

AmpliPhi Biosciences Corp  
Form 10-K  
March 30, 2016

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-K**

(Mark One)

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

**For the fiscal year ended December 31, 2015**

**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**

**San Diego, California 92130**

(Address of principal executive offices, including zip code)

**(858) 800-4868**

(Registrant's telephone number, including area code)

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

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

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required

Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

to submit and post such files). Yes  No

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

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

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

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

As of June 30, 2015, the aggregate market value of voting stock held by non-affiliates of the Registrant, based on the closing price of the Common Stock on June 30, 2015 (the last business day of the Registrant's most recently completed second quarter) as quoted on the OTCQB, was approximately \$37,554,000.

As of March 25, 2016, 5,883,503 shares of the Registrant's Common Stock were outstanding.

**TABLE OF CONTENTS**

**AMPLIPHI BIOSCIENCES CORPORATION**

	Page No.
<b><u>PART I</u></b>	
Item 1. <u>Business</u>	5
Item 1A. <u>Risk Factors</u>	22
Item 1B. <u>Unresolved Staff Comments</u>	37
Item 2. <u>Properties</u>	37
Item 3. <u>Legal Proceedings</u>	37
Item 4. <u>Mine Safety Disclosures</u>	37
<b><u>PART II</u></b>	
Item 5. <u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	37
Item 6. <u>Selected Financial Data</u>	38
Item 7. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	38
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	44
Item 8. <u>Financial Statements and Supplementary Data</u>	44
Item 9. <u>Changes In and Disagreements With Accountants on Accounting and Financial Disclosure</u>	45
Item 9A. <u>Controls and Procedures</u>	45
Item 9B. <u>Other Information</u>	46
<b><u>PART III</u></b>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	47

Item 11.	<u>Executive Compensation</u>	52
Item 12.	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	59
Item 13.	<u>Certain Relationships and Related Transactions and Director Independence</u>	61
Item 14.	<u>Principal Accountant Fees and Services</u>	62
<b><u>PART</u></b>		
<b><u>IV</u></b>		
Item 15.	<u>Exhibits and Financial Statement Schedules</u>	63
	<u>Signatures</u>	64

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

- our estimates regarding anticipated operating losses, capital requirements and needs for additional funds;*
- the impact of our disagreement with one of our principal stockholders on our ability to raise additional capital and the ultimate outcome of that disagreement;*
- our ability to manufacture, or otherwise secure the manufacture of, sufficient amounts of our product candidates for our preclinical studies and clinical trials;*
- our clinical development plans, including planned clinical trials;*
- our research and development plans, including our plans to initiate a clinical trial of AB-SA01 for the treatment of wounds infected with *S. aureus* in the first half of 2016;*
- 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 that are or may become available;*
- our expectations with respect to future growth and investments in our infrastructure, and our ability to effectively manage any such growth;*
- the size and potential growth of the markets for any of our product candidates, and our ability to capture share in or impact the size of those markets;*
- the benefits of our product candidates;*
- market and industry trends;*
- the effects of government regulation and regulatory developments, and our ability and the ability of the third parties with whom we engage to comply with applicable regulatory requirements;*
- the accuracy of our estimates regarding future expenses, revenues, capital requirements and need for additional financing;*
- our expectations regarding future planned expenditures;*
- our ability to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act;*

*our expectations regarding the period during which we qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act;*  
*our ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection of any of our products and product candidates; and*  
*our ability to operate our business without infringing the intellectual property rights of others.*

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

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

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

## EXPLANATORY NOTE

### Note Regarding Restatement of Previously Issued Consolidated Financial Statements

In this Annual Report on Form 10-K, we have restated historical financial statements for the year ended, December 31, 2014, three and six months ended June 30, 2014, three and nine months ended September 30, 2014 and three months ended June 30, 2015 to reflect a revision in accounting for basic and diluted earnings per share.

The error relates to the misapplication of Accounting Standards Codification No. 260, “Earnings Per Share,” or ASC 260, for two matters.

First, we did not properly consider the fact that outstanding shares of our Series B redeemable convertible preferred stock, in certain limited circumstances, have the right to receive additional dividends beyond their accruing dividends, which makes them participating securities. Therefore, consideration of this component of the preferred stock terms is included in computing basic earnings per share pursuant to the two-class method. The Company failed to make such adjustments to the basic income (loss) per share calculations for the prior periods discussed above.

Second, we did not properly account for the adjustments required to net income (loss) attributable to common stockholders in the calculation of diluted net income (loss) per share. The calculation of diluted net income (loss) per share requires that, to the extent that such securities are dilutive to income (loss) per share for the period, an adjustment to net income (loss) used in the calculation is required to remove the change in fair value of the liability classified warrants from the numerator for the period. Likewise, an adjustment to the denominator is required to reflect the related dilutive shares. Similarly, the diluted income (loss) per share calculation also requires an adjustment to net income (loss) used in the calculation to remove the change in the fair value of the Series B redeemable convertible preferred stock embedded derivative (if the Series B redeemable convertible preferred stock is dilutive), including any applicable accretion, and an adjustment to the denominator is required to reflect the related dilutive securities. The Company failed to make such adjustments to the diluted income (loss) per share calculations for the prior periods discussed above.

During the preparation process for this Annual Report on Form 10-K, we recomputed the basic and diluted income (loss) per share amounts for all periods to conform with the provisions of ASC 260.



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

In connection with this restatement, we revised our consolidated statement of operations for the year ended December 31, 2014, and applicable interim periods in 2014 and 2015 to reflect revised basic and diluted income (loss) per share. This adjustment had no impact on our balance sheets, reported loss from operations, net income (loss) attributable to common stockholders, statements of redeemable convertible preferred stock and stockholders' equity, or our statements of cash flows and our cash and cash equivalents balances are unchanged for such periods.

Throughout this Annual Report on Form 10-K, amounts presented from current periods and prior period comparisons have been revised and labeled as "restated" and reflect the amounts on a restated basis.

Tables summarizing the effect of the restatement on the specific line items presented in our historical financial statements for the periods indicated are included in *Note 3 – Significant Accounting Policies* and *Note 17 – Quarterly Financial Data* of the notes to our consolidated financial statements included with this Annual Report on Form 10-K.

## **PART I**

### **Item 1. BUSINESS**

#### **Company History**

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

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

On February 22, 2011, we changed our name to “AmpliPhi Biosciences Corporation.”

In November 2012, we completed the acquisition of Special Phage Holdings Pty Ltd, a company based in Australia, which we refer to as SPH, with the goal of combining SPH’s research on addressing the rapidly escalating problem of antibiotic resistance through the development of a series of bacteriophage-based treatments into our own development program.

In November 2015, our board of directors approved a plan for us to reincorporate as AmpliPhi Biosciences Corporation in the State of Delaware, subject to the approval of our stockholders. We may decide to abandon our plan to reincorporate in the State of Delaware at our election.

#### **Company Overview**

We are a biotechnology company focused on the discovery, development and commercialization of novel phage therapeutics. Phage therapeutics use bacteriophages, a family of viruses, to kill pathogenic bacteria. Phages have powerful and highly selective mechanisms of action that permit them to target and kill specific bacteria. We believe that phages represent a promising means to treat bacterial infections, especially those that have developed resistance to

current therapies, including the so-called multi-drug-resistant or “superbug” strains of bacteria.

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

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

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

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

In March 2013, we entered into an exclusive channel collaboration with Intrexon Corporation, or Intrexon, directed towards the research, development and commercialization of new bacteriophage-based therapies for the treatment of bacterial infections caused by *P. aeruginosa* and *C. difficile*.

In September 2013, we entered into a license agreement, or the Leicester License Agreement, with the University of Leicester to develop a phage therapy to kill certain types of *C. difficile*. Pursuant to the Leicester License Agreement, we may be obligated to pay the University of Leicester a single digit royalty and an aggregate of up to £575,000 in milestone payments.



In June 2013, we entered into a cooperative research and development agreement, or CRADA, with the United States Army Medical Research and Materiel Command focusing on developing bacteriophage therapeutics to treat *S. aureus*, *E. coli* and *P. aeruginosa* infections. Under this CRADA we plan to initiate a clinical trial of AB-SA01 for the treatment of wounds infected with *S. aureus* in the first half of 2016.

In November 2015, our Australian subsidiary, AmpliPhi Australia Pty Ltd, entered into a clinical trial research agreement with the University of Adelaide and the Queen Elizabeth Hospital, both of Adelaide, SA, Australia, to conduct a Phase 1 clinical trial titled “A Phase 1 Investigator Initiated Study to Evaluate the Safety, Tolerability and Preliminary Effectiveness of AB-SA01 in Patients with Chronic Rhinosinusitis Associated with *S. aureus* infection”. The University of Adelaide will sponsor the clinical trial while we will supply AB-SA01 and control the trial protocol. This study will primarily measure the safety and tolerability of AB-SA01 and will secondarily examine the presence of *S. aureus* and symptoms assessed by the patient as well as by the physician using standard questionnaires used by physicians to assess treatment efficacy. We plan to enroll nine patients, divided into three cohorts. The first cohort will receive a twice daily dose of AB-SA01 for seven days. The second cohort will receive the same dose twice daily for 14 days. The third cohort will receive a higher dose of AB-SA01 twice daily for 14 days. Patients will be monitored an additional 30 days following their last day of treatment. Patient screening for this clinical trial commenced in late 2015 the first patient was dosed in January 2016. We expect data from this first clinical trial in the second half of 2016 and are planning to initiate a second clinical trial of AB-SA01 by the first half of 2017.

In January 2016, we entered into an Asset Purchase Agreement with Novolytics Ltd., which we refer to as the Novolytics Purchase Agreement, to purchase certain tangible and intangible assets. Pursuant to the Novolytics Purchase Agreement, we acquired all rights, title and interest to three families of patents. The first family is titled “Bacteriophages useful for therapy and prophylaxis of bacterial infections.” This patent has been granted in the United Kingdom, certain other European countries and India. The second patent family is titled “Anti-bacterial compositions” and has been granted in Australia with prosecution pending in multiple countries including the United States. The last patent family is titled “Novel bacteriophages” and the prosecution is pending in many countries including the United States. We also received clinical isolates for *S. aureus* which will bolster our libraries of clinically relevant strains. Additionally, we received know-how relating to certain formulation processes. We also have access to all previous dialogue between Novolytics and various regulatory organizations including the United Kingdom Medicines and Healthcare Products Regulatory Agency, or MHRA

At December 31, 2015, we had cash and cash equivalents of \$9.4 million. The independent registered public accounting firm that audited our 2015 consolidated financial statements has included in their report an explanatory paragraph referring to our recurring losses and expressing substantial doubt in our ability to continue as a going concern. Our ability to continue as a going concern depends on our ability to raise substantial additional funds through public or private equity offerings, collaborative or licensing arrangements and/or debt financing. We may not be able to raise sufficient capital when required or on acceptable terms.

We have a disagreement with one of our principal stockholders, Third Security, LLC, regarding the interpretation of our Amended and Restated Articles of Incorporation. The disagreement relates to whether it is technically possible for us to satisfy the requirements for automatic conversion of our outstanding shares of Series B redeemable convertible preferred stock (Series B Preferred) pursuant to an underwritten public offering (a Qualified Public Offering). In the fourth quarter of 2015, Third Security informed us that, under its interpretation of our Amended and Restated Articles of Incorporation, the Qualified Public Offering conditions set forth in Article 4 of our Amended and Restated Articles of Incorporation can never be satisfied because our stock is publicly traded on the NYSE MKT, and that the only way all outstanding Series B Preferred can be converted into shares of our common stock (Common Shares) is by obtaining the requisite consent of the Series B Preferred stockholders. We disagree with Third Security's interpretation. Our Amended and Restated Articles of Incorporation also contain various other ambiguities, such as in the provisions relating to the conversion rate for converting Series B Preferred into Common Shares and the stated value of the Series B Preferred following our 50:1 reverse split of our Common Shares in August 2015. The stated value of the Series B Preferred affects other provisions of our Amended and Restated Articles of Incorporation, including the anti-dilution rights for the Series B Preferred as well as the minimum public offering price per share necessary for a public offering to satisfy one of the Qualified Public Offering conditions. These ambiguities, as well as Third Security's interpretation of the Qualified Public Offering conditions, create uncertainty around our capital structure, which may adversely affect our ability to raise capital. If adequate funds are not available on a timely basis on acceptable terms, we may be required to significantly reduce, delay or refocus our research and development programs, sell or relinquish rights to our products, technologies or other assets or merge all or a portion of our business with another entity, any of which could delay the time to market of our product candidates and have a material adverse effect on our business, financial condition and results of operations. This uncertainty around our ability to secure additional financing creates substantial doubt about our ability to continue as a going concern. In order to resolve our disagreement with Third Security, we may also agree to settlement terms that cause significant dilution to holders of our Common Shares and require us to pay significant consideration, or engage in expensive and time-consuming litigation where our interpretation of the Qualified Public Offering conditions may not prevail or the matter may otherwise be resolved in a manner unfavorable to us. For additional information, see "Risk Factors—We have a disagreement with one of our principal stockholders regarding the interpretation of our Amended and Restated Articles of Incorporation" under Item 1A of this Annual Report.

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

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

The CDC's latest report on the matter, *Antibiotic Resistance Threats in the United States, 2013*, notes that there are "potentially catastrophic consequences of inaction" and ranks *C. difficile* as belonging to the highest tier of threat, or "Urgent Threats." Despite the potential market opportunity, only two New Drug Applications, or NDAs, for antibacterial drugs were approved by the FDA between 2010 and 2012 compared to 18 in the period between 1980 and 1984. One of the primary recommendations of the CDC is the development of new antimicrobials to diversify treatment options.

## Product Candidates

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

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

In conjunction with our CRADA with the U.S. Army Medical Research and Materiel Command, we are developing AB-SA01 to treat acute and chronic infections caused by *S. aureus*, including infections caused by MRSA strains of the same bacterium. MRSA infections are one of the most common causes of hospital-acquired (nosocomial) infections. The CDC estimates that more than 850,000 patients were treated for *S. aureus* infections of the skin or soft tissue in 2013 and, due to failure of first line treatment, more than 50% of these patients required a second-line treatment and approximately 35% of them required a third-line treatment. Global Data estimates the market for MRSA infection treatments alone was more than \$2.7 billion in 2007. This market is forecasted to grow to more than \$3.5 billion by 2019.

In connection with our CRADA with the US Army, we submitted a Pre-IND briefing package to the FDA to obtain their feedback on our Chemistry Manufacturing and Control, or CMC, program and plans for our first human clinical trial of AB-SA01 for the treatment of *S. aureus* infections of wound and skin. The FDA concurred with our plan for progressing this bacteriophage product candidate into clinical trials, specifically agreeing with the manufacturing process, product specifications and the absence of any need for non-clinical toxicology data to initiate our first Phase 1 clinical trial. We plan to initiate the Phase 1 clinical trial in the second half of 2016. We are also planning to initiate a second Phase 1 clinical trial in healthy volunteers in the second half of 2016.

Furthermore, in December 2015, we opened a clinical trial at the University of Adelaide Queen Elizabeth Hospital to evaluate the safety and preliminary efficacy of AB-SA01 in chronic rhinosinusitis patients infected with *S. aureus*. The first patient in this clinical trial was dosed in January 2016 and we have continued to dose additional patients through the first quarter of 2016. We expect data from this first clinical trial in the second half of 2016.

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

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

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

In collaboration with Institut Pasteur (Paris, France) and also with the Brompton Hospital, Imperial College (London, United Kingdom), we have demonstrated in the preclinical studies, some of which are described below, that phages can effectively treat infections in animal models of acute *P. aeruginosa* lung infections. The graphic below shows the three groups from a study conducted at the Institute Pasteur. Each group consisted of eight mice. Group 1 was treated with placebo, or PBS; Group 2 was treated with our phage mix; and Group 3 was treated with an antibiotic (note the model was optimized for this antibiotic). The colored regions, measured by light intensity, or luminescence, demonstrate where the *P. aeruginosa* infection is active and the bacteria are actively replicating. By the 24<sup>th</sup> hour, the surviving untreated animals (Group 1) are sacrificed as the infection has spread and in some cases has already proved lethal whereas the two treatment groups (Group 2, phage and Group 3, antibiotic) showed effective reduction of the active infection.



Average luminescence, representing bacteria that remain alive, for each group is shown below:

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

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

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

We were granted an advisory meeting with the MHRA in the first quarter of 2014 to discuss our plans and intend to move the AB-PA01 compound into additional preclinical testing in preparation for a Phase 1/2 clinical trial in CF patients. We also sought advice and comment that our CMC plans were acceptable. The MHRA concurred with our approach and plans as presented, including a first-in-man dose ranging clinical trial in CF patients. We expect to continue product candidate selection and formulation work into mid-2016 and to submit a Clinical Trial Application, or CTA, to the MHRA in the first half of 2017 and we plan to initiate the first clinical trial shortly thereafter.

If we achieve successful proof of concept in this initial clinical indication we may consider developing this compound for the treatment of other acute and chronic lung infections, such as ventilator associated bacterial pneumonia, or VABP, and chronic obstructive pulmonary disease, or COPD. *P. aeruginosa* is the predominant pathogen in both of these indications. We are also currently evaluating our phages in preclinical animal models of chronic rhinosinusitis in collaboration with the University of Adelaide.

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

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

According to the CDC almost 250,000 people each year require hospitalization for CDI and at least 14,000 people die each year in the United States from CDI. The CDC also estimates that 20-40% of CDI recurs with standard antibiotic treatment. We are actively working with researchers at the University of Leicester to develop a phage therapeutic that targets and kills *C. difficile*. We believe that orally delivered phages are well suited to treat CDI. Within this collaboration, researchers at the University of Leicester have discovered phages that have been shown to be effective against clinically-relevant strains of *C. difficile* isolated from around the world. We are also collaborating with Intrexon to develop second generation phages with improved biological characteristics. While current therapies against *C. difficile* are not yet antibiotic-resistant, the CDC has categorized *C. difficile* as an urgent threat and has stated that CDI requires urgent and aggressive action. We believe that there is a significant market opportunity for our product in treating this infection.

Preclinical studies are underway to select and optimize our phage cocktail and manufacturing strains as well as evaluate efficacy in animal models.

#### **Prior Clinical Development**

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

### **Anti-Infective Therapeutics Market**

The market opportunity for antibiotics is large, with the market estimated to reach \$40.3 billion in annual sales globally in 2015. Almost one in every five deaths worldwide occurs as a result of infection and, according to the World Health Organization, or WHO, many bacterial infections will become difficult or impossible to cure as the efficacy of current antibiotic drugs wanes. Despite the advances in antimicrobial and vaccine development, infectious diseases still remain as the third-leading cause of death in the United States and the second-leading cause of death worldwide.

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

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

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



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

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

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

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

### ***Anti-Infective Treatments with Bacteriophages***

#### **Background**

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

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

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

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

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

## **Our Strategy**

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

We supplement our internal resources with world-class scientific and medical collaborations throughout the world. For example, through a collaboration with The University of Adelaide in Australia we conducted preclinical studies showing the ability of *S. aureus* phage preparations to kill clinical isolates from 61 patients demonstrating efficacy of greater than 90%. Furthermore, a *S. aureus* mixture was shown to be safe and efficacious in a preclinical sheep model of chronic rhinosinusitis. This program continues to progress and a clinical trial of patients at the University of Adelaide's Queen Elizabeth Hospital with treatment refractory chronic rhinosinusitis patients infected with *S. aureus* commenced in late 2015 and the first patient was dosed in January 2016.

In collaboration with the U.S. Army, we plan to initiate a clinical trial in 2016 that will support the development of a treatment for *S. aureus* infections for wound and skin infections.

We collaborate with the Royal Brompton Hospital in London where we have demonstrated that a candidate phage product can survive nebulization, was effective in killing over 83% of recent clinical isolates from London patients, and in preclinical mouse models demonstrated that a phage mixture dose-dependently clears *Pseudomonas* infection from the lung and reduced inflammation.

We expect to continue product selection and formulation work for AB-PA01, and in conjunction with the Brompton Hospital, we would expect to conduct a Phase 1/2 study using AB-PA01 to treat CF patients with *P. aeruginosa* lung infections.

Through our collaborations with the University of Leicester and Intrexon, we are also continuing to develop and identify candidate *C. difficile* phages to treat patients suffering from serious gastrointestinal infections.

## Acquisitions

In January 2011, we completed the acquisition of Biocontrol Ltd, with the goal of developing their phage therapy programs using funding from the sale of our legacy gene therapy assets. Under the terms of our acquisition of Biocontrol Ltd, we issued 456,344 shares of our common stock to the shareholders of Biocontrol Ltd with a total fair value of approximately \$8.6 million as of January 6, 2011, resulting in Biocontrol's former shareholders owning approximately 50% of our outstanding equity securities at the time. As a condition to closing the acquisition, Biocontrol Ltd raised approximately £200,000 (US\$310,000) in working capital for use by us.

In November 2012, we acquired SPH pursuant to our offer to acquire all outstanding shares of SPH from its shareholders under the terms of a Shareholder Sale Agreement and a Managers Warranty Deed, collectively referred to as the SPH Agreements, in exchange for up to 800,000 shares of our common stock.

In connection with our acquisition of SPH, we entered into certain other arrangements, including the repayment under a Loan Repayment Deed (as amended) of a \$770,000 loan originally made by Cellabs Pty Ltd, or Cellabs, an Australian company affiliated with Dr. Smithyman, to SPH, a consulting agreement with Dr. Smithyman and the payment of \$3,017 per month to Cellabs for our laboratory space in Australia through December 31, 2015. Under the terms of the Loan Repayment Deed, the loan from Cellabs to SPH was to be repaid and fully satisfied partly in cash and partly by issuing 40,000 shares of our common stock to Cellabs. As of December 31, 2015, \$350,000 has been paid by us to Cellabs and all 40,000 shares have been issued. We paid the remaining balance of \$200,000 under the terms of the Loan Repayment Deed in December 2013. The SPH acquisition also included several phage therapy projects which had reached the pre-clinical or animal study stage, including the Brompton Hospital CF study, the Adelaide University MRSA chronic rhinosinusitis study and the University of Leicester *C. difficile* project. We believe that acquisition of SPH brought substantial phage scientific expertise and know-how to the Company.

In January 2016, we entered into an Asset Purchase Agreement with Novolytics Limited, which we refer to as the Novolytics Purchase Agreement, to purchase certain tangible and intangible assets. Pursuant to the Novolytics Purchase Agreement, we receive all rights, title and interest to three families of patents. The first family is titled "Bacteriophages useful for therapy and prophylaxis of bacterial infections." This patent has been granted in the United Kingdom, certain other European countries and India. The second patent family is titled "Anti-bacterial compositions" and has been granted in Australia with prosecution pending in multiple countries including the U.S. The last patent family is titled "Novel bacteriophages" and the prosecution is pending in many countries including the U.S. We also received clinical isolates for *S. aureus* which will bolster our libraries of clinically relevant strains. Additionally, we received know-how relating to certain formulation processes. We also have access to all previous dialogue between Novolytics and various regulatory organizations including the MHRA.



Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

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

## **Strategic Alliances and Research Agreements**

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

### ***Exclusive Channel Collaboration with Intrexon***

In March 2013, we entered into an exclusive channel collaboration agreement with Intrexon, or the Exclusive Channel Collaboration, that governs a collaboration arrangement in which we use Intrexon's technologies directed towards the research, development and commercialization of new bacteriophage-based therapies to target specific antibiotic-resistant infections. We believe that combining the broadest and most advanced synthetic biology platform with our phage capabilities may lead to the development of innovative second-generation phage product candidates. The Exclusive Channel Collaboration establishes committees comprised of representatives of us and Intrexon that govern activities related to the bacteriophage programs in the areas of project establishment and prioritization, as well as budgets and their approval, chemistry, manufacturing and controls, clinical and regulatory matters, commercialization efforts and intellectual property.

Under the terms of the Exclusive Channel Collaboration, the Company will receive an exclusive, worldwide license to utilize Intrexon's proprietary technology and expertise for the standardized design and production of genetically modified bacteriophages, which we refer to collectively as the Bacteriophage Program. The Exclusive Channel Collaboration seeks to develop bacteriophage-containing human therapeutics, other than AB-PA01, for use in the treatment of bacterial infections associated with *P. aeruginosa* infections and the treatment of infections of *C. difficile*, which we collectively refer to as AmpliPhi Product candidates. The Exclusive Channel Collaboration grants the Company a worldwide license to use patents and other intellectual property of Intrexon in connection with the research, development, use, importing, manufacture, sale and offer for sale of AmpliPhi Product candidates. Such license is exclusive with respect to any clinical development, selling, offering for sale or other commercialization of AmpliPhi Product candidates, and otherwise is non-exclusive. Subject to limited exceptions, we may not sublicense the rights to Intrexon's technology without Intrexon's written consent.

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

and maintenance of Intrexon's patents.

Subject to certain expense allocations and other offsets provided in the Exclusive Channel Collaboration, we agreed to pay Intrexon, on a quarterly basis, tiered royalties on net sales derived in that quarter from the sale of AmpliPhi Product candidates, which are based on or incorporate Intrexon's technology, calculated on a product-by-product basis. If we sublicense a product developed under the collaboration with Intrexon, we have also agreed to pay Intrexon, on a quarterly basis, a certain percentage of revenues received from the sublicensee. Pursuant to the Exclusive Channel Collaboration, Intrexon received 480,000 shares of our common stock as an upfront technology access fee. We may also pay Intrexon up to \$7.5 million in aggregate milestone payments for each product, payable either in cash or equity upon the achievement of certain events. Intrexon is also entitled to tiered royalties as a percentage in the upper-single digits of the net product sales of a product developed under the Exclusive Channel Collaboration. No milestones have been achieved under the Exclusive Channel Collaboration through December 31, 2015.

The Exclusive Channel Collaboration is effective until terminated by either Intrexon or us. Intrexon may terminate the Exclusive Channel Collaboration if we fail to use diligent efforts to develop and commercialize AmpliPhi Product candidates or if we elect not to pursue the development of an AmpliPhi Program identified by Intrexon that is a "Superior Therapy" as defined in the Exclusive Channel Collaboration. We have the right to terminate the Exclusive Channel Collaboration upon 90 days' written notice to Intrexon at any time. Both we and Intrexon have the right to terminate the Exclusive Channel Collaboration upon written notice to the other party if the other party commits a material breach of the agreement and fails to cure such breach within 60 days following written notice.

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

- is being commercialized by us;
  - has received regulatory approval;
  - is a subject of an application for regulatory approval that is pending before the applicable regulatory authority;
  - is the subject of an ongoing Phase 2 or completed Phase 3 clinical trial in the field; or
- if we terminate the Exclusive Channel Collaboration for cause, is the subject of an effective investigational new drug application with the FDA, or for which we have commenced at least one authorized *in vivo* good laboratory practices animal study that is expected to be used for filing an investigational new drug application for such AmpliPhi Product Candidate.

Our obligation to pay royalties described above with respect to these “retained” products will survive termination of the Exclusive Channel Collaboration.

We incurred expenses for services under the Exclusive Channel Collaboration of \$178,000 and \$862,000 for the years ended December 31, 2015 and 2014, respectively.

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

In June 2013, we entered into a CRADA with the U.S. Army Medical Research and Materiel Command. The CRADA will focus on developing bacteriophage therapeutics to treat at least three types of infections: *S. aureus*, *E. coli* and *P. aeruginosa*. The initial indication will be wounds and skin infections from *S. aureus*, which is the leading pathogen in healthcare-associated infections in the United States as a whole, accounting for 30.4% of surgical site infections.

We retain global regulatory ownership and commercial rights to all products developed by us under the CRADA. 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 CRADA expires in June 2018 and can be terminated by either the U.S. Army Medical Research and Materiel Command or us upon 60 days’ written notice to the other party at any time.

### ***University of Leicester Development Agreements***

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

Under these agreements, which we refer to collectively as the Leicester Development Agreements, we are funding the University of Leicester to carry out *in vitro* studies and animal model development work to identify bacteriophage to resolve *C. difficile* infections. We have licensed related patents, materials and know-how from the University of Leicester. Under the Leicester Development Agreements, the University of Leicester will provide the bacteriophage

and act as overall project coordinator for preclinical studies. All rights, title and interest to any intellectual property developed under the Leicester Development Agreements belong to us. Under the Leicester License Agreement, we have exclusive rights to certain patents and materials owned by the University of Leicester, as well as non-exclusive licenses to related know-how.

The collaboration agreement expires in November 2018 and is terminable by either party upon (a) material breach by the other party, subject to a 90-day cure period, (b) the inability of the principal investigator to continue the collaboration or (c) our bankruptcy or winding up of our operations or, commencing on November 13, 2016, with 180 days' notice.

Pursuant to the Leicester License Agreement, we paid an up-front fee and will pay the University of Leicester royalties based on product sales and make certain milestone payments based on product development. We are also required to pay minimum annual fees, which reduce future milestone payments. In the event that we sublicense a product created under the Leicester Development Agreements, we have agreed to pay the University of Leicester certain milestone payments or a certain percentage of any sublicense revenue received by us for the attainment of such milestone, as well as a certain percentage of all royalty payments we receive from any sublicensees.

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

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

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

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

Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

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

## Intellectual Property

### *General*

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

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

As of March 30, 2016, we owned or had exclusive license rights to five U.S. patents and 27 foreign patents, expiring on various dates between 2024 and 2029. These patents relate to the therapeutic uses of bacteriophages, bacteriophage compositions, the sequential use of bacteriophages in combination with conventional antibiotics, genetic sequence variations, biofilm disrupting agents, methods to reduce antibiotic resistance, and methods to design therapeutic combination panels of bacteriophage.

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

Under an existing license from the United Kingdom Secretary of State for the Department of Health (DoH), we have exclusive rights to a patent portfolio related to the use of bacteriophages combined with biofilm-disrupting agents in treating biofilm infections. This portfolio includes one issued patent in the United States (U.S.) and a patent granted in Europe (EP1587520 is validated in France, Germany, Netherlands, Switzerland/Liechtenstein and the United Kingdom). Claims issued in these patents include those directed to compositions and methods related to agents that are able to facilitate the penetration of biofilms, and their combination with therapeutic bacteriophage preparations.

The U.S. patent is expected to expire in November 2026 (absent any extensions). The foreign patents are expected to expire in January 2024 (absent any extensions).

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

Through our wholly owned subsidiary, Biocontrol Ltd, we own three granted U.S. patents and one pending U.S. continuation patent application (US14/919,672) with claims directed generally to bacteriophage compositions, therapeutic methods of using bacteriophages, and methods of treating bacterial infections by sequentially administering bacteriophages in combination with conventional antibiotics. The pending U.S. continuation application relates generally to panels of bacteriophages with different strain specificities for bacterial infections. Corresponding patents have been granted in Australia (AU2004258731), Europe (EP1663265 and EP2570130), Japan (JP5731727 and JP5856556) and Canada (CA2533352). Claims issued in these patents include those directed to therapeutic and non-therapeutic applications of bacteriophage and the sequential use of antibiotics to treat bacterial infections. U.S. patents are expected to expire from July 2024 to March 2027 (absent any extensions). The foreign patents are expected to expire in July 2024 to March 2027 (absent any extensions).

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

Through our wholly owned subsidiary, Biocontrol Ltd, we own one granted U.S. patent, and one pending continuation application related to bacteriophage-induced induction of antibiotic sensitivity for *Pseudomonas aeruginosa*. The granted U.S. patent is expected to expire in July 2029 (absent any extensions). The U.S. continuation application is directed to bacteriophage-induced antibiotic sensitivity for other bacterial species. A corresponding patent has granted in Australia (AU2008224651), and related applications are under examination in Canada, Europe and Japan. Foreign patents in this family are expected to expire in March 2028 (absent any extensions).

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

Through our wholly owned subsidiary, Biocontrol Ltd, we own a PCT application relating to the design of effective combinations of bacteriophages. The PCT application published on November 7, 2013, and national phase applications are currently pending in the U.S., Canada, Europe, Japan, and Australia. Patents issuing from this PCT, if any, are expected to expire in May 2023 (absent any extensions).

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



Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

Pursuant to the terms of the Asset Purchase Agreement with Novolytics Ltd., we own one U.S. patent application (14/686315), which has been refiled as a continuation application, relating to certain phages targeting MRSA via bacteriophage K and bacteriophage P68. A corresponding patent has been granted in Australia (AU2008306626) and China (CN200880110119.7) and related applications are pending in India, Japan, Canada and Europe. The granted foreign patents are expected to expire October 2028 (absent any extensions).

***PCT WO2013/068743 (United Kingdom priority filing 0800149.7); Novel bacteriophage***

Pursuant to the terms of the Asset Purchase Agreement with Novolytics Ltd., we own one U.S. patent application (14/356869). This application again relates to the MRSA therapeutic target area via Phage K mutants and the methods of using bacteriophage K. Related applications are also pending in Australia, China, Canada, India, Japan and Europe. Any potential applications would expire in November 2032.

Our success in preserving market exclusivity for our product candidates relies on patent protection, including extensions to this where appropriate, and on data exclusivity relating to an approved biologic. This may be extended by orphan drug and/or pediatric use protection where appropriate. Once any regulatory period of data exclusivity expires, depending on the status of our patent coverage, we may not be able to prevent others from marketing and selling biosimilar versions of our product candidates. We are also dependent upon the diligence of our appointed agents in national jurisdictions, acting for and on behalf of the Company, which manage the prosecution of pending domestic and foreign patent applications and maintain granted domestic and foreign patents.

## **Competition**

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

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

need for using multiple phages in a product.

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

Our bacteriophage programs may compete with or be synergistic with currently approved antibiotics, and experimental approaches such as novel antibiotics, antimicrobial peptides, antimicrobial vaccines, metals, antisense, monoclonal antibodies and possibly microbiome manipulation. For example, Seres Therapeutics is developing a single-dose capsule (SER-109) consisting of bacterial spores to treat recurrent CDI (*Clostridium difficile* infection). In May 2015, Seres initiated a multi-center, randomized, placebo-controlled Phase 2 clinical trial, to assess the efficacy and safety of SER-109. SER-109, or similar products that may be in development by third parties, could prove to be competitive to or used in conjunction with a bacteriophage therapeutic approach.

## **Manufacturing and Supply**

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

After conducting a global search, we elected to proceed with establishing a wholly-owned cGMP compliant manufacturing facility in Ljubljana, Slovenia. Upon final product selection, we plan to manufacture each of our product candidates in this facility. We have been able to access and hire highly skilled process development and phage manufacturing expertise and believe that we have control of our proprietary platform from phage identification through final product fill and finish. Our facility is comprised of approximately 4,000 sq. ft. of laboratory and office space, where we produce cGMP clinical trial supplies for our current and planned preclinical studies and clinical trials. We believe this facility could be sufficient to meet our manufacturing needs through initial Phase 3 clinical trials. Our current formulation for AB-SA01 is intended for sinonasal or topical delivery via a nasal wash solution or dressed bandage. We plan to further optimize future formulations of our product candidates for delivery to patients with wound and skin infections.

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

### **Commercialization and Marketing**

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

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

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

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

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

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

- completion of preclinical laboratory tests, animal studies and formulation studies according to good laboratory practice requirements, or GLP, or other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin in the United States;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices, or GCPs, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use or uses;
- submission to the FDA of a Biologics License Application 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 Biologics License Application; and
- FDA review and approval, or licensure, of the Biologics License Application which must occur before a biological product can be marketed or sold.

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

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

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

Before testing any compounds with potential therapeutic value in humans, the biological product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product biology, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the biological product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLP. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the Investigational New Drug Application. The Investigational New Drug Application automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the Investigational New Drug Application on a clinical hold within that 30 day time period. In such a case, the Investigational New Drug Application sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be certain that submission of an Investigational New Drug Application will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such clinical trial.

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

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

Phase 1: The biological product is initially introduced into healthy human subjects and tested primarily for safety and dosage tolerance. Absorption, metabolism, distribution and excretion may also be tested.

Phase 2: The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

Phase 3: Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA and other regulatory authorities for approval of a marketing application.

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

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

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

### ***United States Review and Approval Processes***

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

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each Biologics License Application must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual product fee for biologics, and an annual establishment fee on facilities used to manufacture prescription biologics. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on Biologics License Applications for products designated as orphan drugs, unless the product also includes a non-orphan indication.

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

### ***Special FDA Expedited Review and Approval Programs***



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

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

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

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

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

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***

Under the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Amendments, a portion of a product’s patent term that was lost during clinical development and application review by the FDA may be restored.

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

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

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

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

A reference biological product is granted twelve years of exclusivity from the time of first licensure of the reference product. The first biological product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitting under the abbreviated approval pathway for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant’s favor of a lawsuit challenging the biologic’s patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period.

### ***FDA Post-Approval Requirements***

Maintaining substantial compliance with applicable federal, state, local, and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to cGMP. We will rely on third parties for the production of commercial quantities of any products that we may commercialize. We and third party manufacturers of our products are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP and other FDA regulatory requirements. Other post-approval requirements applicable to biological products include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects,

reporting updated safety and efficacy information, and complying with electronic record and signature requirements. After a Biologics License Application is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products.

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

Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products are required to register their facilities with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with 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 biological products, including direct-to-consumer advertising, promotional activities involving the internet, and industry-sponsored scientific and educational activities. While doctors are free to prescribe any product approved by the FDA for any use, a company can only make claims relating to safety and efficacy of a biological product that are consistent with FDA approval, and the company is allowed to actively market a biological product only for the particular use and treatment approved by the FDA. In addition, any claims we make for our products in advertising or promotion must be appropriately balanced with important safety information and otherwise be adequately substantiated. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising, injunctions and potential civil and criminal penalties.

### ***Other Healthcare Laws and Compliance Requirements***

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

### ***International Regulation***

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

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

### ***Pricing and Reimbursement***

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

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

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

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

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

In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors, including government health administrative authorities, managed care providers, private health insurers and other organizations. Third-party payors are increasingly examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy, and, accordingly, significant uncertainty exists as to the reimbursement status of newly approved therapeutics.

Adequate third-party reimbursement may not be available for our products to enable us realize an appropriate return on our investment in research and product development.

## **Research and Development Expenses**

Our research and development expenses were \$4.0 million and \$5.8 million in 2015 and 2014, respectively.

## Employees

As of March 25, 2016, we had 28 full-time employees and two consultants. Of these full-time employees, 23 employees are engaged in research and development activities and five employees are engaged in finance, legal, human resources, facilities and general management. We have no collective bargaining agreements with our employees, we have not experienced any work stoppages and we believe our relations with our employees are good.

## Corporate Information

Our website address is <http://www.ampliphio.com>. Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge through our website as soon as reasonably practicable after they are electronically filed with, or furnished to, the Securities and Exchange Commission, or the SEC. We will also provide the reports in electronic or paper form free of charge upon request. The SEC maintains a website that contains our public filings with the SEC and other information regarding the Company, at [www.sec.gov](http://www.sec.gov). These reports and other information concerning the Company may also be accessed at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Our website and the information contained on, or that can be accessed through our website, will not be deemed to be incorporated by reference in, and are not considered part of, this Annual Report on Form 10-K.

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



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

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

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

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

We have incurred losses in each year since our inception in 1992. Prior to our merger with Biocontrol in January 2011, our accumulated deficit was \$315.5 million. Since January 2011 through December 31, 2015, we have incurred a cumulative deficit of \$47.0 million, and we expect to incur losses for the foreseeable future. We have devoted, and will continue to devote for the foreseeable future, substantially all of our resources to research and development of our product candidates. For the year ended December 31, 2015 we had an operating loss of \$10.2 million. Additional information regarding our results of operations may be found in our consolidated financial statements and in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this report.

Clinical trials and activities associated with discovery research are costly. We do not expect to generate any revenue from the commercial sales of our product candidates in the near term, and we expect to continue to have significant losses for the foreseeable future.

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

*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 FDA, the 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.

***We will need to raise additional capital to continue operations.***

Our consolidated financial statements for the year ended December 31, 2015 were prepared under the assumption that we would continue our operations as a going concern. However, we have had recurring losses from operations, negative operating cash flow and an accumulated deficit.

In December 2013, we raised gross proceeds of approximately \$18.0 million through a private placement of shares of our common stock. In March 2015, we raised gross proceeds of approximately \$13.0 million through a private placement of shares of our common stock. We do not generate any cash from operations and must raise additional

funds in order to continue operating our business. We expect to continue to fund our operations primarily through equity and debt financings in the future. If additional capital is not available 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. As of December 31, 2015, we had cash and cash equivalents of \$9.4 million. We believe that our existing resources will be sufficient to fund our planned operations through the third quarter of 2016.

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

- the costs and timing of our research and development activities;
- the progress and cost of our clinical trials and other research and development activities;
- the cost and timing of securing manufacturing capabilities for our clinical product candidates and commercial products, if any;
- the terms and timing of any collaborative, licensing, acquisition or other arrangements that we may establish;
- the costs and timing of seeking regulatory approvals;
- the costs of filing, prosecuting, defending and enforcing any patent applications, claims, patents and other intellectual property rights; and
- the costs of lawsuits involving us or our product candidates.

We will need to raise additional capital to support our product development activities in 2016 and beyond. We may seek funds through arrangements with collaborators or others that may require us to relinquish rights to the products candidates that we might otherwise seek to develop or commercialize independently. We cannot be certain that we will be able to enter into any such arrangements on reasonable terms, if at all.

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

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

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 status of our product development activities and other business operations, 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 at all. Raising additional capital through the sale of securities could cause significant dilution to our stockholders. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through additional arrangements that may require us to relinquish rights to certain of our products, technologies or potential markets, any of which could delay or require that we curtail or eliminate some or all of our development programs or otherwise have a material adverse effect on our business, financial condition and results of operations. In addition, we may have to delay, reduce the scope of or eliminate some of our research and development, which could delay the time to market for any of our product candidates, if adequate funds are not available.

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

***We have a disagreement with one of our principal stockholders regarding the interpretation of our Amended and Restated Articles of Incorporation.***

We have a disagreement with one of our principal stockholders, Third Security, LLC. Third Security, together with its affiliates, including Randal J. Kirk, is currently the beneficial owner of approximately 27.2% of our outstanding shares of common stock, including securities convertible into common stock (Common Shares). Additionally, Third Security is currently the beneficial owner of approximately 28.5% of our outstanding shares of Series B redeemable convertible preferred stock (Series B Preferred). Julian Kirk, the son of Randal J. Kirk and a member of our Board of Directors, is a Managing Director of Third Security.

Section 4.4.4(b) of Article 4 of our Amended and Restated Articles of Incorporation provides in relevant part as follows:

“Automatic Conversion. The shares of Series B Preferred shall be automatically converted into fully paid and non-assessable Common Shares, at the then applicable Series B Preferred Conversion Rate (i) upon the closing of an underwritten initial public offering with aggregate offering proceeds to [AmpliPhi] of at least \$7,000,000 (after reduction for underwriting discounts and commissions) and a price per share to the public of at least the Series B Stated Value (subject to adjustment in the event of any . . . stock split . . .) upon the closing of which the shares of Common Stock of [AmpliPhi] shall be listed for trading on the . . . New York Stock Exchange . . . or (ii) at the election of the holders of two-thirds (2/3) of the then outstanding shares of Series B Preferred.”

We refer to an underwritten public offering that meets all of the parameters specified in Section 4.4.4(b)(i) of our Amended and Restated Articles of Incorporation as a “Qualified Public Offering.” In June and July 2013, when our shares were not listed on any exchange, we issued shares of Series B Preferred to Third Security and other investors as part of a private placement in which we raised approximately \$13.3 million (the Series B Financing). In December 2013, we filed a Registration Statement on Form 10 and registered our shares for trading on the OTC. In March 2015, we issued Common Shares to Third Security and other investors as part of a private placement in which we raised approximately \$13.0 million. In August 2015, we completed our listing application and our Common Shares began trading on the New York Stock Exchange’s NYSE MKT Exchange (NYSE MKT). Since the Series B Financing, we have not completed an underwritten public offering of our stock.



As part of our ongoing management of our business, we frequently evaluate financing alternatives with the objective of assessing opportunities to raise capital needed for the advancement of our business. We may seek to raise capital through a variety of sources, including the public equity market, private equity financings, collaborative arrangements, licensing arrangements and/or public or private debt. We believe that at such time as we consummate our first underwritten public offering that otherwise meets the specified parameters for a Qualified Public Offering set forth in Section 4.4.4(b)(i) of our Amended and Restated Articles of Incorporation, the Series B Preferred should automatically convert into Common Shares.

In the fourth quarter of 2015, Third Security informed us that, under its interpretation of our Amended and Restated Articles of Incorporation, the Qualified Public Offering conditions set forth in Article 4 of our Amended and Restated Articles of Incorporation can never be satisfied because our stock is publicly traded on the NYSE MKT, and that the only way all outstanding Series B Preferred can be converted to Common Shares is by obtaining the requisite consent of the Series B Preferred stockholders. We disagree with Third Security's interpretation. In an attempt to resolve the disagreement, we formed a special committee of our Board, consisting of disinterested directors Michael Perry, Paul Grint and Vijay Samant (Special Committee), that has been delegated full authority to negotiate and finalize relevant settlement arrangements with Third Security and other holders of Series B Preferred relating to the interpretation of our Amended and Restated Articles of Incorporation. Over the past several months, the Special Committee has attempted to reach a mutually acceptable agreement with Third Security and other holders of the Series B Preferred regarding voluntary conversion of the outstanding Series B Preferred to Common Shares. We cannot assure you that the Special Committee will be able to reach agreement with Third Security or other holders of Series B Preferred on reasonable terms or at all.

Our Amended and Restated Articles of Incorporation also contain various other ambiguities, such as in the provisions relating to the conversion rate for converting Series B Preferred into Common Shares and the stated value of the Series B Preferred following our 50:1 reverse split of our Common Shares in August 2015. The stated value of the Series B Preferred affects other provisions of our Amended and Restated Articles of Incorporation, including the anti-dilution rights for the Series B Preferred as well as the minimum public offering price per share necessary for a public offering to satisfy one of the Qualified Public Offering conditions. These ambiguities, as well as Third Security's interpretation of the Qualified Public Offering conditions, create uncertainty around our capital structure, which may adversely affect our ability to raise capital. If adequate funds are not available on a timely basis on acceptable terms, we may be required to significantly reduce, delay or refocus our research and development programs, sell or relinquish rights to our products, technologies or other assets or merge all or a portion of our business with another entity, any of which could delay the time to market of our product candidates and have a material adverse effect on our business, financial condition and results of operations. This uncertainty around our ability to secure additional financing creates substantial doubt about our ability to continue as a going concern.

Attached to this Annual Report as Exhibits 99.1 and 99.2 are letters dated March 15, 2016 and March 28, 2016 from outside counsel to New River Management VII, LP, the record holder of the shares of Series B Preferred beneficially owned by Third Security. The letters were provided in response to our furnishing drafts of this risk factor to Julian Kirk prior to filing this Annual Report. We express no opinion as to the accuracy of the factual characterizations or legal analyses contained in the letters.

In order to reach agreement with Third Security and/or other holders of Series B Preferred regarding the interpretation of our Amended and Restated Articles of Incorporation and/or voluntary conversion of the outstanding Series B Preferred to Common Shares, we may be required to pay significant consideration, which may include the issuance of additional Common Shares to those holders and which could result in significant dilution to current holders of our Common Shares. If we are unable to reach agreement on acceptable terms with Third Security and/or other holders of Series B Preferred, we may decide to initiate litigation in the State of Washington seeking a declaratory judgment as to the interpretation of our Amended and Restated Articles of Incorporation. Such litigation would be expensive and time consuming, and would utilize valuable capital needed for the operation of our business. There can be no assurance that we would prevail in any litigation regarding our Amended and Restated Articles of Incorporation, that the court would agree with our interpretation of the Qualified Public Offering conditions or any of the ambiguous provisions of our Amended and Restated Articles of Incorporation, or that the court would not interpret any of the provisions of our Amended and Restated Articles of Incorporation in a manner unfavorable to us. If the court in such litigation were to agree with Third Security's interpretation or to otherwise determine the matter unfavorably to us, our ability to raise capital may be severely impaired, which may have a material adverse effect on our business, financial condition and ability to continue operating as a going concern.

***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.***

Our financial statements as of December 31, 2015 were prepared under the assumption that we will continue as a going concern. The independent registered public accounting firm that audited our 2015 consolidated financial statements, in their report, included an explanatory paragraph referring to our recurring losses and expressing substantial doubt in our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. At December 31, 2015, we had cash and cash equivalents of \$9.4 million. Our ability to continue as a going concern depends on our ability to raise substantial additional funds through public or private equity offerings, collaborative or licensing arrangements and/or debt financing.

***We may be required to make cash payments to the holders of our Series B redeemable convertible preferred stock.***

The holders of our shares of Series B Preferred are entitled to receive accruing, cumulative dividends at the rate of 10% per annum, payable in cash at the option of the holders of two-thirds of the shares of Series B Preferred (a) when, as and if declared by our Board of Directors, (b) upon an acquisition of our company or (c) upon redemption of the Series B Preferred. In addition, if holders of Series B Preferred elect to convert their shares to common stock, or if the Series B Preferred is automatically converted pursuant to the provisions of our articles of incorporation, all accrued but unpaid dividends on the Series B Preferred will become payable upon conversion. If such holders elect to receive payment for such dividends in cash, or if dividends are required to be paid upon conversion, we will have less cash available, which will have a negative effect on our operations and financial results. As of December 31, 2015, the aggregate amount of accrued but unpaid dividends was \$3.2 million. In addition, at any time on or after June 26, 2018, the holders of at least two-thirds of the outstanding Series B Preferred may require us to redeem all of the outstanding Series B Preferred for an amount equal to the original issue price per share plus any accrued and unpaid dividends.





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

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

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"). These limitations apply if an "ownership change," as defined by Section 382 of the Code, occurs. If we have experienced an "ownership change" at any time since our formation, we may already be subject to limitations on our ability to utilize our existing net operating losses and other tax attributes to offset taxable income. In addition, future changes in our stock ownership (including in connection with future private or public offerings, as well as changes that may be outside of our control), may trigger an "ownership change" and, consequently, limitations under Sections 382 and 383 of the Code. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other pre-change tax attributes to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As of December 31, 2015, we had U.S. federal and state net operating loss carryforwards of approximately \$182.3 million and \$37.3 million, respectively, foreign NOLs of \$8.5 million and U.S. research and development credits of \$5.2 million, which could be limited if we have experienced or do experience any "ownership changes." We have not completed a study to assess whether an "ownership change" has occurred or whether there have been multiple "ownership changes" since our formation, due to the complexity and cost associated with such a study, and the fact that there may be additional ownership changes in the future.

***For the fiscal year ended December 31, 2014 and 2015, respectively, our management assessed the effectiveness of our internal control over financial reporting and determined that it was not effective. If we fail to remediate this material weakness or to achieve and maintain proper and effective internal control over financial reporting, our ability to produce accurate financial statements on a timely basis could be impaired and our public reporting may be unreliable.***

We are required to maintain internal control over financial reporting adequate to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements in accordance with generally accepted accounting principles. In connection with the restatement of our consolidated financial statements for the second quarter of 2015 and for the quarterly and annual periods of 2014, we determined that we had a material weakness as of December 31, 2014 and December 31, 2015, namely that our internal control over financial reporting, including control over the evaluation and review of complex and non-routine transactions, were not effective. A material weakness means a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the registrant's annual or interim financial statements will not be prevented or detected on a timely basis.

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

We are taking steps to remediate the material weakness in our internal control over financial reporting, including designing additional training programs for relevant personnel and developing specific review procedures regarding the review of complex and non-routine transactions. However, we cannot assure you that these efforts will remediate our material weakness in a timely manner, or at all. If we are unable to successfully remediate our material weakness, or identify any future material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports and we may experience a loss of public confidence, which could have an adverse effect on our business, financial condition and the market price of our common stock and other securities.

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

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

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

## **Risks Related to Our Business**

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

We are developing our product candidates with bacteriophage technology. We have not, nor to our knowledge has any other company, received regulatory approval from the FDA or equivalent foreign agencies for a pharmaceutical drug based on this approach. While *in vitro* studies have characterized the behavior of bacteriophages in cell cultures and there exists a body of literature regarding the use of phage therapy in humans, the safety and efficacy of phage therapy in humans has not been extensively studied in well-controlled modern clinical trials. Most of the prior research on phage-based therapy was conducted in the former Soviet Union prior to and immediately after World War II and lacked appropriate control group design or lacked control groups at all. Furthermore, the standard of care has changed substantially during the ensuing decades since those studies were performed, diminishing the relevance of prior claims of improved cure rates. We cannot be certain that our approach will lead to the development of approvable or marketable drugs.

Developing phage-based therapies on a commercial scale will also require developing new manufacturing processes and techniques. We and our third-party collaborators may experience delays in developing manufacturing capabilities for our product candidates, and may not be able to do so at the scale required to efficiently conduct the clinical trials required to obtain regulatory approval of our product candidates, or to manufacture commercial quantities of our products, if approved.

In addition, the FDA or other regulatory agencies may lack experience in evaluating the safety and efficacy of drugs based on these approaches, which could lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our product candidates.

***Delays in our clinical trials could result in us not achieving anticipated developmental milestones when expected, increased costs and delay our ability to obtain regulatory approval for and commercialize our product candidates.***

Delays in our ability to commence or enroll patients for our clinical trials could result in us not meeting anticipated clinical milestones and could materially impact our product development costs and delay regulatory approval of our product candidates. Planned clinical trials may not be commenced or completed on schedule, or at all. Clinical trials can be delayed for a variety of reasons, including:

- delays in the development of manufacturing capabilities for our product candidates to enable their consistent production at clinical trial scale;
- failures in our internal manufacturing operations that result in our inability to consistently and timely produce bacteriophages in sufficient quantities to support our clinical trials;
- the availability of financial resources to commence and complete our planned clinical trials;
- delays in reaching a consensus with clinical investigators on study design;
- delays in reaching a consensus with regulatory agencies on trial design or in obtaining regulatory approval to commence a trial;
- delays in obtaining clinical materials;
- slower than expected patient recruitment for participation in clinical trials;
- failure by clinical trial sites, other third parties, or us to adhere to clinical trial agreements;
- delays in reaching agreement on acceptable clinical trial agreement terms with prospective sites or obtaining institutional review board approval; and
- adverse safety events experienced during our clinical trials.

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

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

- the therapeutic endpoints chosen for evaluation;
- the eligibility criteria defined in the protocol;
- the perceived benefit of the product candidate under study;
- the size of the patient population required for analysis of the clinical trial's therapeutic endpoints;
- our ability to recruit clinical trial investigators and sites with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents; and
- competition for patients from clinical trials for other treatments.

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

***We have not completed formulation development of any of our product candidates.***

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

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

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

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

- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing or to abandon programs;
- the results obtained in earlier stage clinical testing may not be indicative of results in future clinical trials;
- clinical trial results may not meet the level of statistical significance required by the FDA or other regulatory agencies;
- we, or regulators, may suspend or terminate our clinical trials if the participating patients are being exposed to unacceptable health risks; and
- our product candidates may have unintended or undesirable effects on patients that may delay or preclude regulatory approval of our product candidates or limit their commercial use, if approved.

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

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

To satisfy FDA or foreign regulatory approval standards for the commercial sale of our product candidates, we must demonstrate in adequate and controlled clinical trials that our product candidates are safe and effective. Success in early clinical trials, including Phase 2 trials, does not ensure that later clinical trials will be successful. Our initial results from early stage clinical trials also may not be confirmed by later analysis or subsequent larger clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials and most product candidates that commence clinical trials are never approved for commercial sale.

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

We are developing novel manufacturing processes for our product candidates at our facility in Ljubljana, Slovenia. The manufacturing processes for our product candidates, and the scale up of such processes for clinical trials, is novel, and there can be no assurance that we will be able to complete this work in a timely manner, if at all. Any delay in the development or scale up of these manufacturing processes could delay the start of clinical trials and harm our business. Our facility in Slovenia must also undergo ongoing inspections by JAZMP, the Slovenian agency that regulates and supervises pharmaceutical products in Slovenia, for compliance with their and the European Medicines Agency's, or EMA's, current good manufacturing practice regulations, or cGMP regulations, before the respective product candidates can be approved for use in clinical trials or commercialization. In the event these facilities do not receive a satisfactory cGMP inspection for the manufacture of our product candidates, we may need to fund additional modifications to our manufacturing process, conduct additional validation studies, or find alternative manufacturing facilities, any of which would result in significant cost to us as well as a delay of up to several years in obtaining approval for such product candidate.

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

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

We are currently conducting an investigator-sponsored clinical trial of AB-SA01 at the University of Adelaide in Australia for chronic rhinosinusitis, and may seek to conduct one or more other clinical trials in the future outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of such study data by the FDA is subject to certain conditions. For example, the study must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The study population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical studies conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. In addition, such studies would be subject to the applicable local laws and FDA acceptance of the data would be dependent upon its determination that the studies also complied with all applicable U.S. laws and regulations. There can be no assurance the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept any such data, it would likely result in the need for additional trials, which



would be costly and time consuming and delay aspects of our business plan.

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

The development and commercialization of phage-based antibacterial agents may require us to obtain rights to intellectual property from third parties. For example, pursuant to our Collaborative Research and Development Agreement with the United States Army Medical Research and Materiel Command and the Walter Reed Army Institute of Research, we are 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 conducting an investigator-sponsored clinical trial of AB-SA01 at the University of Adelaide. To the extent that intellectual property is generated as a result of the study that is used in a commercial product, we may be obligated to make payments, such as royalties, licensing fees, and milestone payments. There can be no assurance that such intellectual property rights would be available on commercially reasonable terms, if at all.

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

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

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

Regulatory approval, if obtained, may be made subject to limitations on the indicated uses for which we may market a product. These limitations could adversely affect our potential product revenues. Regulatory approval may also require costly post-marketing follow-up studies. In addition, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping related to the product will be subject to extensive ongoing regulatory requirements. Furthermore, for any marketed product, its manufacturer and its manufacturing facilities will be subject to continual review and periodic inspections by the FDA or other regulatory authorities. Failure to comply with applicable regulatory requirements may, among other things, result in fines, suspensions of regulatory approvals, product recalls, product seizures, operating restrictions and criminal prosecution.

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

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

- compliance with differing or unexpected regulatory requirements for the development, manufacture and, if approved, commercialization of our product candidates;
- difficulties in staffing and managing foreign operations;
- foreign government taxes, regulations and permit requirements;
- U.S. and foreign government tariffs, trade restrictions, price and exchange controls and other regulatory requirements;
- anti-corruption laws, including the Foreign Corrupt Practices Act, or the FCPA;
- economic weakness, including inflation, natural disasters, war, events of terrorism or political instability in particular foreign countries;
- fluctuations in currency exchange rates, which could result in increased operating expenses and reduced revenues, and other obligations related to doing business in another country;
- compliance with tax, employment, immigration and labor laws, regulations and restrictions for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- changes in diplomatic and trade relationships; and
- challenges in enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States.

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

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

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

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

Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. As of March 25, 2016, we had 28 employees. Our success will depend on our ability to retain and motivate personnel and hire additional qualified personnel when required. Competition for qualified personnel in the biotechnology field is intense. We face competition for personnel from other biotechnology and pharmaceutical companies, universities, public and private research institutions and other organizations. We also face competition from other more well-funded and well-established businesses and we may also be viewed as a riskier choice from a job stability perspective due to our relative newer status than longer existing biotech and pharmaceutical companies. We may not be able to attract and retain qualified personnel on acceptable terms given the competition for such personnel. If we are unsuccessful in our retention, motivation and recruitment efforts, we may be unable to execute our business strategy.

***We must manage a geographically dispersed organization.***

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



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

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

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

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

We expect to use third parties, such as clinical research organizations or the U.S. Army, to assist in conducting our clinical trials. However, we may face delays outside of our control if these parties do not perform their obligations in a timely or competent fashion or if we are forced to change service providers. This risk is heightened for clinical trials conducted outside of the United States, where it may be more difficult to ensure that clinical trials are conducted in compliance with FDA requirements. Any third-party that we hire to conduct clinical trials may also provide services to our competitors, which could compromise the performance of their obligations to us. If we experience significant delays in the progress of our clinical trials and in our plans to submit Biologics License Applications, the commercial prospects for product candidates could be harmed and our ability to generate product revenue would be delayed or prevented.

## **Risks Related to Our Intellectual Property**

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

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

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

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

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

patents, our rights under those patents may be challenged and ultimately not provide us with sufficient protection against competitive products or processes.

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

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

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

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

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



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

Our ability to commercialize our product candidates depends on our ability to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. Numerous United States and foreign patents and patent applications, which are owned by third parties, exist in the general field of anti-infective products or in fields that otherwise may relate to our product candidates. If we are shown to infringe, we could be enjoined from use or sale of the claimed invention if we are unable to prove that the patent is invalid. In addition, because patent applications can take many years to issue, there may be currently pending patent applications, unknown to us, which may later result in issued patents that our product candidates may infringe, or which may trigger an interference proceeding regarding one of our owned or licensed patents or applications. There could also be existing patents of which we are not aware that our product candidates may inadvertently infringe or which may become involved in an interference proceeding.

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

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

## Risks Related to Our Industry

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

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

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

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

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

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

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

- delay or failure to complete our clinical trials;
- withdrawal of clinical trial participants;
- decreased demand for our product candidates;
- injury to our reputation;
- litigation costs;
- substantial monetary awards against us; and
- diversion of management or other resources from key aspects of our operations.

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

We have product liability insurance that covers our clinical trials up to a \$10.0 million annual per claim and aggregate limit. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates or any other compound that we may develop. However, insurance coverage is expensive and we may not be able to maintain insurance coverage at a reasonable cost or at all, and the insurance coverage that we obtain may not be adequate to cover potential claims or losses.

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

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

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



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

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

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

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

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

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

### **Risks Related to Our Common Stock**

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

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

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

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

As of December 31, 2015, we had outstanding warrants to purchase 1,209,649 shares of our common stock at an average exercise price of \$8.96 per share, and outstanding options to purchase 669,769 shares of our common stock at an average exercise price of \$8.68 per share. The exercise price and/or the number of shares of common stock issuable upon exercise of the warrants may be adjusted in certain circumstances, including certain issuances of securities at a price equal to or less than the then current exercise price, subdivisions and stock splits, stock dividends, combinations, reorganizations, reclassifications, consolidations, mergers or sales of properties and assets and upon the issuance of certain assets or securities to holders of our common stock, as applicable. Although we cannot determine when these warrants or options will ultimately be exercised, it is reasonable to assume that such warrants and options will be exercised only if the exercise price is below the market price of our common stock. To the extent any of our outstanding warrants or options are exercised, additional shares of our common stock will be issued that will generally be eligible for resale in the public market (subject to limitations under Rule 144 under the Securities Act 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.

As of December 31, 2015, there were 7,527,853 outstanding shares of our Series B redeemable convertible preferred stock. Each share of Series B redeemable convertible preferred stock is convertible into 0.20 shares of common stock and accrues dividends at the rate of 10% per year compounded annually. At December 31, 2015, these shares would be convertible into 1,505,571 shares of common stock and the accrued dividends on these shares totaled \$2.8 million. These shares of Series B redeemable convertible preferred stock also have certain liquidation preferences that in the event of a sale, merger, liquidation or certain reorganization transactions could have the effect of reducing the value attributable to common stockholders.

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

As of December 31, 2015, our executive officers, directors, principal stockholders and their affiliates beneficially owned a majority of our outstanding voting stock. Therefore, these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments

of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

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

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

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

In addition, because we are incorporated in Washington, we are governed by the provisions of Chapter 23B.19 of the Washington Business Corporation Act, which, among other things, restricts the ability of 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 acquirors 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. In addition, pursuant to our articles of incorporation, we are not permitted to pay cash dividends on our common stock until all accrued dividends on the outstanding Series B shares have been paid in full. 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 Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act and the rules of the NYSE MKT. The requirements of these rules and regulations increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and place strain on our personnel, systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition.

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

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

In accordance with NYSE MKT rules, we are required to maintain a majority independent board of directors. The various rules and regulations applicable to public companies make it more difficult and more expensive for us to

maintain directors' and officers' liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to maintain coverage. If we are unable to maintain adequate directors' and officers' insurance, our ability to recruit and retain qualified officers and directors will be significantly curtailed.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We currently have 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 \$1.0 billion or (c) in which we are deemed to be a "large accelerated filer" under the Exchange Act, which means that the market value of our common stock that is held by non-affiliates exceeds \$700 million as of June 30<sup>th</sup> of the prior year, and (ii) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

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

volatile.

35

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

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

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

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

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

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

**Item 1B. UNRESOLVED STAFF COMMENTS**

Not applicable to the Company as a smaller reporting company.

**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 1,550 square feet of lab and office space in Richmond, Virginia, approximately 5,000 square feet of lab space in Brookvale, Australia, and approximately 4,000 square feet of lab and office space in Ljubljana, Slovenia. We believe our facilities are adequate for our current and near-term needs.

**Item 3. LEGAL PROCEEDINGS**

None.

**Item 4. MINE SAFETY DISCLOSURES**

Not applicable.

**PART II**

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

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

The following table sets forth the range of reported high and low sales prices for our common stock on the NYSE MKT for the periods in the table below from August 21, 2015 through December 31, 2015, and the high and low bid

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

quotations for the periods in the table from January 1, 2014 through August 20, 2015. The quotations reflect inter-dealer prices, without retail markup, markdown or commission, and may not represent actual transactions. Consequently, the information provided below may not be indicative of our common stock price under different conditions. All prices prior to August 3, 2015 reflect an adjustment for our 1-for-50 reverse stock split.

	High	Low
Fiscal Year 2015		
Fourth Quarter ended December 31, 2015	\$8.25	\$3.00
Third Quarter ended September 30, 2015	\$11.70	\$3.95
Second Quarter ended June 30, 2015	\$14.25	\$8.00
First Quarter ended March 31, 2015	\$15.00	\$7.50
Fiscal Year 2014		
Fourth Quarter ended December 31, 2014	\$10.25	\$6.12
Third Quarter ended September 30, 2014	\$21.00	\$10.00
Second Quarter ended June 30, 2014	\$28.50	\$18.50
First Quarter ended March 31, 2014	\$32.00	\$25.00

### Holders of Common Stock

As of March 25, 2016, there were 140 holders of record of our common stock. As of such date, there were 5,883,503 shares of our common stock outstanding. In addition, as of such date, there were 21 holders of record of our Series B redeemable convertible preferred stock and 7,527,853 shares of Series B redeemable convertible preferred stock outstanding, convertible into an aggregate of 1,505,571 shares of our common stock based on conversion ratio equal to 0.20 common shares for each share of Series B redeemable convertible preferred stock.

### Dividends

We have never declared or paid any cash dividends or distributions on our common stock. We expect that we will retain all of our available funds and future earnings, if any, for use in the operation and expansion of our business. Subject to the foregoing, the payment of cash dividends in the future, if any, will be at the discretion of our board of directors and will depend upon such factors as earnings levels, capital requirements, restrictions imposed by applicable law, our overall financial condition and any other factors deemed relevant by our board of directors. In addition, we are currently restricted from paying cash dividends on our common stock (i) at a rate greater than the rate at which dividends are paid on our Series B redeemable convertible preferred stock and (ii) until all accrued dividends on our Series B redeemable convertible preferred stock have been paid in full.

## Recent Sales of Unregistered Securities

On March 10, 2015, we entered into subscription agreements to issue an aggregate amount of 1,575,758 shares of common stock as well as warrants to purchase an aggregate 393,939 shares of our common stock for an aggregate purchase price of approximately \$13.0 million as part of a private placement. The purchasers of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of such purchasers was an “accredited” investor” under Rule 506 of Regulation D or not a “U.S. person” under Regulation S.

In connection with our entry into an Asset Purchase Agreement with Novolytics Limited in January 2016, and in exchange for our receipt of release and non-solicitation agreements in favor of us from the shareholders of Novolytics, we issued warrants to purchase up to an aggregate of 170,000 shares of our common stock to such shareholders. The warrants have an exercise price of \$12.00 per share and contain certain registration rights. One half of the shares subject to the warrants become exercisable on the date that is the earlier of 30 days following the expiration of the lock-up period for our next public offering, or December 31, 2016. The remaining shares subject to the warrants become exercisable 60 days thereafter. The warrants will expire upon the later of the close of business of the 24-month anniversary of the date the warrants first become exercisable, as described in the preceding sentence, or the 24-month anniversary of the initial effectiveness of a registration statement covering the exercise shares.

The foregoing description of the terms of the warrants is not complete and is qualified in its entirety by reference to the warrants, the form of which is filed as Exhibit 4.13 to this report.

The warrants were issued in a private placement transaction exempt from registration pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended, and Regulation D and/or Regulation S thereunder. The recipients acquired the warrants for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the warrants. Each of the recipients was an “accredited investor” under Rule 506 of Regulation D or not a “U.S. person” under Regulation S.

## Item 6. SELECTED FINANCIAL DATA

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

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the consolidated financial statements and the related notes contained elsewhere in this Annual Report. Some of the information contained in this discussion and analysis are set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements." Our actual results may differ substantially from those referred to herein due to a number of factors, including but not limited to risks described in the section entitled "Risk Factors" and elsewhere in this Annual Report.

**Overview**

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

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

Our lead product candidate is AB-SA01, for the treatment of *S. aureus* infections, including methicillin-resistant *S. aureus*, or MRSA. We also have AB-PA01 for the treatment of *P. aeruginosa* infections in development, and AB-CD01 for the treatment of *C. difficile* infections in preclinical development.

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. We have raised approximately \$43.6 million in capital to support our operations since the shift in our focus to novel phage therapeutics in February 2011.

To date, we have not generated any product revenue and have primarily financed our operations through the sale and issuance of our equity securities and convertible notes. As of December 31, 2015, we had a cumulative deficit of \$362.5 million. We anticipate that a substantial portion of our capital resources and efforts in the foreseeable future will be focused on completing the development and obtaining regulatory approval of our product candidates.



We currently expect to use our existing cash and cash equivalents for the continued research and development of our product candidates and for working capital and other general corporate purposes.

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

We may also use a portion of our existing cash and cash equivalents for the potential acquisition of, or investment in, product candidates, technologies, formulations or companies that complement our business, although we have no current understandings, commitments or agreements to do so. We expect that these funds will not be sufficient to enable us to complete all necessary development of any potential product candidates. Accordingly, we will be required to obtain further funding through one or more other public or private equity offerings, debt financings, collaboration or licensing arrangements or other sources. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs.

## **Recent Developments**

### ***Restatement of Previously Issued Financial Statements***

In this Annual Report on Form 10-K, we have restated certain historical financial statements for the year ended, December 31, 2014, three and six months ended June 30, 2014, three and nine months ended September 30, 2014 and three months ended June 30, 2015 to reflect a revision in accounting for basic and diluted earnings per share.

The error relates to the misapplication of Accounting Standards Codification No. 260, "Earnings Per Share," or ASC 260 for two matters.

First, we did not properly consider the fact that outstanding shares of our Series B redeemable convertible preferred stock, in certain limited circumstances, have the right to receive additional dividends beyond their accruing dividends, which makes them participating securities. Therefore, consideration of this component of the preferred stock terms is included in computing basic earnings per share pursuant to the two-class method. The Company failed to make such adjustments to the basic income (loss) per share calculations for the prior periods discussed above.

Second, we did not properly account for the adjustments required to net income (loss) attributable to common stockholders in the calculation of diluted net income (loss) per share. The calculation of diluted net income (loss) per share requires that, to the extent that such securities are dilutive to income (loss) per share for the period, an adjustment to net income (loss) used in the calculation is required to remove the change in fair value of the liability classified warrants from the numerator for the period. Likewise, an adjustment to the denominator is required to reflect the related dilutive shares. Similarly, the diluted income (loss) per share calculation also requires an adjustment to net income (loss) used in the calculation to remove the change in the fair value of the Series B redeemable convertible preferred stock embedded derivative (if the Series B redeemable convertible preferred stock is dilutive), including any applicable accretion, and an adjustment to the denominator is required to reflect the related dilutive securities. The Company failed to make such adjustments to the diluted income (loss) per share calculations for the prior periods discussed above.

During the preparation process for this Annual Report on Form 10-K, we recomputed the basic and diluted income (loss) per share amounts for all periods to conform with the provisions of ASC 260.

In connection with this restatement, we revised our consolidated statement of operations for the year ended December 31, 2014, and applicable interim periods in 2014 and 2015 to reflect revised basic and diluted income (loss) per share. This adjustment had no impact on our balance sheets, reported loss from operations, net income (loss) attributable to common stockholders, statements of redeemable convertible preferred stock and stockholders' equity, or our statements of cash flows and our cash and cash equivalents balances are unchanged for such periods.

Throughout this Annual Report on Form 10-K, amounts presented from current periods and prior period comparisons have been revised and labeled as "restated" and reflect the amounts on a restated basis.

Tables summarizing the effect of the restatement on the specific line items presented in our historical financial statements for the periods indicated are included in *Note 3 – Significant Accounting Policies* and *Note 17 – Quarterly Financial Data* of the notes to our consolidated financial statements included with this Annual Report on Form 10-K.

## **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 \$362.5 million as of December 31, 2015, \$47.0 million of which has been accumulated since January of 2011, when we began our focus on bacteriophage development. These circumstances raise substantial doubt about our ability to continue as a going concern. The accompanying financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty concerning our ability to continue as a going concern.



In December 2013, we raised gross proceeds of approximately \$18.0 million through a private placement of shares of our common stock. In March 2015, we raised gross proceeds of approximately \$13.0 million through a private placement of shares of our common stock. We do not generate any cash from operations and must raise additional funds in order to continue operating our business. We frequently evaluate financing alternatives with the objective of assessing opportunities to raise capital needed for the advancement of our business. We may seek to raise capital through a variety of sources, including the public equity market, private equity financings, collaborative arrangements, licensing arrangements and/or public or private debt. We may also seek to establish other funding facilities or pursue opportunities for the divestiture of certain intellectual property and/or other assets. If we pursue and successfully raise additional capital through the sale of equity and/or debt securities, the rights of our existing stockholders may be adversely impacted and our existing stockholders could suffer dilutions. 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. As of December 31, 2015, we had cash and cash equivalents of \$9.4 million. We believe that our existing resources will be sufficient to fund our planned operations through the third quarter of 2016.

Our ability to raise additional funds will depend, in part, on the status of our product development activities and other business operations, as well as factors related to financial, economic, and market conditions, many of which are beyond our control.

In addition, we have a disagreement with one of our principal stockholders, Third Security, LLC, regarding the interpretation of our Amended and Restated Articles of Incorporation. The disagreement relates to whether it is technically possible for us to satisfy the requirements for automatic conversion of our outstanding shares of Series B Preferred pursuant to an underwritten public offering (a Qualified Public Offering). In the fourth quarter of 2015, Third Security informed us that, under its interpretation of our Amended and Restated Articles of Incorporation, the Qualified Public Offering conditions set forth in Article 4 of our Amended and Restated Articles of Incorporation can never be satisfied because our stock is publicly traded on the NYSE MKT, and that the only way all outstanding Series B Preferred can be converted into Common Shares is by obtaining the requisite consent of the Series B Preferred stockholders. We disagree with Third Security's interpretation. Our Amended and Restated Articles of Incorporation also contain various other ambiguities, such as in the provisions relating to the conversion rate for converting Series B Preferred into Common Shares and the stated value of the Series B Preferred following our 50:1 reverse split of our Common Shares in August 2015. The stated value of the Series B Preferred affects other provisions of our Amended and Restated Articles of Incorporation, including the anti-dilution rights for the Series B Preferred as well as the minimum public offering price per share necessary for a public offering to satisfy one of the Qualified Public Offering conditions. These ambiguities, as well as Third Security's interpretation of the Qualified Public Offering conditions, create uncertainty around our capital structure, which may adversely affect our ability to raise capital. In order to resolve our disagreement with Third Security, we may also agree to settlement terms that cause significant dilution to holders of our Common Shares and require us to pay significant consideration, or engage in expensive and time-consuming litigation where our interpretation of the Qualified Public Offering conditions may not prevail or the matter may otherwise be resolved in a manner unfavorable to us. For additional information, see "Risk Factors—We have a disagreement with one of our principal stockholders regarding the interpretation of our Amended and Restated Articles of Incorporation" under Item 1A of this Annual Report.

We cannot be certain that sufficient funds will be available to us when required or on acceptable terms, if at all. If adequate funds are not available on a timely basis or on acceptable terms, we may be required to significantly reduce or refocus our operations or to obtain funds through additional arrangements that may require us to relinquish rights to certain of our products, technologies or potential markets, any of which could delay or require that we curtail or eliminate some or all of our development programs or otherwise have a material adverse effect on our business, financial condition and results of operations. This uncertainty around our ability to secure additional financing creates substantial doubt about our ability to continue as a going concern.

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

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

### ***Goodwill***

Costs of investments in purchased companies in excess of the underlying fair value of net assets at the date of acquisition are recorded as goodwill and assessed annually for impairment. If considered impaired, goodwill will be written down to fair value and a corresponding impairment loss recognized. As of December 31, 2015, we have recorded goodwill of \$7.6 million due to the 2012 acquisition of SPH's know-how and phage libraries and the 2011 acquisition of Biocontrol's patents and phage library. In management's opinion, no goodwill has been impaired as of December 31, 2015.

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

In Process Research & Development (IPR&D) assets represent capitalized incomplete research projects that we acquired through business combinations. Such assets are initially measured at their acquisition date fair values. The fair value of the research projects is recorded as intangible assets on the consolidated balance sheet rather than expensed regardless of whether these assets have an alternative future use. The amounts capitalized are being accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of research and development efforts associated with the projects. Upon successful completion of each project, we make a determination as to the then remaining useful life of the intangible asset and begin amortization. We test our

indefinite-lived intangibles, including IPR&D assets, for impairment at least quarterly. As of December 31, 2015, we have recorded IPR&D of \$12.4 million related to the 2012 acquisition of SPH's know-how and phage libraries and the 2011 acquisition of Biocontrol's know-how and phage library. In management's opinion, no IPR&D has been impaired as of December 31, 2015.

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

We account for stock options and restricted stock units related to our stock incentive plans under the provisions of ASC 718, which requires the recognition of the fair value of stock-based compensation. The fair value of stock options and restricted stock units was estimated using a Black-Scholes option valuation model. This model requires the input of subjective assumptions in implementing ASC 718, including expected dividend, expected life, expected volatility and forfeiture rate of each award, as well as the prevailing risk-free interest rate and the fair value of the underlying common stock on the date of grant. The fair value of equity-based awards is amortized over the vesting period of the award, and we have elected to use the straight-line method of amortization. Actual results could differ from our assumptions, which may cause us to record adjustments to increase or decrease compensation expense, in future periods.

### ***Warrant and Preferred Shares Conversion Feature Liability***

We account for warrants and the preferred shares conversion feature with anti-dilution provisions under the guidance of ASC 815, Derivatives and Hedging and Emerging Issue Task Force Statement 07-5: *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock*, which require the warrants and the preferred shares conversion feature to be recorded as a liability and adjusted to fair value in each reporting period. We estimate the fair values of these securities using a Monte Carlo valuation model. As a result of the revaluation of these liabilities to fair value at each reporting date, we recorded gains of \$9.9 million and \$37.2 million for the years ended December 31, 2015 and 2014, respectively.

### **JOBS Act**

In April 2012, the JOBS Act was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an “emerging growth company.” We have irrevocably elected not to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. As an “emerging growth company” we are not be required to, among other things, (i) provide an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding a supplement to the auditor’s report providing additional information about the audit and the financial statements (auditor discussion and analysis) and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer’s compensation to median employee compensation. These exemptions will apply until the earliest to occur of (i) the last day of the fiscal



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

## **Financial Overview**

### ***Revenue***

To date, our revenues have come primarily from sub-licensing agreements. We have not generated any revenues from the sale of our product candidates and do not expect to generate any revenue from the sale of our product candidates in the near term.

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

Research and development costs consist of the costs associated with our research and discovery activities, conducting clinical trials, manufacturing development efforts and activities related to regulatory filings. Our research and development expenses consist of salaries, non-cash stock-based compensation, costs of outside collaborators and outside services, laboratory supplies, royalty and license costs, contract research organizations, and facility, occupancy and utility expenses, offset by the benefit of any Australian government research grants. We expense research and development costs as incurred. We expect annual research and development expenses will increase significantly in the future as we progress with development.

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

General and administrative expenses consist primarily of salaries and related costs for our personnel in the executive, finance, patent, accounting and other administrative functions, including non-cash stock-based compensation. Other costs include consulting costs for functions for which we either do not or only partially staff internally, including public relations, market research and recruiting, professional fees for legal and accounting services, insurance and facility costs.

### *Severance Charge*

We incurred severance charges in 2015 and 2014 related to the departures of certain of our executives. The charges consist of cash compensation and benefits and non-cash stock-based compensation expense pursuant to their employment agreements with us.

### *Other Income (Expense)*

Gain (loss) on warrant and derivative liabilities represents the change in fair value on revaluation of our warrant and preferred stock conversion liabilities, driven primarily by changes in our common stock price, interest rates and remaining estimated life of these liabilities. Any interest earned on our cash and cash equivalents is not considered significant to our financial statements.

## **Results of Operations**

### **Comparison of the Years Ended December 31, 2015 and 2014**

#### *Revenue*

For the years ended December 31, 2015 and 2014, we recognized revenues related to sub-licensing agreements from our former gene therapy program of \$0.5 million and \$0.4 million, respectively.

#### *Research and Development*

Research and development expenses for the year ended December 31, 2015 totaled \$4.0 million compared to \$5.8 million for the year ended December 31, 2014. This decline of \$1.8 million was primarily attributable to lower non-clinical spending in 2015 as compared to 2014, the inclusion in 2014 of initial start-up costs related to our Slovenia cGMP manufacturing facility, the benefit from Australian government research grants of \$0.5 million, and the impact of lower average exchange rates in 2015 as compared to 2014. Partially offsetting these factors were higher

costs related to our Slovenian facility being operational for a full year in 2015 as compared to a partial year in 2014.

Research and development expenses are expected to increase in 2016 compared to 2015 as we accelerate both non-clinical research studies, hire additional research and development staff, continue with clinical trials, and continue our discovery efforts.

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

General and administrative expenses for the year ended December 31, 2015 were \$6.4 million compared to \$6.9 million for the same period of 2014. This decrease was primarily attributable to \$0.6 million expensed in 2014 related to payments to certain stockholders as required by the terms of our Series B Preferred Stock Purchase Agreement and lower compensation and stock-based compensation expenses, which were partially offset by higher legal and accounting expenses.

### ***Severance Charge***

We recorded a severance charge of \$0.3 million in 2015 related to the departure of an executive, which included severance period cash compensation and benefits and non-cash stock-based compensation expense related to the accelerated vesting of stock options. We also recorded a severance charge in 2014 of \$1.9 million related to the departure of our former Chief Executive Officer, which included severance-period cash compensation and benefits and non-cash stock-based compensation expense related to the accelerated vesting of stock options

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

We recorded gains of \$0.6 million and \$9.5 million for the years ended December 31, 2015 and 2014, respectively, for the change in fair value on revaluation of our warrant liability. These gains were primarily attributable to a decline in the value of our common stock at December 31, 2015 and December 31, 2014 as compared to the prior year end values. We will continue to adjust this liability until the earlier of exercise or expiration of the warrants.

For the years ended December 31, 2015 and 2014, we recorded a gain of \$9.3 million and \$27.8 million, respectively, related to the change in fair value of our Series B preferred stock liability. These gains were primarily attributable to a decline in the value of our common stock at December 31, 2015 and December 31, 2014 as compared to the prior year-end values. We will continue to adjust this liability until conversion of the Series B redeemable convertible preferred stock into common stock.

We recorded other expenses of \$0.3 million in 2015, which consisted primarily of the costs related to warrants issued to placement agents in conjunction with our March 2015 private placement of common stock.

### ***Income Taxes***

We incurred net operating losses for the years ended December 31, 2015 and 2014 and accordingly, we did not pay any U.S. federal or state income taxes. As of December 31, 2015, we had U.S. gross net operating loss carry-forwards, or "NOLs", of approximately \$182.3 million, foreign NOLs of \$8.5 million, \$3.0 million of which was generated in 2015 and domestic research tax credit carry-forwards of approximately \$5.2 million. The carry-forwards will begin to expire in 2019. Our gross net operating loss carry-forwards are subject to certain limitations on annual utilization as a result of changes in ownership of the Company, as defined by U.S. federal and state tax laws.

### ***Net Operating Losses***

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

### **Comparison of the Years Ended December 31, 2014 and 2013**

#### ***Revenue***

For the years ended December 31, 2014 and 2013, we recognized revenues related to sub-licensing agreements from our former gene therapy program of \$0.4 million and \$0.1 million, respectively.

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

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

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

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

### ***Severance Charge***

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

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

We recorded a gain of \$9.5 million for the year ended December 31, 2014 for the change in fair value on revaluation of our warrant liability. This gain was primarily attributable to a decline in the value of our common stock at December 31, 2014 as compared to December 31, 2013.

We recorded a gain of \$27.8 million for the year ended December 31, 2014 for the change in fair value on revaluation of our Series B preferred stock liability. This gain was primarily attributable to a decline in the value of our common stock price at year end.

### ***Income Taxes***

We incurred net operating losses for the years ended December 31, 2014 and 2013 and, accordingly, we did not pay any federal or state income taxes. As of December 31, 2014, we had approximately \$178.0 million in U.S., Australian, Slovenian, and UK gross net operating loss carry-forwards and research tax credit carry-forwards of approximately \$3.9 million. The carry-forwards began to expire in 2012. Our gross net operating loss carry-forwards are subject to certain limitations on annual utilization as a result of changes in ownership of the Company, as defined by federal and state tax laws. Our current carry-forwards will begin to expire in 2019.

***Net Operating Losses***

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

**Cash Flow Summary**

We had cash and cash equivalents of \$9.4 million and \$6.6 million at December 31, 2015 and 2014, respectively.

Net cash used in operating activities for the year ended December 31, 2015 was \$9.8 million. We recorded net loss for the period of \$0.5 million, including a non-cash gain on warrant liability of \$0.6 million, a non-cash gain on Series B preferred stock derivative liability of \$9.3 million, a deferred income tax benefit of \$0.1 million, and a non-cash gain of \$0.1 million related to the re-valuation of a liquidated damages liability. Non-cash charges for warrants issued to placement agents related to our March 2015 private placement of common stock, stock-based compensation expense, depreciation expense, and patent amortization expense, which collectively represented a source of cash of approximately \$1.0 million. An increase in prepaid expenses and other current assets, primarily related to accrued Australian government research and development grants, a reduction in accrued severance and a reduction in accounts receivable were partially offset by an increase in accounts payable and dividends payable and collectively represented a \$0.2 million use of cash used in operating activities during the year ended December 31, 2015.

Net cash used in investing activities was \$0.2 million and \$1.2 million for the years ended December 31, 2015 and December 31, 2014, respectively. Net cash used in investing activities for the year ended December 31, 2014 was primarily attributable to the leasehold improvements and the purchase of equipment for our Slovenia manufacturing facility.

Cash provided by financing activities for the year ended December 31, 2015 totaled \$12.8 million, and was comprised of the gross proceeds of \$13.0 million from the March 2015 private placement of common stock and warrants to purchase common stock, less \$0.6 million of commissions and other cash expenses related to the issuance. We also received \$0.4 million in proceeds from the exercise of warrants during 2015.

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

We invested \$1.2 million in property and equipment in 2014, primarily related to our new cGMP manufacturing facility in Slovenia.

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

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



As of December 31, 2015, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. Therefore, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

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

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

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

**AMPLIPHI BIOSCIENCES CORPORATION**

**INDEX TO AUDITED CONSOLIDATED FINANCIAL STATEMENTS**

**AmpliPhi Biosciences Corporation**

<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets as of December 31, 2015 and 2014</u>	F-3
<u>Consolidated Statements of Operations for the Years Ended December 31, 2015 and 2014 (restated)</u>	F-4
<u>Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) for the Years Ended December 31, 2015 and 2014</u>	F-5
<u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2015 and 2014</u>	F-6
<u>Notes to Consolidated Financial Statements for the Years Ended December 31, 2015 and 2014</u>	F-7

F-1

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

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

We have audited the accompanying consolidated balance sheets of AmpliPhi Biosciences Corporation as of December 31, 2014 and 2015, and the related consolidated statements of operations, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of AmpliPhi Biosciences Corporation at December 31, 2014 and 2015, and the consolidated results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

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

As discussed in Note 3 to the consolidated financial statements, the December 31, 2014 consolidated financial statements have been restated to correct an error in basic and diluted loss per share and diluted weighted average shares outstanding for the year ended December 31, 2014.

/s/ Ernst & Young LLP

Richmond, Virginia

March 30, 2015

F-2

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

	December 31, 2015	2014
Assets		
Current assets		
Cash and cash equivalents	\$9,370,000	\$6,581,000
Accounts receivable	125,000	100,000
Prepaid expenses and other current assets	521,000	339,000
Total current assets	10,016,000	7,020,000
Property and equipment, net	1,131,000	1,220,000
In process research and development	12,446,000	12,446,000
Acquired patents, net	338,000	369,000
Goodwill	7,562,000	7,562,000
Total assets	\$31,493,000	\$28,617,000
Liabilities, Series B redeemable convertible preferred stock and stockholders' equity		
Current liabilities		
Accounts payable, accrued expenses and other	\$1,464,000	\$1,167,000
Deferred revenue	245,000	244,000
Accrued severance	308,000	457,000
Dividends payable	368,000	-
Total current liabilities	2,385,000	1,868,000
Series B preferred stock derivative liability	1,493,000	12,320,000
Warrant liability	6,000	5,826,000
Accrued severance	-	98,000
Deferred tax liability	3,005,000	3,078,000
Total liabilities	6,889,000	23,190,000
Series B redeemable convertible preferred stock		
\$0.01 par value, 10,000,000 shares authorized, 7,527,853 shares issued and outstanding at December 31, 2015 and 8,671,040 shares issued and outstanding at December 31, 2014 (liquidation preference of \$13,383,000 and \$14,042,000 at December 31, 2015 and December 31, 2014, respectively)	11,890,000	1,990,000
Stockholders' equity		
Common stock, \$0.01 par value, 670,000,000 shares authorized, 5,883,503 shares issued and outstanding at December 31, 2015 and 3,983,182 shares issued and outstanding at December 31, 2014	59,000	40,000
Additional paid-in capital	375,177,000	365,403,000
Accumulated deficit	(362,522,000)	(362,006,000)
Total stockholders' equity	12,714,000	3,437,000
Total liabilities, Series B redeemable convertible preferred stock and stockholders' equity	\$31,493,000	\$28,617,000

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

F-3

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

	Year Ended December 31,	
	2015	2014
Revenue	\$475,000	\$409,000
Operating expenses		
Research and development	3,992,000	5,805,000
General and administrative	6,421,000	6,850,000
Severance charge	289,000	1,864,000
Total operating expenses	10,702,000	14,519,000
Loss from operations	(10,227,000)	(14,110,000)
Other income (expense)		
Change in fair value of warrant liability	610,000	9,455,000
Change in fair value of Series B stock derivative liability	9,330,000	27,764,000
Other expense	(302,000)	-
Other income (expense), net	9,638,000	37,219,000
(Loss) income before taxes	(589,000)	23,109,000
Income tax benefit	73,000	-
Net (loss) income	\$(516,000)	\$23,109,000
Accretion of Series B redeemable convertible preferred stock	(10,278,000)	(1,285,000)
Net (loss) income attributable to common stockholders	\$(10,794,000)	\$21,824,000
Per share information:		
Net (loss) income per share of common stock – basic - restated for the year ended December 31, 2014	\$(1.99)	\$4.21
Weighted average number of shares of common stock outstanding – basic	5,411,204	3,746,639
Net loss per share of common stock – diluted - restated for the year ended December 31, 2014	\$(1.99)	\$(2.33)
Weighted average number of shares of common stock outstanding – diluted - restated for the year ended December 31, 2014	5,411,204	5,886,730

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

## AmpliPhi Biosciences Corporation

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

	Redeemable Convertible Preferred Stock		Stockholders' Equity (Deficit)				Total Stockholders' Equity (Deficit)
	Series B Shares	Amount	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	
Balances, December 31, 2013	8,859,978	\$707,000	3,650,711	\$36,000	\$362,454,000	\$(385,115,000)	\$(22,625,000)
Net income	-	-	-	-	-	23,109,000	23,109,000
Accretion of dividends on Series B redeemable convertible preferred stock	-	1,285,000	-	-	(1,285,000 )	-	(1,285,000 )
Warrants exercised	-	-	54,683	1,000	1,594,000	-	1,595,000
Conversion of Series B redeemable convertible preferred stock to common stock	(188,938 )	(2,000 )	37,788	1,000	706,000	-	707,000
Stock-based compensation	-	-	-	-	775,000	-	775,000
Stock-based compensation - severance	-	-	-	-	1,161,000	-	1,161,000
Shares released from escrow	-	-	240,000	2,000	(2,000 )	-	-
Balances, December 31, 2014	8,671,040	\$1,990,000	3,983,182	\$40,000	\$365,403,000	\$(362,006,000)	\$3,437,000
Net loss	-	-	-	-	-	(516,000 )	(516,000 )
Accretion of dividends on Series B redeemable convertible preferred stock	-	1,307,000	-	-	(1,307,000 )	-	(1,307,000 )



Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

Amount reclassified to Series B redeemable convertible stock to accrete to its redemption value	-	8,971,000	-	-	(8,971,000 )	-	(8,971,000 )
Conversion of Series B redeemable convertible preferred stock to common stock	(1,143,187)	(378,000 )	228,637	2,000	1,504,000	-	1,506,000
Common stock issued in March 2015 financing, net of fair value of warrants issued	-	-	1,575,758	16,000	8,250,000	-	8,266,000
Warrants exercised	-	-	56,645	1,000	1,072,000	-	1,073,000
Warrants reclassified from liabilities to equity due to amendment of warrants	-	-	-	-	5,462,000	-	5,462,000
Warrants reclassified from liabilities to equity due to increase in authorized shares	-	-	-	-	3,281,000	-	3,281,000
Exercise of common stock options and other	-	-	39,281	-	-	-	-
Stock-based compensation	-	-	-	-	479,000	-	479,000
Stock-based compensation - severance	-	-	-	-	4,000	-	4,000
Balances, December 31, 2015	7,527,853	\$ 11,890,000	5,883,503	\$ 59,000	\$ 375,177,000	\$(362,522,000)	\$ 12,714,000

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

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

	Year Ended December 31,	
	2015	2014
Operating activities:		
Net (loss) income	\$(516,000 )	\$23,109,000
Adjustments required to reconcile net (loss) income to cash used in operating activities:		
Change in fair value of warrant liability	(610,000 )	(9,455,000 )
Change in fair value of Series B preferred stock derivative liability	(9,330,000 )	(27,764,000)
Gain on re-valuation of liquidated damages liability	(120,000 )	-
Warrants issued to placement agents	213,000	-
Deferred taxes	(73,000 )	-
Amortization of patents	31,000	31,000
Depreciation	299,000	127,000
Stock-based compensation	479,000	775,000
Stock-based compensation - severance	4,000	1,161,000
Changes in operating assets and liabilities, net:		
Accounts receivable	(25,000 )	(92,000 )
Accounts payable, accrued expenses, deferred revenue and other	296,000	(977,000 )
Accrued severance	(247,000 )	555,000
Prepaid expenses and other current assets	(182,000 )	(42,000 )
Net cash used in operating activities	(9,781,000 )	(12,572,000)
Investing activities:		
Purchases of property and equipment	(210,000 )	(1,202,000 )
Net cash used in investing activities	(210,000 )	(1,202,000 )
Financing activities		
Proceeds from warrant exercises	396,000	-
Proceeds from issuance of common stock, net	12,384,000	-
Net cash provided by financing activities	12,780,000	-
Net increase (decrease) in cash and cash equivalents	2,789,000	(13,774,000)
Cash and cash equivalents, beginning of period	6,581,000	20,355,000
Cash and cash equivalents, end of period	\$9,370,000	\$6,581,000
Supplemental schedule of non-cash financing activities:		
Accretion of Series B redeemable convertible preferred stock	\$10,278,000	\$1,285,000
Fair value of warrant liability upon issuance	4,210,000	-
Fair value of warrant liability converted upon exercise	-	1,595,000

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

## **AmpliPhi Biosciences Corporation**

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

**December 31, 2015 and December 31, 2014**

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

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

The Company is a development stage company and has incurred net losses since its inception, has negative operating cash flows, and had an accumulated deficit of \$362.5 million and \$362.0 million as of December 31, 2015 and December 31, 2014, respectively. The Company completed a \$13.0 million private placement of its common stock in March 2015, which provided net proceeds of approximately \$12.4 million after commissions to placement agents. In the opinion of management, the Company’s cash and cash equivalents are sufficient to fund its planned operations through the third quarter of 2016. This estimate is based on the Company’s current product development plans, projected staffing expenses, working capital requirements, and capital expenditure plans.

#### **2. Liquidity**

The Company has prepared these 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, has negative operating cash flows and has an accumulated deficit of \$362.5 million as of December 31, 2015, \$47.0 million of which has been accumulated since January of 2011, when the Company began its focus on bacteriophage development. 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, 2015, the Company had cash and cash equivalents of \$9.4 million. Management believes that our existing resources will be sufficient to fund our planned operations through the third quarter of 2016.

The Company's ability to raise additional funds will depend, in part, on the status of its product development activities and other business operations, as well as factors related to financial, economic, and market conditions, many of which are beyond its control. In addition, the Company has a disagreement with one of its principal stockholders, Third Security, LLC, regarding the interpretation of the Company's Amended and Restated Articles of Incorporation. The disagreement relates to whether it is technically possible for the Company to satisfy the requirements for automatic conversion of the Company's outstanding shares of Series B Redeemable Convertible Preferred Stock (Series B Preferred) pursuant to an underwritten public offering (a Qualified Public Offering). In the fourth quarter of 2015, Third Security informed the Company that, under its interpretation of the Amended and Restated Articles of Incorporation, the Qualified Public Offering conditions set forth in Article 4 of the Amended and Restated Articles of Incorporation can never be satisfied because the Company's stock is publicly traded on the NYSE MKT, and that the only way all outstanding Series B Preferred can be converted into common stock is by obtaining the requisite consent of the Series B Preferred stockholders. The Company disagrees with Third Security's interpretation. The Amended and Restated Articles of Incorporation also contain various other ambiguities, such as in the provisions relating to the conversion rate for converting Series B Preferred into common stock and the stated value of the Series B Preferred following the Company's 50:1 reverse split of its common stock in August 2015. The stated value of the Series B Preferred affects other provisions of the Amended and Restated Articles of Incorporation, including the anti-dilution rights for the Series B Preferred as well as the minimum public offering price per share necessary for a public offering to satisfy one of the Qualified Public Offering conditions. These ambiguities, as well as Third Security's interpretation of the Qualified Public Offering conditions, create uncertainty around the Company's capital structure, which may adversely affect the Company's ability to raise capital.

The Company cannot be certain that sufficient funds will be available to it when required or on acceptable terms, if at all. If adequate funds are not available on a timely basis or on acceptable terms, the Company may be required to significantly reduce or refocus its operations or to obtain funds through additional arrangements that may require the Company to relinquish rights to certain of its products, technologies or potential markets, any of which could delay or require that it curtail or eliminate some or all of its development programs or otherwise have a material adverse effect on the business, financial condition and results of operations. This uncertainty around the Company's ability to secure additional financing creates substantial doubt about its ability to continue as a going concern.

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

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

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

***Restatement of Prior Period Financial Statements***

The Company has determined that a restatement is required to the previously reported basic and diluted income (loss) per share for the year ended December 31, 2014, three and six months ended June 30, 2014, three and nine months ended September 30, 2014 and three months ended June 30, 2015. The correction has no impact on the Company's consolidated balance sheets, statement of operations, or the consolidated statement of cash flows as previously reported for the aforementioned periods. Furthermore, the correction does not impact any other previously reported periods in 2014 and 2015.

The Company has not amended its previously-filed Annual Reports on Form 10-K or Quarterly Reports on Form 10-Q for the periods affected by the restatement. The financial information related to basic and diluted income (loss) per share that has been previously filed or otherwise reported for these periods is superseded by the information in this Form 10-K, and the financial statements and related financial information contained in such previously-filed reports should no longer be relied upon. No other changes were made to these previously filed reports other than those disclosures related to basic and diluted income (loss) per share.

The calculation of basic income (loss) per share requires consideration of the fact that the outstanding shares of the Company's Series B redeemable convertible preferred stock, in certain limited circumstances, have the right to receive additional dividends beyond their accruing dividends and are consequently participating securities. Therefore, consideration of this component of the preferred stock terms is included in computing basic earnings per share pursuant to the two-class method. The Company failed to make such adjustments to the basic income (loss) per share calculations for the prior periods discussed above.

The calculation of diluted income (loss) per share requires that, to the extent such securities are dilutive to income/loss per share for the period, an adjustment to net income (loss) used in the calculation is required to remove the change in fair value of the liability classified warrants from the numerator for the period. Likewise, an adjustment to the denominator is required to reflect the related dilutive shares. Similarly, the diluted income (loss) per share calculation also requires an adjustment to net loss used in the calculation to remove the change in fair value of the Series B redeemable convertible preferred stock embedded derivative (if the Series B redeemable convertible preferred stock is dilutive), including any applicable accretion, and an adjustment to the denominator is required to reflect the related dilutive securities. The Company failed to make such adjustments to the diluted income (loss) per share calculations for the prior periods discussed above.

The table below illustrates a reconciliation of the components of the numerator and denominator included in the calculations of basic and diluted income (loss) per share and the impact of the correction of the error on the basic and diluted income (loss) per share amounts.

Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

	Year Ended December 31, 2014	
Basic income per share - as originally reported	\$ 5.82	
Difference in basic income per share	(1.61)	)
Basic income per share - restated	\$ 4.21	
Diluted loss per share - as originally reported	\$ 3.37	
Difference in diluted loss per share	(5.70)	)
Diluted loss per share - restated	\$ (2.33)	)
Numerator		
As originally reported	\$ 21,824,000	
Correction - adjustment related to preferred stockholders' participation in the Company's undistributed earnings	(6,067,000)	)
Numerator for use in basic income per share, as restated	15,757,000	
Correction - adjustments related to warrants and preferred stock	(29,474,000)	)
Numerator for use in diluted loss per share, as restated	\$ (13,717,000)	)
Denominator		
As originally reported	6,472,093	
Less antidilutive shares previously incorrectly included in denominator	(585,363)	)
Denominator for use in diluted loss per share, as restated	5,886,730	

The denominator for the basic income per share calculation remains unchanged from the amount previously reported.

The tables in *Note 17 – Quarterly Financial Data* illustrate a reconciliation of the components of the numerator and denominator included in the calculations of basic and diluted income (loss) per share for the three and six months ended June 30, 2014, three and nine months ended September 30, 2014 and the three months ended June 30, 2015.

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

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

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

Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. This process may result in actual results differing materially from those estimated amounts used in the preparation of the financial statements if these results differ from historical experience, or other assumptions do not turn out to be substantially accurate, even if such assumptions are reasonable when made. In preparing these financial statements, management used significant estimates in the following areas, among others: the determination of the fair value of stock-based awards, the fair value of liability-classified preferred stock derivatives, the fair value of liability-classified warrants, the valuation of long-lived assets, including in-process research and development (IPR&D), patents and goodwill, accrued expenses and the recoverability of the Company's net deferred tax assets and related valuation allowance.

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

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

### ***Accounts Receivable***

Accounts receivable amounts are stated at their face amounts less any allowance. Provisions for doubtful accounts are estimated based on assessment of the probable collection from specific customer accounts and other known factors. As of December 31, 2015 and December 31, 2014, management determined no allowance for doubtful accounts was required.

### ***Property and Equipment***

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

	<b>Estimated Useful Lives</b>
Laboratory equipment	5 – 7 years
Office and computer equipment	1 – 5 years
Leasehold improvements	Shorter of lease term or useful life

The Company reviews long-lived assets 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 are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed their fair value, which is measured based on the projected discounted future net cash flows arising from the assets. No impairment losses have been recorded since inception.



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

Prepaid and other current assets consist primarily of prepaid insurance, Australian government research grants receivable, deferred licensing costs, and deposits.

### ***In-Process Research & Development and Goodwill***

In-process research & development (IPR&D) assets represent capitalized incomplete research projects that the Company acquired through business combinations. Such assets are initially measured at their acquisition date fair values. The fair value of the research projects is recorded as intangible assets on the consolidated balance sheet rather than expensed regardless of whether these assets have an alternative future use. The amounts capitalized are being accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of research and development efforts associated with the projects. Upon successful completion of each project, the Company will make a determination as to the then remaining useful life of the intangible asset and begin amortization.

Costs of investments in purchased companies in excess of the underlying fair value of net assets at the date of acquisition are recorded as goodwill and assessed annually for impairment. If considered impaired, goodwill will be written down to fair value and a corresponding impairment loss recognized.

The Company reviews the carrying value of IPR&D and goodwill for potential impairment on an annual basis and at any time that events or business conditions indicate that it may be impaired. As permitted under Accounting Standards Codification Topic 350 (ASC 350), through December 31, 2015, the Company elected to base its assessment of potential impairment on qualitative and quantitative factors, as applicable. The quantitative measure is based upon an estimate of future discounted cash flows. The discounted cash flows model indicates the fair value based on the present value of the cash flows expected to be generated in the future. Significant estimates in the discounted cash flows model include: the weighted average cost of capital; probability of success of research; expected future revenues from products; expected future operating costs; long-term rate of growth and profitability of the business; and working capital effects. Based on our assessment, IPR&D and goodwill were not impaired as of December 31, 2015.

### ***Patents***

Patents are recorded at fair value and are amortized using the straight-line method over their estimated useful lives.

During the year ended December 31, 2011, the rights to Biocontrol Limited’s patents were acquired by the Company and patents in the amount of \$493,000 were recorded. These patents are amortized over their useful life through December 2026. Annual patent amortization expense for the years ending December 31 are estimated as follows:

	Patent Amortization
2016	\$ 31,000
2017	31,000
2018	31,000
2019	31,000
2020	31,000
Thereafter	183,000
Total patent amortization expense	\$ 338,000

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

The Company accounts for stock-based payments under the applicable accounting standard which requires measurement of compensation cost for all share-based payment awards at fair value on the date of grant and recognition of compensation cost over the requisite service period (typically the vesting period) for awards expected to vest.

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

The Company accounts for both warrants with anti-dilution adjustment provisions and other features and preferred share features with anti-dilution adjustment provisions under the applicable accounting guidance which requires the warrant and the preferred share features to be recorded as liabilities and adjusted to fair value at each reporting period.

### ***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 technology licenses, collaborative research arrangements and agreements to provide research and development services. Revenue under technology licenses typically consists of nonrefundable, up-front license fees, technology access fees, royalties on product sales, and various other payments. The Company classifies advance payments received in excess of amounts earned as deferred revenue.

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

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

### ***Income Taxes***

Income taxes are recorded in accordance with the applicable accounting guidance which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. 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 accounts for uncertain tax positions in accordance with the applicable accounting guidance. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of December 31, 2015 and 2014, the Company does not have any significant uncertain tax positions.

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

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

Diluted net (loss) income per share of common stock is computed by dividing 1) the net (loss) income attributable to common stockholders, adjusted by income (loss) related to potential diluted preferred stock and warrants to purchase shares of our common stock by the sum of 2) the weighted average number of shares of common stock outstanding during the period plus the potential dilutive effects of preferred stock and warrants to purchase common stock and stock options outstanding during the period calculated in accordance with the treasury stock method, although these shares, options and warrants are excluded if their effect is anti-dilutive. There was no difference between net loss and diluted net loss for the year ended December 31, 2015.

### ***Other Comprehensive Income (Loss)***

The Company recorded no comprehensive income other than net income for the periods reported.

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

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update, or ASU, No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The ASU creates a single source of revenue guidance for companies in all industries. The new standard provides guidance for all revenue arising from contracts with customers and affects all entities that enter into contracts to provide goods or services to their customers, unless the contracts are within the scope of other accounting standards. It also provides a model for the measurement and recognition of gains and losses on the sale of certain nonfinancial assets. This guidance, as amended, must be adopted using either a full retrospective approach for all periods presented or a modified retrospective approach and will be effective for fiscal years beginning after December 15, 2017. The Company has not yet evaluated the potential impact of adopting the guidance on its consolidated financial statements.

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

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

F-11

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, which defines management's responsibility to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures if there is substantial doubt about its ability to continue as a going concern. The pronouncement is effective for annual reporting periods ending after December 15, 2016 with early adoption permitted. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

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

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

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

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

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

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

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The Company does not use derivative financial instruments to hedge exposures to cash-flow, market or foreign-currency risks. However, the Company has entered into certain financial instruments and contracts, such as

Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

detachable common stock warrants and the issuance of preferred stock with detachable common stock warrants with features that are either i) not afforded equity classification or ii) embody risks not clearly and closely related to host contracts. These instruments are required to be carried as derivative liabilities, at fair value.

The Company estimates fair values of these derivatives utilizing Level 3 inputs. The Company uses the Monte Carlo valuation technique for derivatives as it embodies all of the requisite assumptions (including trading volatility, remaining term to maturity, market price, strike price, risk free rates) necessary to fair value these instruments.

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

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

	Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
December 31, 2015				
Liabilities				
Series B redeemable convertible preferred stock	\$ -	\$ -	\$ 1,493,000	\$ 1,493,000
Warrant liability	-	-	6,000	6,000
Total liabilities	\$ -	\$ -	\$ 1,499,000	\$ 1,499,000
December 31, 2014				
Liabilities				
Series B redeemable convertible preferred stock	\$ -	\$ -	\$ 12,320,000	\$ 12,320,000
Warrant liability	-	-	5,826,000	5,826,000
Total liabilities	\$ -	\$ -	\$ 18,146,000	\$ 18,146,000

There were no transfers between Level 1, Level 2 or Level 3 of the fair value hierarchy for the years ended December 31, 2015 and 2014.

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

	Warrant Liability	Series B Redeemable Preferred Stock
Balance, December 31, 2014	\$5,826,000	\$ 12,320,000
Issuances	4,210,000	-
Exercises	(677,000 )	-
Conversions to common stock	-	(1,497,000 )
Warrants reclassified from liabilities to equity due to amendment of warrants	(5,462,000)	-
Warrants reclassified from liabilities to equity due to increase in authorized shares	(3,281,000)	-
Changes in estimated fair value	(610,000 )	(9,330,000 )
Balance as of December 31, 2015	\$6,000	\$ 1,493,000

The fair value of the warrants on the date of issuance and on each re-measurement date for warrants classified as liabilities is estimated using the Monte Carlo valuation model. For this liability, the Company develops its own assumptions that do not have observable inputs or available market data to support the fair value. This method of valuation involves using inputs such as the fair value of the Company's common stock, stock price volatility, the contractual term of the warrants, risk-free interest rates and dividend yields. Due to the nature of these inputs, the valuation of the warrants is considered a Level 3 measurement. The following assumptions were used at December 31, 2015 and December 31, 2014:

	December 31, 2015 Series <sup>(1)</sup>	December 31, 2014 Series <sup>(1)</sup>			
	2011	2011	June 2013	July 2013	December 2013
Volatility	112	% 155	% 155	% 155	% 151
Expected term (years)	0.98	1.98	3.49	3.54	3.98
Risk-free interest rate	0.64	% 0.67	% 1.23	% 1.25	% 1.37
Dividend yield	0.00	% 0.00	% 0.00	% 0.00	% 0.00
Exercise price	\$ 23.00	\$23.00	\$7.00	\$7.00	\$ 12.50
Common stock closing price	\$ 3.98	\$10.50	\$10.50	\$10.50	\$ 10.50



(1) See *Note 11 – Warrants* below for further description of the respective series of warrants.

The warrant liability is recorded on the accompanying consolidated balance sheets and is marked-to-market at each reporting period, with the change in fair value recorded as a component of change in fair value of warrant liability on the Company's statements of operations.

The fair value of the Series B preferred stock derivative liability on each measurement date is estimated using the Monte Carlo valuation model. For this liability, the Company develops its own assumptions that do not have observable inputs or available market data to support the fair value. This method of valuation involves using inputs such as the fair value of the Company's common stock, stock price volatility, the expected term of the Series B Preferred, risk-free interest rates and dividend yields. Due to the nature of these inputs, the valuation of the Series B preferred conversion liability is considered a Level 3 measurement. The following assumptions were used at December 31, 2015 and December 31, 2014:

	December 31, 2015		December 31, 2014	
Volatility	108 to 117	%	91	%
Expected term (years), weighted average	0.50 to 2.50		1.25	
Risk-free interest rate	0.49 to 1.19	%	0.36	%
Dividend yield	0.00	%	0.00	%
Exercise price	\$ 7.00		\$ 7.00	
Common stock closing price	\$ 3.98		\$ 10.50	

The Series B preferred stock derivative liability is recorded on the accompanying consolidated balance sheet and is marked-to-market each reporting period, with the change in fair value recorded as a component of change in fair value of Series B preferred stock derivative liability on the Company's statements of operations.

## 5. Net (Loss) Income per Common Share

The following table sets forth the computation of basic and diluted net (loss) income per share for the periods indicated (refer to *Note 3 – Significant Accounting Policies* for more information regarding the December 31, 2014 restatement):

	Year Ended December 31, 2015			Year Ended December 31, 2014		
	Net loss (Numerator)	Shares (Denominator)	Per share amount	Net income (loss) (Numerator)	Shares (Denominator)	Per share amount
Basic net (loss) income per common share:						
Net (loss) income and share amounts	\$(516,000 )	5,411,204		\$23,109,000	3,746,639	
Accretion of Series B redeemable convertible preferred stock	(10,278,000)	-		(1,285,000 )	-	
Net (loss) income attributable to common stockholders	(10,794,000)	5,411,204		21,824,000	3,746,639	
Adjustment related to preferred stockholders' participation in the Company's undistributed earnings	-	-		(6,067,000 )	-	
Basic (loss) income per share - restated for the year ended December 31, 2014	\$(10,794,000)	5,411,204	\$ (1.99 )	\$15,757,000	3,746,639	\$ 4.21
Diluted net loss per common share:	-	-		1,285,000	-	

Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

Accretion of Series B redeemable convertible preferred stock							
Adjustment related to preferred stockholders' participation in the Company's undistributed earnings	-	-	6,067,000	-			
Change in fair value of Series B stock derivative liability	-	-	(27,760,000)	-			
Dilutive shares related to Series B	-	-	-	1,748,288			
Change in fair value of warrant liability related to dilutive warrants	-	-	(9,066,000)	-			
Dilutive shares related to warrants	-	-	-	391,803			
Net loss attributable to common stockholders - diluted - restated for the year ended December 31, 2014	\$(10,794,000)	5,411,204	\$ (1.99 )	\$(13,717,000)	5,886,730		\$ (2.33 )

The following outstanding securities at December 31, 2015 and 2014 have been excluded from the computation of diluted weighted shares outstanding for the years ended December 31, 2015 and 2014, as they would have been anti-dilutive:

	December 31,	
	2015	2014 (restated)
Options	669,769	440,695
Series B redeemable convertible preferred stock	7,527,853	-
Warrants	656,211	167,711

## 6. Property and Equipment

Property and equipment consist of the following:

	December 31,	
	2015	2014
Laboratory equipment	\$1,494,000	\$1,454,000
Office and computer equipment	53,000	59,000
Leasehold improvements	188,000	185,000
Total gross fixed assets	1,735,000	1,698,000
Less: accumulated depreciation and amortization	(604,000 )	(478,000 )
Property and equipment, net	\$1,131,000	\$1,220,000

Depreciation expense totaled \$299,000 and \$127,000 for the years ended December 31, 2015 and 2014, respectively.

## 7. Income Taxes

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

	December 31,	
	2015	2014
Deferred tax assets/(liabilities)		
Net operating loss carry-forwards	\$65,425,000	\$61,332,000
Research and orphan drug credit carry-forwards	5,181,000	3,855,000
Depreciation and amortization	(3,000 )	(8,000 )
Stock options and other	479,000	1,381,000
Intangible assets	(3,079,000 )	(3,155,000 )
Net deferred tax assets/(liabilities)	68,003,000	63,405,000
Valuation allowance for deferred tax assets	(71,008,000)	(66,483,000)
Net deferred tax assets/(liabilities)	\$(3,005,000 )	\$(3,078,000 )

At December 31, 2015, the Company had U.S. gross net operating loss carry-forwards, or “NOLs”, of approximately \$182.3 million, foreign NOLs of \$8.5 million, \$3.0 million of which was generated in 2015 and domestic research tax credit carry-forwards of approximately \$5.2 million. The carry-forwards may be further subject to the application of

Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

Section 382 of the Internal Revenue Code of 1986 or the “Code”, as discussed further below. The NOL carry-forwards will begin to expire in 2019. The domestic research tax credit carry-forward will begin to expire in 2019. The Company has provided a valuation allowance to offset the deferred tax assets due to the uncertainty of realizing the benefits of the net deferred tax asset.

	December 31,	
	2015	2014
Percent of pre-tax income:		
U.S. federal statutory income tax rate	34.0 %	34.0 %
Warrant liability and preferred stock conversion liability	573.8 %	(54.9)%
Difference in foreign vs U.S. statutory rates	(21.8 )%	- %
Stock option forfeitures & expirations	(138.2)%	- %
State taxes, net of federal benefit	- %	3.7 %
Non-deductible stock issuance costs	(17.9 )%	- %
R&D expenses associated with Australian research grants	27.8 %	- %
Effect of tax rate changes	12.4 %	- %
All other	(2.9 )%	1.0 %
Subtotal	467.2 %	(16.2)%
Change in valuation allowance	(454.8)%	16.2 %
Effective income tax rate	12.4 %	0.00 %

F-15

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

The Company does not have any material unrecognized tax benefits as of December 31, 2015.

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

The Company has a policy of recognizing tax related interest and penalties as additional tax expense when incurred. During the years ended December 31, 2015 and 2014, the Company did not recognize any interest and penalties.

## **8. Commitments and Contingencies**

### ***Operating Leases***

Rent expense under operating leases was \$192,000 and \$314,000 in 2015 and 2014, respectively.

Future minimum lease payments, including termination fees, under noncancelable lease agreements as of December 31, 2015, are as follows:

	Operating Lease
2016	\$76,000
2017	39,000
2018	39,000
2019	5,000
Total minimum lease payments	\$ 159,000

The Company entered into an agreement with Virginia Biotechnology Research Partnership Authority for Richmond, Virginia laboratory space. This agreement has an expiration date of August 31, 2016, with the option to terminate the lease with 60 days' notice. At December 31, 2015, the Company's minimum payment commitment for the Richmond laboratory space was \$14,000.

In May 2015, the Company entered into an agreement with Virginia Biotechnology Research Partnership Authority for Richmond, Virginia office space. This agreement has an expiration date of October 31, 2016, with the option to terminate the lease with 60 days' notice. At December 31, 2015, the Company's minimum payment commitment for the Richmond office space is \$18,000.

In June 2015, the Company entered into an agreement with Savills Studley, Inc. for San Diego, California office space. The agreement expired on June 30, 2015, and renews on a monthly basis, until terminated by the Company. At December 31, 2015, the Company's minimum payment commitment for the San Diego office space was \$5,000.

In December 2014, the Company entered into an agreement with Nevis Limited and Charter Limited for laboratory space in Bedfordshire, United Kingdom with an initial expiration date of December 2017. The Company terminated this agreement effective December 31, 2015.

In February 2014, the Company entered into an agreement with Avtotehna d.o.o. for manufacturing and research space in Ljubljana, Slovenia. The lease has a termination date of February 2019, with extension provisions at the option of the Company, and a monthly payment is \$3,244. At December 31, 2015, our minimum payment commitment for the Ljubljana space was \$122,000. In addition, the Company expended \$185,000 in 2014 for leasehold improvements related to this facility. These costs are being amortized on a straight-line basis over the life of the related lease.

The Company is subject to legal claims and actions related to the operations of its business. The Company does not expect the ultimate outcome of any such actions to have a material impact on its consolidated financial position or results of operations.

## 9. Collaborative and Other Agreements

In September 2015, the Company entered into a non-exclusive patent license agreement with Takara Bio Inc. (the Takara Agreement). Under this agreement Takara licensed certain patents related to AAV1 Vector gene delivery systems, for which the Company is an exclusive licensor with the University of Pennsylvania. The Company received a \$40,000 non-refundable, up-front licensing payment which was recognized in revenue in 2015 and is entitled to receive royalties from Takara of 12.0% of net license product sales and 6.0% of service revenues associated with the licensed products. The agreement calls for minimum annual royalties of \$15,000 beginning in 2015 which are payable in arrears in February on each anniversary thereafter. The minimum royalty amount was recognized in revenue in 2015. In addition, the Takara Agreement provides milestone fees to the Company of \$30,000 of the first \$1,000,000 of licensed product revenues by Takara and an additional \$40,000 when cumulative net sales of the licensed product by Takara exceed \$2,000,000.

The Company is party to other sub-licensing agreements for its former gene delivery systems. The Company receives annual maintenance fees and royalties based on the activities of the licensees. The amounts are reported in revenues in accordance with our revenue recognition policy.

In June 2013, the Company entered into a Collaborative Research and Development Agreement with the United States Army Medical Research and Materiel Command and the Walter Reed Army Institute of Research. The Collaborative Research and Development Agreement is focused on developing and commercializing bacteriophage therapeutics to treat *S. aureus* infections. During the year ended December 31, 2015, the Company recorded no payments under the Collaborative Research and Development Agreement. During the year ended December 31, 2014, the Company paid Walter Reed Army Institute of Research \$207,000 for services provided under the Collaborative Research and Development Agreement. This amount is included in research and development expense in 2014.

In April 2013, the Company entered into a collaboration agreement with the University of Leicester to develop a phage therapy that targets and kills all toxin types of *C. difficile*. In August 2013, the Company entered into a collaboration agreement with both the University of Leicester and the University of Glasgow to carry out certain animal model development work. Under these agreements, which are referred to collectively as the Leicester Development Agreements, the Company provides payments to the University of Leicester to carry out *in vitro* and to the University of Glasgow to carry out animal model development work on the University of Leicester's development of a bacteriophage therapeutic to resolve *C. difficile* infections. The Company licensed related patents, materials and know-how from the University of Leicester. Under the Leicester Development Agreements, the University of Leicester will provide the bacteriophage and act as overall project coordinator for the development work. All rights, title and interest to any intellectual property developed under the Leicester Development Agreements belong to the Company. Under the Leicester License Agreement, the Company has exclusive rights to certain background intellectual property of the University of Leicester, for which it will pay the University of Leicester royalties based on product sales and make certain milestone payments based on product development. In November 2015, the Company renewed this collaboration, effective as of November 12, 2015. This agreement expires November 12, 2018. During



the year ended December 31, 2015, the Company recorded \$265,000 in expenses to the University of Leicester under the Leicester Development Agreements, with cash payments totaling \$290,000. During the year ended December 31, 2014, the Company recorded \$232,000 in expenses to the University of Leicester under the Leicester Development Agreements, with cash payments totaling \$182,000. During the year ended year ended December 31, 2015, the Company paid and expensed amounts to the University of Glasgow under the Leicester Development Agreements of \$61,000. During the year ended December 31, 2014, the Company paid and expensed amounts to the University of Glasgow under the Leicester Development Agreements of \$184,000.

In March 2013, the Company entered into an Exclusive Channel Collaboration Agreement with Intrexon Corporation. This agreement allows the Company to utilize Intrexon's synthetic biology platform for the identification, development and production of bacteriophage-containing human therapeutics. The Company paid a one-time technology access fee in 2013 to Intrexon of \$3,000,000 in common stock. Pursuant to the agreement, the Company is required to pay Intrexon, in cash or stock to be valued based on the market price of our common stock, milestone fees of \$2,500,000 for the initiation and commencement of the first Phase 2 trial and \$5,000,000 upon the first regulatory approval of any product in any major market country. With regard to each product sold by the Company, the Company is required to pay, in cash, tiered royalties on a quarterly basis based on net sales of AmpliPhi Products, calculated on a product-by-product basis. No milestones have been met and no milestone payments have been paid or accrued for through December 31, 2015. The Exclusive Channel Collaboration is effective until terminated by either Intrexon or the Company. Intrexon may terminate the Exclusive Channel Collaboration if the Company fails to use diligent efforts to develop and commercialize AmpliPhi Product candidates or if the Company elects not to pursue the development of an AmpliPhi Program identified by Intrexon that is a "Superior Therapy" as defined in the Exclusive Channel Collaboration. The Company has the right to terminate the Exclusive Channel Collaboration upon 90 days' written notice to Intrexon at any time. Both the Company and Intrexon have the right to terminate the Exclusive Channel Collaboration upon written notice to the other party if the other party commits a material breach of the agreement and fails to cure such breach within 60 days following written notice. During the year ended December 31, 2015, the Company recorded \$178,000, in expenses under the Exclusive Channel Collaboration Agreement, with cash payments totaling \$125,000. During the year ended December 31, 2014, the Company recorded \$862,000, in expenses under the Exclusive Channel Collaboration Agreement, with cash payments totaling \$941,000.

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

On June 13, 2013, the Company's Board of Directors approved a resolution designating 10,000,000 shares of Preferred Stock as Series B redeemable convertible preferred stock (Series B) with an initial stated value of \$1.40 and par value of \$0.01. Each Series B share is convertible into 0.20 shares of common stock and is entitled to the number of votes equal to the number of shares of common stock into which such Series B share may be converted. These Series B shares may be converted to common stock by the holder of the shares at any time. The Series B shares may be automatically converted into common stock upon the election of the holders of at least two-thirds of the outstanding Series B shares. In addition, pursuant to the Company's Articles of Incorporation, the Series B shares are automatically convertible into common stock upon an underwritten initial public offering by the Company, with aggregate proceeds to the Company of at least \$7.0 million and a price per share to the public of at least the Series B stated value of \$1.40 per share upon the closing of which the shares of common stock of the Company are listed for trading on a major national stock exchange.

Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

Holders of the Series B shares are entitled to receive cumulative, cash dividends at the rate of 10% of the Series B stated value. Such dividends accrue from day-to-day commencing on the original issue date, whether or not earned or declared by the Board of Directors, and are compounded annually. No dividends have been declared or paid through December 31, 2015.

F-17

At any time on or after June 26, 2018, the holders of at least two-thirds of the outstanding Series B shares may require the Company to redeem all of the outstanding Series B shares for an amount equal to the original issue price per share plus any accrued and unpaid dividends.

Holders of the Series B are entitled to a liquidation preference in an amount equal to the Series B stated value of \$1.40 per share plus all accrued and unpaid dividends in the event of a liquidation, dissolution, or winding-up of the Company, or in the event the Company merges with or is acquired by another entity.

As noted in *Note 2 – Liquidity*, the Company has a disagreement with one of its principal stockholders, Third Security, LLC, regarding the interpretation of the Company’s Amended and Restated Articles of Incorporation. The disagreement relates to whether it is technically possible for the Company to satisfy the requirements for automatic conversion of the Company’s outstanding shares of Series B Redeemable Convertible Preferred Stock (Series B Preferred) pursuant to an underwritten public offering.

In connection with the private placement of Series B, the Company recorded a liability for an embedded derivative that required bifurcation under the applicable accounting guidance. The embedded derivative includes a redemption feature, multiple dividend features, as well as multiple conversion features with specified anti-dilution adjustments for certain financing transactions involving the issuance of securities at a price below a minimum non-diluting issuance price of \$7.00 per share.

The following table summarizes the conversions of Series B shares to common stock pursuant to Series B stockholder elections during the year ended December 31, 2015:

Conversion Date	Series B Shares Converted	Common Stock Issued	Amount Reclassified from Liability into Stockholders' Equity <sup>(1)</sup>
April 8, 2015	107,100	21,420	\$ 219,000
May 4, 2015	23,587	4,717	36,000
May 11, 2015	250,000	50,000	381,000
July 16, 2015	262,500	52,500	318,000
August 13, 2015	500,000	100,000	543,000
Totals	1,143,187	228,637	\$ 1,497,000

- (1) Not inclusive of \$9,000 reclassified from Series B redeemable convertible preferred stock and liabilities for dividends payable of \$368,000 upon conversion of these shares.

The Company re-measured the fair value of the derivative feature and recorded a gain of \$9,330,000 for the year ended December 31, 2015 to adjust the liability associated with the conversion feature to its estimated fair value of \$1,493,000 as of December 31, 2015.

At December 31, 2015, the Company reclassified \$8,971,000 from additional paid-in capital to Series B redeemable convertible preferred stock to adjust the Series B redeemable convertible preferred stock to its redemption value at that date.

At December 31, 2015, the Company recorded dividends payable of \$368,000 to former holders of preferred stock, which are classified as current liabilities on the Company's Balance Sheet at that date.

## 11. Warrants

In connection with the March 16, 2015 private placement of 1,575,758 shares of the Company's common stock at a price per share of \$8.25, the Company issued warrants (Series March 2015) to purchase an aggregate of 393,939 shares of common stock at an exercise price of \$10.75 per share to the purchasers of the common stock. In addition, the Company issued warrants to purchase an aggregate of 94,545 shares of common stock at an exercise price of \$10.75 per share to the placement agents as a cost of issuing the common stock. These warrants expire in March 2020 and provided for a contingent cash payment of \$2.5 million in liquidated damages to the holders of the warrants in the event the Company failed to either (i) increase the number of shares of common stock the Company is authorized to issue or (ii) effect a reverse split of the common stock, in either event sufficient to permit the exercise in full of the Warrants in accordance with their terms. Due to these provisions, the Company accounted for these warrants as liability instruments prior to the third quarter of 2015, after these conditions were met. The Company measured the fair value of these warrants on March 16, 2015 and recorded an initial warrant liability of \$4,210,000, of which \$3,396,000 represented the initial fair value of the warrants issued to investors and \$814,000 as the initial fair value of the warrants issued to the placement agents. The Company recorded other expenses of \$213,000 for the year ended December 31, 2015 representing a portion of the initial fair value of warrants issued to the placement agents attributable to the initial fair value of the warrants issued.

In connection with the December 2013 private placement of 1,440,140 shares of the Company's common stock at a price per share of \$12.50, the Company issued warrants (Series December 2013) to purchase an aggregate of 86,408 shares of common stock at an exercise price of \$12.50 per share to the placement agents. These warrants, which expire December 2018, contain specified anti-dilution adjustment provisions for certain financing transactions involving the issuance of securities below a specified price and contain net settlement provisions. Due to these provisions, the Company accounted for these warrants as liability instruments. As a result of the March 16, 2015 private placement of common stock at a price of \$8.25 per share, the anti-dilution adjustment provisions of these warrants resulted in an adjustment to their exercise price to \$8.25 as of March 16, 2015.

F-18

In connection with the private placement of Series B, which occurred through two closings on June 26, 2013 and July 15, 2013, the Company issued warrants (Series June 2013 and Series July 2013, respectively) to purchase an aggregate of 600,805 shares of common stock at an exercise price of \$7.00 per share. These warrants, which expire in June 2018 and in July 2018, respectively, contain anti-dilution adjustment provisions and contain net settlement provisions. Due to these provisions, the Company accounts for these warrants as liability instruments. The Company measured the fair value of these warrants on June 26, 2013 and July 15, 2013 and recorded initial warrant liabilities of \$4,285,000 and \$674,000, respectively, as part of the private placement proceeds and expensed \$759,000 for warrants issued to the placement agent.

In January 2011, we completed the acquisition of Biocontrol Limited, an antimicrobial biotechnology company based in the United Kingdom, with the goal of developing their phage therapy programs using funding from the sale of our legacy gene therapy assets. On December 22, 2011, in connection with our acquisition of Biocontrol, the Company issued warrants (Series 2011) to purchase up to 27,103 shares of its common stock. These warrants expire in December 2016 and are exercisable at a price of \$23.00 per share. As the terms of these warrants require that they be settled in registered shares of common stock, the Company accounts for these warrants as liability instruments.

The Company estimates the fair values of all warrants accounted for as liability instruments using a Monte Carlo valuation model.

From February through May 2013, in connection with the issuance of new convertible promissory notes, the Company issued warrants (Series 2013 Convertible Notes Warrants) to purchase up to 140,608 shares of its common stock. These warrants expire February through May 2018 and are exercisable at a price of \$7.00 per share. The Company classifies these warrants as equity instruments.

On April 1, 2015, 52,120 warrants, issued on June 26, 2013, were exercised, resulting in the issuance of 52,120 shares of common stock and \$630,000 being reclassified from the warrant liability account and into stockholders' equity, based on the fair value of the warrants on the exercise date. On April 29, 2015, 4,525 warrants, issued on June 26, 2013, were exercised, resulting in the issuance of 4,525 shares of common stock and \$46,000 was reclassified from the warrant liability account and into stockholders' equity, based on the fair value of the warrants on the exercise date.

On May 8, 2015, the Company, upon approval of more than two-thirds of the holders of the 2013 warrants issued on June 26, 2013, July 15, 2013 and December 23, 2013, amended these warrants to remove certain anti-dilution adjustment provisions. As a result of this amendment, all outstanding warrants from those issuance dates were reclassified as equity instruments resulting in the reclassification of \$5,462,000 from the warrant liability to stockholders' equity, reflecting the fair value of these warrants on the amendment date.

Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

On August 3, 2015, the stockholders of the Company approved a 1-for-50 reverse stock split of the Company's common stock and increased the number of authorized shares of common stock to 670,000,000. As a result, the warrants issued in conjunction with the March 2015 private placement of common stock were reclassified from liability instruments to equity instruments. Accordingly, \$3,281,000 was reclassified from warrant liability to stockholders' equity, reflecting the fair value of these warrants on the effective date of the reverse split, and the accrued fair value of liquidated damages in the amount of \$120,000 was recorded as other income within the caption "Other expense" on the Company's statement of operations.

The Company re-measured the fair value of the warrant liability and recorded a gain of \$610,000 for the year ended December 31, 2015, reflecting a decrease in the liability associated with the warrants at their estimated fair value, which totaled \$6,000 as of December 31, 2015.

All exercise prices and share amounts of warrants are after giving consideration to the 1-for-50 reverse split of the Company's common stock which was effective August 7, 2015.

The following table provides a summary of warrants outstanding, issued or exercised for the year ended December 31, 2015. Also included is the average exercise price per share and the aggregate proceeds to the Company if exercised as of December 31, 2015.

	Series		June 2013 and July 2013		December 2013		2013 Convertible Notes		Totals		
	March 2015		Series B Warrants								
	Shares	Exercise Price	Shares	Exercise Price	Shares	Exercise Price	Shares	Exercise Price	Shares	Exercise Price	Shares
Balance, December 31, 2014	-	\$-	523,691	\$7.00	86,408	\$12.50	140,608	\$7.00	27,103	\$23.00	777,810
Issuances	488,484	10.75	-	-	-	-	-	-	-	-	488,484
Exercises	-	-	(56,645)	7.00	-	-	-	-	-	-	(56,645)
Balance, December 31, 2015	488,484	\$10.75	467,046	\$7.00	86,408	\$8.25	140,608	\$7.00	27,103	\$23.00	1,209,644
Aggregate proceeds if exercised	\$5,251,203		\$3,269,322		\$712,866		\$984,254		\$623,369		\$10,838,414

## 12. Stock Incentive Plan Compensation

The Company's 2013 Stock Incentive Plan (Stock Incentive Plan) provides for the issuance of incentive awards, or awards, in the form of non-qualified and incentive stock options, stock appreciation rights, stock grants and restricted stock units. 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. 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. Every non-employee member of the Company's Board of Directors may also receive an annual non-qualified stock option or restricted stock unit grant. Upon the exercise of stock options, the Company issues the resulting shares from shares reserved for issuance under the Stock Incentive Plan.

The Company accounts for stock options and restricted stock units related to its stock incentive plans under the provisions of ASC 718, which requires the recognition of the fair value of stock-based compensation. The fair value of stock options and restricted stock units was estimated using a Black-Scholes option valuation model. This model requires the input of subjective assumptions in implementing ASC 718, including expected dividend, expected life, expected volatility and forfeiture rate of each award, as well as the prevailing risk-free interest rate and the fair value of the underlying common stock on the date of grant. The fair value of equity-based awards is amortized over the vesting period of the award, and the Company has elected to use the straight-line method of amortization. The assumptions used in the Black-Scholes option valuation model for the years ended December 31, 2015 and 2014 are set forth below.

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

- *Expected Dividend* : The Company does not anticipate paying any dividends on its common stock.
- *Expected Life* : The expected life represents the period that the Company expects its stock-based awards to be outstanding. For awards in fiscal 2014, the Company's expected life was based on historical experience. During fiscal 2015, the Company's expected life assumption was based on the simplified method set forth in the SEC Staff Accounting Bulletin 110, as the Company determined the use of this method provides a more reasonable estimate of expected life. The Company's estimation of the expected life for stock options granted to parties other than employees or directors is the contractual term of the option award.
- *Expected Volatility* : The Company's expected volatility represents the weighted average historical volatility of the shares of its common stock for the expected life of the stock options.
- *Risk-Free Interest Rate* : The Company bases the risk-free interest rate used on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent remaining term. Where the expected term of its stock-based awards does not correspond with the terms for which interest rates are quoted, the Company performs a straight-line interpolation to determine the rate from the available term maturities.
- *Forfeiture Rate* : The Company applies an estimated forfeiture rate that is derived from historical forfeited shares. If the actual number of forfeitures differs from our estimates, the Company may record additional adjustments to



compensation expense in future periods.

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

	Years Ended December 31,			
	2015		2014	
Risk-free interest rate	1.55 to 1.78	%	1.30	%
Expected volatility	139.0	%	160.9	%
Expected term (in years)	6.0 to 10.0		4.0	
Expected dividend yield	0.0	%	0.0	%

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

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

	Year Ended December 31,	
	2015	2014
Research and development	\$122,000	\$143,000
General and administrative	357,000	632,000
Severance charge	4,000	1,161,000
Total stock-based compensation expense	\$483,000	\$1,936,000

The severance charge component of stock incentive plan compensation relates to accelerated vesting of stock (1) options held by the Company's former Chief Executive Officer and a former executive per the terms of their employment agreements.

The following table summarizes stock option activity for the year ended December 31, 2015:

	Options Outstanding				
	Shares Available For Grant	Shares	Weighted Average Exercise Price	Average Remaining Contractual Term (Years)	Intrinsic Value
Balance, December 31, 2014	785,000	440,695	\$ 9.37	8.18	\$640,837
Increase in authorized shares	520,000	-	-	-	-
Granted	(596,569)	596,569	8.47	-	-
Exercised	-	(214,815)	8.00	-	(383,994)
Forfeited	4,375	(4,812)	13.64	-	-
Expired	10,625	(147,868)	10.71	-	-
Balance, December 31, 2015	723,431	669,769	\$ 8.68	9.29	\$-
Vested or expected to vest at December 31, 2015		552,340	\$ 10.03	9.21	\$-
Exercisable at December 31, 2015		67,084	\$ 10.03	6.71	\$-

The intrinsic value of options exercisable as of December 31, 2015 was \$0.0 million, based on the Company's closing stock price of \$3.98 per share and a weighted average exercise price of \$10.03 per share.

The Company uses the Black-Scholes option-pricing model to estimate the fair value of standard stock options at the grant date. The Black-Scholes model requires the Company to make certain estimates and assumptions, including estimating the fair value of the Company's common stock, assumptions related to the expected price volatility of the Company's common stock, the period during which the options will be outstanding, the rate of return on risk-free investments and the expected dividend yield for the Company's common stock. The Company uses Monte Carlo valuation models to estimate the fair value of certain stock options with market-based vesting requirements. This method of option pricing involves the use of inputs such as the market value of the Company's common stock, stock price volatility, the period during which the options will be outstanding, the rate of return on risk-free investments, expected dividend yield for the Company's stock, and certain estimates of future value of the Company's common stock.

During 2015, the Company issued 596,569 common stock options to its executives, board members, and consultants with a weighted average exercise price \$8.47 per share. Included in this amount were 399,716 stock options, with an exercise price of \$9.45, awarded to its Chief Executive Officer, pursuant to his employment agreement dated April 24, 2015.

As of December 31, 2015, there was \$3.6 million of total unrecognized compensation expense related to unvested stock options that will be recognized over the weighted average remaining period of 6.71 years.

***Shares Reserved For Further Issuance***

As of December 31, 2015, the Company had reserved shares of its common stock for future issuance as follows:

	Shares Reserved
Stock options outstanding	669,769
Available for future grants under the Stock Incentive Plan	723,431
Warrants	1,209,649
Total shares reserved	2,602,849

**13. Employee Retirement Plan**

The Company sponsors an employee retirement plan under Section 401(k) of the Internal Revenue Code of 1986, as amended. All of the Company's employees who meet minimum eligibility requirements are eligible to participate in the plan. Matching contributions to the 401(k) plan are made at the discretion of the Company's Board of Directors. The Company suspended matching contributions effective January 1, 2009 and accordingly no matches were approved in 2014 or 2015.

#### 14. Related Parties

As of December 31, 2015 and December 31, 2014, \$56,000 and \$3,000, respectively, of current liabilities were due to related parties.

Randal J. Kirk, the father of Julian P. Kirk, a member of our board of directors, directly and through certain affiliates, has voting and dispositive power over a majority of the outstanding capital stock of Intrexon. Randal J. Kirk is also deemed a holder of more than five percent of the shares of our common stock, as described in the section entitled “Security Ownership of Certain Beneficial Owners and Management” in our definitive proxy statement for the 2015 annual meeting of stockholders. In March 2013, the Company entered into an Exclusive Channel Collaboration Agreement with Intrexon Corporation. This agreement allows the Company to utilize Intrexon’s synthetic biology platform for the identification, development and production of bacteriophage-containing human therapeutics. The Company paid a one-time technology access fee in 2013 to Intrexon of \$3,000,000 in common stock. The Company is required to pay Intrexon, in cash or stock, milestone fees for the initiation and commencement of the first Phase 2 trial of \$2,500,000 and \$5,000,000 upon the first regulatory approval of any product in any major market country. With regard to each product sold by the Company, the Company will pay, in cash, tiered royalties on a quarterly basis based on net sales of AmpliPhi Products, calculated on a product-by-product basis. No milestones have been met and no milestone payments have been paid to Intrexon through December 31, 2015. The Company paid \$125,000 and \$941,000 to Intrexon in 2015 and 2014, respectively, for technical services rendered under the agreement.

#### 15. Stockholders’ Equity

On March 16, 2015, the Company issued and sold 1,575,758 shares of common stock in a private placement at a price of \$8.25 per share, for aggregate proceeds of \$13.0 million. In conjunction with this private placement, the Company issued warrants to purchase an aggregate of 393,939 shares of common stock at an exercise price of \$10.75 per share to the purchasers of the common stock. The Company paid \$833,000 in fees to its placement agents, along with the issuance of warrants to purchase an aggregate of 94,545 shares of common stock at an exercise price of \$10.75 per share. The Company initially valued these warrants as liability instruments and recorded a liability of \$4,210,000 as of March 16, 2015. In the first quarter of 2015, the Company recorded \$213,000 of other expenses representing the portion of the initial warrant value of the placement agent warrants related to the initial fair value of the warrants issued to the purchasers of the common stock. The remainder of the initial fair value of the warrants of \$3,996,000 was treated as a reduction of additional paid-in-capital. In addition, \$218,000 of the fees paid to its placement agent were expensed as other expenses in the year ended December 31, 2015 as they also represented issuance costs related to the initial fair value of the warrants issued to the purchasers of the common stock. The derived value associated with these warrants was reclassified from liabilities to equity in the third quarter of 2015 in connection with the increase in the authorized number of common shares.

**16. Severance Charge**

In 2015, the Company recorded a severance charge of \$289,000 related to the departure of an executive, which included severance period compensation and benefits and stock-based compensation related to the accelerated vesting of stock options.

The Company incurred a severance charge of \$1,864,000 in 2014 related to the departure of its Chief Executive Officer in September 2014. The charge consisted of severance-period cash compensation and benefits and non-cash stock-based compensation expense related to the accelerated vesting of stock options, pursuant to his employment agreement with the Company.

The severance accrual related to cash compensation and benefits as of December 31, 2014 and December 31, 2015 is as follows:

Accrued severance, December 31, 2014	\$ 555,000
Cash payments in 2015	(529,000)
Additions in 2015	282,000
Accrued severance, December 31, 2015	\$ 308,000

**17. Quarterly Financial Data (Unaudited)**

Subsequent to the issuance of the consolidated financial statements for the period ended September 30, 2015, the Company identified errors as described in *Note 3 – Significant Accounting Policies* that affected the interim consolidated financial statements for the three and six months ended June 30, 2014, three and nine months ended September 30, 2014 and the three months ended June 30, 2015. Accordingly, the previously issued consolidated financial statements for the aforementioned periods have been restated to correct for these errors below and summarized in the tables that follow.

The Company corrected its calculation of basic and diluted income (loss) per share of common stock for the changes to net income (loss) and errors in the calculation of the weighted average diluted shares.

The following tables present the impact of these corrections:

	Three Months Ended June 30, 2015	Three Months Ended September 30, 2014	Nine Months Ended September 30, 2014	Three Months Ended June 30, 2014	Six Months Ended June 30, 2014
Basic income per share - as originally reported	\$ 1.58	\$ 5.58	\$ 6.19	\$ 3.69	\$ 0.53
Difference in basic income per share	(0.31 )	(1.71 )	(1.82 )	(1.13 )	(0.06 )
Basic income per share - restated	\$ 1.27	\$ 3.87	\$ 4.37	\$ 2.56	\$ 0.47
Diluted income per share - as originally reported	\$ 1.17	\$ 3.30	\$ 3.53	\$ 2.09	\$ 0.30
Difference in diluted loss per share	(1.50 )	(4.16 )	(5.49 )	(2.72 )	(1.36 )
Diluted loss per share - restated	\$ (0.33 )	\$ (0.86 )	\$ (1.96 )	\$ (0.63 )	\$ (1.06 )
<b>Numerator</b>					
As originally reported	\$ 8,941,000	\$ 20,884,000	\$ 22,818,000	\$ 13,555,000	\$ 1,934,000
Correction - adjustment related to preferred stockholders' participation in the Company's undistributed earnings	(1,716,000 )	(6,391,000 )	(6,703,000 )	(4,166,000 )	(202,000 )
Numerator for use in basic income per share, as restated	\$ 7,225,000	\$ 14,493,000	\$ 16,115,000	\$ 9,389,000	\$ 1,732,000
Correction - adjustment related to warrants and preferred stock	(9,707,000 )	(19,459,000 )	(27,624,000 )	(13,131,000 )	(8,009,000 )
Numerator for use in diluted income (loss) per share, as restated	\$ (2,482,000 )	\$ (4,966,000 )	\$ (11,509,000 )	\$ (3,742,000 )	\$ (6,277,000 )
<b>Denominator</b>					
As originally reported	7,658,556	6,319,802	6,472,093	6,497,619	6,514,181
Less antidilutive shares previously incorrectly included in denominator	(113,069 )	(532,898 )	(587,830 )	(591,594 )	(585,363 )
Denominator for use in diluted loss per share, as restated	7,545,487	5,786,904	5,884,263	5,906,025	5,928,818

The denominator for the basic income per share calculation remains unchanged from the amount previously reported.

The following table summarizes the outstanding securities that have been excluded from the computation of diluted weighted shares outstanding.

Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

	Three Months Ended June 30, 2015	Three Months Ended September 30, 2014	Nine Months Ended September 30, 2014	Three Months Ended June 30, 2014	Six Months Ended June 30, 2014
Options, as restated	360,635	436,632	436,632	499,380	499,380
Warrants, as restated	167,711	167,711	140,608	140,608	140,608
Shares in escrow, as restated	-	240,000	240,000	240,000	240,000
Total	528,346	844,343	817,240	879,988	879,988

F-23

The following tables summarize the unaudited quarterly statements of operations for the Company for 2015 and 2014. The tables include all necessary adjustments, consisting only of normal recurring adjustments necessary in the opinion of management for a fair statement of the results for interim periods.

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

	2014			
	Three-Months Ended March 31,	Three-Months Ended June 30,	Three-Months Ended September 30,	Three-Months Ended <b>December 31,</b> <b>(1)</b>
Revenue	\$ 104,000	\$ 101,000	\$ 103,000	\$ 101,000
Total operating expenses	2,638,000	3,849,000	5,334,000	2,698,000
Loss from operations	(2,534,000 )	(3,748,000 )	(5,231,000 )	(2,597,000 )
Other income (expense), net	(8,773,000 )	17,621,000	26,438,000	1,933,000
Income tax benefit	-	-	-	-
Net (loss) income	(11,307,000)	13,873,000	21,207,000	(664,000 )
Accretion of Series B redeemable convertible preferred stock	(314,000 )	(318,000 )	(323,000 )	(330,000 )
Net (loss) income attributable to common stockholders	(11,621,000)	13,555,000	20,884,000	(994,000 )
Net (loss) income per share of common stock – basic - restated for the three months ended June 30, 2014 and September 30, 2014	(3.18 )	2.56	3.87	(0.25 )
Net loss per share of common stock – diluted - restated for the three months ended June 30, 2014 and September 30, 2014	(3.18 )	(0.63 )	(0.86 )	(0.44 )



(1) Not previously reported.

## **18. Subsequent Events**

In January 2016, the Company entered into an Asset Purchase Agreement with Novolytics Ltd. (the “Novolytics Purchase Agreement”), to purchase certain tangible and intangible assets. Pursuant to the Novolytics Purchase Agreement, the Company received all rights, title and interest held by Novolytics to three families of patents. In consideration for the assets acquired, the Company paid cash consideration of \$146,000 and we issued warrants to purchase up to an aggregate of 170,000 shares of our common stock. The warrants have an exercise price of \$12.00 per share and contain certain registration rights. One half of the shares subject to the warrant become exercisable on the date that is the earlier of 30 days following the expiration of the lock-up period for our next public offering, or December 31, 2016. The remaining shares subject to the warrant become exercisable 60 days thereafter. The warrants will expire upon the later of the close of business of the 24-month anniversary of the date the warrants first become exercisable, as described in the preceding sentence, or the 24-month anniversary of the initial effectiveness of a registration statement covering the exercise shares. The fair value of the consideration granted and the allocation to the assets acquired will be determined and reported in the first quarter of 2016.

F-24

## **PART III**

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

None.

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

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

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

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

***Management's Report on Internal Control Over Financial Reporting***

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

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

As of December 31, 2015, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013). In adopting the 2013 Framework, management assessed the applicability of the principles within each component of internal control and determined whether or not they have been adequately addressed within the current system of internal control and adequately documented. Based on this assessment, management, under the supervision and with the participation of our principal executive officer and principal financial officer, identified a material weakness in our internal control over financial reporting and concluded that, as of December 31, 2015, our internal control over financial reporting was not effective at the reasonable assurance level based on those criteria.

Specifically, we concluded that we did not maintain adequate and effective internal control in the area of complex and non-routine transactions and in the application of Accounting Standards Codification No. 260, "Earnings Per Share," or ASC 260, as of December 31, 2015 and 2014. As a result, restatements of our consolidated financial statements have been necessary. Our financial statements have been restated for the year ended December 31, 2014, three and six months ended June 30, 2014, three and nine months ended September 30, 2014 and three months ended June 30, 2015 for the presentation of diluted net income (loss) per share in our consolidated statement of operations.

***Remediation of Material Weakness***

During 2015 and the first quarter of 2016, we implemented certain improvements to our internal control and financial reporting processes to address the material weaknesses in our internal control over financial reporting in 2015 and 2014 in the area of complex and non-routine transactions. These improvements include the following:

appointed an experienced Interim Chief Financial Officer in 2015, who continues to serve as our consultant, with significant experience in public company reporting, multinational operations and multi-location organizational structures;

appointed an experienced Chief Financial Officer in January 2016 with significant experience in public company reporting and complex transactions;

engaged consultants with experience in the review of unique and complex accounting topics, who consulted with management on complex transactions and reporting;

commenced designing additional training programs for relevant personnel and development of specific review procedures regarding the review of complex and non-routine transactions; and

implemented standardized financial control and reporting processes.

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

*Changes in Internal Control Over Financial Reporting.*

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

**Item 9B. OTHER INFORMATION**

None.

46

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

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

**MANAGEMENT**

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

<b>Name</b>	<b>Age</b>	<b>Position(s)</b>
M. Scott Salka	54	Chief Executive Officer, Director
Steve R. Martin	55	Chief Financial Officer
Wendy S. Johnson	64	Interim Chief Operating Officer, Director
<b>Non-Employee Directors</b>		
Jeremy Curnock Cook <sup>(2)</sup> <sup>(3)</sup>	66	Chairman of the Board
Louis Drapeau <sup>(1)</sup> <sup>(3)</sup>	72	Director
Michael S. Perry, Ph.D. <sup>(1)</sup> <sup>(2)</sup> <sup>(3)</sup>	56	Director
Julian P. Kirk	42	Director
Vijay B. Samant <sup>(1)</sup>	63	Director
Paul C. Grint, M.D. <sup>(2)</sup>	58	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

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

**Executive Officers**

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

**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.

**Wendy S. Johnson** has served as our Interim Chief Operating Officer since September 2014 and has served as a member of our board of directors since May 2014. 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.

## Non-Employee Directors

**Jeremy Curnock Cook** has served as a member of our board of directors since July 1995 and as Chairman of the board of directors since February 1998. From September 2014 to May 2015, he served as our Interim Chief Executive Officer. Mr. Curnock Cook has served as Chairman of International Bioscience Managers Limited, a corporate and investment advisory firm, since 2000, and also currently serves as Managing Director of Bioscience Managers Pty Ltd, a medical sciences fund manager. From 1987 to 2000, Mr. Curnock Cook was a director of Rothschild Asset Management Limited, a corporate and investment advisory company, and was responsible for the Rothschild Bioscience Unit. Mr. Curnock Cook founded the International Biochemicals Group in 1975, which was sold in 1985 to Royal Dutch Shell, where he served as Managing Director until 1987. He also serves as a member of the board of directors of Avita Medical Ltd, Nexus6 Ltd and SeaDragon Ltd, all private companies. Mr. Curnock Cook received an M.A. in natural sciences from Trinity College, Dublin.

**Louis Drapeau** has served as a member of our board of directors since March 2011. Since October 2007 through February 2016, Mr. Drapeau has served in various management positions of InSite Vision, a traded ophthalmology drug development company that was acquired in October 2015, including Vice President and Chief Financial Officer and Chief Executive Officer from November 2008 to December 2010. Prior to InSite Vision, he served as Chief Financial Officer, Senior Vice President, Finance, at Nektar Therapeutics, a biopharmaceutical company, from January 2006 to August 2007. Prior to Nektar, he served as Acting Chief Executive Officer from August 2004 to May 2005 and as Senior Vice President and Chief Financial Officer from August 2002 to August 2005 for BioMarin Pharmaceutical Inc. Previously, Mr. Drapeau spent 30 years at Arthur Andersen, including 19 years as an Audit Partner in Arthur Andersen's Northern California Audit and Business Consulting practice, which included 12 years as Managing Partner. Since February 2007, Mr. Drapeau has served as a member of the board of Bio-Rad Laboratories, Inc., a publicly traded pharmaceutical company. Mr. Drapeau received a B.S. in mechanical engineering and an M.B.A. from Stanford University.

**Michael S. Perry, D.V.M., Ph.D.** has served as a member of our board of directors since November 2005. Since January of 2016 Dr. Perry has served as Senior Vice President and Chief Scientific Officer of Business Development and Licensing for Novartis AG. From September 2014 to January 2016 he served as Chief Scientific Officer for the Cell and Gene Therapy Unit of Novartis Pharmaceuticals Corporation and from October 2012 to September 2014, he served as Global Head of Stem Cell Therapy and Vice President of the Integrated Hospital Care Franchise for Novartis Pharmaceuticals Corporation. Prior to rejoining Novartis in October 2012, he was a Venture Partner with Bay City Capital, a venture capital firm, from 2005 to September 2012. While serving in this capacity, he concurrently served as President and Chief Medical Officer at Poniard Pharmaceuticals, Inc., a publicly held drug development company, from 2009 to 2011. Dr. Perry also previously served as Chief Development Officer of VIA Pharmaceuticals, Inc., a publicly held biotechnology company, from 2005 to 2009. Dr. Perry served as Chairman and Chief Executive Officer of Extropy Pharmaceuticals, Inc., a privately held pediatric specialty pharmaceutical company, from 2003 to 2005. From 2002 to 2003, Dr. Perry served as President and Chief Executive Officer of Pharsight Corporation, a publicly held software and consulting services firm. From 2000 to 2002, Dr. Perry served as Global Head of Research and Development for Baxter Healthcare's BioScience Division (now Baxalta). From 1997 to 2000, Dr. Perry served as President and Chief Executive Officer of SyStemix Inc. and Genetic Therapy Inc., two



wholly-owned subsidiaries of Novartis Pharma. Dr. Perry served as Vice President of Regulatory Affairs for Novartis from 1994 to 1997. Prior to 1994, Dr. Perry held various management positions with Syntex Corporation (now Roche), Schering-Plough Corporation (now Merck) and BioResearch Laboratories, Inc. Dr. Perry received a Doctor of Veterinary Medicine (DVM), a Ph.D. in biomedical science-pharmacology specialty and an Honours B.Sc. in physics from the University of Guelph in Ontario, Canada. He is also a graduate of the Harvard Business School International Management Forum. Dr. Perry has served as Adjunct Professor in the Gates Center for Regenerative Medicine at the University of Colorado School of Medicine, Anschutz Medical Campus since November 2013. He has served as a member of the board of directors of Arrowhead Research Corporation since December 2011 and as a member of the board of directors of Avita Medical Ltd since February 2013.

**Julian P. Kirk** has served as a member of our board of directors since June 2013. Since 1999, Mr. Kirk has served as a Managing Director of Third Security, LLC, where he has worked since the firm's inception with several portfolio companies of its managed investment funds. He is also involved with oversight of Third Security, LLC's internal operations. Since October 2012, he has served on the board of directors of Fibrocell Science, Inc. Since August 2010, he has served on the board of directors of the New River Valley Economic Development Alliance. From October 2006 to December 2011, he served as a member of the board of directors of IntelliMat, Inc. and as Co-Chairman of the board of directors from September 2008 to December 2011. From September 2005 to December 2011, Mr. Kirk served as President of Harvest Pharmaceuticals Inc. Mr. Kirk also served as Chairman of the board of managers of ECDS, LLC from June 2008 to March 2010. Mr. Kirk graduated as an Echols Scholar from the University of Virginia.

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

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

## **Board Composition**

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

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

In March 2016, our board of directors undertook a review of the independence of each director and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. In making this determination, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. As a result of this review, our board of directors determined that Jeremy Curnock Cook, Louis Drapeau, Michael Perry, Vijay Samant and Paul Grint qualify as "independent" directors within the meaning of the NYSE MKT rules. Our board of directors also concluded that M. Scott Salka and Wendy Johnson were not at such time "independent" directors within the meaning of the NYSE MKT rules given their roles as Chief Executive Officer and Interim Chief Operating Officer, respectively. Our board of

directors also concluded that Julian P. Kirk was not independent at such time as a result of his relationship with Randal J. Kirk and Third Security, LLC. See “Risk Factors—We have a disagreement with one of our principal stockholders regarding the interpretation of our Amended and Restated Articles of Incorporation” under Item 1A of this Annual Report.

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

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

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

### **Board Leadership Structure**

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

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

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

## **Board Committees**

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

### ***Audit Committee***

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

- evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors and to present the committee's conclusion to our board of directors;
- reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non-audit services;
- monitoring the rotation of partners of our independent auditors on our audit engagement team as required by law;
- prior to engagement of any independent auditor, and at least annually thereafter, reviewing relationships that may reasonably be thought to bear on their independence, and assessing and otherwise taking the appropriate action to

- oversee the independence of our independent auditor;
- reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the caption “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and discussing the statements and reports with our independent auditors and management;
- reviewing with our independent auditors and management significant issues that arise regarding accounting principles and financial statement presentation and matters concerning the scope, adequacy and effectiveness of our internal control over financial reporting;
- reviewing with management and our auditors any earnings announcements and other public announcements regarding material developments;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding internal accounting controls, accounting or auditing matters and other matters;
- preparing the report that the SEC requires in our annual proxy statement;
- reviewing and providing oversight of any related-person transactions in accordance with our related-person transactions policy and reviewing and monitoring compliance with legal and regulatory responsibilities, including our code of business conduct and ethics;
- reviewing on a periodic basis our investment policy; and
- reviewing and evaluating on an annual basis its own performance, including its compliance with its charter.

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

### *Compensation Committee*

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

- reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) our overall compensation strategy and policies;
- reviewing and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) the compensation and other terms of employment of our executive officers;
- reviewing and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) performance goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;

- reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;
- evaluating risks associated with our compensation policies and practices and assessing whether risks arising from our compensation policies and practices for our employees are reasonably likely to have a material adverse effect on us;
- reviewing making recommendations to the full board of directors regarding the type and amount of compensation to be paid or awarded to our non-employee board members;
- establishing policies with respect to votes by our stockholders to approve executive compensation as required by Section 14A of the Exchange Act and determining our recommendations regarding the frequency of advisory votes on executive compensation, to the extent required by law;
- reviewing and assessing the independence of compensation consultants, legal counsel and other advisors as required by Section 10C of the Exchange Act;
- administering our equity incentive plans;
- establishing policies with respect to equity compensation arrangements;
- reviewing the competitiveness of our executive compensation programs and evaluating the effectiveness of our compensation policy and strategy in achieving expected benefits to us;
- reviewing and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) the terms of any employment agreements, severance arrangements, change-of-control protections and any other compensatory arrangements for our executive officers;
- reviewing the adequacy of its charter on a periodic basis;
- reviewing with management and approving our disclosures, if any, under the caption “Compensation Discussion and Analysis” and related tables in our periodic reports or proxy statements to be filed with the SEC;
- preparing the report that the SEC requires in our annual proxy statement; and
- reviewing and assessing on an annual basis its own performance.

### ***Nominating and Corporate Governance Committee***

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

- identifying, reviewing and evaluating candidates to serve on our board of directors consistent with criteria approved by our board of directors;
- evaluating director performance on management and the board and applicable committees of the board and determining whether continued service on our board is appropriate;
- evaluating, nominating and recommending individuals for membership on our board of directors;
- evaluating nominations by stockholders of candidates for election to our board of directors;
- considering and assessing the independence of members of our board of directors;
- developing a set of corporate governance policies and principles, periodically reviewing and assessing these policies and principles and their application and recommending to our board of directors any changes to such policies and

principles;

- reviewing the adequacy of its charter on an annual basis; and
- annually evaluating the performance of the nominating and corporate governance committee.

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

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

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

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

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

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

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

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

**Item 11. EXECUTIVE  
COMPENSATION**

**Executive Compensation**

Our named executive officers for the year ended December 31, 2015, which consist of all individuals who served as our principal executive officer during 2015, our two most highly compensated executive officers other than our principal executive officer who were serving as executive officers as of December 31, 2015 and one former executive officer who would have been among the most highly compensated executive officers if such individual had been serving as of December 31, 2015, are:



- M. Scott Salka, our Chief Executive Officer and Director;
- Jeremy Curnock Cook, our former interim Chief Executive Officer and President and current Chairman of the Board;
- David E. Boshier, our former Interim Chief Financial Officer and current consultant; and
- Wendy S. Johnson, our Interim Chief Operating Officer and Director.

In January 2016, Steve Martin commenced employment with us as our Senior Vice President and Chief Financial Officer. Although Mr. Martin is not one of our named executive officers for the year ended December 31, 2015, we have included information regarding Mr. Martin's compensation in this report where it may be material to an understanding of our executive compensation program.

### Summary Compensation Table

The following table provides information regarding the compensation paid during the last two fiscal years to our named executive officers for the year ended December 31, 2015.

Name and Principal Position	Year	Salary	Bonus	Option Awards <sup>(1)</sup>	Non-Equity Incentive Plan Compensation	All Other Compensation	Total
Michael Scott Salka, Chief Executive Officer <sup>(2)</sup>	2015	\$264,263	\$-	\$3,469,919	\$ 85,000	\$ 4,925	\$3,824,107
Jeremy Curnock Cook, Former Interim Chief Executive Officer and President and Current Chairman of the Board of Directors <sup>(3)</sup>	2015	\$-	\$100,000	\$223,949	\$ -	\$ 58,250	<sup>(6)</sup> \$382,199
	2014	\$-	\$-	\$-	\$ -	\$ 50,325	\$50,325
David E. Boshier, Former Interim Chief Financial Officer and Current Consultant <sup>(4)</sup>	2015	\$308,650	\$-	\$-	\$ -	\$ -	\$308,650
	2014	\$127,125	\$-	\$-	\$ -	\$ -	\$127,125
Wendy S. Johnson, Interim Chief Operating Officer and Director <sup>(5)</sup>	2015	\$270,000	\$25,000	\$289,373	\$ -	\$ 30,000	<sup>(6)</sup> \$614,373
	2014	\$60,000	\$-	\$-	\$ -	\$ 7,324	\$67,324

In accordance with SEC rules, this column represents the aggregate grant date fair value of the option awards granted during 2015 and 2014 (if any) computed in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718 for stock-based compensation transactions (ASC 718).

- (1) Assumptions used in the calculation of these amounts are included in the notes to our audited financial statements incorporated herein by reference. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options.
- (2) Mr. Salka commenced employment with us as Chief Executive Officer on May 18, 2015. Mr. Curnock Cook served as interim Chief Executive Officer and President from September 15, 2014 until May 18, 2015. Mr. Curnock Cook did not receive or earn any compensation in 2014 or 2015 for his role as interim Chief Executive Officer, except that in September 2015, he was paid a discretionary lump sum cash payment of \$100,000 and awarded an option grant to purchase 31,000 shares of common stock in recognition of his services as interim Chief Executive Officer. Mr. Salka has served as our Chief Executive Officer since May 18, 2015. Mr. Curnock Cook continues to serve as Chairman of our Board of Directors.
- (3) Mr. Boshier served as interim Chief Financial Officer from July 1, 2014 to January 18, 2016. Mr. Boshier continues to serve as a consultant.
- (4) Ms. Johnson has served as interim Chief Operating Officer since her appointment on September 15, 2014. Ms. Johnson joined the Board of Directors on May 19, 2014.
- (5) Represents Board of Director retainers paid to Mr. Curnock Cook and Ms. Johnson in 2015.

## Base Salary

The base salary or consulting compensation of our named executive officers, as applicable, is generally determined and approved by our Board of Directors, based on the recommendation of the Compensation Committee. The Board of Directors approved an annual base salary of \$425,000 for Mr. Salka, which became effective on May 18, 2015 in connection with his commencement of employment with us.

Mr. Curnock Cook did not receive or earn any base salary or consulting fees in 2015 for his role as interim Chief Executive Officer and President. In September 2015, upon recommendation from the Compensation Committee, the Board of Directors approved a discretionary \$100,000 cash payment to Mr. Curnock Cook in recognition of his service as interim Chief Executive Officer from September 2014 to May 2015.

Mr. Boshier and Ms. Johnson were paid monthly consulting fees for their interim officer roles during 2015. During all of 2015, Mr. Boshier was compensated at a rate of \$5,000 per month plus \$300 for any hours worked in excess of 20 hours per month. Ms. Johnson was compensated at a rate of \$20,000 per month for her consulting services as Interim Chief Operating Officer from January 1, 2015 until June 30, 2015, which rate was increased to \$25,000 per month effective on July 1, 2015.

## **Bonus Opportunity**

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

The Board of Directors and/or Compensation Committee generally will consider each executive officer's individual contributions towards reaching our corporate goals and may also establish specific individual goals for our executive officers as it determines appropriate. There is no minimum bonus percentage or amount established for the named executive officers and, as a result, the bonus amounts vary based on corporate and individual performance, as applicable. Under the terms of his offer letter agreement described below, Mr. Salka is eligible to receive an annual performance-based bonus for 2015 equal to, at target, 40% of his annual salary based on our achievement of certain performance goals, pro-rated for Mr. Salka's services during 2015. Under the terms of her consulting agreement described below, Ms. Johnson is eligible to receive up to \$200,000 in cash bonus payments upon achievement of specific goals relating to dosing the first patient in the first and second clinical trials utilizing our drug product. Mr. Boshier is not entitled to any specific target or maximum bonus for company or individual performance in 2015.

Mr. Salka's 2015 bonus was based entirely on corporate goals relating to our clinical trial progress, manufacturing capabilities being established, certain organizational achievements and for listing our company on a major stock exchange.

No specific corporate or individual goals were established for Mr. Boshier for 2015.

Ms. Johnson was eligible to earn a bonus of \$175,000 upon dosing of the first patient in the first clinical trial utilizing our drug product in 2015 (or alternatively, a bonus of \$75,000 if such milestone was met after 2015 and prior to March 31, 2016) and a bonus of \$25,000 upon dosing of the first patient the second clinical trial utilizing our drug product before March 31, 2016.

In January 2016, the Compensation Committee reviewed the corporate performance goals for Mr. Salka and determined that on an overall basis, we had achieved 50% of such goals for 2015, based on the evaluation of the results by the Compensation Committee and considering the importance of each goal to our company. The Compensation Committee assessed the goals established for Ms. Johnson's bonus and determined that she had not met the goals in 2015 because no patients were dosed in 2015. However, the Compensation Committee awarded Ms. Johnson a discretionary bonus of \$25,000, in recognition of significant progress towards the goal which was supported by the patient screenings which occurred in 2015, although no patients were dosed until January 2016. Ms. Johnson has earned performance bonuses in 2016 based on the achievement of the established goals and additional achievements in the first quarter of 2016.

### **Equity-Based Awards**

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

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

In August 2015, our Board of Directors granted an option to purchase 399,716 shares of common stock to Mr. Salka at a per share exercise price of \$9.45. One-third of the shares underlying the option vest over a four-year period, subject to Mr. Salka's continued service with us, and two-thirds of the shares underlying the option vest upon satisfaction of certain business goals relating to a \$20M capital raise and human clinical trial milestones for our phage products.

In September 2015, in recognition of his service as interim Chief Executive Officer from September 2014 to May 2015, our Board of Directors granted an option to purchase 31,100 shares of common stock to Mr. Curnock Cook at a per share exercise price of \$6.38. The option vests over a four-year period, subject to Mr. Cook's continued service with us.

In September 2015, pursuant to her consulting agreement, our Board of Directors granted Ms. Johnson an option for 49,965 shares at an exercise price per share of \$7.46, half of which vests monthly over a one-year period and half of which vests upon the achievement of certain clinical trial milestones for our drug product, in each case subject to Ms. Johnson's continued service with us.

Our Board of Directors also granted each of Mr. Curnock Cook and Ms. Johnson stock options for an aggregate of 7,400 shares and 16,200 shares, respectively, in September 2015 for services on our Board of Directors, which is described below under "—Non-Employee Director Compensation".

In January 2016, pursuant to his offer letter agreement, our Board of Directors granted Mr. Martin an option to purchase 99,919 shares of common stock at a per share exercise price of \$2.85. Twenty-five percent of the shares subject to the option vest on the one-year anniversary of Mr. Martin's commencement of employment with us and the remainder vest in equal monthly installments thereafter, subject to Mr. Martin's continued service with us.

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

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

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

under “—Equity-Based Awards”.

*Mr. Boshier.* Mr. Boshier provides services as an independent contractor on an interim basis as our Interim Chief Financial Officer pursuant to a services agreement between us and The Fahrenheit Group, LLC (of which Mr. Boshier is a managing director) dated June 30, 2014. Under this services agreement, we pay \$5,000 per month to The Fahrenheit Group, LLC for Mr. Boshier's services, up to 20 hours per month, and \$300 per hour for any additional services in excess of 20 hours per month. The services may be terminated at any time upon thirty days' written notice from either party or as otherwise agreed to between us and The Fahrenheit Group, LLC.

*Ms. Johnson.* We entered into an agreement with Ms. Johnson in September 2014 which provided for Ms. Johnson's services as an independent contractor on an interim basis as our Chief Operating Officer. The agreement had an original term until December 31, 2014, which was further extended in January 2015 to March 31, 2015. Under the agreement, Ms. Johnson was entitled to compensation at the rate of \$20,000 per month. In September 2015, we entered into a consulting agreement with Ms. Johnson, which supersedes her prior agreement, effective July 1, 2015. Under the terms of her consulting agreement, Ms. Johnson is entitled to receive monthly compensation of \$25,000 for consulting services of at least 120 hours per month, cash bonus payments up to an aggregate of \$200,000 upon the achievement of certain Company milestones and an option to purchase a number of shares of our common stock under our 2013 Plan equal to 0.5% of the number of shares of common stock outstanding on a fully-diluted basis, which was granted in September 2015 and is described above under "—Equity-Based Awards". The consulting agreement will terminate on July 1, 2016, unless earlier terminated pursuant to its terms. We can terminate the consulting agreement at any time for cause, or for any other reason upon 90 days written notice to Ms. Johnson, provided that no such termination can be effective before March 31, 2016. Ms. Johnson can terminate the agreement upon our material breach upon 30 days written notice, or for any other reason upon 45 days written notice.

#### **Agreements with our Chief Financial Officer**

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

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

*Mr. Salka.* Under the terms of his offer letter agreement, Mr. Salka is entitled to receive 12 months of continued base salary if his employment with us is terminated without cause or if he resigns for good reason, provided that Mr. Salka executes an effective release of claims against us.

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

All of 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, 2015.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards:		
			Number of Securities Underlying Unexercised Options (#) Unearned	Option Exercise Price (\$)	Option Expiration Date
Mr. Salka	-	133,238	(1) 266,478	(1) \$9.45	8/5/2025
Mr. Curnock Cook	-	6,500	(2) -	\$6.38	9/20/2025
	-	-	900	(3) \$6.38	9/20/2025
	-	31,100	(4) -	\$6.38	9/20/2025
	6,600	2,200	(5) -	\$10.00	10/23/2022
	60	-	(6) -	\$190.00	5/8/2016
	1,800	-	(7) -	\$13.50	5/29/2019
Mr. Boshier	-	-	-	\$-	-
Ms. Johnson	10,409	14,574	(8) 24,982	(8) \$7.46	9/8/2025
	-	6,500	(9) -	\$6.38	9/20/2025
	-	-	9,700	(10) \$6.38	9/20/2025

One-third of the shares underlying the 399,716 share option grant vest over a four-year period commencing on May 18, 2015 (with 25% vesting on the one-year anniversary of the commencement of Mr. Salka's employment and the balance vesting in monthly installments thereafter), subject to Mr. Salka's continued service with us, and two-thirds of the shares underlying the 399,716 share option grant vest upon satisfaction of certain business goals relating to a \$20M capital raise and human clinical trial milestones for our phage products.

The shares underlying this option will vest on the one-year anniversary of August 3, 2015, the date of our most recent annual meeting of stockholders. This option was granted to Mr. Cook for his services as a non-employee director and is described below under "—Non-Employee Director Compensation."

The shares underlying this option will vest on the date that the market price of our common stock reaches \$25.00 per share before the option expires. This option was granted to Mr. Cook for his services as a non-employee director and is described below under "—Non-Employee Director Compensation."

The shares underlying this option will vest on an equal monthly basis over a four-year period commencing on May 1, 2015.

6.25% of the total shares underlying this option vested and became exercisable on January 23, 2013. 6.25% of the total shares underlying this option vests and becomes exercisable on the first business day of each three (3) month period thereafter, subject to continued service through each vesting date.

100.00% of the total shares underlying this option vested and became exercisable on May 8, 2007.

25.00% of the total shares underlying this option vested and became exercisable on May 29, 2009. 37.50% of the  
(7) total shares underlying this option vests and became exercisable on the first business day of each twelve (12) month period thereafter.

One-half of the shares underlying this option will vest and become exercisable upon the achievement of certain  
(8) clinical trial milestones for our drug product, and one-half of the shares will vest on an equal monthly basis over the 12 months following July 1, 2015, in each case subject to Ms. Johnson's continued service through each vesting date.

The shares underlying this option will vest on the one-year anniversary of August 3, 2015, the date of our most  
(9) recent annual meeting of stockholders. This option was granted to Ms. Johnson for her services as a non-employee director and is described below under "—Non-Employee Director Compensation."

The shares underlying this option will vest on the date that the market price of our common stock reaches \$25.00  
(10) per share before the option expires. This option was granted to Ms. Johnson for her services as a non-employee director and is described below under "—Non-Employee Director Compensation."

All of the stock options held by our named executive officers listed in the table above were granted under and subject to the terms of our 2013 Stock Incentive Plan, our 2009 Targeted Genetics Stock Incentive Plan, or our 2012 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, 2015.

### **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**

***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. The 2013 Plan replaces the Targeted Genetics Corporation Stock Incentive Plan and the 2012 Stock Incentive Plan.

As of December 31, 2015, there were outstanding options to purchase 673,169 shares of common stock and 723,431 shares of common stock remaining available for the grant of new awards under the 2013 Plan, subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

The 2013 Plan permits the granting of stock options (both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify), restricted stock, restricted stock units, and performance-based awards. The exercise price of each stock option will be determined by our plan administrator but may not be less than 100% of the fair market value of our common stock on the date of grant or, in the case of an incentive stock option granted to a 10% owner, less than 110% of the fair market value of our common stock on the date of grant. The term of each stock option will be fixed by the plan administrator and may not exceed 10 years from the date of grant. The plan administrator will determine at what time or times each option may be exercised.

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

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

Our Board of Directors may amend or terminate the 2013 Plan at any time. The plan administrator may amend the terms of any outstanding award granted under the 2013 Plan, but no such action may adversely affect the holder's rights under an outstanding award without the holder's consent. Certain amendments to the 2013 Plan require the approval of our stockholders. No awards may be granted under the 2013 Plan after the date that is 10 years from the date of adoption by our Board of Directors.

***2009 Targeted Genetics Stock Incentive Plan and 2012 Stock Incentive Plan***

Our Board of Directors and stockholders adopted the 2009 Targeted Genetics Stock Incentive Plan in March 2009. Our Board of Directors adopted our 2012 Stock Incentive Plan in October 2012. There are no shares of common stock remaining for future awards under the 2009 Targeted Genetics Stock Incentive Plan and the 2012 Stock Incentive Plan. We refer to the 2009 Targeted Genetics Stock Incentive Plan and the 2012 Stock Incentive Plan together as the Former Plans.

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

Our Board of Directors may amend or terminate the Former Plans at any time. Our Board of Directors may also amend the terms of any outstanding award, provided that no amendment to an award may materially impair any of the rights of a participant under any awards previously granted without his or her written consent.

### Non-Employee Director Compensation

The following table and related footnotes show the compensation paid during the year ended December 31, 2015 to our non-employee directors. The only type of stock awards held by any of our non-employee directors as of December 31, 2015 were stock option awards.

Name	Fees Earned or Paid in		Option Awards	All Other Compensation	Total
	Cash				
Louis Drapeau <sup>(1)</sup>	\$47,750	\$73,306	\$ -	\$ -	\$121,056
Michael S. Perry, Ph.D. <sup>(2)</sup>	\$44,750	\$68,465	\$ -	\$ -	\$113,215
Anthony Smithyman, Ph.D. <sup>(3)</sup>	\$10,000	\$-	\$ -	\$ -	\$10,000
Julian P. Kirk <sup>(4)</sup>	\$30,000	\$84,927	\$ -	\$ -	\$114,927
Vijay Samant <sup>(5)</sup>	\$7,028	\$83,866	\$ -	\$ -	\$90,894
Paul C. Grint <sup>(6)</sup>	\$6,875	\$83,866	\$ -	\$ -	\$90,741



- (1) As of December 31, 2015, Mr. Drapeau held stock options for an aggregate of 16,200 shares, of which 2,100 shares were vested and exercisable.
- (2) As of December 31, 2015, Mr. Perry held stock options for an aggregate of 18,840 shares, of which 5,615 shares were vested and exercisable.
- (3) Dr. Smithyman resigned from our Board of Directors on April 16, 2015. As of December 31, 2015, Mr. Smithyman did not hold any stock options
- (4) As of December 31, 2015, Mr. Kirk held stock options for an aggregate of 16,200 shares, of which no shares were vested and exercisable.
- (5) Mr. Samant joined our Board of Directors in November 2015. As of December 31, 2015, Mr. Samant held stock options for an aggregate of 16,200 shares, of which no shares were vested and exercisable.
- (6) Mr. Grint joined our Board of Directors in November 2015. As of December 31, 2015, Mr. Grint held stock options for an aggregate of 16,200 shares, of which no shares were vested and exercisable.

From January until September 2015, our non-employee directors were paid annual cash retainers for their service on the Board of Directors and committees. The chairman of the Board of Directors received an annual cash retainer of \$30,000 and each other non-employee director received an annual cash retainer of \$20,000. For the Audit Committee, the committee chair received an additional annual cash retainer of \$7,500 and each member received an additional annual cash retainer of \$4,000. For the Compensation Committee and Nominating and Corporate Governance Committee, each chair received an additional annual cash retainer of \$4,000 and each member received an additional annual cash retainer of \$2,500.

During 2015, Mr. Curnock Cook, Mr. Salka and Ms. Johnson served on our Board of Directors. As an employee, Mr. Salka did not receive cash or equity compensation for his services as a director during 2015. Mr. Curnock Cook and Ms. Johnson were compensated for their services as non-employee directors in 2015. As named executive officers, the compensation of each of Messrs. Cook and Salka and Ms. Johnson for services on the Board of Directors and with respect to Mr. Curnock Cook, as Chairman of the Board of Directors, are reflected in the Summary Compensation Table above.

In September 2015, the Board of Directors approved a revised compensation structure for our non-employee directors. Effective as of July 1, 2015, the chairman of the Board will receive an annual cash retainer of \$60,000 and each other non-employee director will receive an annual cash retainer of \$40,000. For the Audit Committee, the committee chair will receive an additional annual cash retainer of \$15,000 and each member will receive an additional annual cash retainer of \$6,000. For the Compensation Committee, the committee chair will receive an additional annual cash retainer of \$10,000 and each member will receive an additional annual cash retainer of \$5,000. For the Nominating and Corporate Governance Committee, the committee chair will receive an additional annual cash retainer of \$5,000 and each member will receive an additional annual cash retainer of \$3,000.

On September 21, 2015, our Board of Directors granted options to purchase shares of common stock to each of the following members of our Board of Directors as follows:

Name	Shares Subjected	Shares Subjected
	to	to
	<b>Standard Vesting</b> <sup>(1)</sup>	<b>Performance Vesting</b> <sup>(2)</sup>
Mr. Curnock Cook	6,500	900
Dr. Perry	6,500	6,300
Mr. Drapeau	6,500	7,300
Mr. Kirk	6,500	9,700
Ms. Johnson	6,500	9,700

(1) 25% of the shares subject to the option will vest one year following the date of grant, and the remaining shares will vest in 36 equal monthly installments thereafter.

(2) All of the shares will vest upon the market price of our common stock reaching \$25.00 per share during the term of the option.

On November 5, 2015, our Board of Directors granted options to purchase shares of common stock to each of the following new members of our Board of Directors, who each commenced services in November 2015, as follows:

Name	<b>Options</b> (1)
Mr. Samant	16,200
Dr. Grint	16,200

(1) 25% of the shares subject to the option will vest one year following the date of grant, and the remaining shares will vest in 36 equal monthly installments thereafter.



**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 5,886,503 shares of common stock outstanding as of February 29, 2016.

Information with respect to beneficial ownership has been furnished by each director, officer or beneficial owner of more than 5% of our common stock, unless otherwise indicated. 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 29, 2016, which is 60 days after February 29, 2016. 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.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned †	Percentage of Shares Beneficially Owned †	
5% or Greater Stockholders Randal J. Kirk <sup>(1)</sup> c/o Third Security, LLC	1,764,199	27.2	%

Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

1881 Grove Avenue Radford, Virginia 24141 Pendientes Limited <sup>(2)</sup>	946,873	13.9	%
Ballacarrick, Poolvaish Road Isle of Man, IM9 4PJ Broadfin Healthcare Master Fund, LTD <sup>(3)</sup>	653,814	9.8	%
20 Genesis Close Ansbacher House, Second Floor Grand Cayman KY1-1108 Cayman Islands Phillip Asset Management Limited <sup>(5)</sup>	384,140	6.3	%
Level 12, 15 William Street Melbourne VIC Australia			
Directors and Named Executive Officers			
M. Scott Salka	4,200	*	
Jeremy Curnock Cook <sup>(6)</sup>	396,450	6.5	%
Louis Drapeau <sup>(7)</sup>	11,951	*	
Michael S. Perry, Ph.D. <sup>(8)</sup>	6,303	*	
Julian P. Kirk	-	-	
Vijay B. Samant	-	-	
Paul C. Grint, M.D.	-	-	
Wendy Johnson <sup>(9)</sup>	19,737	*	
David E. Boshier	-	-	
<b>All current executive officers and directors as a group (9 persons) <sup>(10)</sup></b>	<b>439,552</b>	<b>7.4</b>	<b>%</b>

† Our Amended and Restated Articles contain potential ambiguities, such as in the provisions of the Amended and Restated Articles of Incorporation relating to anti-dilution rights for the Series B Preferred as well as the rate of converting Series B Preferred into shares of common stock. These potential ambiguities create uncertainty around our capitalization. For purposes of reporting beneficial ownership under Item 12 of this Annual Report on 10-K, each share of Series B Preferred is reflected as being convertible into 0.20 shares of our common stock at the option of the holder.

\* Represents beneficial ownership of less than 1%.

Based solely upon a Schedule 13D filed with the SEC on March 16, 2015. According to the Schedule 13D and giving effect to the Reverse Stock Split, consists of (a) 758,814 shares of common stock held by NRM VII Holdings I, LLC, which we refer to as NRM VII Holdings, (b) 428,571 shares of common stock issuable upon conversion of Series B redeemable convertible preferred stock held by NRM VII Holdings, (c) 107,143 shares of common stock issuable upon exercise of warrants held by NRM VII Holdings, (d) 758,787 shares of common stock held by Intrexon Corporation, and (e) 69,697 shares of common stock issuable upon exercise of warrants held Intrexon Corporation. Third Security, LLC is the Manager of Third Security Capital Partners VII, LLC, which is the Manager of NRM VII Holdings. Third Security, LLC has sole voting and investment power over the shares beneficially owned by NRM VII Holdings listed in the foregoing clauses (a) and (b), and consequently

(1) Third Security beneficially owns approximately 14.6% of our common stock. Randal J. Kirk is the Manager of Third Security, LLC. Shares held by this entity may be deemed to be indirectly beneficially owned (as defined under Rule 13d-3 promulgated under the Exchange Act) by Mr. Kirk. Mr. Kirk disclaims beneficial ownership of such shares, except to the extent of any pecuniary interest therein. Randal J. Kirk, directly and through certain affiliates, has voting and dispositive power over a majority of the outstanding capital stock of Intrexon Corporation. Mr. Kirk may therefore be deemed to have voting and dispositive power over the shares of the issuer owned by Intrexon Corporation. Shares held by Intrexon Corporation may be deemed to be indirectly beneficially owned (as defined under Rule 13d-3 promulgated under the Exchange Act) by Mr. Kirk. Mr. Kirk disclaims beneficial ownership of such shares, except to the extent of any pecuniary interest therein.

Based solely upon a Form 4 filed with the SEC on February 24, 2014 filed by Gwynn Williams, who may be deemed to control Pendinas Limited. According to the Form 4 and giving effect to the Reverse Stock Split,

(2) consists of 645,012 shares of common stock issuable upon conversion of shares of Series B redeemable convertible preferred stock and 301,861 shares of common stock issuable upon exercise of warrants.

Based solely upon a Schedule 13G filed with the SEC on February 12, 2016. According to the Schedule 13G, this amount consists of 552,000 shares of our common stock and 68,000 shares of common stock issuable upon the exercise of warrants. Broadfin Capital, LLC serves as investment adviser to Broadfin Healthcare Master Fund, LTD with the power to direct investments and/or sole power to vote the shares owned by Broadfin Healthcare Master Fund, LTD. Kevin Kotler is the Managing Member of Broadfin Capital, LLC. Mr. Kotler has voting and dispositive power over the shares held by Broadfin Healthcare Master Fund, LTD. Mr. Kotler disclaims beneficial ownership of all shares beneficially owned, except to the extent of his pecuniary interests in such shares.

Based solely upon a Schedule 13G filed with the SEC on February 16, 2016. According to the Schedule 13G, this amount consists of (a) an aggregate of 53,600 shares of common stock, (b) an aggregate of 163,717 shares of common stock issuable upon conversion of shares of Series B redeemable convertible preferred stock, (c) and an aggregate of 107,142 shares of common stock issuable upon the exercise of warrants, each held by RA Capital Management, LLC and RA Capital Healthcare Fund, L.P. RA Capital Management, LLC is the sole general partner of RA Capital Healthcare Fund, L.P. Peter Kolchinsky is the manager of RA Capital Management, LLC and may be deemed to have voting and investment power over the shares beneficially owned by RA Capital Healthcare Fund, L.P. and RA Capital Management, LLC. Each of the foregoing persons and entities disclaim beneficial ownership of the securities held by them except to the extent of his or its pecuniary interest therein.

(5)

Consists of (a) 188,455 shares of common stock held by One Fund Management Limited as Trustee for Asia Pacific Healthcare Fund II, which is also known as Phillip Asset Management Limited as Trustee for Asia Pacific Healthcare Fund II (“Phillip Asset Management”), (b) 142,857 shares of common stock issuable upon conversion of Series B redeemable convertible preferred stock held by Phillip Asset Management, and (c) an aggregate of 52,828 shares of common stock issuable upon exercise of warrants held by Phillip Asset Management. Phillip Asset Management holds all securities in its capacity as trustee for Bioscience Managers Pty Ltd. Jeremy Curnock Cook, the Chairman of the Company’s Board of Directors, is a Managing Director and holds an ownership interest in Bioscience Managers Pty Ltd.

- (6) Includes the shares reference in Footnote 5 above and 9,010 shares of common stock that Mr. Cook has the right to acquire from us within 60 days of February 29, 2016, pursuant to the exercise of stock options.
  - (7) Includes 1,951 shares of common stock that Mr. Drapeau has the right to acquire from us within 60 days of February 29, 2016, pursuant to the exercise of stock options.
  - (8) Includes 2,763 shares of common stock that Dr. Perry has the right to acquire from us within 60 days of February 29, 2016, pursuant to the exercise of stock options.
  - (9) Includes 18,737 shares of common stock that Ms. Johnson has the right to acquire from us within 60 days of February 29, 2016, pursuant to the exercise of stock options.
- Consists of (a) 205,855 shares of common stock, (b) 142,857 shares of common stock issuable upon conversion of Series B redeemable convertible preferred stock, (c) 52,828 shares of common stock issuable upon exercise of warrants, and (d) 34,612 shares of common stock exercisable within 60 days of February 29, 2016.

### **Equity Compensation Plan Information**

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

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

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

The following table provides information as of December 31, 2015 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 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 <sup>(1)</sup>	599,669	\$ 8.52		723,431
Equity compensation plans not approved by security holders <sup>(2)</sup>	70,100	\$ 10.00		-
Total	669,769	\$ 8.68		723,431

(1)The 2009 Plan and 2013 Plan.

(2)The 2012 Plan.

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

The following includes a summary of transactions since January 1, 2014 to which we have been a party, in which the amount involved in the transaction exceeded the lesser of \$120,000 or one percent of the average of our total assets at year end for the last two completed fiscal years,, and in which any of our directors, executive officers or, to our

knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described in the sections above entitled “Executive Compensation” and “Non-Employee Director Compensation.”

### **Sale of Common Stock**

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

In addition, in connection with the March 2015 private placement, we sold an aggregate of 278,788 shares and 69,697 shares underlying warrants to Intrexon Corporation. Randal J. Kirk, the father of Julian P. Kirk, a member of our board of directors, directly and through certain affiliates, has voting and dispositive power over a majority of the outstanding capital stock of Intrexon Corporation. Randal J. Kirk is also deemed a holder of more than five percent of the shares of our common stock, as described in the section entitled “Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters”. In connection with the March 2015 private placement, we entered into a registration rights agreement with Intrexon and certain other purchasers in the private placement, pursuant to which we registered for resale on Form S-1 (File No. 333-203454) 824,848 shares of common stock (on a post-August 2015 reverse split basis) held or issuable upon exercise of warrants by Intrexon.

### **Exclusive Channel Collaboration**

Pursuant to the exclusive channel collaboration with Intrexon, we agreed to pay Intrexon royalties as a percentage in the upper-single digits of the net product sales of a product developed under the collaboration, and may also pay up to \$7.5 million in aggregate milestone payments for each product developed. Intrexon owns more than five percent of our common stock.

### **Employment Agreements**

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



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

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

### **Indemnification Agreements**

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

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

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

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

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



but not limited to:

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

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

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

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

The following table represents aggregate fees billed to us for the fiscal years ended December 31, 2015 and December 31, 2014 by Ernst & Young LLP, our current principal accountant.

	Fiscal Year Ended December 31, 2015	Fiscal Year Ended December 31, 2014
Audit Fees	\$428,588	\$382,000
Audit Related Fees	-	-
Tax Fees	-	-
All Other Fees	-	-
Total	\$428,588	\$382,000

The following table represents aggregate fees billed to us for the fiscal years ended December 31, 2015 and December 31, 2014 by PBMares, LLP, our former principal accountant.

	Fiscal Year	Fiscal Year
--	----------------	----------------

Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

	Ended December 31, 2015	Ended December 31, 2014
Audit Fees	\$ 51,551	\$ 132,775
Audit Related Fees	-	118,950
Tax Fees	-	-
All Other Fees	-	69,947
Total	\$ 51,551	\$ 321,672

Representatives of Ernst & Young LLP attended all of the meetings of the Audit Committee occurring between and including the dates of January 20, 2015 and December 31, 2015. Representatives of PBMares, LLP attended all of the meetings of the Audit Committee during the period commencing on January 1, 2014 and ending on January 20, 2015.

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

**PART IV**

**Item 15. EXHIBITS**

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

	<b>Page</b>
Report of Independent Registered Public Accounting Firm	F-2
Balance Sheets	F-3
Statements of Operations and Comprehensive Loss	F-4
Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)	F-5
Statements of Cash Flows	F-6
Notes to Financial Statements	F-7

2. *Financial Statement Schedules.* None.

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

## SIGNATURES

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

### AMPLIPHI BIOSCIENCES CORPORATION

By: /s/ Michael Scott Salka

Name: Michael Scott Salka

Title: Chief Executive Officer

(Principal Executive Officer)

By: /s/ Steve R. Martin

Name: Steve R. Martin

Title: Chief Financial Officer

(Principal Financial and Accounting Officer)

Date: March 30, 2016

**SIGNATURES AND POWER OF ATTORNEY**

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

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

<b>SIGNATURE</b>	<b>TITLE</b>	<b>DATE</b>
/s/ Michael Scott Salka Michael Scott Salka	Chief Executive Officer <i>(Principal Executive Officer)</i>	March 30, 2016
/s/ Steve R. Martin Steve R. Martin	Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	March 30, 2016
/s/ Wendy S. Johnson Wendy S. Johnson	Interim Chief Operating Officer and Director	March 30, 2016
/s/ Jeremy Curnock Cook Jeremy Curnock Cook	Chairman of the Board of Directors	March 30, 2016
/s/ Louis Drapeau Louis Drapeau	Director	March 30, 2016
/s/ Michael S. Perry, Ph.D. Michael S. Perry, Ph.D.	Director	March 30, 2016
Julian P. Kirk	Director	_____, 2016
/s/ Vijay B. Samant	Director	March 30, 2016

Vijay B. Samant

/s/ Paul C. Grint, M.D.  
Paul C. Grint, M.D.

Director

March 30, 2016

65

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description of Document</b>
3.1	Amended and Restated Articles of Incorporation of the Registrant, as amended (incorporated by reference to Exhibit 3.1 to the Quarterly Report on Form 10-Q, filed on November 16, 2015).
3.2	Amended and Restated Bylaws of the Registrant, as amended (incorporated by reference to Exhibit 3.2 to the Quarterly Report on Form 10-Q, filed on November 16, 2015).
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
4.3	Form of Warrant to Purchase Shares of Common Stock issued to purchasers in June 2013, July 2013 and December 2013 in connection with private placements (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
4.4	Subscription Agreement to Purchase Series B Preferred Stock and Common Stock Warrants, dated June 26, 2013 (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
4.5	Registration Rights Agreement, dated December 16, 2013, by and among the Registrant and certain purchasers of the Registrant's Common Stock (incorporated by reference to Exhibit 4.4 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
4.6	Subscription Agreement to Purchase Common Stock and Warrants, dated December 16, 2013 (incorporated by reference to Exhibit 4.5 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
4.7	Subscription Agreement to Purchase Common Stock and Warrants, dated March 10, 2015 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed March 19, 2015).
4.8	Form of Common Stock Warrant issued to purchasers in March 2015 private placement (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, filed March 19, 2015).
4.9	Registration Rights Agreement, dated March 10, 2015, by and among the Registrant and certain purchasers of the Registrant's Common Stock (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K, filed March 19, 2015).
4.10	Form of Amendment to Warrants to Purchase Shares of Common Stock issued to purchasers in June 2013, July 2013 and December 2013 in connection with private placements (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed on May 15, 2015).

Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

- 4.11 Form of Warrant to Purchase Shares of Common Stock issued in connection with the Registrant's acquisition of Biocontrol Ltd in December 2011.
- 4.12 Form of Warrant to Purchase Shares of Common Stock issued in connection with the issuance of convertible notes of the Registrant in February 2013, March 2013, April 2013 and May 2013.
- 4.13 Form of Warrant to Purchase Shares of Common Stock issued in connection with the Registrant's acquisition of certain assets of Novolytics Limited in February 2016.
- 10.1 Loan Repayment Deed, dated September 28, 2012, by and among the Registrant, Cellabs Pty Ltd and Special Phage Holdings Pty Ltd. (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
- 10.2 Exclusive Channel Collaboration Agreement, dated as of March 29, 2013, by and between the Registrant and Intrexon Corporation (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
- 10.3 Stock Issuance Agreement, dated as of March 29, 2013, by and between the Registrant and Intrexon Corporation (incorporated by reference to Exhibit 10.3 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
- 10.4\* Collaboration Agreement, dated as of April 24, 2013, by and between the Registrant and the University of Leicester (incorporated by reference to Exhibit 10.4 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).



- 10.5\* License, dated as of September 5, 2013, by and between the Registrant and the University of Leicester (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
- 10.6 Cooperative Research and Development Agreement, dated as of June 13, 2013, by and between the Registrant and United States Army Medical Research and Materiel Command (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
- 10.7 Agreement of Lease, dated as of February 23, 2011, by and between the Registrant and Virginia Biotechnology Research Partnership Authority (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
- 10.8 Lease, dated as of December 8, 2011, by and between Biocontrol Limited, Nevis Limited and Charter Limited (incorporated by reference to Exhibit 10.11 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
- 10.9+ Targeted Genetics Corporation 2009 Stock Incentive Plan (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
- 10.10+ AmpliPhi Biosciences Corporation 2012 Stock Incentive Plan (incorporated by reference to Exhibit 10.13 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
- 10.11+ Form of Stock Option Agreement under AmpliPhi Biosciences Corporation 2012 Stock Incentive Plan (incorporated by reference to Exhibit 10.14 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
- 10.12\* License Agreement, dated as of July 3, 2007, by and between the Registrant and Health Protection Agency, Centre for Emergency Preparedness and Response (incorporated by reference to Exhibit 10.18 to the Registration Statement on Form S-1 (File No. 333-193458), filed January 21, 2014, as amended).
- 10.13 Stockholder Sale Agreement, dated as of September 8, 2012, by and among the Registrant, 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 Registration Statement on Form S-1 (File No. 333-193458), filed January 21, 2014, as amended).
- 10.14 Agreement and Plan of Merger, dated as of November 12, 2010, by and among the Registrant, Sheffield Acquisition 1, Inc., and Sheffield Acquisition 2, Inc. (incorporated by reference to Exhibit 10.20 to the Registration Statement on Form S-1 (File No. 333-193458), filed January 21, 2014, as amended).
- 10.15+ AmpliPhi Biosciences Corporation 2013 Stock Incentive Plan (incorporated by reference to Exhibit 10.21 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
- 10.16+ Form of Grant Notice and Stock Option Agreement under AmpliPhi Biosciences Corporation 2013 Stock Incentive Plan.
- 10.17 Agreement of Lease of Business Premises, dated as of February 21, 2014, by and between Avotehna d.d. and AmpliPhi, Biotehnološke Raziskave in Razvoj, d. o. o. (incorporated by reference to Exhibit 10.22 to the

Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).

10.18 Collaboration Agreement, dated as of November 9, 2014, by and between the Registrant and the University of Leicester (incorporated by reference to Exhibit 10.23 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).

10.19+ Interim Chief Operating Officer Agreement, dated as of September 18, 2014, by and between the Registrant and Wendy S. Johnson (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed on November 14, 2014).

10.20+ Amendment to Interim Chief Operating Officer Agreement, dated as of January 15, 2015, by and between the Registrant and Wendy S. Johnson (incorporated by reference to Exhibit 10.25 to the Registration Statement on Form S-1 (File No. 333-203454), filed on April 16, 2015, as amended).

10.21 Agreement of Sublease, dated as of April 17, 2015, by and between the Registrant and Virginia Biotechnology Research Partnership Authority (incorporated by reference to Exhibit 10.26 to the Annual Report on Form 10-K, as amended, filed on April 30, 2015)

10.22+ Consulting Agreement, dated as of September 3, 2015, by and between the Registrant and Wendy S. Johnson (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q, filed on November 16, 2015)

Edgar Filing: AmpliPhi Biosciences Corp - Form 10-K

- 10.23+ Offer Letter, dated as of April 28, 2015, by and between the Registrant and M. Scott Salka.
- 10.24+ Master Services Agreement, dated as of June 30, 2014, by and between the Registrant and The Fahrenheit Group, LLC.
- 10.25\* Collaboration Agreement, dated as of November 4, 2015, by and between the Registrant and the University of Leicester.
- 10.26 Asset Purchase Agreement, dated as of January 4, 2016, by and between the Registrant and Novolytics Limited.
- 10.27+ Offer Letter, dated as of January 18, 2016, by and between the Registrant and Steve R. Martin (incorporated by reference to Exhibit 99.1 to the Current Report on Form 8-K, filed on January 19, 2016).
- 10.28+ Form of Indemnity Agreement with the Registrant's Directors and Executive Officers (incorporated by reference to Exhibit 99.2 to the Current Report on Form 8-K, filed on January 19, 2016).
- 21.1 Subsidiaries of the Registrant.
- 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.
- 99.1 Letter from DLA Piper LLP (outside counsel to New River Management VII, LP, an affiliate of Third Security, LLC), dated March 15, 2016.
- 99.2 Letter from DLA Piper LLP (outside counsel to New River Management VII, LP, an affiliate of Third Security, LLC), dated March 28, 2016.
- 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.**

68