AmpliPhi Biosciences Corp
Form 8-K
October 11, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the

Securities Exchange Act of 1934

Date of report (Date of earliest event reported): October 11, 2018

Commission File Number: 001-37544

AmpliPhi Biosciences Corporation

(Exact name of Registrant as specified in its charter)

Washington **(State or other jurisdiction of incorporation or organization)**	**91-1549568** **(IRS Employer Identification No.)**

3579 Valley Centre Drive, Suite 100

San Diego, California 92130

(Address of principal executive offices)

(858) 829-0829

(Registrant's Telephone number)

N/A

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Registrant under any of the following provisions (see General Instruction A.2. below):

¨Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company x

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

Item 8.01 Other Events.

We are filing the following information for the purpose of updating certain aspects of our clinical development plan for AB-SA01 and our risk factors, as contained in our other filings with the Securities and Exchange Commission.

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

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

In September 2018, we received the official minutes from our August 2018 Type B pre-IND meeting. The FDA expressed general agreement with our proposed clinical trial designs and, based on the current FDA feedback, no additional clinical or nonclinical data are required to proceed with two proposed randomized clinical trials. The first such clinical trial would be a Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-SA01, administered intravenously with the best available antibiotic therapy, compared to placebo plus best available antibiotic therapy, in approximately 100 patients with *S. aureus* bacteremia. The second such clinical trial would be a Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-SA01, administered by intra-articular injection and then intravenously with the best available antibiotic therapy, compared to placebo plus the best available antibiotic therapy, in approximately 100 patients with a hip or knee prosthetic joint infection due to *S. aureus* as an adjunct to surgical treatment. We are actively seeking and intend to continue to seek non-dilutive financing and explore other opportunities to conduct these clinical trials of AB-SA01. We may also choose to conduct one or more smaller-scale clinical trials of similar design as an alternative to conducting the approximately 100 patient clinical trials described above in an effort to reduce clinical trial expenditures. It is possible that results from such smaller-scale clinical trials may not be viewed by the FDA or other regulatory agencies as sufficient for the advancement of AB-SA01 into Phase 2 trials, including potentially registrational Phase 2 trials, due to the smaller trial populations even if the trial results are otherwise positive, which in turn could result in the FDA or other regulatory agencies requiring us to conduct additional studies beyond those that would have been required if we had conducted trials of approximately 100 patients as proposed in our August 2018 Type B pre-IND meeting. We

expect that we would produce our proprietary bacteriophage therapeutics for these clinical trials at our wholly owned manufacturing facility, which is good manufacturing practices (GMP) certified by the governmental authorities in the jurisdiction in which it operates. We believe our GMP-facility has the capacity to produce our proprietary bacteriophage therapeutics for these clinical trials through a potential biologics license application filing and potential approval.

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

Risk Factor

We have a limited number of unreserved shares available for future issuance, which may impair our ability to conduct future financing and other transactions.

Our amended and restated articles of incorporation currently authorize us to issue up to 67,000,000 shares of common stock and 10,000,000 shares of preferred stock. As of September 30, 2018, we had a total of approximately 40,531,692 shares of common stock that were authorized and available for future issuance. The number of authorized, unissued and unreserved shares may be significantly reduced as a result of equity or equity-based financing transactions that we conduct from time to time.

If we are unable to enter into new arrangements to issue shares of our common stock or securities convertible or exercisable into shares of our common stock, our ability to complete equity-based financings or other transactions that involve the potential issuance of our common stock or securities convertible or exercisable into our common stock, will be limited. In lieu of issuing common stock or securities convertible into our common stock in any future equity financing transactions, we may need to issue some or all of our authorized but unissued shares of preferred stock, which would likely have superior rights, preferences and privileges to those of our common stock, or we may need to issue debt that is not convertible into shares of our common stock, which may require us to grant security interests in our assets and property and/or impose covenants upon us that restrict our business. If we are unable to issue additional shares of common stock or securities convertible or exercisable into our common stock, our ability to enter into strategic transactions such as acquisitions of companies or technologies, may also be limited. If we propose to amend our amended and restated articles of incorporation to effectively increase our authorized shares of common stock, such a proposal would require the approval by the holders of a majority of our outstanding shares of common stock, and we cannot assure you that such a proposal would be adopted. If we are unable to complete financing, strategic or other transactions due to our inability to issue additional shares of common stock or securities convertible or exercisable into our common stock, our financial condition and business prospects may be materially harmed.

Forward-Looking Statements

Statements in this report that are not statements of historical fact are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, without limitation, statements regarding our clinical development plan for AB-SA01. Words such as “believe,” “anticipate,” “plan,” “expect,” “intend,” “will,” “may,” “goal,” “potential” and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements necessarily contain these identifying words. Among the factors that could cause actual results to differ materially from those indicated in these forward-looking statements are risks and uncertainties

associated with bacteriophage product candidate development, both generally and specifically through expanded access regulations, our financial condition, and other risks and uncertainties described in our Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the Securities and Exchange Commission (SEC), and our subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. All forward-looking statements are qualified in their entirety by this cautionary statement, and we undertake no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this report.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: October 11, 2018 **AmpliPhi Biosciences Corporation**

By: /s/ Steve R. Martin
Name: Steve R. Martin
Title: Chief Financial Officer