AmpliPhi Biosciences Corp
Form S-1
December 14, 2017
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As filed with the Securities and Exchange Commission on December 14, 2017
Registration No. 333-

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

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

AmpliPhi Biosciences Corporation
(Exact Name of Registrant as Specified in Its Charter)

| Washington | 2836 | 91-1549568 |
|---|---|---|
| (State or Other Jurisdiction of Incorporation or Organization) | (Primary Standard Industrial Classification Code Number) | (I.R.S. Employer Identification Number) |

3579 Valley Centre Drive, Suite 100
San Diego, California 92130
(858) 829-0829
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Paul C. Grint, M.D.
Chief Executive Officer
AmpliPhi Biosciences Corporation
3579 Valley Centre Drive, Suite 100
San Diego, California 92130
(858) 829-0829
(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

Copies to:
Thomas A. Coll, Esq.
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Cooley LLP
4401 Eastgate Mall
San Diego, California 92121
(858) 550-6000

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.
If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended (the "Securities Act"), check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

CALCULATION OF REGISTRATION FEE

| Title of each class of securities to be registered(1) | Proposed maximum aggregate offering price | Amount of registration fee |
|---|---|---|
| Common stock, $0.01 par value per share | $ | |
| Warrants to purchase shares of common stock | $ | |
| Shares of common stock issuable upon exercise of the warrants | $ | |
| Total | $ 10,000,000(2) | $ 1,245 |

(1)
Pursuant to Rule 416, the securities being registered hereunder include such indeterminate number of additional securities as may be issuable to prevent dilution resulting from stock splits, stock dividends or similar transactions.

(2)
Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) under the Securities Act.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and we are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION, DATED DECEMBER 14, 2017

Shares of Common Stock

Warrants to Purchase Shares of Common Stock

We are offering up to shares of our common stock and warrants to purchase an aggregate of shares of our common stock (and the shares of common stock that are issuable from time to time upon exercise of the warrants). Each share of common stock is being sold together with a warrant to purchase share of our common stock, at an exercise price of $ per share. The warrants will be exercisable immediately and will expire years from the date of issuance. The shares of common stock and the accompanying warrants can only be purchased together in this offering but will be issued separately and will be immediately separable upon issuance. Our common stock is listed on the NYSE American under the symbol "APHB." On December 13, 2017, the last reported sale price of our common stock on the NYSE American was $1.01 per share. The public offering price per share of common stock and accompanying warrant will be determined by us at the time of pricing, may be at a discount to the current market price, and the recent market price used throughout this prospectus may not be indicative of the final offering price. There is no established public trading market for the warrants, and we do not expect a market to develop. In addition, we do not intend to apply for a listing of the warrants on any national securities exchange.

All sales will be evidenced by separate subscription agreements between us and the investors in this offering. will serve as escrow agent for the deposit and disbursement of the purchase price of the shares and warrants sold in this offering. See "Plan of Distribution" on page 21 of this prospectus for more information regarding these arrangements.

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

| | Per Share and Accompanying Warrant | Total |
|---|---|---|
| Public offering price and proceeds, before expenses, to us(1) | $ | $ |

(1) The public offering price is $ per share of common stock and $ per accompanying warrant.

Because there is no minimum offering amount required as a condition to closing in this offering, the actual total offering amount and proceeds to us, before expenses, may be substantially less than the amount set forth above.

Investing in our securities involves a high degree of risk. See the section entitled "Risk Factors" beginning on page 6 of this prospectus and elsewhere in this prospectus for a discussion of information that should be considered in connection with an investment in our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

We currently anticipate that the closing of this offering will take place on or about , 2018. On the closing date, we will issue the shares of common stock and accompanying warrants to the investors and receive funds in the amount of the aggregate purchase price.

The date of this prospectus is , 2018

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We have not authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the securities offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: We have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus outside the United States.

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PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus or incorporated by reference into this prospectus from our filings with the Securities and Exchange Commission, or SEC, listed in the section of the prospectus entitled "Incorporation of Certain Information by Reference." Because it is only a summary, it does not contain all of the information that you should consider before purchasing our securities in this offering and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere or incorporated by reference into this prospectus. You should read the entire prospectus, the registration statement of which this prospectus is a part, and the information incorporated by reference herein in their entirety, including the "Risk Factors" and our financial statements and the related notes incorporated by reference into this prospectus, before purchasing our securities in this offering. Unless the context requires otherwise, references in this prospectus to "AmpliPhi," "we," "us" and "our" refer to AmpliPhi Biosciences Corporation together with its wholly owned subsidiaries.

Overview

Our Company

We are a biotechnology company pioneering the development of therapies for antibiotic-resistant infections using bacteriophage-based technology. Phages have powerful and highly selective mechanisms of action that permit them to bind to and kill specific bacteria. We believe that phages represent a promising means to treat bacterial infections, especially those that have developed resistance to current therapies, including the so-called multi-drug-resistant or "superbug" strains of bacteria.

The extensive use of antibiotics since the beginning of the modern antibiotics era in the 1940s has resulted in drug resistance among many disease-causing bacteria. According to the U.S. Centers for Disease Control and Prevention, or CDC, resistance to antibiotics threatens to reverse many of the key medical advances of the last half-century. Examples of clinically important microbes that are rapidly developing resistance to available antimicrobials, many of which are included on the World Health Organization Priority Pathogens List published in February 2017, include bacteria that cause skin, bone, lung and bloodstream infections (e.g., Staphylococcus aureus, or S. aureus, and methicillin-resistant S. aureus, or MRSA), pneumonia and lung infections in both community and hospital settings and cystic fibrosis, or CF, patients (e.g., S. aureus, Acinetobacter baumannii, or A. baumanii, Pseudomonas aeruginosa, or P. aeruginosa, and Klebsiella pneumonia, or K. pneumoniae), meningitis (e.g., Streptococcus pneumonia, or S. pneumonia), urinary tract and gastrointestinal infections (e.g., P. aeruginosa, E. coli and Clostridium difficile, or C. difficile). As phages kill bacteria in ways entirely unlike the mechanisms used by traditional antibiotics, we believe that most multi-drug resistant bacteria will be susceptible to phage therapy. Furthermore, should resistant bacteria emerge or evolve, we believe it will remain possible to identify phages that can effectively kill these resistant bacteria.

Our goal is to be the leading developer of phage therapeutics. We are combining our expertise in the manufacture of drug-quality bacteriophages and our proprietary approach and expertise in identifying, characterizing and developing naturally occurring bacteriophages with that of collaboration partners in bacteriophage biology, synthetic biology and manufacturing, to develop state-of-the-art bacteriophage products. We are developing phage products to combat multi- or pan-drug-resistant bacterial pathogens, leveraging advances in sequencing and molecular biology. We have developed certain phage combinations that we believe maximize efficacy and minimize phage resistance. We currently have product candidates in clinical and preclinical development for the treatment of S. aureus infections, including MRSA and P. aeruginosa infections. We intend to develop these product candidates for the treatment of serious or life-threatening, multi-drug resistant, or MDR, infections. We also intend to seek to advance our chronic rhinosinusitis, or CRS, program and preclinical CF program through partnerships, arrangements and/or with additional outside funding. In April 2017, the U.S. Food and Drug Administration, or FDA, provided positive feedback on our previously submitted detailed development proposal to commence a Phase 2 trial with our proprietary bacteriophage cocktail AB-SA01 for the treatment of antibiotic-resistant S. aureus infections in patients with CRS, which feedback followed a Type B telephonic meeting held with us on February 21, 2017. In the official minutes from the meeting, the FDA acknowledged that phage therapy is an exciting approach to treatment of multi-drug-resistant organisms and expressed a commitment to addressing the unique regulatory challenges that might arise during product development.

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We believe our bacteriophage technology may have unique application in the area of targeted medicine, and in May 2017, we announced a new strategic emphasis on targeted therapies for serious or life-threatening antibiotic-resistant infections. In particular, we believe our bacteriophage technology can be used to develop targeted therapies for patients who suffer from serious or life-threatening antibiotic-resistant bacterial infections and who have limited or no other satisfactory treatment options. Moreover, we believe our ability to target phage therapies for antibiotic-resistant infections, combined with the ability of bacteriophage to re-sensitize drug-resistant populations to antibiotics, represents what could be a powerful tool against the growing challenge of antibiotic-resistant infections. Under existing single-patient expanded access guidelines (also referred to as "compassionate use"), established by the regulatory agencies, we have begun to provide targeted phage therapies to patients suffering from severe MDR infections who have failed prior therapies. We believe this strategic approach will not only provide potential benefit to patients to whom we are able to provide targeted phage therapies, but also provide the clinical and microbiological data from these cases that we expect to support the potential validation of the clinical utility of phage therapy, identify the most promising indications for further clinical development of our AB-SA01 and AB-PA01 product candidates for S. aureus and P. aeruginosa, define optimal treatment regimens, and inform our future discussions with the FDA and other regulatory agencies in 2018 or later on defining a potential path to market approval. We are initially making targeted phage therapies available under the appropriate expanded access guidelines in the United States and in Australia, where we collaborate with select leading hospitals and key opinion leaders to identify and select eligible patients. We believe that the United States and Australia have a favorable regulatory framework and clinical expertise with respect to treating patients under single-patient expanded access guidelines.

Our emphasis on targeted therapies builds upon our prior successes using tailored bacteriophage therapies under emergency investigational new drug applications to treat individual patients battling life-threatening, MDR bacterial pathogens who had exhausted their treatment options. In March 2016, we collaborated with several academic institutions and a U.S. Navy laboratory to produce a targeted bacteriophage therapy that successfully treated a critically ill, comatose patient with an MDR A. baumannii infection. Shortly after phage therapy was initiated, the patient emerged from the coma and continued to improve under an ongoing combination of phage and antibiotic therapies until the infection was cleared. To date, the infection has not returned. Additionally, in December 2007 our wholly owned subsidiary, Special Phage Services, was instrumental in developing a targeted phage therapy that, together with a course of antibiotics, eliminated a previously antibiotic-resistant P. aeruginosa infection in the bladder of a female cancer patient.

We are implementing the targeted therapy strategy and, through December 14, 2017 have provided bacteriophage investigational therapies AB-SA01 and AB-PA01 for seven patients suffering from serious and life-threatening infections under emergency investigational new drug applications, or INDs, in the United States or Special Access Scheme Category A in Australia.

Risks Associated with Our Business and this Offering

Our business and our ability to implement our business strategy are subject to numerous risks, as more fully described in the section of this prospectus entitled "Risk Factors" and under similarly titled headings of the documents incorporated herein by reference. You should read these risks before you invest in our securities. We may be unable, for many reasons, including those that are beyond our control, to implement our business strategy. In particular, risks associated with our business include:

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

- 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.

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

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- Our targeted phage therapies strategy may not be successful, which in turn could adversely affect our business.

- 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.

- 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.

- If you purchase our securities in this offering, you will incur immediate and substantial dilution.

- We will have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Corporate and Other Information

We were incorporated under the laws of the State of Washington in March 1989 as a wholly owned subsidiary of Immunex Corporation and began operations as an independent company in 1992 as Targeted Genetics Corporation. In January 2011, we completed the acquisition of Biocontrol Ltd, 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.

In February 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 programs.

In August 2015, we effected a 1-for-50 reverse split of our common stock. The share and per share information described in this prospectus that occurred prior to the reverse split have been adjusted to give retrospective effect to the reverse split.

In April 2017, we effected a 1-for-10 reverse split of our common stock. The share and per share information described in this prospectus that occurred prior to the reverse split have been adjusted to give retrospective effect to the reverse split.

Our principal executive offices are located at 3579 Valley Centre Drive, Suite 100, San Diego, California 92130. The telephone number at our principal executive office is (858) 829-0829. Our website address is www.ampliphibio.com. 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 prospectus. You should not rely on our website or any such information in making your decision whether to purchase our securities in this offering.

This prospectus contains references to our trademarks and to trademarks and trade names belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

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Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act, or JOBS Act, enacted in April 2012. An "emerging growth company" may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in the documents incorporated by reference into this prospectus;

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act;

- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration 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 may use these provisions until the last day of our fiscal year following the fifth anniversary of the first sale of our equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended, or the Securities Act, after we became a reporting company under the Securities Exchange Act of 1934, as amended, or the Exchange Act, pursuant to our registration statement on Form 10 (File No. 000-23930). However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed approximately $1.0 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We are also a "smaller reporting company" as defined in Exchange Act and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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The Offering

Common stock offered by us in this offering
shares

Warrants offered by us in this offering
Warrants to purchase an aggregate of shares of our common stock. Each share of our common stock is being sold together with a warrant to purchase share of our common stock. Each warrant will have an exercise price of $ per share, will be immediately exercisable and will expire on the anniversary of the original issuance date. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the warrants.

Common stock to be outstanding after this offering
shares (assuming none of the warrants issued in this offering are exercised).

Use of proceeds
We intend to use the net proceeds from this offering for general corporate purposes, including manufacturing expenses, clinical trial expenses, including potentially a Phase 2 clinical trial of AB-SA01 for the treatment of antibiotic-resistant S. aureus infections in patients with CRS, research and development expenses, and general and administrative expenses. See “Use of Proceeds.”

Risk factors
You should read the “Risk Factors” section of this prospectus for a discussion of certain of the factors to consider carefully before deciding to purchase any shares of our common stock and accompanying warrants in this offering.

National Securities Exchange Listing
Our common stock is listed on the NYSE American under the symbol “APHB.” We do not intend to list the warrants on any securities exchange or nationally recognized trading system.

The number of shares of our common stock to be outstanding after this offering is based on 9,325,595 shares of common stock outstanding as of September 30, 2017 and assumes the sale and issuance by us of shares of common stock in this offering and excludes, as of September 30, 2017:

- 1,116,765 shares of common stock issuable upon the exercise of outstanding stock options, at a weighted-average exercise price of $3.19 per share;
- 4,580 shares of common stock reserved for future grant under our 2016 Equity Incentive Plan, or the 2016 plan;
- 21,016 shares of common stock reserved for future issuance under our 2016 Employee Stock Purchase Plan, or the ESPP; and
- 8,712,220 shares of common stock issuable upon the exercise of outstanding warrants, at a weighted-average exercise price of $2.91 per share.

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## RISK FACTORS

Investing in our securities involves a high degree of risk. You should consider carefully the risks described below, together with all of the other information included or incorporated by reference in this prospectus, including the risks and uncertainties discussed under "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2016 and in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, before deciding whether to purchase shares of our common stock and accompanying warrants in this offering. All of these risk factors are incorporated herein in their entirety. The risks described below and incorporated by reference are material risks currently known, expected or reasonably foreseeable by us. If any of these risks actually materialize, our business, prospects, financial condition, and results of operations could be seriously harmed. This could cause the trading price of our common stock and the value of the warrants to decline, resulting in a loss of all or part of your investment.

### Risks Related to this Offering

**You will experience immediate and substantial dilution if you purchase securities in this offering.**

As of September 30, 2017, our net tangible book value was approximately $4.8 million, or $0.52 per share. Since the price per share of our common stock being offered in this offering is substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution with respect to the net tangible book value of the common stock you purchase in this offering. Based on the assumed combined public offering price of $ per share of common stock and accompanying warrant being sold in this offering (the last reported sale price of our common stock on the NYSE American on , 2018), and our net tangible book value per share as of September 30, 2017, if purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of $ per share with respect to the net tangible book value of the common stock. See the section entitled "Dilution" for a more detailed discussion of the dilution you will incur if you purchase common stock in this offering.

**There is no public market for the warrants being offered in this offering.**

There is no established public trading market for the warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the warrants on any securities exchange or nationally recognized trading system, including the NYSE American. Without an active market, the liquidity of the warrants will be limited.

**We will have broad discretion in the use of the net proceeds from this offering and may not use them effectively.**

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section entitled "Use of Proceeds," and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management may not apply the net proceeds from this offering in ways that ultimately increase the value of your investment. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

**There may be future sales of our securities or other dilution of our equity, which may adversely affect the market price of our common stock.**

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

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Holders of warrants purchased in this offering will have no rights as common stockholders until such holders exercise their warrants and acquire our common stock.

Until holders of warrants acquire shares of our common stock upon exercise of the warrants, holders of warrants will have no rights with respect to the shares of our common stock underlying such warrants. Upon exercise of the warrants, the holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

Even if this offering is successful, we will need to raise additional capital in the future to continue operations, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

We have had recurring losses from operations, negative operating cash flow and an accumulated deficit. 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 September 30, 2017, we had cash and cash equivalents of $7.7 million. We estimate that we will receive net proceeds of approximately $ million from the sale of the securities offered by us in this offering, based on the assumed public offering price of $ per share (the last reported sale price of our common stock on the NYSE American on $ per accompanying warrant, and after deducting the estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the warrants issued in this offering. We currently anticipate that our existing resources, together with the expected net proceeds from this offering based on the assumed combined public offering price of $ per share and accompanying warrant (and assuming that all of the shares offered hereby are purchased, but excluding the proceeds, if any, from the exercise of the warrants issued in this offering), will be sufficient to fund our planned operations until . However, there is no minimum offering amount required as a condition to closing this offering, and therefore the actual total offering proceeds to us, before expenses, may be substantially less. In the event of a decrease in the net proceeds to us from this offering as a result of a decrease in the assumed public offering price or the number of shares offered by us, we may need to raise additional capital sooner than we anticipate. In addition, we cannot provide assurances that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate.

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;
- whether and when we receive future Australian tax rebates, if any;
- the costs and timing of seeking regulatory approvals;
-

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

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

We may seek 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.

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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, the success of our preclinical studies and clinical trials and other product development activities, regulatory events, our ability to identify and enter into in-licensing or other strategic arrangements, and other events or conditions that may affect our value or prospects, as well as factors related to financial, economic and market conditions, many of which are beyond our control. We cannot be certain that sufficient funds will be available to us when required or on acceptable terms, if at all. Raising additional capital through the sale of securities could cause significant dilution to our stockholders. If we are unable to secure additional funds on a timely basis or on acceptable terms, we may be required to defer, reduce or eliminate significant planned expenditures, restructure, curtail or eliminate some or all of our development programs or other operations, dispose of technology or assets, pursue an acquisition of our company by a third party at a price that may result in a loss on investment for our stockholders, enter into arrangements that may require us to relinquish rights to certain of our product candidates, technologies or potential markets, file for bankruptcy or cease operations altogether. Any of these events could have a material adverse effect on our business, financial condition and results of operations. Moreover, if we are unable to obtain additional funds on a timely basis, there will be substantial doubt about our ability to continue as a going concern and increased risk of insolvency and loss of investment by our stockholders.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- our estimates regarding anticipated operating losses, capital requirements and needs for additional funds;
- our ability to raise additional capital when needed and to continue as a going concern;
- 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 and other research and development plans and expectations;
- 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 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 and other third parties over whom we have limited control;
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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;

- our expectations with respect to our new targeted phage therapies strategy, including the ability to demonstrate on the timeframe we anticipate, or at all, proof-of-concept sufficient to support regulatory approval;

- 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 outcome of any litigation in which we or any of our officers or directors may be involved;

- 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;

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- 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 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;

- our expected use of the net proceeds from this offering; and

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

In some cases, you can identify these statements by terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “inten “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative of those terms, and similar expressio convey uncertainty of future events or outcomes. 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 prospectus and are subject to risks and uncertainties. We discuss many of these risks in greater detail in the documents incorporated by reference herein, usually under the heading “Risk Factors.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

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

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

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USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately $ million from the sale of the securities offered by us in this offering, based on the assumed combined public offering price of $ per share and accompanying warrant (the last reported sale price of our common stock on the NYSE American on , 2018), and after deducting the estimat offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the warrants issued in this offering.

A $ increase or decrease in the assumed combined public offering price of $ per share and accompanying warrant would increase or decrease the expected net proceeds of the offering to us by approximately $ million. An increase of shares from the assumed number of shares sold in this offering would increase the expected net proceeds of the offering to us by approximately $ million, assuming the combined public offering price of $ per share and accompanying warrant remains the same. A decrease of shares from the assumed number of shares sold in this offering would decrease the expected net proceeds of the offering to us by approximately $ million, assuming the assumed combined public offering price of $ per share and accompanying warrant remains the same.

We currently intend to use the net proceeds from this offering for general corporate purposes, including manufacturing expenses, clinical trial expenses, including potentially a Phase 2 clinical trial of AB-SA01 for the treatment of antibiotic-resistant