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): April 27, 2023

Arbutus Biopharma Corporation
(Exact name of registrant as specified in its charter)

British Columbia, Canada	**001-34949**	**98-0597776**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 April 27, 2023, Arbutus Biopharma Corporation ("the Company") issued a press release announcing that clinical data for AB-729, the Company's RNAi therapeutic, and preclinical data for AB-161, the Company's next-generation oral HBV specific RNA destabilizer, were presented as late-breaker oral presentations at the Global Hepatitis Summit 2023 in Paris. 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 April 27, 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: April 27, 2023

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

EXHIBIT 99.1

Arbutus Provides AB-729 Clinical Data and AB-161 Preclinical Data as Oral Presentations at the Global Hepatitis Summit 2023

Seven patients with cHBV remain off all treatment and continue to maintain low levels of HBV DNA and HBsAg for at least one and half years post- AB-729 treatment

AB-161 provides robust anti-HBV activity including suppression of HBV RNA and HBsAg production in preclinical models

WARMINSTER, Pa., April 27, 2023 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS), a clinical-stage biopharmaceutical company leveraging its extensive virology expertise to develop novel therapeutics that target specific viral diseases, today announced that clinical data for AB-729, an RNAi therapeutic, and preclinical data for AB-161, a next-generation oral HBV specific RNA destabilizer, were presented as late-breaker oral presentations at the Global Hepatitis Summit 2023 in Paris.

Man-Fung Yuen, D.Sc., M.D., Ph.D., Chief of Division of Gastroenterology and Hepatology, Department of Medicine, The University of Hong Kong and principal investigator for the AB-729-001 clinical trial, presented data on nine patients with chronic hepatitis B virus infection (cHBV) who completed 48 weeks of treatment with AB-729, and 24 weeks later met protocol-defined criteria to also stop nucleos(t)ide analogue (NA) therapy. Two patients have restarted therapy – one at the investigator's request after the week 20 visit which was previously presented at AASLD in November 2022, and one that met the protocol-defined HBV DNA criteria to restart NA therapy after the week 36 visit. In the 78% of patients (7 of 9) that remain off NA therapy for 44-64 weeks (over 1.5 years since last AB-729 dose), HBV DNA remains low and HBsAg remains below baseline (-0.8 to -1.6 $\log_{10}$ IU/mL). No adverse effects or ALT flares have occurred in these patients during follow-up.

"These data are extremely encouraging, especially the low levels of HBsAg and HBV DNA in most patients persisting for at least a year and a half after their last dose of AB-729. Furthermore, the lack of ALT flares experienced by these patients suggests that the host immune system is controlling the virus," commented Professor Yuen. "AB-729 has a differentiated clinical profile compared to current treatment options for patients with cHBV, which include 48 weeks of interferon treatment or life-long NA therapy to keep HBV DNA levels suppressed. We look forward to continuing to monitor these patients for functional cure."

Professor Yuen also presented post-treatment follow-up data for the seven HBV DNA negative, HBeAg positive patients (Cohort K) enrolled in the same trial. The mean $\log_{10}$ change from baseline in HBsAg was -2.57 IU/mL at week 48 (n=5) and -1.86 IU/mL at follow-up week 48 (n=5). Mean log decline in HBeAg was >1.0 $\log_{10}$ at the last follow up visit, even though HBeAg was low at baseline in some patients. One patient achieved both HBsAg and HBeAg less than the lower limit of quantitation (LLOQ = 0.07 IU/mL and = 0.11 IU/mL, respectively) with detectable anti-HBs antibodies. Two other patients achieved either HBsAg or HBeAg <LLOQ during the trial.

Professor Yuen, continued, "I remain impressed with the post-treatment follow-up data from the AB-729-001 clinical trial which continues to show that AB-729 treatment produces robust and comparable declines in HBsAg regardless of dose, dosing interval, or baseline characteristics."

William Collier, Arbutus' President and Chief Executive Officer, commented, "These data reinforce our confidence in AB-729's potential role as a cornerstone agent in a curative combination treatment for cHBV. We remain committed to advancing AB-729, which we believe is the only RNAi therapeutic in development for HBV that has clinically shown its ability to reduce HBV DNA and HBsAg and boost the immune system."

AB-729 is currently being evaluated in two Phase 2a clinical trials, one in combination with an HBV antigen-specific immunotherapeutic (Vaccitech's VTP-300) and another with pegylated interferon alfa-2a (IFN). Both of these trials will report preliminary data this year.

At the same congress, Dr. Angela M. Lam, Vice President of Biology at Arbutus Biopharma, presented preclinical antiviral data and mechanism of action profiling of AB-161, a potent small-molecule HBV RNA destabilizer being developed as an orally administered antiviral agent for the treatment of cHBV infection. The data show that AB-161 provides robust anti-HBV activity including suppression of HBV RNA and HBsAg production *in vitro* and *in vivo*. In AAV-HBV infected mice, AB-161 reduces circulating HBsAg levels in a dose-dependent manner. Data from the mechanism of action studies show that AB-161 promotes viral transcript degradation and reduces viral proteins and viral replication. Preclinical pharmacokinetic data and repeat dose toxicology studies show enhanced liver concentrations and lack of peripheral neuropathy.

Dr. Michael J. Sofia, Chief Scientific Officer of Arbutus Biopharma, stated, "These data support the ability of AB-161 to selectively degrade HBV RNAs, thus reducing HBsAg levels and inhibiting viral replication. The differentiated anti-HBV mode of action of AB-161 compared to other classes of HBV inhibitors suggest that AB-161 may be an important component in a combination regimen to provide a functional cure for cHBV. We have recently initiated a Phase 1 clinical trial in healthy subjects and look forward to sharing the initial data in the second half of this year."

The above oral presentations can be accessed through the Publications section of the Arbutus website at https://www.arbutusbio.com/publications/.

About AB-729

AB-729 is an RNA interference (RNAi) therapeutic specifically designed to reduce all HBV viral proteins and antigens, including hepatitis B surface antigen, which is thought to be a key prerequisite to enable reawakening of a patient's immune system to respond to the virus. AB-729 targets hepatocytes using Arbutus' novel covalently conjugated *N*-Acetylgalactosamine (GalNAc) delivery technology that enables subcutaneous delivery. Clinical data generated thus far has shown single- and multi-doses of AB-729 to be generally safe and well-tolerated while providing meaningful reductions in hepatitis B surface antigen and hepatitis B DNA. AB-729 is currently in multiple Phase 2a clinical trials.

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; and the potential for our product candidates to achieve success in clinical trials.

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; and Arbutus and its collaborators may never realize the expected benefits of the collaborations; market shifts may require a change in strategic focus.

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.

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Investors and Media

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