

**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): March 16, 2023

Arbutus Biopharma Corporation

(Exact name of registrant as specified in its charter)

British Columbia, Canada

(State or Other Jurisdiction of Incorporation)

001-34949

(Commission File Number)

98-0597776

(I.R.S. Employer Identification No.)

701 Veterans Circle

Warminster, Pennsylvania 18974

(Address of Principal Executive Offices) (Zip Code)

(267) 469-0914

(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 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))

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, without 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 March 16, 2023, Arbutus Biopharma Corporation (“Arbutus”) issued a press release announcing that the first subject has been dosed in the Phase 1 clinical trial evaluating the safety, tolerability, and pharmacokinetics of AB-161, Arbutus’ oral RNA destabilizer. AB-161 is being developed for use in an all-oral combination regimen to potentially provide a functional cure for patients with hepatitis B virus (HBV). A copy of the press release is filed herewith as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.**(d) Exhibits.****Exhibit Number** **Description**

| | |
|----------------------|---|
| 99.1 | Press Release dated March 16, 2023 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

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: March 16, 2023

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

Arbutus Doses First Subject in Phase 1 Clinical Trial with its Oral RNA Destabilizer, AB-161

Initial data expected in the second half of 2023

WARMINSTER, Pa., March 16, 2023 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS) (“Arbutus”), a clinical-stage biopharmaceutical company leveraging its extensive virology expertise to develop novel therapeutics that target specific viral diseases, today announced that the first subject has been dosed in the Phase 1 clinical trial evaluating the safety, tolerability, and pharmacokinetics of AB-161, Arbutus’ oral RNA destabilizer. AB-161 is being developed for use in an all-oral combination regimen to potentially provide a functional cure for patients with hepatitis B virus (HBV).

“We are pleased to move AB-161 into Phase 1 clinical development,” said William Collier, President and Chief Executive Officer of Arbutus Biopharma. “AB-161 was designed to reduce HBsAg levels and inhibit viral replication by selectively inhibiting essential host proteins that are important in stabilizing HBV RNAs from degradation. We remain committed to advancing our pipeline of assets to develop a functional cure for chronic HBV and look forward to sharing the initial data from the Phase 1 clinical trial of AB-161 in the second half of 2023.”

The Phase 1 double-blind, randomized, placebo-controlled, clinical trial is designed to investigate the safety, tolerability, and pharmacokinetics of oral administration of AB-161 in healthy subjects. The trial will enroll unique cohorts of ten healthy subjects each (8 active, 2 placebo) to receive single doses of AB-161. Safety assessments will be performed continuously and after day 7, if acceptable, the next cohort of subjects will be enrolled to receive an escalated dose of AB-161. A food effect assessment will also be conducted at a dose considered safe and well-tolerated and close to the anticipated therapeutic dose in chronic HBV patients.

Initial data from this Phase 1 single-ascending dose clinical trial in healthy subjects are expected in the second half of 2023.

About AB-161

AB-161 is our next generation oral small molecule RNA destabilizer, specifically designed to target the liver. Mechanistically, RNA destabilizers target the host proteins PAPD5/7, which are involved in regulating the stability of HBV RNA transcripts. In doing so, RNA destabilizers lead to the selective degradation of HBV RNAs, thus reducing HBsAg levels and inhibiting viral replication. To provide a proprietary all-oral treatment regimen for patients with cHBV, we believe inclusion of a small molecule RNA destabilizer is key.

About HBV

Hepatitis B is a potentially life-threatening liver infection caused by the hepatitis B virus (HBV). HBV can cause chronic infection which leads to a higher risk of death from cirrhosis and liver cancer. Chronic HBV infection represents a significant unmet medical need. The World Health Organization estimates that over 290 million people worldwide suffer from chronic HBV infection, while other estimates indicate that approximately 2.4 million people in the United States suffer from chronic HBV infection. Approximately 820,000 people die every year from complications related to chronic HBV infection despite the availability of effective vaccines and current treatment options.

About Arbutus

Arbutus Biopharma Corporation (Nasdaq: ABUS) is a clinical-stage biopharmaceutical company leveraging its extensive virology expertise to develop novel therapeutics that target specific viral diseases. Our current focus areas include Hepatitis B virus (HBV), SARS-CoV-2, and other coronaviruses. To address HBV, we are developing a RNAi therapeutic, an oral PD-L1 inhibitor, and an oral RNA destabilizer to potentially identify a combination regimen with the aim of providing a functional cure for patients with chronic HBV by suppressing viral replication, reducing surface antigen and reawakening the immune system. We believe our lead compound, AB-729, is the only RNAi therapeutic with evidence of immune re-awakening. AB-729 is currently being evaluated in multiple phase 2 clinical trials. We also have an ongoing drug discovery and development program directed to identifying novel, orally active agents for treating coronaviruses, (including SARS-CoV-2), for which we have nominated a compound and have begun IND-enabling pre-clinical studies. In addition, we are also exploring oncology applications for our internal PD-L1 portfolio. For more information, visit www.arbutusbio.com.

Forward-Looking Statements and Information

This press release 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 press release include statements about our future development plans for our product candidates; the expected cost, timing and results of our clinical development plans and clinical trials with respect to our product candidates; our expectations with respect to the release of data from our clinical trials and the expected timing thereof; our expectations and goals for our collaborations with third parties and any potential benefits related thereto; the potential for our product candidates to achieve success in clinical trials; and our expected financial condition, including the anticipated duration of cash runways and timing regarding needs for additional capital.

With respect to the forward-looking statements contained in this press release, Arbutus has made numerous assumptions regarding, among other things: the effectiveness and timeliness of preclinical studies and clinical trials, and the usefulness of the data; the timeliness of regulatory approvals; the continued demand for Arbutus' assets; and the stability of economic and market conditions. While Arbutus considers these assumptions to be reasonable, these assumptions are inherently subject to significant business, economic, competitive, market and social uncertainties and contingencies, including uncertainties and contingencies related to the ongoing COVID-19 pandemic and patent litigation matters.

Additionally, there are known and unknown risk factors which could cause Arbutus' 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 pre-clinical studies and 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 product candidate; Arbutus may elect to change its strategy regarding its product candidates and clinical development activities; Arbutus may not receive the necessary regulatory approvals for the clinical development of Arbutus' products; economic and market conditions may worsen; uncertainties associated with litigation generally and patent litigation specifically; Arbutus and its collaborators may never realize the expected benefits of the collaborations; market shifts may require a change in strategic focus; and the ongoing COVID-19 pandemic could significantly disrupt Arbutus' clinical development programs.

A more complete discussion of the risks and uncertainties facing Arbutus appears in Arbutus' Annual Report on Form 10-K, Arbutus' Quarterly Reports on Form 10-Q and Arbutus' continuous and periodic 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 Arbutus 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.

Contact Information

Investors and Media

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