

**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): October 31, 2022

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 October 31, 2022, Arbutus Biopharma Corporation (“the Company”) issued a press release announcing that the Company will be presenting three posters with clinical data from its lead clinical compound, AB-729, an RNAi therapeutic, and its preclinical oral PD-L1 inhibitor, AB-101, at The American Association for the Study of Liver Diseases (AASLD) – The Liver Meeting® 2022, taking place from November 4-8, 2022 in Washington, DC. 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 October 31, 2022](#)
104 Cover page interactive data file (formatted as inline XBRL).

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: October 31, 2022

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

Arbutus Announces Three Poster Presentations with Clinical Data from AB-729 and Preclinical Data from AB-101 at AASLD - The Liver Meeting® 2022

Conference Call and Webcast to discuss the new data being presented at AASLD scheduled for 8:45 AM ET, Friday, November 4, 2022

WARMINSTER, Pa., Oct. 31, 2022 (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 the Company will be presenting three posters with clinical data from its lead clinical compound, AB-729, an RNAi therapeutic, and its preclinical oral PD-L1 inhibitor, AB-101, at The American Association for the Study of Liver Diseases (AASLD) – The Liver Meeting® 2022, taking place from November 4-8, 2022 in Washington, DC.

Poster #1:

Title: Hepatitis B viral control maintained during extended follow up of HBeAg- chronic hepatitis B subjects who discontinued nucleos(t)ide analogue (NA) therapy after completion of AB-729 treatment, and in HBeAg+ subjects still on NA therapy

Poster Number: 5047

Abstract Number: 38876

Presentation Type: Late-Breaking Poster Presentation

Presentation Time: Monday, November 7: 1:00 – 2:00 PM ET

Authors: Man-Fung Yuen, Jacinta Holmes, Simone I Strasser, Apinya Leerapun, Wattana Sukeepaisarnjaroen, Pisit Tangkijvanich, Varun Sharma, Elina Medvedeva, Emily P Thi, Gastón Picchio, Timothy Eley, Karen D Sims

Data Summary: Data is being reported on nine patients who have completed from 16 to 40 weeks of follow-up after discontinuing both AB-729 and NA therapy. No patients met the protocol-defined NA restart criteria. At the last available timepoint, all HBV DNA levels were <1000 IU/mL and HBsAg levels for all patients remained well below pre-study levels. In conclusion, NA-therapy discontinuation after NA+AB-729 treatment was well-tolerated in HBeAg negative subjects who achieved HBsAg <100 IU/mL and resulted in sustained low HBV DNA and HBsAg levels up to 40 weeks off all therapy. These results suggest new viral set points via immune control.

Poster #2:

Title: Combination Treatment with HBV-Targeting GalNAc-siRNA and Small-Molecule PD-L1 Inhibitor Increases HBV-Specific Immune Responses in a Chronic Hepatitis B Infection Mouse Model

Poster Number: 1000 - 1999

Abstract Number: 1221

Presentation Type: Poster

Presentation Time: Friday, November 4: 12:00 – 1:00 PM ET

Authors: Emily P Thi, Ingrid Graves, Arpita Mondal, Andrew G Cole, Gavin Heffernan, Christina L Iott, Seyma Ozturk, Sharie C Ganchua, Dan Nguyen, Kim Stever, Kristi Y Fan, Jorge G Quintero, Steven G Kultgen, Amanda Pohl, Troy O Harasym, Angela M Lam, and Michael J Sofia

Data Summary: Pre-clinical data showing that the combination of an HBV-targeting RNAi and AB-101 in mice infected with HBV, results in increased production of HBV-specific T-cells compared to administering an RNAi or AB-101 alone.

Poster #3:

Title: Evaluation of the Vebicorvir, NRTI and AB-729 Combination in virologically Suppressed Patients with HBeAg Negative Chronic Hepatitis B Virus Infection: Interim Analysis from an Open Label Phase 2 Study

Poster Number: 5064

Abstract Number: 38874

Presentation Type: Late-Breaking Poster Presentation

Presentation Time: Monday, November 7: 1:00 PM – 2:00 PM

Authors: Jacob George, Diana Stefanova-Petrova, Krasimir Antonov, Zina Valaydon, Scott Davison, Scott Fung, Fei Chen, Curtis Cooper, Stuart Roberts, Marie-Louise Vachon, Carla S Coffin, Brian Conway, Gail Matthews, Mariana Radicheva, Steven J Knox, Ran Yan, Emily P Thi, Calvin Chan, Jieming Liu, Katie Zomorodi, Timothy Eley, Michele Anderson, Karen Sims, Luisa M Stamm, Gaston Picchio, Grace Wang, Rozalina Balabanska, Gerry MacQuillan, Magdy Elkhatab

Data Summary: Sixty-five patients were randomized to receive VBR (Vebicorvir)+729+NA (Nucleoside Analogue) (n=32), VBR+NA (n=16) or 729+NA (n=17) for 48 weeks. The preliminary data indicate that adding VBR to AB-729+NA does not result in greater on-treatment improvements in markers of active HBV infection as compared to AB-729+NA alone. All regimens were safe and well-tolerated.

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 enabling subcutaneous delivery. Clinical data generated thus far has shown single- and multi-doses of AB-729 to be generally safe and well-tolerated, while also providing meaningful reductions in hepatitis B surface antigen and hepatitis B DNA. AB-729 is currently in multiple Phase 2a clinical trials.

About AB-101

Immune checkpoints such as PD-1/PD-L1 play an important role in the induction and maintenance of immune tolerance and in T-cell activation. We have identified a class of small molecule oral PD-L1 inhibitors that we believe will allow for controlled checkpoint blockade, enable oral dosing, and mitigate systemic safety issues typically seen with checkpoint antibody therapies. Our lead oral PD-L1 inhibitor candidate, AB-101, is currently in IND-enabling studies. We believe AB-101, when used in combination with other approved and investigational agents, could potentially allow us to realize our mission of achieving a functional cure for HBV chronically infected patients. We are also exploring oncology applications for our internal PD-L1 portfolio.

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 capsid inhibitor, 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. It 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 coronavirus (including SARS-CoV-2). In addition, we are exploring oncology applications for our internal PD-L1 portfolio. For more information, visit www.arbutusbio.com.

Forward-Looking Statements

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 the expected protection from the new patent; 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 patent protection; 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

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