

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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): **July 15, 2019**

Arbutus Biopharma Corporation

(Exact name of registrant as specified in charter)

British Columbia, Canada
(State or other jurisdiction
of incorporation)

001-34949
(Commission
File Number)

98-0597776
(IRS Employer
Identification No.)

**701 Veterans Circle
Warminster, Pennsylvania**
(Address of principal executive offices)

18974
(Zip Code)

(604) 419-3200

Registrant's telephone number, including area code

(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:

- Written communication 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 communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Shares, no par value	ABUS	The Nasdaq Stock Market LLC

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

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.

Item 8.01 Other Events.

On July 15, 2019, Arbutus Biopharma Corporation (the “Company”) announced preliminary results from a Phase 1a/1b clinical trial in healthy subjects and two cohorts of chronic hepatitis B (“CHB”) subjects who received AB-506 monotherapy. A detailed analysis of these Phase 1a/1b preliminary results will be submitted for presentation at a future scientific meeting later this year.

Summary of preliminary results with AB-506

- No serious adverse events (“SAEs”) or clinically significant safety findings were observed in healthy subjects (N=33). Importantly, alanine aminotransferase (“ALT”) levels and other liver function tests remained normal throughout the 10 days of dosing in healthy subjects.
- Mean hepatitis B virus (“HBV”) DNA and HBV RNA decreases at Day 28 (end of treatment) ranged from -2.0 log (160mg dose) to -2.8 log (400mg dose) and -2.4 log (for both doses), respectively, comparable with other capsid inhibitors currently in development.
- No SAEs were observed in CHB subjects (N= 24).
- Four CHB subjects (two in each of the cohorts) experienced Grade 4 ALT flares which returned to baseline levels upon AB-506 discontinuation or completion of the 28-day treatment period. Aspartate aminotransferase values were also elevated to a lesser degree, however, none of the subjects met the criteria for drug induced liver injury as bilirubin values and liver synthetic function remained normal. All four ALT flares occurred after the subjects experienced a >2 log decline in HBV DNA from baseline.
 - The Company believes at least one of the ALT flare cases was immune-mediated and beneficial, as one subject in the 400 mg cohort who experienced a Grade 4 ALT flare also had notable declines in Hepatitis B surface antigen and Hepatitis B e-antigen of -1.4 log and -2.0 log, respectively, by Day 100 following AB-506 discontinuation. This subject was immediately put on nucleoside analog therapy after AB-506 discontinuation per investigator’s decision. In addition, serum-based cytokine analysis of this subject showed an abrupt increase in IFN-gamma at the time of the flare, suggesting an immune-mediated response. For the other 3 subjects the Company continues to investigate the nature of the flares.
 - Of these four subjects, two (one in each cohort) were asymptomatic, the other two (one in each cohort) had various mild to moderate adverse events at the time of their flares, one with mild heaviness in head, flatulence, discomfort and moderate fatigue, one with mild rash (knees, ankles, fingers and buttock).
- Two subjects in the 160 mg cohort experienced Grade 2 ALT flares. Both were asymptomatic and returned to baseline levels upon completing the 28-day treatment period.

Next Steps

The Company intends to initiate a healthy subjects study testing 28 days of dosing in the second half of 2019. A detailed analysis of the Phase 1a/1b preliminary results, including a complete characterization of the ALT flare cases and preliminary results from the new 28 day study in healthy subjects, will be submitted for presentation at a scientific meeting later this year.

About the AB-506 Phase 1a/1b Clinical Trial

AB-506-001 is a double-blind, randomized, placebo controlled, single and multiple dose clinical trial evaluating the safety, tolerability and pharmacokinetics of AB-506, an oral class II capsid inhibitor, in healthy subjects and HBV-DNA positive subjects with chronic HBV infection. The healthy subject portion of the clinical trial and two cohorts of CHB subjects have been completed. The healthy subject portion consisted of a single ascending dose part in which subjects were randomized 6:2 (active: placebo), n=21, to receive AB-506 doses ranging from 30-1000 mg, including investigation of food effect, and a multiple dose part in which subjects (randomized 10:2, n=12) received 400 mg of AB-506 once daily for 10 days. The third part of the study is enrolling HBV DNA+, HBeAg-positive or -negative CHB subjects (randomized 10:2; n=12 per cohort) at different doses of AB-506, with or without a nucleoside analog, once daily for 28 days. Dosing of additional cohorts is planned.

About AB-506

AB-506 is an oral HBV capsid inhibitor. HBV core protein assembles into a capsid structure, which is required for viral replication. The current standard-of-care therapy for HBV, primarily nucleoside analogues that work by stopping the viral polymerase, significantly reduce virus replication, but not completely. Capsid inhibitors inhibit replication by preventing the assembly of functional viral capsids and also by inhibiting the uncoating step of the viral life cycle thus reducing the formation of new covalently closed circular DNA, the viral reservoir which resides in the cell nucleus.

Forward-Looking Statements and Information

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, and forward-looking information within the meaning of Canadian securities laws (collectively, “forward-looking statements”). Forward-looking statements in this report include statements about the safety and efficacy of AB-506 and the timing and expectations regarding the Company’s ongoing clinical trials.

With respect to the forward-looking statements contained in this report, the Company has made numerous assumptions regarding, among other things: the effectiveness and timeliness of preclinical and clinical trials, and the usefulness of the data; the availability and timing of data from clinical trials; and the adequacy of any clinical models. While the Company considers these assumptions to be reasonable, these assumptions are inherently subject to significant business, economic, competitive, market and social uncertainties and contingencies.

Additionally, there are known and unknown risk factors which could cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements contained herein. Known risk factors include, among others: anticipated clinical trials may be more costly or take longer to complete than anticipated, and may never be initiated or completed, or may not generate results that warrant future development of the tested drug candidate; the possibility that preliminary data of the Phase 1a/1b clinical trial are not indicative of final data from all subjects in the clinical trial and final data may not be positive with regard to the safety or efficacy of AB-506; the Company may not receive the necessary regulatory approvals for the clinical development of the Company's products; economic and market conditions may worsen; and market shifts may require a change in strategic focus.

A more complete discussion of the risks and uncertainties facing the Company appears in the Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and periodic and continuous disclosure filings, which are available at www.sedar.com and at www.sec.gov. All forward-looking statements herein are qualified in their entirety by this cautionary statement, and the Company disclaims any obligation to revise or update any such forward-looking statements or to publicly announce the result of any revisions to any of the forward-looking statements contained herein to reflect future results, events or developments, except as required by law.

SIGNATURE

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.

Arbutus Biopharma Corporation

Date: July 18, 2019

By: /s/ David C. Hastings
Name: David C. Hastings
Title: Chief Financial Officer