;
- whether and when the proposed merger with C3J Therapeutics, Inc. will be consummated, including the likelihood of the satisfaction of certain conditions to the completion of the proposed merger;
- whether and when the proposed $10.0 million private placement to be completed immediately following the closing of the proposed merger with C3J Therapeutics, Inc. will be consummated;

- our expected benefits of and the potential value to be created by the consummation of the proposed merger with C3J Therapeutics, Inc.;
- 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 a 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 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 began 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 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.

In mid-2018, we compiled the treatment results from our single-patient access program data from 2017 and 2018 and we submitted to the FDA suggested clinical trial designs for continued development of our bacteriophage programs. In September 2018, we announced that we had received the official minutes from our August 2018 Type B Pre-IND meeting with the FDA regarding our proposed clinical development of AB-SA01 for the treatment of *S. aureus* bacteremia infections as well as patients with a hip or knee prosthetic joint infection due to *S. aureus*. The FDA expressed general agreement with our proposed clinical trial designs and, based on the current FDA feedback, no additional clinical or nonclinical data are required to proceed with two proposed randomized clinical trials. The first such clinical trial would be a Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-SA01, administered intravenously with the best available antibiotic therapy, compared to placebo plus best available antibiotic therapy, in approximately 100 patients with *S. aureus* bacteremia. The second such clinical trial would be a Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-SA01, administered by intra-articular injection and then intravenously with the best available antibiotic therapy, compared to placebo plus the best available antibiotic therapy, in approximately 100 patients with a hip or knee prosthetic joint infection due to *S. aureus* as an adjunct to surgical treatment. We expect that we would produce our proprietary bacteriophage therapeutics for these clinical trials at our wholly owned manufacturing facility, which is good manufacturing practices (GMP) certified by the governmental authorities in the jurisdiction in which it operates. We believe our GMP-facility has the capacity to produce our proprietary bacteriophage therapeutics for these clinical trials through a potential filing of a biologics license application and potential approval.

In September 2018, we also received positive feedback from the FDA regarding our clinical development plans for AB-PA01 for the treatment of *P. aeruginosa* infections. Resistant *P. aeruginosa* is designated as ‘Priority 1: Critical’ pathogen on the World Health Organization’s Priority Pathogens List and as ‘Serious Threat’ by the U.S. Centers for Disease Control and Prevention. The FDA expressed general agreement with our proposed clinical trial designs and, based on the current FDA feedback, no additional clinical or nonclinical data are required to proceed with two proposed randomized clinical trials. The first such clinical trial would be a Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-PA01, administered intravenously with the best available antibiotic therapy, compared to placebo plus best available antibiotic therapy, in approximately 100 patients with hospital-acquired and ventilator-associated pneumonia due to *P. aeruginosa*. The second clinical trial would be a Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-PA01, administered intravenously with the best available antibiotic therapy, compared to placebo plus best available antibiotic therapy, in approximately 100 patients with P. aeruginosa bacteremia. We intend to seek non-dilutive financing and explore other opportunities to conduct these clinical trials.

In addition, in September 2018 we provided updated topline clinical results for our ongoing single-patient expanded access program. 84% of patients achieved treatment success (physician’s assessment) at the end of bacteriophage therapy, defined as complete resolution or significant improvement of baseline signs and symptoms. We have now received clinical outcome results for 21 of the patients provided with our investigational bacteriophage therapeutics, across seven hospitals, and with serious or life-threatening infections not responding to antibiotic therapy. See the detailed clinical results in the paragraphs below.

Following the announcement of the positive FDA feedback and updated topline data results, we raised capital On October 16, 2018, from an underwritten public offering in which we sold 14,875,000 shares of common stock and 2,125,000 pre-funded warrants to purchase common stock, and common warrants to purchase 17,500,000 shares of common stock. Aggregate net proceeds from the offering were $5.8 million. Beginning in December of 2017, we engaged Ladenburg Thalmann to perform a strategic review of alternatives including a merger or sale. With the recent FDA feedback and known existing and sources of capital, we continued to believe that a strategic transaction would be an option to continue to advance the bacteriophage technology of the Company.

On January 3, 2019, we entered into an Agreement and Plan of Merger and Reorganization with C3J Therapeutics Inc. ("C3J"), a private clinical stage biotechnology company focused on the development of novel targeted antimicrobials, which included the proposed business combination ("Merger") of the C3J and Ceres Merger Sub, Inc, a wholly owned subsidiary of ours, with C3J as the surviving company, subject to shareholder approval.

At the effective time of the Merger, we anticipate that each share of C3J common stock outstanding immediately prior to the effective time of the Merger will be converted into the right to receive approximately 0.6892 shares of AmpliPhi common stock, subject to adjustment to account for a reverse split of AmpliPhi common stock at a reverse split ratio of between1-for-3 and 1-for-20, inclusive, to be determined by AmpliPhi's board of directors and to be implemented prior to the consummation of the Merger.

Immediately following the Merger, the former C3J security holders will own approximately 70% of the aggregate number of shares of AmpliPhi common stock and the security holders of AmpliPhi as of immediately prior to the Merger will own approximately 30% of the aggregate number of shares of AmpliPhi common stock on a fully diluted basis.

In addition, on February 5, 2019, certain existing C3J shareholders executed a Share Purchase Agreement with us pursuant to which the shareholders agreed, subject to the satisfaction of customary closing condition, to purchase $10.0 million in common stock of the combined company upon the closing of the Merger at a price per share equal to (i) $40.0 million, divided by (ii) the total number of shares of our common stock outstanding on a fully diluted, as-converted basis, assuming the conversion, exercise or settlement of all outstanding options, warrants, and restricted stock units as of immediately after the effective time of the Merger, but excluding (A) any shares of common stock issuable pursuant to the Share Purchase Agreement and (B) any shares of our common stock reserved for issuance under any equity incentive plan, stock option plan or similar arrangement but for which awards have not yet been granted as of the effective time of the Merger and (C) any shares of common stock issuable in connection with out-of-the-money options and out-of-the-money warrants. Based on our and C3J's respective current capitalizations, we expect the purchase price per share to be approximately $0.36.

Clinical Results for Expanded Access Program

On September 17, 2018, we announced updated topline clinical results for our ongoing single-patient expanded access program. 84% of patients achieved treatment success (physician's assessment) at the end of bacteriophage therapy, defined as complete resolution or significant improvement of baseline signs and symptoms.

We have now received clinical outcome results for 21 of the patents to whom we have provided our investigational bacteriophage therapeutics, at seven hospitals, with serious or life-threatening infections not responding to antibiotic therapy. Of the 21 patients, 57% were male and 43% were female, and the mean age was 57 years old with patients ranging from 16 years old to 96 years old. These patients were treated with AB-SA01 or AB-PA01, along with antibiotics, under single-patient expanded access programs in the United States (Emergency INDs, per the FDA) or Australia (Special Access Scheme, per the Australian Therapeutic Goods Administration).

Through our expanded access program, 15 patients with serious *S. aureus* infections were treated with AB-SA01 and six patients with serious *P. aeruginosa* infections were treated with AB-PA01. The treated patients' infections included bacteremia and septicemia, native and prosthetic valve endocarditis, recurrent pneumonia (cystic fibrosis, post-transplant, VAPB), ventilator-associated pneumonia, prosthetic joint infection, ventricular assist device infection, septicemia due to burns, chronic rhinosinusitis and others. Over 1,000 bacteriophage doses were administered as part of the expanded access program including, over 400 doses of AB-SA01, of which over 300 doses were administered intravenously. Treatment of AB-SA01 was well-tolerated in all patients with no treatment-related serious adverse events, or SAEs. Over 600 doses of AB-PA01 were administered, including over 400 doses administered intravenously. Treatment of AB-PA01 was well-tolerated in five patients. One patient discontinued treatment of AB-PA01 due to Grade 1 and 2 adverse events, which resolved within 18 hours. There were no treatment-related SAEs.

Of the patients in the modified intent-to-treat population, or mITT, 84% (16 out of 19) achieved treatment success at the end of therapy. Treatment success, as determined by the treating physician, was defined as a complete resolution or significant improvement of baseline signs and symptoms. mITT population was defined as all patients who met the criteria for clinical diagnosis, whose bacterial isolate was susceptible to phage and who received at least one dose of phage.

The following chart shows the safety and tolerability results of our expanded access program:

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The following chart shows the clinical outcomes at the end of therapy of our expanded access program:

The following chart shows the patient disposition from our expanded access program:

AB-SA01 (*S. Aureus*) Clinical Development Plan

We conducted meetings with the FDA in February 2017 and August 2018 regarding our proposed clinical development of AB-SA01. During the February 2017 meeting with the FDA, we received feedback on our previously submitted detailed development proposal to commence a Phase 2 trial with AB-SA01 for the treatment of antibiotic-resistant *S. aureus* infections in patients with chronic rhinosinusitis. In the official minutes from that meeting, the FDA acknowledged that phage therapy is an exciting approach for treatment of multi-drug-resistant organisms and expressed a commitment to addressing the unique regulatory challenges that might arise during product development. In addition, the FDA Center for Biologics Evaluation and Research stated that the clinical safety and effectiveness data collected during development, including from emergency case studies, could inform future discussions for clinical development and ultimately, the regulatory pathway to approval. During the August 2018 meeting with the FDA, which was a Type B pre-IND meeting, we shared the clinical and microbiological results for patients treated with AB-SA01 under our single-patient expanded access program in 2017 and 2018 and the proposed design of randomized controlled clinical trials that we developed based on input from key infectious disease physician opinion leaders, in order to establish a Phase 2 development plan for multiple indications, including bacteremia and prosthetic joint infection.

In September 2018, we received the official minutes from our August 2018 Type B pre-IND meeting. The FDA expressed general agreement with our proposed clinical trial designs and, based on the current FDA feedback, no additional clinical or nonclinical data are required to proceed with two proposed randomized clinical trials. The first such clinical trial would be a Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-SA01, administered intravenously with the best available antibiotic therapy, compared to placebo plus best available antibiotic therapy, in approximately 100 patients with *S. aureus* bacteremia. The second such clinical trial would be a Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-SA01, administered by intra-articular injection and then intravenously with the best available antibiotic therapy, compared to placebo plus the best available antibiotic therapy, in approximately 100 patients with a hip or knee prosthetic joint infection due to *S. aureus* as an adjunct to surgical treatment. We are actively seeking and intend to continue to seek non-dilutive financing and explore other opportunities to conduct these clinical trials of AB-SA01. We may also choose to conduct one or more smaller-scale clinical trials of similar design as an alternative to conducting the

approximately 100 patient clinical trials described above in an effort to reduce clinical trial expenditures. It is possible that results from such smaller-scale clinical trials may not be viewed by the FDA or other regulatory agencies as sufficient for the advancement of AB-SA01 into Phase 2 trials, including potentially registrational Phase 2 trials, due to the smaller trial populations even if the trial results are otherwise positive, which in turn could result in the FDA or other regulatory agencies requiring us to conduct additional studies beyond those that would have been required if we had conducted trials of approximately 100 patients as proposed in our August 2018 Type B pre-IND meeting. We expect that we would produce our proprietary bacteriophage therapeutics for these clinical trials at our wholly owned manufacturing facility, which is good manufacturing practices (GMP) certified by the governmental authorities in the jurisdiction in which it operates. We believe our GMP-facility has the capacity to produce our proprietary bacteriophage therapeutics for these clinical trials through a potential biologics license application filing and potential approval.

Furthermore, we continue to investigate whether AB-SA01 may be eligible for Fast Track Designation and for approval under the Limited Population pathway, or LPAD pathway, which is intended to facilitate development of therapeutics to treat serious or life-threatening infections in a limited population of patients with unmet need. Products eligible for approval under the LPAD pathway may follow streamlined approaches for clinical development, which may involve smaller, shorter, or fewer clinical trials to help reduce the overall product development timeline.

AB-PA01 (*P. aeruginosa*) Clinical Development Plan

In September 2018, we received positive feedback, via written response, from the FDA regarding our development plans for AB-PA01, without the need for a Type B pre-IND meeting. The FDA expressed general agreement with our proposed clinical trial designs and, based on the current FDA feedback, no additional clinical or nonclinical data are required to proceed with two proposed randomized clinical trials. The first such clinical trial would be a Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-PA01, administered intravenously with the best available antibiotic therapy, compared to placebo plus best available antibiotic therapy, in approximately 100 patients with hospital-acquired and ventilator-associated pneumonia (HAP/VAP) due to *P. aeruginosa*. The second clinical trial would be a Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-PA01, administered intravenously with the best available antibiotic therapy, compared to placebo plus best available antibiotic therapy, in approximately 100 patients with *P. aeruginosa* bacteremia.

We considered the clinical development timelines for both the AB-SA01 and AB-PA01 development programs. We concluded in the fourth quarter of 2018 that since the AB-SA01 program is further advanced in the development process, the AB-SA01 program will continue to be advanced and the AB-PA01 program will not be pursued in the near term. As we are not actively pursuing the AB-PA01 program, we have recorded an impairment charge of approximately $1.9 million within operating expenses of the consolidated statement of operations in the fourth quarter of 2018.

Our Pipeline

Our development pipeline of product candidates is as follows:

AB-SA01 covers approximately 95% of *S. aureus* strains, including multi-drug-resistant infections, and AB-PA01 covers approximately 80% of *P. aeruginosa* strains, including multi-drug-resistant infections.

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. Based on our market research, we estimate that there are more than 300,000 serious *S. aureus* infections in the United States each year, including approximately 150,000 cases of *S. aureus* bacteremia each year that lead to approximately 30,000 deaths each year.

The Centers for Disease Control and Prevention estimates that 1.5 million people in the United States develop bacteremia each year and approximately 250,000 deaths occur as a direct result of infection. It is estimated that one in three patients who die in the hospital have bacteremia. Bacteremia is the most expensive condition treated at U.S. hospitals, costing approximately $24 billion annually. *S. aureus* is the second most common pathogen associated with bacteremia, causing approximately 150,000 cases each year and approximately 30,000 deaths.

Prosthetic joint infection is a difficult to treat and costly condition. There are more than one million knee and hip joint replacements performed in the U.S. each year, which is projected to increase to over four million each year by 2030. There are approximately 50,000 prosthetic joint infections each year, with approximately 20% caused by *S. aureus*. Prosthetic joint infection is costly with the annual inpatient costs exceeding $1 billion and rapidly rising.

The historical and projected number of infected total hip arthroplasty and total knee arthroplasty in the United States are as follows:

(3) Kurtz S et al. 2012. The Journal of Arthroplasty; 27(8): S1.

Prosthetic joint infection is difficult to treat because biofilm formation increases bacterial resistance to antibiotics. The current standard of care is a combination of surgery and antibiotics, with significant patient morbidity, high costs and up to 30% failure rate. The current standard of care includes a two-stage revision: surgery to remove the infected joint, four to six weeks of intravenous antibiotics, surgery to implant a new joint, followed by six weeks of antibiotics.

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.

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 will expire in June 2020 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, 2018, we owned or had exclusive license rights to a total of 68 patents and applications: 7 U.S. patents, 4 U.S. non-provisional patent applications, 8 U. S. provisional patent applications, 1 pending Patent Cooperation Treaty (PCT) application, 41 foreign patents, and 7 foreign patent applications, with nominal expiration on various dates between 2024 and 2039. 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. To our knowledge, several biotechnology companies, including C3J Therapeutics, Adaptive Phage Therapeutics, Pherecydes Pharma, BiomX, Epibiome, Intralytix, iNtRON, PhageLux, EnBiotix, Fixed-Phage, Locus Biosciences, Phagomed, Phi Therapeutics, TechnoPhage and LytPhage, Inc., as well as academic institutions, have discovery stage or clinical 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 2018, Contrafect completed 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;

- 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 effectiveness 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;

- mode of bacteriophage replication and targeting to specific species of bacteria;

- relevant animal models in preclinical studies; and

- clinical safety and effectiveness.

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 signed by and a copy provided to each clinical trial subject or his or her legal authorized 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 may 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, Limited Population, 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. 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 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, accelerated approval, and, as of 2018, for antibacterial and antifungal therapies, approval under the Limited Population Pathway. 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 if there is 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. The limited population pathway for antibacterial and antifungal drugs or biologics (LPAD) may enable streamlined development of safe and effective medicines that overcome the unmet needs of a limited population of patients with serious bacterial infections.

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 and approval under LPAD 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. Approval under LPAD is for a limited population of patients; labeling statements for the limited use of the product are removed when supplemental data substantiates expansion of the patient population.

Eligibility for a drug or biologic product to be licensed under LPAD includes treatment of a serious or life-threatening infection in a limited population of patients with unmet medical need. FDA also considers the severity, rarity or prevalence of the infection and the lack of alternative treatment in the limited population the therapeutic is intended for. It is possible for qualifying therapies to complete a streamlined clinical program to demonstrate substantial evidence of effectiveness and safety in the limited population. Drugs or biological products approved under LPAD can also receive fast track and breakthrough designations as well as accelerated and priority review of the marketing application. LPAD-required limitations of labeling are removed when supplemental data demonstrating a favorable benefit-risk profile in a broader population corroborates label expansion. We intend to request approval under LPAD in the BLA for our product candidates if applicable.

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 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 may 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 events, reporting periodic 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, complete response letters, 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, or EU, 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 EU 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 EU do not follow price structures of the U.S. and generally tend to be significantly lower.

Other U.S. 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 but not limited to, the Centers for Medicare & Medicaid Services, or CMS,, other divisions of the U.S. Department of Health and Human Services, or HHS (e.g., the Office of Inspector General, the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments). For example, our business practices, including any future sales, marketing and scientific/educational grant programs may be required to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the patient data privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA, transparency requirements, and similar state, local and foreign laws, each as amended.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item, good, facility or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, and other individuals and entities on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, the intent standard under the federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the Affordable Care Act, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. Rather, if “one purpose” of the remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. In addition, the Affordable Care Act codified case law that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act (discussed below).

The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to, among others, a federal healthcare program that the person knows or should know is for a medical or other item or service that was not provided as claimed or is false or

fraudulent.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. Several pharmaceutical and other healthcare companies are being investigated or, in the past, have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses.

HIPAA created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and their implementing regulations, imposes requirements on certain types of individuals and entities relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates that are independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act within the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) annually report information to CMS related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, physicians and teaching hospitals and certain ownership and investment interests held by physicians and their immediate family

members.

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In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private “qui tam” actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage, and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, or also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor’s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor’s determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may

not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Different pricing and reimbursement schemes exist in other countries. In the EU, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on healthcare pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the Affordable Care Act has substantially changed healthcare financing and delivery by both governmental and private insurers. Among the Affordable Care Act provisions of importance to the pharmaceutical and biotechnology industries, in addition to those otherwise described above, are the following:

- created an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs that began in 2011;
- increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price (AMP);
- created a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts, off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;
- extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and added new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expanded of the entities eligible for discounts under the 340B Drug Discount Program;
- created a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- expanded healthcare fraud and abuse laws, including the Foreign Corrupt Practices Act (FCPA) and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;
- required reporting of certain financial arrangements with physicians and teaching hospitals;
- required annual reporting of certain information regarding drug samples that manufacturers and distributors provide to physicians;
- established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending; and
- created a licensure framework for follow on biologic products.

Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been legal and political challenges to certain aspects of the Affordable Care Act. Since January 2017, the current U.S. President has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act. In December 2017, Congress repealed the tax penalty for an individual's failure to maintain Affordable Care Act-mandated health insurance, commonly known as the "individual mandate", as part of the Tax Cuts and Jobs Act of 2017 (Tax Act).

On January 22, 2018, the current U.S. President signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018 (BBA), among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". Congress is continuing to consider legislation that would alter other aspects of the Affordable Care Act. The ultimate content, timing or effect of

any healthcare reform legislation on the U.S. healthcare industry is unclear. In July 2018, CMS published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act.

We anticipate that the Affordable Care Act, if substantially maintained in its current form, will continue to result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Further legislation or regulation could be passed that could harm our business, financial condition and results of operations. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and federal and state legislative activity designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the U.S. President's administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the U.S. President's administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. On January 31, 2019, the HHS Office of Inspector General proposed modifications to federal Anti-Kickback Statute safe harbors which, among other things, may affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. While some of these and other proposed measures may require authorization through additional legislation to become effective, Congress and the U.S. President's administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

The Foreign Corrupt Practices Act

The FCPA prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Europe / Rest of World Government Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval of a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the EU, for example, a clinical trial application must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the clinical trial application is approved in accordance with a country's requirements, clinical trial development may proceed. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug or biological product under EU regulatory systems, we must submit an MAA. The application used to file the BLA in the United States is similar to that required in the EU, with the exception of, among other things, country-specific document requirements.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we or our potential collaborators fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

European Union General Data Protection Regulation

In addition to EU regulations related to the approval and commercialization of our products, we may be subject to the EU's General Data Protection Regulation (GDPR). The GDPR imposes stringent requirements for controllers and processors of personal data of persons in the EU, including, for example, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of data, such as health data, and additional obligations when we contract with third-party processors in connection with the processing of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States and other third countries. In addition, the GDPR provides that EU member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

The GDPR applies extraterritorially. Over time we may expand our business operations to include additional operations in the EU. With such expansion, we would be subject to increased governmental regulation, including the GDPR, in the EU countries in which we operate. Failure to comply with the requirements of the GDPR and the applicable national data protection laws of the EU member states may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. GDPR regulations may impose additional responsibility and liability in relation to the personal data that we process and we may be required to put in place additional mechanisms to ensure compliance with the new data protection rules.

California Consumer Privacy Act

California recently enacted legislation that has been dubbed the first "GDPR-like" law in the United States. Known as the California Consumer Privacy Act, or CPPA, it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. When it goes into effect on January 1, 2020, the CCPA will require covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. Legislators have stated that amendments will be proposed to the CCPA before it goes into effect, but it remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA may impact (possibly significantly) our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Employees

As of March 8, 2019, we had thirty full-time employees and one temporary employee. Of these thirty-one employees, twenty-five employees were engaged in research and development activities and six 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 have a month-to-month lease of approximately 500 square feet of lab space in Richmond, Virginia. In addition, we lease 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*. 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 the Proposed Merger with C3J

If the proposed Merger with C3J is not consummated, AmpliPhi's business could suffer materially and

AmpliPhi's stock price could decline.

The consummation of the proposed Merger with C3J is subject to a number of closing conditions, including the approval by our shareholders, approval by NYSE American of our Supplemental Listing Application of our common stock in connection with the Merger, and other customary closing conditions. We are targeting a closing of the transaction in May 2019.

If the proposed Merger is not consummated, we may be subject to a number of material risks, and our business and stock price could be adversely affected, as follows:

- We have incurred and expect to continue to incur significant expenses related to the proposed Merger with C3J, even if the Merger is not consummated.

- The Merger Agreement contains covenants restricting our solicitation of competing acquisition proposals and the conduct of our business between the date of signing the Merger Agreement and the closing of the Merger. As a result, significant business decisions and transactions before the closing of the Merger require the consent of C3J. Accordingly, we may be unable to pursue business opportunities that would otherwise be in our best interest as a standalone company. We have invested significant time and resources in the transaction process and if the Merger Agreement is terminated we will have limited ability to continue our current operations without obtaining additional financing.

- We could be obligated to pay C3J a $1.0 million termination fee in connection with the termination of the Merger Agreement, depending on the reason for the termination.

- Our customers, prospective customers, collaborators and other business partners and investors in general may view the failure to consummate the Merger as a poor reflection on our business or prospects.

- Some of our suppliers, distributors, collaborators and other business partners may seek to change or terminate their relationships with us as a result of the proposed Merger.

- As a result of the Merger, current and prospective employees could experience uncertainty about their future roles within the combined company. This uncertainty may adversely affect our ability to retain our key employees, who may seek other employment opportunities.

- Our management team may be distracted from day to day operations as a result of the Merger.

In addition, if the Merger Agreement is terminated and our board of directors determines to seek another business combination, it may not be able to find a third party willing to provide equivalent or more attractive consideration than the consideration to be provided by each party in the proposed Merger with C3J. In such circumstances, our board of directors may elect to, among other things, divest all or a portion of our business, or take the steps necessary to liquidate all of our business and assets, and in either such case, the consideration that we or our shareholders receive may be less attractive than the consideration to be received by us pursuant to the Merger Agreement and the concurrent $10.0 million private placement.

Some of AmpliPhi's off icers and directors have conflicts of interest that may influence them to support or approve the Merger.

Our officers and directors participate in arrangements that provide them with interests in the Merger that are different from our shareholders, including, among others, to the extent applicable, their continued service as an officer or director of the combined company, retention and severance benefits, the acceleration of restricted stock and stock option vesting and continued indemnification. These interests, among others, may influence our officers and directors to support or approve the Merger.

The Merger may be completed even though material adverse changes may result from the announcement of the Merger, industry-wide changes and other causes.

In general, either party can refuse to complete the Merger if there is a material adverse change affecting the other party following January 3, 2019, the date of the Merger Agreement. However, some types of changes do not permit either party to refuse to complete the Merger, even if such changes would have a material adverse effect on us or C3J, to the extent they resulted from the following (unless, in some cases, they have a disproportionate effect on us or C3J, as the case may be):

- changes in the general business or economic conditions affecting the industry in which we and C3J, and their respective affiliates, operate;
- acts of war, armed hostilities or terrorism;
- changes in financial, banking or securities markets;
- changes caused by the performance of any action required to be taken by the Merger Agreement;
- any change in, or any compliance with or action taken for the purpose of complying with, any federal, state, national, foreign, material local or municipal or other law, statute, constitution, principle of common law, resolution, ordinance, code, edict, decree, rule, regulation, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any governmental authority;
- any change in U.S. generally accepted accounting principles;

- the taking of any action required to be taken by the Merger Agreement;

- with respect to us, any change in the stock price or trading volume of our common stock;

- with respect to us, any failure to meet analysts' expectations or projections;

- with respect to us, any clinical trial programs or studies, including any adverse data, event or outcome arising out of or related to any such programs or studies; and

- with respect to us, the announcement of the Merger Agreement or the pendency of the Merger.

If adverse changes occur but we and C3J must still complete the Merger, the combined company's stock price may suffer.

The market price of the combined company's common stock may decline as a result of the Merger.

The market price of the combined company's common stock may decline as a result of the Merger for a number of reasons, including if:

- the combined company does not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial or industry analysts;

- the effect of the Merger on the combined company's business and prospects is not consistent with the expectations of financial or industry analysts; or

- investors react negatively to the effect on the combined company's business and prospects from the Merger.

Our shareholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger.

If the combined company is unable to realize the strategic and financial benefits currently anticipated from the Merger, our shareholders will have experienced substantial dilution of their ownership interest without receiving any commensurate benefit. Significant management attention and resources will be required to integrate the two companies. Delays in this process could adversely affect the combined company's business, financial results, financial condition and stock price following the Merger. Even if the combined company were able to integrate the business

operations successfully, there can be no assurance that this integration will result in the realization of the full benefits of synergies, innovation and operational efficiencies that may be possible from this integration and that these benefits will be achieved within a reasonable period of time.

During the pendency of the Merger, we and C3J will be subject to contractual limitations set forth in the Merger Agreement that restrict the parties' ability to enter into business combination transactions with another party.

Covenants in the Merger Agreement impede the ability of us or C3J to make acquisitions or complete other transactions that are not in the ordinary course of business pending completion of the Merger. As a result, if the Merger is not completed, the parties may be at a disadvantage to their competitors. In addition, while the Merger Agreement is in effect and subject to limited exceptions, each party is prohibited from soliciting, initiating, encouraging or taking actions designed to facilitate any inquiries or the making of any proposal or offer that could lead to the entering into certain extraordinary transactions with any third party, such as a sale of assets, an acquisition of our common stock, a tender offer for our common stock, a Merger or other business combination outside the ordinary course of business. Any such transactions could be favorable to such party's shareholders.

Because the lack of a public market for C3J's common stock makes it difficult to evaluate the fairness of the Merger, C3J's shareholders may receive consideration in the Merger that is greater than or less than the fair market value of C3J's common stock.

The outstanding share capital of C3J is privately held and is not traded in any public market. The lack of a public market makes it difficult to determine the fair market value of C3J. Since the number of shares of our common stock to be issued to C3J's shareholders was determined based on negotiations between the parties, it is possible that the value of our common stock to be issued in connection with the Merger will be greater than the fair market value of C3J.

The combined company will incur significant transaction costs as a result of the Merger, including investment banking, legal and accounting fees. In addition, the combined company will incur significant consolidation and integration expenses which cannot be accurately estimated at this time. Actual transaction costs may substantially exceed estimates and may have an adverse effect on the combined company's financial condition and operating results.

Because the Merger will result in an ownership change under Section 382 of the Internal Revenue Code for us, our pre-Merger net operating loss carryforwards and certain other tax attributes will be subject to limitations. The net operating loss carryforwards and other tax attributes of C3J and of the combined organization may also be subject to limitations as a result of ownership changes.

If a corporation undergoes an "ownership change" within the meaning of Section 382 of the Code ("Section 382"), the corporation's net operating loss carryforwards and certain other tax attributes arising from before the ownership change are subject to limitations on use after the ownership change. In general, an ownership change occurs if there is a

cumulative change in the corporation's equity ownership by certain stockholders that exceeds fifty percentage points over a rolling three-year period. Similar rules may apply under state tax laws. The Merger will result in an ownership change for us and, accordingly, our net operating loss carryforwards and certain other tax attributes will be subject to limitations (or disallowance) on their use after the merger. C3J's net operating loss carryforwards may also be subject to limitation as a result of prior shifts in equity ownership and/or the Merger. Additional ownership changes in the future could result in additional limitations on our, C3J's and the combined organization's net operating loss carryforwards. Consequently, even if the combined organization achieves profitability, it may not be able to utilize a material portion of our, C3J's or the combined organization's net operating loss carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations.

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 support our operations.

This Annual Report on Form 10-K for the year ended December 31, 2018 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, 2018 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, 2018, we had cash and cash equivalents of $8.2 million, and we have had recurring losses from operations and negative operating cash flows since inception.

We will need to raise additional capital to support our operations and product development activities. In the near term, we expect to continue to fund our operations, if at all, primarily through equity and debt financings in the future, including, if the proposed Merger with C3J is consummated, through the $10.0 private placement of the combined company's common stock immediately following the consummation of the Merger as described in more detail elsewhere in this report. We may also 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. 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 until mid-2019, we cannot provide assurances that our estimates are accurate, 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.

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 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;

- public or private debt; and/or

- government contracts or grants.

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, 2018, our accumulated deficit was $406.3 million, $90.8 million of which has been accumulated since January of 2011, when we began our focus on bacteriophage development, and we expect to incur losses for the foreseeable future. We have devoted, and will continue to devote for the foreseeable future, substantially all of our resources to research and development of our product candidates. For the years ended December 31, 2018 and 2017, we had losses from operations of $12.5 million and $16.2 million, respectively. Additional information regarding our results of operations may be found in our consolidated financial statements and in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included 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, 2018, we had federal net operating loss carryforwards of approximately $197.1 million, of which $10.3 million will expire in 2019 unless utilized, and the remaining carryforwards will expire in taxable years 2020 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 public offerings in November 2016, May 2017, January 2018, March 2018 and October 2018, 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 the Combined Company

The risks described above under the heading “Risks Related to Our Financial Condition and Need for Additional Capital” are generally expected to apply to the combined company if the Merger with C3J is completed.

Risks Related to Our Business

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. 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.

In September 2018, we received the official minutes from our August 2018 Type B pre-IND meeting with the FDA regarding our AB-SA01 bacteriophage therapy product candidate. The FDA expressed general agreement with our proposed clinical trial designs and, based on the current FDA feedback, no additional clinical or nonclinical data are required to proceed with two proposed randomized clinical trials. The first such clinical trial would be a Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-SA01, administered intravenously with the best available antibiotic therapy, compared to placebo plus best available antibiotic therapy, in approximately 100 patients with *S. aureus* bacteremia. The second such clinical trial would be a Phase 1/2 randomized, controlled clinical

trial to evaluate the safety and efficacy of AB-SA01, administered by intra-articular injection and then intravenously with the best available antibiotic therapy, compared to placebo plus the best available antibiotic therapy, in approximately 100 patients with a hip or knee prosthetic joint infection due to *S. aureus* as an adjunct to surgical treatment. We are actively seeking and intend to continue to seek non-dilutive financing and explore other opportunities to conduct these clinical trials of AB-SA01. However, there can be no assurance that such non-dilutive financing or other opportunities will be available to us on a timely basis, on favorable terms, or at all. We may also choose to conduct one or more smaller-scale clinical trials of similar design as an alternative to conducting the approximately 100 patient clinical trials described above in an effort to reduce clinical trial expenditures. It is possible that results from such smaller-scale clinical trials may not be viewed by the FDA or other regulatory agencies as sufficient for the advancement of AB-SA01 into Phase 2 trials, including potentially registrational Phase 2 trials, due to the smaller trial populations even if the trial results are otherwise positive, which in turn could result in the FDA or other regulatory agencies requiring us to conduct additional studies beyond those that would have been required if we had conducted trials of approximately 100 patients as proposed in our August 2018 Type B pre-IND meeting.

In September 2018, we received positive feedback, via written response, from the FDA regarding our development plans for AB-PA01, without the need for a Type B pre-IND meeting. The FDA expressed general agreement with our proposed clinical trial designs and, based on the current FDA feedback, no additional clinical or nonclinical data are required to proceed with two proposed randomized clinical trials. The first such clinical trial would be a Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-PA01, administered intravenously with the best available antibiotic therapy, compared to placebo plus best available antibiotic therapy, in approximately 100 patients with hospital-acquired and ventilator-associated pneumonia (HAP/VAP) due to *P. aeruginosa*. The second clinical trial would be a Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-PA01, administered intravenously with the best available antibiotic therapy, compared to placebo plus best available antibiotic therapy, in approximately 100 patients with *P. aeruginosa* bacteremia. We intend to seek non-dilutive financing and explore other opportunities to conduct these clinical trials. However, there can be no assurance that such non-dilutive financing or other opportunities will be available to us on a timely basis, on favorable terms, or at all. We may not be able to utilize the limited population pathway for antibacterial and antifungal drugs or biologics (LPAD), and even if we are able to do so, will be restricted in the population for which our products would be labeled.

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 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, in the United States and Australia. 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.

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.

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.

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.

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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.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business.

We and any potential collaborators may be subject to federal, state and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the HIPAA, as amended by HITECH. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

International data protection laws, including Regulation 2016/679, known as the General Data Protection Regulation (GDPR) may also apply to health-related and other personal information obtained outside of the United States. The GDPR went into effect on May 25, 2018. The GDPR introduced new data protection requirements in the European Union, as well as potential fines for noncompliant companies of up to the greater of €20 million or 4% of annual global revenue. The regulation imposes numerous new requirements for the collection, use and disclosure of personal information, including more stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulators and affected individuals of personal data breaches, extensive new internal privacy governance obligations and obligations to honor expanded rights of individuals in relation to their personal information (e.g., the right to access, correct and delete their data). In addition, the GDPR includes restrictions on cross-border data transfer. The GDPR will increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules. Further, the United Kingdom’s vote in favor of exiting the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear whether the United Kingdom will enact data protection legislation equivalent to the GDPR and how data transfers to and from the United Kingdom will be regulated.

In addition, California recently enacted legislation that has been dubbed the first “GDPR-like” law in the United States. Known as the California Consumer Privacy Act, or CPPA, it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. When it goes into effect on January 1, 2020, the CCPA will require covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. Legislators have stated that amendments will be proposed to the CCPA before it goes into effect, but it remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA may impact (possibly significantly) our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals’ privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.

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;

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- 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 the Combined Company

The risks described above under the heading "Risks Related to Our Business" are generally expected to apply to the combined company if the Merger with C3J is completed.

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 the Combined Company

The risks described above under the heading “Risks Related to Our Reliance on Third Parties” are generally expected to apply to the combined company if the Merger with C3J is completed.

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;
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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 the Combined Company

The risks described above under the heading "Risks Related to Our Intellectual Property" are generally expected to apply to the combined company if the Merger with C3J is completed.

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 the Combined Company

The risks described above under the heading "Risks Related to Our Industry" are generally expected to apply to the combined company if the Merger with C3J is completed.

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, 2018, we had outstanding common warrants to purchase an aggregate of 26,961,187 shares of our common stock at a weighted-average exercise price of $1.08 per share, which includes 1,175,000 of pre-funded warrants, each exercisable for one share of our common stock at an aggregate purchase price per share of $0.39, of which $0.38 per share was pre-funded at the closing of our October 2018 public offering. If the Merger with C3J is consummated, we will be required to repurchase outstanding warrants exercisable for an aggregate of 274,879 shares of AmpliPhi common stock concurrently with the closing of the Merger, at an estimated aggregate repurchase price of approximately $38,000. We also had outstanding options to exercise 1,150,065 shares of our common stock at a weighted-average exercise price of $3.08 per share. Following the completion of our underwritten public offering in October 2018 in which we sold shares of our common stock at a price of $0.39 per share, the exercise price of warrants outstanding at September 30, 2018 and exercisable for 168,498 shares of our common stock was reduced from $0.57 per share to $0.32 per share in accordance with an exercise price adjustment feature contained in such warrants. The exercise price of such warrants is subject to further reduction in the future in connection with certain circumstances, including certain issuances of securities at a price less than the then-current exercise price, subdivisions and stock splits. 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.

Certain warrants outstanding that were issued in connection with the June 2016 Financing and November 2016 Financing are required to be settled in cash upon the closing of the Merger. Total cash consideration is not expected to be significant and will be paid from our existing cash resources at the time of settlement.

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.

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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.

Risks Related to the Combined Company

The risks described above under the heading “Risks Related to Our Common Stock” are generally expected to apply to the combined company if the Merger with C3J is completed.

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."

Holders of Common Stock

As of March 8, 2019, there were 89 holders of record of our common stock. As of such date, there were 32,294,008 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

The selected consolidated financial data set forth below as of December 31, 2018 and 2017, and for the years ended December 31, 2018 and 2017, are derived from our audited consolidated financial statements included elsewhere in this report. This information should be read in conjunction with those consolidated financial statements, the notes thereto, and with "*Management's Discussion and Analysis of Financial Condition and Results of Operations*."

	For the year ended December 31,	
	2018	2017
Statement of Operations Data:		
Revenue	$ -	$ 115,000
Loss from operations	$ (12,524,000)	$ (16,156,000)
Net loss	$ (12,110,000)	$ (12,838,000)
Net loss per share, basic	$ (0.64)	$ (2.01)
Net loss per share, diluted	$ (0.64)	$ (2.18)
Shares used in computing net loss per share, basic	18,980,796	6,387,425
Shares used in computing net loss per share, diluted	19,059,895	6,574,117

	As of December 31,	
	2018	2017
Balance Sheet Data:		
Cash and cash equivalents	$8,157,000	$5,132,000
Working capital	5,836,000	3,417,000
Total assets	11,887,000	11,138,000
Total liabilities	3,413,000	3,407,000
Accumulated deficit	(406,316,000)	(394,206,000)
Total stockholders' equity	$8,474,000	$7,731,000

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 clinical-stage biotechnology company focused on precisely targeted bacteriophage therapeutics for patients with serious and life-threatening antibiotic-resistant bacterial infections. Phages have a powerful and highly selective mechanism of action that enables 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. We are a leading developer of bacteriophage 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 to develop state-of-the-art therapeutics. We are developing bacteriophage products to combat multi- or pan-drug-resistant bacterial pathogens, leveraging advances in sequencing and molecular biology. We have developed certain bacteriophage combinations that we believe maximize efficacy and minimize development of resistance.

We have two product candidates, AB-SA01 and AB-PA01 for the treatment of *Staphylococcus aureus,* or *S. aureus,* infections, including methicillin-resistant *S. aureus*, or MRSA, and *Pseudomonas aeruginosa*, or *P. aeruginosa,* infections, respectively. Our interest and ability to advance these two product candidates through clinical development depend on the availability of outside funding. In the fourth quarter of 2018, we determined that we would focus on the AB-SA01 research program and accordingly, we concluded that the AB-PA01 IPR&D asset were fully impaired as of

December 31, 2018, due to continued compressed market capitalization of the Company, and limited funding availability. We recorded an impairment charge of approximately $1.9 million within operating expenses of the consolidated statement of operations for the year ended December 31, 2018, offset by an income tax benefit of $328,000. Furthermore, there was no impairment of our AB-SA01 IPR&D asset in December 2018 and we anticipate to advance the AB-SA01 program into phase 2 clinical trials in 2019.

We have two product candidates, AB-SA01 and AB-PA01 for the treatment of Staphylococcus aureus, or S. aureus, infections, including methicillin-resistant S. aureus, or MRSA, and Pseudomonas aeruginosa, or P. aeruginosa, infections, respectively. Our interest and ability to advance these two product candidates through clinical development depend on the availability of outside funding. In the fourth quarter of 2018, we considered the clinical development timelines for both the AB-SA01 and AB-PA01 development programs and concluded that since the AB-SA01 program is further advanced in the development process, the AB-SA01 program will continue to be advanced and the AB-PA01 program will not be pursued in the near term. Accordingly, the Company determined that the AB-PA01 IPR&D asset was fully impaired as of December 31, 2018. We recorded an impairment charge of approximately $1.9 million within operating expenses of the consolidated statement of operations for the year ended December 31, 2018, offset by an income tax benefit of $328,000. Furthermore, there was no impairment of our AB-SA01 IPR&D asset in December 2018 and we anticipate to advance the AB-SA01 program into phase 2 clinical trials in 2019.

Under existing single-patient expanded access guidelines (also referred to as “compassionate use”), established by the regulatory agencies, we have provided targeted phage therapies to patients suffering from severe antibiotic-resistant infections who have failed prior antibiotic therapies. We believe this strategic approach not only provides potential benefit to patients who have few or no other acceptable therapeutic options, but also generates 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 product candidates for *S. aureus* , define optimal treatment regimens, and inform our discussions with the U.S. Food and Drug Administration, or 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 regulatory expanded access guidelines in the United States and in Australia, where we collaborate with select leading hospitals and key infectious disease physician opinion leaders to identify eligible patients. We believe that the United States and Australia have favorable regulatory frameworks 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, 2018, we have received approximately $71.3 million in net proceeds from the issuance of our equity securities and convertible debt securities. As of December 31, 2018, we had an accumulated deficit of $406.3 million, $90.8 million of which has been accumulated since January of 2011, when our company began its focus on bacteriophage development. We anticipate that a substantial portion of our capital resources and efforts in the foreseeable future will be focused on completing the development and obtaining regulatory approval of our product candidates.

We currently expect to use our existing cash and cash equivalents for the continued research and development of our product candidates, including through our 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 $3.4 million, after deducting placement agent fees and other offering expenses. On March 22, 2018, we completed a registered direct offering of 2,743,640 shares of common stock at an offering price of $1.10 per share, for aggregate gross proceeds of $3.0 million. We received net proceeds from the offering of approximately $2.8 million, after deducting placement agent fees and other offering expenses. On October 16, 2018, we completed an underwritten public offering and sold 14,875,000 shares of our common stock and 2,125,000 pre-funded warrants to purchase common stock, and common stock warrants to purchase 17,500,000 shares of common stock. The combined price to the public for each share of common stock and accompanying common stock warrant was $0.40. The

combined price to the public for each pre-funded warrant and accompanying common stock warrant was $0.39. Each pre-funded warrant is exercisable for one share of common stock at an exercise price of $0.01 per share. The common stock warrants are exercisable at a price of $0.40 per share of common stock, and will expire five years from the date of issuance. We received net proceeds from the offering of approximately $5.8 million, after deducting the underwriting discount and commissions and other offering expenses payable by us.

In September 2018, we announced that we had received the official minutes from our August 2018 Type B Pre-IND meeting with the FDA regarding our proposed clinical development of AB-SA01 for the treatment of *S. aureus* bacteremia infections as well as patients with a hip or knee prosthetic joint infection due to *S. aureus*. The FDA expressed general agreement with our proposed clinical trial designs and, based on the current FDA feedback, no additional clinical or nonclinical data are required to proceed with two proposed randomized clinical trials. The first such clinical trial would be a Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-SA01, administered intravenously with the best available antibiotic therapy, compared to placebo plus best available antibiotic therapy, in approximately 100 patients with *S. aureus* bacteremia. The second such clinical trial would be a Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-SA01, administered by intra-articular injection and then intravenously with the best available antibiotic therapy, compared to placebo plus the best available antibiotic therapy, in approximately 100 patients with a hip or knee prosthetic joint infection due to *S. aureus* as an adjunct to surgical treatment. We expect that we would produce our proprietary bacteriophage therapeutics for these clinical trials at our wholly owned manufacturing facility, which is good manufacturing practices (GMP) certified by the governmental authorities in the jurisdiction in which it operates. We believe our GMP-facility has the capacity to produce our proprietary bacteriophage therapeutics for these clinical trials through a potential filing of a biologics license application and potential approval.

In September 2018, we also received positive feedback from the FDA regarding our clinical development plans for AB-PA01 for the treatment of *P. aeruginosa* infections. Resistant *P. aeruginosa* is designated as ‘Priority 1: Critical’ pathogen on the World Health Organization’s Priority Pathogens List and as ‘Serious Threat’ by the U.S. Centers for Disease Control and Prevention. The FDA expressed general agreement with our proposed clinical trial designs and, based on the current FDA feedback, no additional clinical or nonclinical data are required to proceed with two proposed randomized clinical trials. The first such clinical trial would be a Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-PA01, administered intravenously with the best available antibiotic therapy, compared to placebo plus best available antibiotic therapy, in approximately 100 patients with hospital-acquired and ventilator-associated pneumonia due to *P. aeruginosa*. The second clinical trial would be a Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-PA01, administered intravenously with the best available antibiotic therapy, compared to placebo plus best available antibiotic therapy, in approximately 100 patients with P. aeruginosa bacteremia. We intend to seek non-dilutive financing and explore other opportunities to conduct these clinical trials.

In addition, in September 2018 we provided updated topline clinical results for our ongoing single-patient expanded access program. 84% of patients achieved treatment success (physician’s assessment) at the end of bacteriophage therapy, defined as complete resolution or significant improvement of baseline signs and symptoms. We have now received clinical outcome results for 21 of the patients provided with our investigational bacteriophage therapeutics, across seven hospitals, and with serious or life-threatening infections not responding to antibiotic therapy.

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Recent Events

On January 3, 2019, we entered into an Agreement and Plan of Merger and Reorganization, which included the proposed business combination ("Merger") of the C3J, a private clinical stage biotechnology company focused on the development of novel targeted antimicrobials and Ceres Merger Sub, Inc, a wholly owned subsidiary of AmpliPhi, with C3J as the surviving company, subject to shareholder approval.

At the effective time of the Merger, we anticipate that each share of C3J common stock outstanding immediately prior to the effective time of the Merger will be converted into the right to receive approximately 0.6892 shares of AmpliPhi common stock, subject to adjustment to account for a reverse split of AmpliPhi common stock at a reverse split ratio of between1-for-3 and 1-for-20, inclusive, to be determined by AmpliPhi's board of directors and to be implemented prior to the consummation of the Merger.

Immediately following the Merger, the former C3J security holders will own approximately 70% of the aggregate number of shares of AmpliPhi common stock and the security holders of AmpliPhi as of immediately prior to the Merger will own approximately 30% of the aggregate number of shares of AmpliPhi common stock on a fully diluted basis.

In addition, on February 5, 2019, certain existing C3J shareholders executed a Share Purchase Agreement with us pursuant to which the shareholders agreed, subject to the satisfaction of customary closing condition, to purchase $10.0 million in common stock of the combined company upon the closing of the Merger at a price per share equal to (i) $40.0 million, divided by (ii) the total number of shares of our common stock outstanding on a fully diluted, as-converted basis, assuming the conversion, exercise or settlement of all outstanding options, warrants, and restricted stock units as of immediately after the effective time of the Merger, but excluding (A) any shares of common stock issuable pursuant to the Share Purchase Agreement and (B) any shares of our common stock reserved for issuance under any equity incentive plan, stock option plan or similar arrangement but for which awards have not yet been granted as of the effective time of the Merger and (C) any shares of common stock issuable in connection with out-of-the-money options and out-of-the-money warrants. Based on our and C3J's respective current capitalizations, we expect the purchase price per share to be approximately $0.36.

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2017

Revenue

For the years ended December 31, 2018 and 2017, we recognized revenues related to sub-licensing agreements from our former gene therapy program of $0 and $115,000, respectively. The decrease of $115,000 was attributable to the termination of a sublicense agreement in 2017.

Research and Development

Research and development expenses for the year ended December 31, 2018 were $4.9 million compared to $2.9 million for the year ended December 31, 2017. During 2018 and 2017, we received tax incentive payments of approximately $1.2 million and $2.0 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, 2018 and 2017, research and development expenses, excluding any benefit from tax incentive payments, were $6.1 million and $4.9 million, respectively. The increase of $1.2 million was primarily related to a $0.7 million increase in clinical activities and related professional and consulting expenses, a $0.2 million increase in salary expenses, and $0.3 million increase in lab supplies.

General and Administrative

General and administrative expenses for the year ended December 31, 2018 were $5.7 million compared to $7.6 million for the year ended December 31, 2017. The $1.9 million decrease was primarily attributable to $0.5 million in severance costs incurred in 2017, $0.2 million decrease in non-cash stock-based compensation, a $0.4 million decrease in legal, investor relations and other professional and consulting fees, a $0.2 million decrease in incentive compensation 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 in-process research and development (IPR&D) assets were $1.9 million and $5.8 million for the year ended December 31, 2018 and 2017, 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. In the fourth quarter of 2018, we considered the clinical development timelines for both the AB-SA01 and AB-PA01 development programs. We concluded that since the AB-SA01 program is further advanced in the development process, the AB-SA01 program will continue to be advanced and the AB-PA01 program will not be pursued in the near term. As we are not

actively pursuing the AB-PA01 program, we have recorded an impairment charge of approximately $1.9 million within operating expenses of the consolidated statement of operations in the fourth quarter of 2018, offset by an income tax benefit of $328,000. As of December 31, 2018, our IPR&D assets had a remaining book value of $2.8 million for the Staphylococcal program.

Other Expense

For the year ended December 31, 2018, we recorded a net gain of $86,000 related to the change in fair value of our derivative liabilities, warrants issued in the November 2016 and June 2016 financings, and the net gain was primarily attributable in part to a decline in our common stock price for the period of measurement.

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.

Income Taxes

The income tax benefit was $0.3 million and $1.3 million for the year ended December 31, 2018 and 2017, respectively. The income tax benefit is related to a reduction of the existing deferred tax liability as a result of a $1.9 million and $5.8 million impairment charge for our IPR&D assets discussed above.

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 $406.3 million as of December 31, 2018, $90.8 million of which has been accumulated since January of 2011, when we began our focus on bacteriophage development. These circumstances raise substantial doubt about our ability to continue as a going concern. The accompanying financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and 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 $8.2 million and $5.1 million at December 31, 2018 and 2017, respectively. We believe our existing cash resources, will be sufficient to fund our planned operations into mid-2019. 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, 2018 was $9.4 million, as compared to $9.2 million for the year ended December 31, 2017. Total non-cash adjustments to net loss was $2.4 million and $4.1 million for the year ended December 31, 2018 and 2017, respectively. Total changes in operating assets and liabilities resulted in an increase of $0.3 million and a reduction of $0.5 million in cash used in operations activities for the year ended December 31, 2018 and 2017, respectively.

Investing activities

Net cash used in investing activities was $44,000 and $58,000 for the years ended December 31, 2018 and 2017, respectively, and was attributable to purchases of property and equipment.

Financing activities

Cash provided by financing activities was $12.5 million for the year ended December 31, 2018 and was primarily comprised of 1) net cash proceeds of $5.8 million from the October 2018 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 $1.0 million, 2) net cash proceeds of $6.2 million from our January 2018 and March 2018 offerings of common stock, after deducting offering costs paid of approximately $0.9 million, and 3) $0.2 million from the exercise of warrants for common stock.

Cash provided by financing activities was $8.7 million for the year ended December 31, 2017 and was primarily comprised of 1) 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, and 2) payment of $0.8 million repayment of our note payable.

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;
- Public or private debt; and
- government contracts or grants.

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.

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.

We considered the clinical development timelines for both the AB-SA01 and AB-PA01 development programs. The Company concluded in the fourth quarter of 2018 that since the AB-SA01 program is further advanced in the development process, the AB-SA01 program will continue to be advanced and the AB-PA01 program will not be pursued in the near term. As we are not actively pursuing the AB-PA01 program, the Company has recorded an impairment charge of approximately $1.9 million within operating expenses of the consolidated statement of operations in the fourth quarter of 2018.

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. For stock options granted to parties other than employees or directors, the Company elects, on a grant by grant basis, to use the expected term or 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 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 $86,000 and $2.0 million for the years ended December 31, 2018 and 2017, respectively, recorded as a component of other expenses 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 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, 2018, 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

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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, 2018 and 2017, the related consolidated statements of operations, 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, 2018 and 2017, 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 and has stated that substantial doubt exists about the Company’s 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 25, 2019

AmpliPhi Biosciences Corporation

Consolidated Balance Sheets

	December 31, 2018	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 8,157,000	$ 5,132,000
Prepaid expenses and other current assets	251,000	253,000
Total current assets	8,408,000	5,385,000
Property and equipment, net	503,000	816,000
In-process research and development	2,731,000	4,661,000
Acquired patents, net	245,000	276,000
Total assets	$ 11,887,000	$ 11,138,000
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 2,572,000	$ 1,968,000
Total current liabilities	2,572,000	1,968,000
Derivative liabilities	22,000	292,000
Deferred tax liability	819,000	1,147,000
Total liabilities	3,413,000	3,407,000
Commitments and Contingencies (Note 8)		
Stockholders' equity		
Common stock, $0.01 par value; 217,000,000 authorized and 32,294,008 shares issued and outstanding at December 31, 2018; 67,000,000 authorized and 9,498,928 shares issued and outstanding at December 31, 2017	323,000	95,000
Additional paid-in capital	414,467,000	401,842,000
Accumulated deficit	(406,316,000)	(394,206,000)
Total stockholders' equity	8,474,000	7,731,000
Total liabilities and stockholders' equity	$ 11,887,000	$ 11,138,000

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

AmpliPhi Biosciences Corporation

Consolidated Statements of Operations

	Year Ended December 31,	
	2018	2017
Revenue	$-	$115,000
Operating expenses		
Research and development	4,892,000	2,881,000
General and administrative	5,702,000	7,590,000
Impairment charges	1,930,000	5,800,000
Total operating expenses	12,524,000	16,271,000
Loss from operations	(12,524,000)	(16,156,000)
Other expense		
Change in fair value of derivative liabilities	86,000	2,010,000
Other expense, net	-	6,000
Total other income (expense), net	86,000	2,016,000
Loss before income taxes	(12,438,000)	(14,140,000)
Income tax benefit	328,000	1,302,000
Net loss	(12,110,000)	(12,838,000)
Per share information:		
Net loss per share, basic	$(0.64)	$(2.01)
Weighted average shares outstanding, basic	18,980,796	6,387,425
Net loss per share, diluted	$(0.64)	(2.18)
Weighted average shares outstanding, diluted	19,059,895	$6,574,117

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

AmpliPhi Biosciences Corporation

Consolidated Statements of Stockholders' Equity

	Stockholders' Equity Common Stock				
	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
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 reclasssified 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
Common stock issued in registered public financings, net of offering costs	6,743,640	67,000	6,091,000	-	6,158,000
Common stock and pre-funded warrants issued in October 2018 financing, net of offering costs	15,825,000	159,000	5,671,000	-	5,830,000
Warrants exercised	217,400	2,000	196,000	-	198,000
Warrant derivative liability reclasssified to equity due to exercise of warrants	-	-	184,000	-	184,000
Common stock issued under the employee stock purchase plan	9,040	-	5,000	-	5,000
Stock-based compensation	-	-	478,000	-	478,000
Net loss	-	-	-	(12,110,000)	(12,110,000)
Balances, December 31, 2018	32,294,008	$323,000	$414,467,000	$(406,316,000)	$8,474,000

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

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AmpliPhi Biosciences Corporation

Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2018	2017
Operating activities:		
Net loss	$(12,110,000)	$(12,838,000)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative liabilities	(86,000)	(2,010,000)
Stock-based compensation	478,000	700,000
Depreciation	358,000	343,000
Amortization of patents	31,000	31,000
Impairment charges	1,930,000	5,800,000
Deferred taxes	(328,000)	(1,302,000)
Charge for common stock issuance	-	519,000
Other non-cash adjustments, net	-	22,000
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	2,000	381,000
Accounts payable and accrued liabilities	343,000	(838,000)
Net cash used in operating activities	(9,382,000)	(9,192,000)
Investing activities:		
Purchases of property and equipment	(44,000)	(58,000)
Net cash used in investing activities	(44,000)	(58,000)
Financing activities:		
Proceeds from sale of common stock and related warrants, net of offering costs	12,248,000	9,353,000
Proceeds from exercises of warrants	198,000	130,000
Proceeds from stock issuances under employee stock purchase plan	5,000	3,000
Principal payments on note payable	-	(815,000)
Net cash provided by financing activities	12,451,000	8,671,000
Net increase (decrease) in cash and cash equivalents	3,025,000	(579,000)
Cash and cash equivalents, beginning of period	5,132,000	5,711,000
Cash and cash equivalents, end of period	$8,157,000	$5,132,000
Supplemental schedule of non-cash financing activities:		
Offering costs included in accounts payable	$260,000	$-
Property and equipment included in accounts payable	-	39,000

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

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.

As discussed in more details in Note 13, Subsequent Events, in January 2019, the Company announced that it entered into a merger agreement with C3J Therapeutics, Inc. ("C3J"), a private clinical stage biotechnology company focused on the development of novel targeted antimicrobials in an all-stock transaction, subject to shareholder approval. In addition, certain existing C3J shareholders have committed to invest $10 million in the combined company, subject to customary conditions.

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, 2018, the Company had cash and cash equivalents of $8.2 million. Considering the Company's current cash resources, management believes the Company's existing resources, without considering any effect of the pending merger with C3J and related financing, will be sufficient to fund the Company's planned operations into mid-2019. 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

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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 on long-lived assets have been recorded through December 31, 2018.

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.

During the fourth quarter ended December 31, 2018, the Company considered the development timelines for both the AB-SA01 and AB-PA01 development programs. The Company concluded that as the AB-SA01 program is further advanced in the development process, this program will continue to be advanced and the AB-PA01 program will not be pursued in the near term. The Company also performed the annual evaluation of its IPR&D assets for impairment in the fourth quarter of 2018. The impairment analysis considered the Company's focus on the AB-SA01 product candidate, and the resulting impact on the AB-PA01 development timeline, which resulted in the conclusion that the IPR&D assets related to its AB-PA01 Pseudomonas phage program was impaired in full. An impairment charge of approximately $1.9 million was recorded within operating expenses of the consolidated statement of operations for the year ended December 31, 2018, offset by an income tax benefit of $0.3 million. In addition, the Company performed a quantitative analysis of the fair value of its Staphylococcal phage program as of December 31, 2018, using a net present value model of projected income and expenses and a discount rate of 19.4%. Based on this analysis, the fair value of the Staphylococcal phage program was greater than its carrying value as of December 31, 2018. Consequently, no impairment was noted for the IPR&D assets related to the Staphylococcal phage program.

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 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. There was no impairment existed for IPR&D assets as of December 31, 2017.

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, 2018, the gross amount of patent assets was $493,000 with accumulated amortization of $248,000. Annual patent amortization expense for the next five years and thereafter are estimated as follows:

	Patent Amortization
2019	31,000
2020	31,000
2021	31,000
2022	31,000
2023	31,000
Thereafter through December 2026	90,000
Total patent amortization expense	$ 245,000

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Stock-Based Compensation

Compensation expense related to stock options granted to employees and non-employees 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 Warrants 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. The Company does not currently have any contracts with customers as stipulated within ASC 606, *Revenue from Contracts with Customers.*

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 $1.2 million and $2.0 million during the third quarter of 2018 and third quarter of 2017, 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, 2018 and 2017, the Company had unrecognized tax benefits related to its domestic research tax credits of approximately $1.7 million and $2.1 million, respectively.

Basic and Diluted Net Loss per Share

Basic net loss per 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 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 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.

Recent Accounting Pronouncements Not Yet Adopted

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 right-of-use (“ROU”) 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 and mandates a modified retrospective transition method with practical expedients available. The Company plans to implement the guidance on January 1, 2019 using a modified retrospective transition basis for leases existing as of the period of adoption. The Company plans to utilize the practical expedients to carry forward its historical assessment of whether existing agreements are or contain a lease and the classification of the Company’s existing lease arrangements. Although the Company has not fully completed assessing the impact of the adoption of this standard, the Company expects that its real-estate operating lease

commitments will be recognized as lease liabilities with corresponding right-of-use assets upon adoption, resulting in an increase in the assets and liabilities of the consolidated balance sheet. The Company expects that the adoption will have a material impact on our 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 August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820). The new guidance removes, modifies and adds to certain disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement. This new guidance will be effective for the company as of January 1, 2020. The Company plans to adopt this ASU as of January 1, 2020 and does not anticipate the adoption will have a material impact on its consolidated financial position or results of operations.

Recently Adopted Accounting Standards

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 is effective for fiscal years beginning after December 15, 2017 with early adoption permitted. The Company adopted this ASU as of January 1, 2018 using the modified retrospective approach. As of January 1, 2018, the Company had no revenue contracts and therefore the adoption did not have an impact on the Company's 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. The Company adopted this ASU as of January 1, 2018 and the adoption did not have an 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 with early adoption permitted. The Company elected to early adopt this ASU as of January 1, 2018 and the adoption did not have an impact on the Company's consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which amends the FASB Accounting Standards Codification in order to simplify the accounting for share-based payments granted to nonemployees for goods and services. Under the ASU, most of the guidance on such payments to nonemployees will be aligned with the requirements for share-based payments granted to employees. The guidance mandates the modified retrospective approach and is effective for annual and interim reporting periods beginning after December 31, 2018, with early adoption permitted. The Company elected to early adopt this ASU as of June 30, 2018 and the adoption did not have an impact on the Company's consolidated financial statements.

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.

The Company estimates the fair values of derivative liabilities utilizing Level 3 inputs. No derivative liabilities have been transferred between the classification levels. Estimating the 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, 2018 and 2017 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, 2018				
Liabilities				
June 2016 offering warrant liability	$ -	$ -	$ 1,000	$1,000

November 2016 offering warrant liability	-	-	21,000	21,000
Total liabilities	$ -	$ -	$ 22,000	$22,000
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

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

	June 2016 Offering Warrant Liability	November 2016 Offering Warrant Liability	Total Derivative Liabilities
Balance, December 31, 2017	$ 32,000	$ 260,000	$292,000
Changes in estimated fair value	(31,000)	(55,000)	(86,000)
Exercised warrants	-	(184,000)	(184,000)
Balance, December 31, 2018	$ 1,000	$ 21,000	$22,000

The Company estimates the fair value of the June 2016 offering warrant liability at each reporting date using the Black-Scholes valuation model. Inputs used in this valuation model include the Company’s stock price volatility, risk-free interest rates and expected term of the warrants.

Historically, the Company estimated the fair value of the November 2016 offering warrant liability at each reporting date using the Monte Carlo valuation model. Inputs used in the Monte Carlo valuation model included the Company’s stock price volatility, risk-free interest rates and expected term of the warrants. Effective March 31, 2018, due primarily to the significant decrease in the number of warrants outstanding, the Company simplified the method used and changed to the Black Scholes valuation model, which approximates the Monte Carlo valuation model.

5. Net Loss per 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, 2018	2017
Basic and diluted net loss per share calculation:		
Net loss, basic	$(12,110,000)	$(12,838,000)
Change in fair value of November 2016 warrants	(55,000)	(1,524,000)
Net loss, diluted	$(12,165,000)	$(14,362,000)
Weighted average shares outstanding, basic	18,980,796	6,387,425
Net loss per share, basic	$(0.64)	$(2.01)
Weighted average shares outstanding, diluted	19,059,895	6,574,117

Net loss per share, diluted	$(0.64)	$(2.18)

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 exercise price downward adjustments made through December 31, 2017. The dilutive effect of the November 2016 warrants on net loss per share of common stock (diluted) reflects these exercise price adjustments.

The following outstanding securities at December 31, 2018 and 2017 have been excluded from the computation of diluted weighted average shares outstanding for the years ended December 31, 2018 and 2017, as they would have been anti-dilutive:

	Year Ended December 31,	
	2018	2017
Options	1,150,065	1,115,865
Warrants	26,961,187	8,225,087
Total	28,111,252	9,340,952

6. Balance Sheet Details

Property and Equipment, net

Property and equipment consisted of the following:

	December 31,	
	2018	2017
Laboratory equipment	$1,771,000	$1,727,000
Office and computer equipment	72,000	71,000
Leasehold improvements	188,000	188,000
Total	2,031,000	1,986,000
Less: accumulated depreciation and amortization	(1,528,000)	(1,170,000)
Property and equipment, net	$503,000	$816,000

Depreciation expense totaled $358,000 and $343,000 for the years ended December 31, 2018 and 2017, respectively.

Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consisted of the following:

	December 31,	
	2018	2017
Accounts payable	$729,000	$578,000
Accrued compensation	1,352,000	1,050,000
Other accrued expenses	453,000	302,000
Dividends payable	38,000	38,000
	$2,572,000	$1,968,000

7. Income Taxes

Loss before income taxes consisted of the following components:

	Year Ended December 31,	
	2018	2017
United States	$(7,221,000)	$(6,934,000)
Foreign	(5,217,000)	(7,206,000)
Total	$(12,438,000)	$(14,140,000)

The benefit from income taxes consisted of the following components:

	Year Ended December 31,	
	2018	2017
Current:		
Federal	$ -	$ -
State	-	-
Foreign	-	-
	-	-
Deferred:		
Federal	-	-
State	-	-
Foreign	(328,000)	(1,302,000)
	(328,000)	(1,302,000)
Total	$ (328,000)	$ (1,302,000)

The Company recorded an income tax benefit of $328,000 and $1.3 million for the year ended December 31, 2018 and 2017, respectively, related to a reduction of the existing deferred tax liability as a result of a $1.9 million and $5.8 million impairment charge to the Company's IPR&D assets for the year ended December 31, 2018 and 2017, respectively.

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

	December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$ 44,157,000	$ 44,049,000
Research and development and other tax credits, net	2,523,000	3,109,000
Stock-based compensation	272,000	188,000
Other	196,000	165,000
	47,148,000	47,511,000
Valuation allowance	(47,148,000)	(47,511,000)
Total deferred tax assets	-	-
Deferred tax liabilities:		
In-process research and development	(819,000)	(1,147,000)
Total deferred tax liabilities	$ (819,000)	$ (1,147,000)

At December 31, 2018, the Company had federal net operating loss ("NOL") carryforwards of approximately $197.1 million, of which $10.3 million will expire in 2019 unless utilized. Of the remaining carryforwards, $180.5 million will expire in tax years 2020 through 2037. The NOL's generated in tax years 2018 and forward will carry forward indefinitely, but the deductibility of such federal net operating losses is limited. The Company had state NOL carryforwards of $7.2 million which will begin to expire in 2032. The Company had foreign NOL carryforwards of $10.0 million as of December 31, 2018, $0.9 million of which was generated in 2018. At December 31, 2018, the Company had federal research and development ("R&D") tax credit carryforwards of approximately $2.5 million, net of a reserve for uncertain tax positions of $1.7 million. The R&D tax credit carryforwards will begin to expire in tax years 2019 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,	
	2018	2017
U.S. federal statutory income tax rate	21.0 %	34.0 %
Adjustments for tax effects of:		
Fair value of derivative liabilities	0.2 %	3.6 %
Foreign rate differential	0.3 %	(4.4)%
Stock-based compensation	(0.3)%	(1.0)%
State taxes, net of federal benefit	0.3 %	(1.7)%
Australia refundable R&D tax offset	(4.6)%	(2.4)%
NOL and credit expiration	(20.3)%	- %
Effect of change in statutory tax rates	(0.3)%	(184.2)%
Change in reserve of uncertain tax positions	3.2 %	- %
Change in valuation allowance	3.4 %	170.9 %
All other	(0.1)%	(5.6)%
Effective income tax rate	2.8 %	9.2 %

On December 22, 2017, the U.S. Tax Cuts and Jobs Act (the "Tax Reform Act" or the "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 provides a measurement period that should not extend beyond one year from the Tax Reform Act enactment date for companies to complete the accounting relating to the Act. To the extent that a company's accounting for Tax Reform-related income tax effects is incomplete, but the company is able to determine a reasonable estimate, it must record a provisional estimate in its financial statements. 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 was the Company's best estimate. 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. As of December 31, 2018, the Company has completed its evaluation of the potential impacts of the Tax Reform Act and there was no change to the Company's previous analysis.

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 $1.7 million related to its federal R&D tax credits as of December 31, 2018. 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 2017 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, 2018 and 2017, 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 $5,000 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 2019 and February 2023, 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 $210,000 and $208,000 for the years ended December 31, 2018 and 2017, respectively.

Future minimum annual lease payments under the Company's noncancelable operating leases as of December 31, 2018, are as follows:

	Operating Leases
2019	81,000
2020	67,000
2021	67,000
2022	67,000
2023	11,000
Total minimum lease payments	$293,000

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. Capital Stock and Warrants

On December 17, 2018, the Company's shareholders approved to amend the amended and restated articles of incorporation to increase the number of authorized shares of our common stock from 67,000,000 to 217,000,000.

Underwritten Public Offerings 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.

On October 16, 2018, the Company completed an underwritten public offering and sold 14,875,000 shares of its common stock and 2,125,000 pre-funded warrants to purchase common stock, and common warrants to purchase 17,500,000 shares of common stock. The combined price to the public for each share of common stock and accompanying common warrant was $0.40. The combined price to the public for each pre-funded warrant and accompanying common warrant was $0.39. Each pre-funded warrant is 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 $0.40 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 $5.8 million, after deducting 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 October 2018 offering and determined that the warrants should be classified as equity instruments.

Registered Offerings of Common Stock

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 $3.4 million, after deducting placement agent fees and other offering expenses payable by the Company. On March 22, 2018, the Company completed a registered direct offering of 2,743,640 shares of its common stock at an offering price of $1.10 per share, for aggregate gross proceeds of $3.0 million. The Company received net proceeds from the offering of approximately $2.8 million, after deducting placement agent fees and other offering expenses payable by the Company.

Common Stock Issuance Agreement

On April 8, 2016, the Company entered into the Common Stock Issuance Agreement (the "CSIA") with certain former holders of the Company's Series B redeemable convertible preferred stock (the "Holders"). Pursuant to terms of the CSIA, the Company 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. 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.

On June 27, 2017, the Company and the Holders entered into an amendment to the CSIA (the "Amendment") to, among other things, terminate the Price Protection Obligations. In consideration for the termination of 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.

Warrants

At December 31, 2018, outstanding warrants to purchase shares of common stock, accounted for as equity or liabilities, are as follows:

Shares Underlying Outstanding	Exercise	Expiration

Warrants		Price		Date
16,984		$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
168,498		$0.32	(1)	November 22, 2021
7,920,933		$1.50		May 10, 2022
17,500,000		$0.40		October 15, 2023
1,175,000	(2)	$0.01		October 15, 2023
26,961,187				

(1) Exercise price of these warrants was reduced from $0.57 to $0.32 per share in connection with the October 2018 Financing. 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 an exercise price adjustment provision in the warrant agreements.

(2) In connection with the October 2018 Financing, the Company issued pre-funded warrants to purchase a total of 2,125,000 shares of the Company's common stock for $0.01 a share, out of which 950,000 shares were exercised as of December 31, 2018, and warrants to purchase 1,175,000 shares of the Company's common stock remained outstanding as of December 31, 2018.

During the year ended December 31, 2018, warrants to purchase 217,400 shares of the Company's common stock, originally issued in connection with the November 2016 and May 2017 public offerings, were exercised for proceeds to the Company of $198,000. 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. During the year ended December 31, 2018, warrants to purchase 28,331 shares of the Company's common stock expired. 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. The weighted average exercise price of outstanding warrants to purchase common stock at December 31, 2018 was $1.08 per share.

10. 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. Under the 2016 Plan, the number of shares authorized for issuance automatically increases annually beginning January 1, 2017 and through January 1, 2026.

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,			
	2018		2017	
Risk-free interest rate	2.74 to 2.99	%	1.27 to 2.36	%
Expected volatility	121 to 126	%	117 to 144	%
Expected term (in years)	6.02		2.0 to 9.1	
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. For stock options granted to parties other than employees or directors, the Company elects, on a grant by grant basis, to use the expected term or 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 measured at the grant date using the Black-Scholes valuation model. The stock-based compensation expense related to the grant of

stock options to non-employees was not significant for the years ended December 31, 2018 and 2017.

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,	
	2018	2017
Research and development	$ 326,000	$ 171,000
General and administrative	152,000	529,000
Total stock-based compensation	$ 478,000	$ 700,000

Stock option transactions during the years ended December 31, 2018 and 2017 are presented below:

	Options Outstanding			
	Shares	Weighted Average Exercise Price	Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
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	
Granted	37,500	1.18		
Forfeited/Cancelled	(3,300)	11.54		
Outstanding at December 31, 2018	1,150,065	$ 3.08	8.03	$ -
Vested and expected to vest at December 31, 2018	864,952	$ 3.79	7.78	$ -
Exercisable at December 31, 2018	402,642	$ 5.86	6.73	$ -

The aggregate intrinsic value of options at December 31, 2018 is based on the Company's closing stock price on that date of $0.21 per share. As of December 31, 2018, there was $630,000 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 2.0 years.

Shares Reserved For Future Issuance

As of December 31, 2018, the Company had reserved shares of its common stock for future issuance as follows:

	Shares Reserved
Stock options outstanding	1,150,065
Employee stock purchase plan	46,472
Available for future grants under the 2016 Plan	446,226
Warrants	26,961,187
Total shares reserved	28,603,950

11. Employee Retirement Plan

The Company's employees participate in 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 $2,000 and $12,000 for the years ended December 31, 2018 and 2017, respectively, and the contributions were recorded to operating expense in the consolidated statements of operations.

12. Related Party

On March 22, 2018, the Company completed a registered direct offering of 2,743,640 shares of its common stock at a price of $1.10 per share, including 181,820 shares sold to One Funds Management Limited as Trustee for Asia Pacific Healthcare Fund II ("One Funds"). Two members of the Company's board of directors are affiliated with One Funds.

The Company incurred travel reimbursement expenses of approximately $50,000 and $22,000 payable to Biosciences Managers during the year ended December 31, 2018 and 2017, respectively. 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 One Funds in connection with the CSIA Amendment (See Note 9). Two members of the Company's board of directors are affiliated with One Funds.

13. Subsequent Events

On January 3, 2019, the Company and C3J Therapeutics Inc. ("C3J"), a private clinical stage biotechnology company focused on the development of novel targeted antimicrobials entered into an Agreement and Plan of Merger and Reorganization, which included the proposed business combination ("Merger") of the C3J and Ceres Merger Sub, Inc., a wholly owned subsidiary of AmpliPhi, with C3J as the surviving company, subject to shareholder approval.

At the effective time of the Merger, the Company anticipates that each share of C3J common stock outstanding immediately prior to the effective time of the Merger will be converted into the right to receive approximately 0.6892 shares of AmpliPhi common stock, subject to adjustment to account for a reverse split of AmpliPhi common stock at a reverse split ratio of between 1-for-3 and 1-for-20, inclusive, to be determined by AmpliPhi's board of directors and to be implemented prior to the consummation of the Merger.

Immediately following the Merger, the former C3J security holders will own approximately 70% of the aggregate number of shares of AmpliPhi common stock and the security holders of AmpliPhi as of immediately prior to the Merger will own approximately 30% of the aggregate number of shares of AmpliPhi common stock on a fully diluted basis.

On February 5, 2019, certain existing C3J shareholders executed a Share Purchase Agreement with the Company pursuant to which the shareholders agreed, subject to the satisfaction of customary closing condition, to purchase $10.0 million in common stock of the combined company upon the closing of the Merger at a price per share equal to (i) $40.0 million, divided by (ii) the total number of shares of the Company's common stock outstanding on a fully diluted, as-converted basis, assuming the conversion, exercise or settlement of all outstanding options, warrants, and restricted stock units as of immediately after the effective time of the Merger, but excluding (A) any shares of common stock issuable pursuant to the Share Purchase Agreement and (B) any shares of the common stock reserved for issuance under any equity incentive plan, stock option plan or similar arrangement but for which awards have not yet been granted as of the effective time of the Merger and (C) any shares of common stock issuable in connection with out-of-the-money options and out-of-the-money warrants. Based on the Company's and C3J's respective current capitalizations, the Company expects the purchase price per share to be approximately $0.36.

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, 2018, 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, 2018.

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, 2018, 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, 2018, 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.

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. There were no changes in our internal control over financial reporting during the quarter ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our 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 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. That evaluation did not identify any change in our internal control over

financial reporting that occurred during our latest fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

Pursuant to the terms of the Merger Agreement between us and C3J entered into on January 3, 2019, the Merger Agreement provided that either party could terminate the Merger Agreement if the closing of the Merger had not occurred by May 3, 2019 (the "Closing Deadline"), subject to extension in certain circumstances. On March 25, 2019, we and C3J entered into an amendment to the Merger Agreement, pursuant to which the parties agreed to extend the Closing Deadline to June 1, 2019, subject to extension in certain circumstances.

The foregoing description of the amendment to the Merger Agreement is not complete and is qualified in its entirety by reference to the full text of the amendment, a copy of which is attached to this report as Exhibit 2.5.

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 1, 2019.

Name	Age	Position(s)
Paul C. Grint, M.D.	61	Chief Executive Officer, Director
Steve R. Martin	58	Chief Financial Officer
Non-Employee Directors		
Jeremy Curnock Cook (2) (3)	69	Chairman of the Board
Louis Drapeau (1) (2) (3)	74	Director
Michael S. Perry, Ph.D. (1) (2) (3)	59	Director
Vijay B. Samant (1)	66	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).

Non-Employee Directors

Jeremy Curnock Cook has served as a member of our board of directors since July 1995 and as Chairman of the board of directors since February 1998. From September 2014 to May 2015, he served as our Interim Chief Executive Officer. Mr. Curnock Cook has served as Chairman of International Bioscience Managers Limited, a corporate and investment advisory firm, since 2000, and also currently serves as Managing Director of Bioscience Managers Pty Ltd, a medical sciences fund manager from 1987 to 2000. Mr. Cook was a director of Rothschild Asset Management Limited, a corporate and investment advisory company, and was responsible for the Rothschild Bioscience Unit. Mr. Curnock Cook founded the International Biochemicals Group in 1975, which was sold in 1985 to Royal Dutch Shell, where he served as Managing Director until 1987. He also serves as a member of the board of directors of 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. 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 Forum. Dr. Perry has served as Adjunct Professor in the Gates Center for Regenerative Medicine at the University of Colorado School of Medicine, Anschutz Medical Campus and since November 2013. 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, most recently serving as Chief Operating Officer of the Merck Vaccine Division from 1998 to 2000. 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. 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 an elected member of the Board of Managers of the Columbia University School of Engineering Alumni Association for the past 18 years and has also served as the chair of the prestigious Pupin medal selection committee since 1990. 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;
- 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, 2018, all of our directors, officers and greater than 10% stockholders complied with the Section 16(a) filing requirements.

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, 2018, which consist of our principal executive officer and our two most highly compensated executive officers other than our principal executive officer who were serving as executive officers as of December 31, 2018 are:

- Dr. Paul Grint, our Chief Executive Officer;
- Steve Martin, our Chief Financial Officer; and
- Dr. Igor Bilinsky, our former Chief Operating Officer. Dr. Bilinsky served as our Senior our Senior Vice President, Chief Operating Officer, from January 30, 2017 to January 14, 2019.

Summary Compensation Table

The following table provides information regarding the compensation paid during the last two fiscal years to our named executive officers for the year ended December 31, 2018.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($) (1)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)

Paul C. Grint	2018	475,000	-	-	143,000	-	618,000
Chief Executive Officer	2017	277,083	-	154,163	50,000	18,750 (3)	499,996
Steve Martin	2018	320,000	-	-	109,000		429,000
Senior VP and Chief Financial Officer	2017	320,000	-	154,072	173,409	-	647,481
Igor P. Bilinsky	2018	350,000	-	-	-		350,000
Former Senior VP and Chief Operating Officer (2)	2017	323,525	-	201,173	183,805	-	708,503

(1) In accordance with SEC rules, this column represents the aggregate grant date fair value of the option awards granted during 2017 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 10 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. There were no stock-based compensation granted to our executives in 2018.

(2) On January 14, 2019, we terminated the employment of our Chief Operating Officer, Igor P. Bilinsky, Ph.D. In connection with his termination, Dr. Bilinsky is entitled to certain severance benefits including continuation of payments totaling $350,000 in equal monthly installments for twelve months from January 14, 2019, as described below under the section titled “Potential Payments and Benefits upon Termination or Change in Control”.

(3) Represents board of directors service retainers paid to Dr. Grint in 2017 for board services provided prior to his commencement of employment as Chief Executive Officer in May 2017.

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 2018 and 2017 was $475,000.

Mr. Martin’s annual base salary for 2018 and 2017 was $320,000.

Dr. Bilinsky’s annual base salary for 2018 and 2017 was $350,000.

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 the first calendar quarter, 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 was eligible to receive an annual performance-based bonus for 2018 equal to, at target, 50% of his annual salary based on our achievement of certain performance goals. Mr. Martin was eligible to receive an annual performance-based bonus for 2018 equal to, at target, 40% of his annual salary based on our achievement of certain performance goals. Dr. Bilinsky was eligible to receive an annual performance-based bonus for 2018 equal to, at target, 40% of his annual salary based on our achievement of certain performance goals.

Annual performance bonus amounts for 2017 and 2018 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 2019, the compensation committee reviewed the corporate performance goals for Dr. Grint and Mr. Martin and also considered other external factors impacting the valuation of the Company. Based on the evaluation of the overall 2018 results by the compensation committee the following cash bonus awards were determined: Dr. Grint $143,000 and Mr. Martin $109,000.

Dr. Bilinsky was not eligible for an annual discretionary bonus for the 2018 calendar year because his employment was terminated before bonuses were determined and calculated; however, pursuant to the terms of his separation agreement, he is eligible for a bonus payment of $50,000 if the contemplated merger with C3J Therapeutics, Inc. closes on or before June 30, 2019.

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.” We did not grant any stock-based awards to the Company’s executives or board of director members during 2018.

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 not less than 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 was at will and was terminable by us or Dr. Bilinsky at any time. Under the terms of the agreement, Dr. Bilinsky was 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. On January 14, 2019, we terminated the employment of Dr. Bilinsky. In connection with his termination, Dr. Bilinsky is entitled to certain severance benefits including continuation of payments totaling $350,000 in equal monthly installments for twelve months from January 14, 2019, as described below under the Section titled "Potential Payments and Benefits upon Termination or Change in Control".

Potential Payments and Benefits upon Termination or Change in Control

Dr. Grint and Mr. Martin. Under the terms of the offer letter agreements with Dr. Grint and Mr. Martin, each of these named executive officers 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.

Dr. Bilinsky. In accordance with the terms of his offer letter agreement, upon the termination of Dr. Bilinsky's employment on January 14, 2019 and following his delivery to us of a general release of claims, Dr. Bilinsky is entitled to continued payment of his base salary for 12 months following his termination date (totaling $350,000). In addition, we entered into a separation agreement with Dr. Bilinsky providing for (i) a payment of $50,000 if the contemplated Merger with C3J closes on or before June 30, 2019, paid on the first payroll date following the closing of the Merger and (ii) accelerated vesting of all outstanding unvested equity incentive awards as of his termination

date.

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."

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, 2018.

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	1,256	(1)	364	(1)	0		56.50	11/4/2025
					285,113	(2)	0.91	9/6/2027
	59,399		130,677	(1)	0		0.91	9/6/2027
	60,655		131,041					
Mr. Martin	7,287	(1)	2,704	(1)	0		28.50	1/17/2026
	16,128	(3)	0		0		4.30	3/31/2021
	43,437		95,563	(1)	0		0.91	9/6/2027
	66,852		98,267					
Dr. Bilinsky	11,857		12,875	(1)(4)	0		4.60	1/29/2027
	17,641	(3)	0		0		4.30	3/31/2021
	34,501		52,660	(1)(4)	0		0.74	5/29/2027
	63,999		65,535					

(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) These options were cancelled on January 1, 2019 because performance criteria were not met.

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

(4) One hundred percent of the unvested shares became vested upon termination of Dr. Bilinsky's employment on January 14, 2019.

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, 2018.

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 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, 2018, there were 46,472 shares available for future issuance under the ESPP.

Non-Employee Director Compensation

The following table and related footnotes show the compensation accrued during December 31, 2018, and not yet paid as of the filing date, to our non-employee directors, other than Dr. Grint whose 2018 compensation is set forth above under "Executive Compensation" above.

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Name	Fees Earned or Paid in Cash ($)	Option Awards ($) (1)	All Other Compensation ($)	Total ($)
Jeremy Curnock Cook (2)	70,000	-	-	70,000
Louis Drapeau (3)	63,000	-	-	63,000
Michael S. Perry, Ph.D. (4)	59,000	-	-	59,000
Vijay Samant (5)	46,000	-	-	46,000
Wendy S. Johnson (6)	40,000	-	-	40,000

(1) In accordance with SEC rules, this column represents the aggregate grant date fair value of the option awards granted during 2018 and 2017 (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 10 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, 2018, Mr. Cook held stock options for an aggregate of 15,810 shares, of which 15,296 shares were vested and exercisable.

(3) As of December 31, 2018, Mr. Drapeau held stock options for an aggregate of 12,520 shares, of which 11,686 shares were vested and exercisable.

(4) As of December 31, 2018, Dr. Perry held stock options for an aggregate of 12,640 shares, of which 11,906 shares were vested and exercisable.

(5) As of December 31, 2018, Mr. Samant held stock options for an aggregate of 12,520 shares, of which 12,156 shares were vested and exercisable.

(6) As of December 31, 2018, Ms. Johnson held stock options for an aggregate of 17,516 shares, of which 16,442 shares were vested and exercisable.

In September 2015, the board of directors approved a revised compensation structure for our non-employee directors. In 2018, 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 and 2018 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. Dr. Grint did not receive compensation for service as a director in 2018.

No non-employee directors received any stock option grants in 2018.

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 32,294,008 shares of common stock outstanding as of February 28, 2019.

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, 2019, which is 60 days after January 31, 2019. 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
Directors and Named Executive Officers		
Paul C. Grint, M.D. (1)	77,226	*
Jeremy Curnock Cook (2)	482,404	1.5 %
Louis Drapeau (3)	12,738	*
Michael S. Perry, Ph.D. (4)	478,658	1.5 %
Vijay B. Samant (5)	12,289	*
Wendy S. Johnson (6)	16,594	*
Steve R. Martin (7)	79,644	*
Igor P. Bilinsky, Ph.D. (8)	129,534	*
All current executive officers and directors as a group (8 persons) (9)	822,617	2.6 %

* Represents beneficial ownership of less than 1%.

(1) Consists of 599 shares of common stock and 76,627 shares of common stock that Dr. Grint has the right to acquire from us within 60 days of February 28, 2019, pursuant to the exercise of stock options.

(2)

Consists of (a) 330 shares of common stock, (b) 411,105 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 55,365 shares of common stock, and (c) 15,604 shares of common stock that Mr. Cook has the right to acquire from us within 60 days of February 28, 2019, pursuant to the exercise of stock options.

(3) Consists of 1,000 shares of common stock and 11,738 shares of common stock that Mr. Drapeau has the right to acquire from us within 60 days of February 28, 2019, pursuant to the exercise of stock options.

(4) Consists of (a) 230 shares of common stock, (b) 411,105 shares referenced held by One Funds, an entity with which Dr. Perry is affiliated, and warrants exercisable for 55,365 shares of common stock, and (c) 11,958 shares of common stock that Dr. Perry has the right to acquire from us within 60 days of February 28, 2019, pursuant to the exercise of stock options.

(5) Consists of 12,289 shares of common stock that Mr. Samant has the right to acquire from us within 60 days of February 28, 2019, pursuant to the exercise of stock options.

(6) Consists of 100 shares of common stock and 16,494 shares of common stock that Ms. Johnson has the right to acquire from us within 60 days of February 28, 2019, pursuant to the exercise of stock options.

(7) Consists of 376 shares of common stock and 79,268 shares of common stock that Mr. Martin has the right to acquire from us within 60 days of February 28, 2019, pursuant to the exercise of stock options.

(8) Consists of 129,534 shares of common stock that Dr. Bilinsky has the right to acquire from us within 60 days of February 28, 2019, pursuant to the exercise of stock options.

(9) Includes the shares described in footnotes (1) through (8) 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, 2018 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)
Equity compensation plans approved by security holders	1,145,855	$ 2.72	446,226
Equity compensation plans not approved by security holders	4,210	$ 100	-
Total	1,150,065	$ 3.08	446,226

(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, 2017 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.”

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.

Registered Direct Offering

On March 22, 2018, we completed a registered direct offering of 2,743,640 shares of our common stock at a price of $1.10 per share, including 181,820 shares sold to One Funds Management Limited as Trustee for Asia Pacific Healthcare Fund II ("One Funds"). Jeremy Curnock Cook and Michael S. Perry, D.V.M., Ph.D., each a current member of our board of directors, are managing directors of Biosciences Managers, an investment entity affiliated with One Funds.

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, 2018 and 2017.

	Fiscal Year Ended December 31, 2018	Fiscal Year Ended December 31, 2017
Audit Fees	$ 270,000	$ 324,000
Audit Related Fees	120,560	97,000
Tax Fees	-	-
All Other Fees	-	-
Total	$ 390,560	$ 421,000

Representatives of Ernst & Young LLP attended all of the meetings of the Audit Committee occurring during the years ended December 31, 2018 and 2017.

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:

	Page
Report of Independent Registered Public Accounting Firm	52
Consolidated Balance Sheets	53
Consolidated Statements of Operations	54
Consolidated Statements of Stockholders' Equity	55
Consolidated Statements of Cash Flows	56
Notes to Consolidated Financial Statements	57

2. *Financial Statement Schedules*. None.

3. *Exhibits.*

The exhibits listed in the Exhibit Index below are filed or incorporated by reference as part of this Annual Report.

Item 16. Form 10-K Summary

None.

Exhibit Index

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).
2.4	Agreement and Plan of Merger and Reorganization, dated January 3, 2019, by and among the Company, C3J Therapeutics and Merger Sub (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the SEC on January 4, 2019).
2.5	Amendment, dated March 25, 2019, to Agreement and Plan of Merger and Reorganization, dated January 3, 2019, by and among the Company, C3J Therapeutics and Merger Sub.
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 3.2 to the Company's Quarterly Report on Form 10-Q, filed on November 8, 2018).
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 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).
4.4	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).
4.5	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).
4.6	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).
4.7	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)).
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+	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).
10.14+	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).
10.15+	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).

10.16+	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).
10.17	Cooperative Research and Development Agreement, dated as of June 13, 2013, by and between the Company and United States Army Medical Research and Materiel Command (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form 10, as amended (File No. 000-23930), filed with the SEC on December 16, 2013).
10.18	Engagement letter agreement, dated December 13, 2017, as amended on December 17, 2018, by and between the Company and Ladenburg Thalmann & Co. Inc.
10.19	Form of Company Support Agreement, dated January 3, 2019, by and between C3J Therapeutics and each of the parties named in each agreement therein (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on January 4, 2019).
10.20	Form of C3J Therapeutics Support Agreement, dated January 3, 2019, by and between the Company and each of the parties named in each agreement therein (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on January 4, 2019).
10.21	Form of Company Lock-Up Agreement, dated January 3, 2019, by each of the parties named in each agreement therein (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed with the SEC on January 4, 2019).
10.22	Form of C3J Lock-Up Agreement, dated January 3, 2019, by each of the parties named in each agreement therein (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K, filed with the SEC on January 4, 2019).
10.23	Form of Share Purchase Agreement by and among AmpliPhi Biosciences Corporation, C3J Therapeutics, Inc. and certain shareholders of C3J Therapeutics, Inc., dated as of February 5, 2019 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on February 7, 2019).
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 or received.**

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 25, 2019 By: /s/ Paul C. Grint, M.D.
Name: Paul C. Grint, M.D.
Title: Chief Executive Officer
(Principal Executive Officer)

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 25, 2019
/s/ Steve R. Martin Steve R. Martin	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 25, 2019
/s/ Jeremy Curnock Cook Jeremy Curnock Cook	Chairman of the Board of Directors	March 25, 2019

/s/ Louis Drapeau Louis Drapeau	Director	March 25, 2019
/s/ Wendy S. Johnson Wendy S. Johnson	Director	March 25, 2019
/s/ Michael S. Perry, Ph.D. Michael S. Perry, Ph.D.	Director	March 25, 2019
/s/ Vijay B. Samant Vijay B. Samant	Director	March 25, 2019