# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
# Washington, D.C. 20549

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# FORM 8-K

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## CURRENT REPORT

**Pursuant to Section 13 or 15(d)**
**of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): December 14, 2021**

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

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| **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)

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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 December 14, 2021, Arbutus Biopharma Corporation ("Arbutus") and Antios Therapeutics, Inc. ("Antios") announced that the first patient has been dosed in a triple combination treatment in patients with chronic hepatitis B virus (HBV) infection. A single cohort in the ongoing Antios Phase 2a SAVE-1 (Sustained Anti-Viral Efficacy) clinical trial will evaluate a triple combination of Antios' proprietary active site polymerase inhibitor nucleotide (ASPIN), ATI-2173, Arbutus' proprietary GalNAc delivered RNAi therapeutic, AB-729, and tenofovir disoproxil fumarate (TDF), a nucleotide reverse transcriptase inhibitor. A copy of the press release is filed herewith as Exhibit 99.1 hereto and is incorporated by reference herein.

**Item 9.01. Financial Statements and Exhibits.**

**(d) Exhibits.**

| **Exhibit Number** | **Description** |
|---|---|
| 99.1 | Press release dated December 14, 2021 |
| 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: December 14, 2021

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

**EXHIBIT 99.1**

# Antios Therapeutics and Arbutus Biopharma Announce First Patient Dosed in Phase 2a Combination Trial of ATI-2173, AB-729 and Tenofovir Disoproxil Fumarate in Patients with Chronic Hepatitis B Virus Infection

MENDHAM, N.J. and WARMINSTER, Pa., Dec. 14, 2021 (GLOBE NEWSWIRE) -- Antios Therapeutics, Inc. (“Antios”) and Arbutus Biopharma Corporation (Nasdaq: ABUS) today announced that the first patient has been dosed in a triple combination treatment in patients with chronic hepatitis B virus (HBV) infection. A single cohort in the ongoing Antios Phase 2a SAVE-1 (Sustained Anti-Viral Efficacy) clinical trial will evaluate a triple combination of Antios’ proprietary active site polymerase inhibitor nucleotide (ASPIN), ATI-2173, Arbutus’ proprietary GalNAc delivered RNAi therapeutic, AB-729, and tenofovir disoproxil fumarate (TDF), a nucleotide reverse transcriptase inhibitor.

The multi-center, double-blind, combination clinical trial plans to enroll 40 patients including a cohort of 10 patients with chronic HBV infection assigned 8:2 to active drugs (ATI-2173+AB-729) or matching placebos. The active drugs (ATI-2173+AB-729) or placebos will be administered in combination with 300 mg of tenofovir disoproxil fumarate. ATI-2173 and tenofovir disoproxil fumarate will be administered orally and by injections once daily for 90 days. AB-729 will be administered by subcutaneous injection at Day 28 and Day 90. Following this 90-day treatment period, patients will be followed-up for safety and sustained antiviral responses for six additional months.

“The need for a functional cure for HBV is clear. Current therapies only partially suppress HBV replication and require ongoing treatment, adding to patient burden,” said Douglas Mayers, M.D., Chief Medical Officer and Co-Founder of Antios. “By combining AB-729 with ATI-2173 and tenofovir disoproxil fumarate, we hope to reduce hepatitis B surface antigens and sustain HBV DNA suppression while off treatment.”

ATI-2173 is the only ASPIN in clinical development and pre-clinical data to date for ATI-2173, alone or combined with TDF, indicate the potential for sustained HBV DNA suppression off treatment, unique among approved nucleos(t)ides and investigational anti-HBV therapies.

Dr. Gaston Picchio, Chief Development Officer of Arbutus, commented, “In our common endeavor to find a cure for chronic HBV, we are eager to evaluate the combination of these two unique assets which we expect will allow us to further understand the potential benefits of such combination therapy for patients with chronic HBV.”

AB-729 is an RNAi therapeutic that inhibits viral replication and reduces all HBV antigens. In clinical trials to date, AB-729 has demonstrated positive safety and tolerability data as well as meaningful reductions in HBV surface antigen.

**About ATI-2173**

ATI-2173, Antios Therapeutics' lead once-daily, oral drug candidate for treating HBV, is an investigational phosphoramidate prodrug of clevudine monophosphate. ATI-2173 has the potential, if approved, to become the cornerstone of a curative HBV regimen. It is the only Active Site Polymerase Inhibitor Nucleotide (ASPIN) in clinical development and its mechanism of action is designed to be complementary to other approaches that also seek to achieve a functional cure. ATI-2173 is currently in Phase 2a clinical development. The SAVE-1 (Sustained Anti-Viral Efficacy) trial is an ongoing, double-blind, randomized, placebo-controlled study of 30 patients designed to assess the safety and efficacy of 25 and 50 mg doses of ATI-2173 daily for 90 days in combination with tenofovir disoproxil fumarate (TDF) compared with TDF plus ATI-placebo (control) in chronic HBV-infected subjects.

**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 a Phase 2a clinical trial in combination with Peg-IFNα-2a and nucleos(t)ide analog (“NA”) therapy.

**About HBV**

Hepatitis B is a potentially life-threatening liver infection caused by HBV. HBV can cause chronic infection which leads to a higher risk of death from cirrhosis and liver cancer. Chronic HBV infection (CHB) represents a significant unmet medical need. The World Health Organization estimates that up to 300 million people worldwide suffer from chronic HBV infection, while other estimates indicate that approximately 2 million people in the United States suffer from chronic HBV infection. Approximately 900,000 people die every year from complications related to chronic HBV infection despite the availability of effective vaccines and current treatment options.

**About Antios Therapeutics, Inc.**

Antios Therapeutics is a clinical-stage biopharmaceutical company focused on the development of innovative therapies to treat and cure viral diseases. Its lead drug candidate ATI-2173 – the only Active Site Polymerase Inhibitor Nucleotide (ASPIN) in clinical development – has the potential, if approved, to become the cornerstone of a curative therapeutic regimen for chronic HBV. Antios recently entered into an agreement with IRBM to acquire a novel series of fourth-generation capsid assembly modulators (CAMs) to further expand Antios' portfolio of differentiated molecules in the HBV space. HBV is a major unmet global health problem affecting up to 300 million people worldwide, more than hepatitis C and HIV combined. For more information, please visit www.antiostherapeutics.com.

**About Arbutus**

Arbutus Biopharma Corporation (Nasdaq: ABUS) is a clinical-stage biopharmaceutical company primarily focused on discovering, developing and commercializing a broad portfolio of assets with different modes of action to provide a cure for people with chronic hepatitis B virus (HBV) infection. The Company is advancing multiple product candidates with distinct mechanisms of action that suppress viral replication, reduce surface antigen and reawaken the immune system. Arbutus believes this three-prong approach is key to transforming the treatment and developing a potential cure for chronic HBV infection. Arbutus' HBV product pipeline includes RNA interference (RNAi) therapeutics, oral capsid inhibitors, oral compounds that inhibit PD-L1 and oral HBV RNA destabilizers. In addition, Arbutus has an ongoing drug discovery and development program directed to identifying orally active agents for treating coronaviruses (including COVID-19). 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, including the expected trial design of the triple combination trial with Antios; our expectations regarding the results of the triple combination trial with Antios; 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.

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, may never be initiated or completed, or may not generate results that warrant future development of the tested product candidate; Arbutus or Antios 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; market shifts may require a change in strategic focus; and the ongoing COVID-19 pandemic could significantly disrupt Arbutus' or its partners' 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.

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