AmpliPhi Biosciences Corp
Form 8-K
January 03, 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): January 3, 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.

On January 3, 2018, we announced interim, topline results for the first seven patients treated with our investigational bacteriophage product candidates, AB-SA01 and AB-PA01, under our ongoing single-patient expanded access program. The patients in this program were severely ill and unresponsive to antibiotic treatment at the time of enrollment and were treated under emergency investigational new drug applications in the United States or under the Special Access Scheme in Australia.

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

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

No bacterial isolates resistant to the bacteriophage therapeutics were detected during the bacteriophage treatment course. Additional analyses of these data are ongoing, and presentations or publications of the detailed results are planned.

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: January 3, 2018 **AmpliPhi Biosciences Corporation**

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