

**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 4, 2021**

**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 2.02. Results of Operations and Financial Condition.**

On March 4, 2021, Arbutus Biopharma Corporation (the "Company") issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2020 and certain other information. A copy of the press release is furnished as Exhibit 99.1 hereto.

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

**(d) Exhibits.**

<u>Exhibit Number</u>	<u>Description</u>
<a href="#">99.1</a>	<a href="#">Press release dated March 4, 2021</a>
104	Cover page interactive data file (formatted as inline XBRL).

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**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 4, 2021

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

## Arbutus Reports Fourth Quarter and Year End 2020 Financial Results and Provides Corporate Update

**AB-729, Arbutus' proprietary subcutaneously delivered RNAi agent, demonstrates robust and continuous declines in hepatitis B surface antigen (HBsAg) in subjects with chronic hepatitis B (HBV) with favorable safety and tolerability data**

**Reductions in HBsAg seen in both HBV DNA negative and HBV DNA positive subjects support a potential dosing schedule for AB-729 as infrequently as every 8 to 12 weeks**

**Several AB-729 Phase 2 proof-of-concept combination clinical trials expected to initiate this year**

**AB-836, Arbutus' proprietary oral capsid inhibitor, on track to begin a Phase 1a/1b clinical trial in healthy volunteers and subjects with HBV in the first half of 2021**

**Conference Call and Webcast Scheduled Today at 8:45 AM ET**

WARMINSTER, Pa., March 04, 2021 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS), a clinical-stage biopharmaceutical company primarily focused on developing a cure for people with chronic hepatitis B virus (HBV) infection, as well as therapies to treat coronaviruses (including COVID-19), today reports its fourth quarter and year-end 2020 financial results and provides a corporate update.

William Collier, President and Chief Executive Officer of Arbutus, stated, "Our current data set for AB-729, our lead compound in development for HBV, has grown substantially over the past 12 months and increases our confidence that it has the potential to be a cornerstone drug in future HBV combination regimens."

Mr. Collier added, "Looking ahead, 2021 is expected to provide us with important insights regarding the potential therapeutic value of several compounds in our proprietary HBV pipeline including: longer term Phase 1a/1b dosing results for AB-729; the initiation of a Phase 2 combination clinical trial with AB-729 and Assembly Biosciences' lead core inhibitor; initiation of Phase 2 clinical trials for AB-729 and one or more approved or investigational agents; and initial Phase 1a/1b data from our proprietary oral capsid inhibitor, AB-836."

Dr. Gaston Picchio, Chief Development Officer of Arbutus, commented, "AB-729 has shown impressive reductions in HBsAg with an unremarkable longer term safety profile in the clinical data from our Phase 1a/1b clinical trial. The data that has emerged from this clinical trial so far is encouraging and it suggests that AB-729 could potentially be dosed less frequently than every 4 weeks potentially providing a competitive advantage. As a matter of fact, we are testing a dosing schedule of every 8 weeks in our Phase 2 clinical trial in collaboration with Assembly."

Dr. Picchio added, "We are pleased that we have initiated screening for our proof-of-concept Phase 2 clinical trial combining AB-729 with Assembly Biosciences' lead core inhibitor candidate, also known as a capsid inhibitor, vebicorvir, and a nucleos(t)ide reverse transcriptase inhibitor."

### Pipeline Update

#### **AB-729**

- Arbutus is currently conducting a single- and multi-dose Phase 1a/1b clinical trial to determine the safety, tolerability, pharmacokinetics, and pharmacodynamics of AB-729 in healthy subjects and in subjects with chronic HBV infection.
- Results to date demonstrate that treatment of AB-729 using the 60 mg and 90 mg doses has been well tolerated after a single dose. Efficacy results to date suggest that repeat dosing using the 60 mg dose every 4 weeks resulted in a continuous and robust mean HBsAg decline at week 24 (-1.84 log<sub>10</sub> IU/mL, N=7). Repeat dosing using the 60 mg dose every 8 weeks results in comparable mean HBsAg declines relative to the 60 mg dose every 4 weeks at week 16 (-1.37 log<sub>10</sub> IU/mL vs -1.44 log<sub>10</sub> IU/mL, p<0.7). In HBV DNA positive CHB subjects, a single 90 mg AB-729 dose resulted in robust mean HBsAg (-1.02 log<sub>10</sub> IU/mL) and HBV DNA (-1.53 log<sub>10</sub> IU/mL) declines at week 12, as well as decreases in HBV RNA and core-related antigen. Similar mean HBsAg reductions were observed in HBV DNA positive and negative CHB subjects supporting complete target engagement by AB-729.
- Arbutus expects to provide additional data from ongoing cohorts of the Phase 1a/1b clinical trial in the first half of 2021, except for initial data from the 90 mg every 12 week cohort which is expected in the second half of 2021. Based on these results, Arbutus intends to advance AB-729 into two Phase 2 combination trials with one or more approved or investigational agents in the second half of 2021 with dosing of AB-729 as infrequently as every 8 or 12 weeks.
- Arbutus and Assembly initiated screening in a Phase 2 proof-of-concept combination clinical trial to evaluate AB-729 in combination with Assembly Biosciences' lead core (capsid) inhibitor candidate vebicorvir and a nucleos(t)ide reverse transcriptase inhibitor for the treatment of subjects with chronic HBV infection. The randomized, multi-center, open-label Phase 2 clinical trial will evaluate the safety, pharmacokinetics, and antiviral activity of the triple combination of VBR, AB-729 and an NrtI compared to the double combinations of VBR with an NrtI and AB-729 with an NrtI. Approximately 60 virologically-suppressed subjects with HBeAg negative chronic HBV are expected to be enrolled in the first cohort of

the trial. Subjects will be dosed for 48 weeks with VBR 300 mg orally once daily and AB-729 60 mg subcutaneously every 8 weeks, with a 48-week follow-up period.

### **AB-836: Oral Capsid Inhibitor**

- In January 2020, Arbutus selected AB-836 as its next-generation oral capsid inhibitor. AB-836 is from a novel chemical series differentiated from competitor compounds with the potential for increased efficacy and an enhanced resistance profile. Arbutus completed CTA/IND-enabling studies in the fourth quarter of 2020 and anticipates initiating a Phase 1a/1b clinical trial for AB-836 in the first half of 2021.

### **Early R&D Programs**

- Arbutus' drug discovery efforts are focused on follow-on compounds for its current HBV pipeline and new small molecule antiviral medicines to treat COVID-19 and future coronavirus outbreaks. Arbutus expects to continue to advance its research in its oral PD-L1 inhibitor, RNA-destabilizer and coronavirus programs.

### **Genevant Sciences Ltd.**

Arbutus owns approximately 16% of the common equity of Genevant Sciences Ltd. ("Genevant"), a company Arbutus launched with Roivant Sciences, Ltd. and to which Arbutus licensed exclusive rights to its lipid nanoparticle ("LNP") and ligand conjugate delivery technologies for RNA-based applications outside of HBV. We are entitled to receive tiered low single-digit royalties on future sales of Genevant products covered by the licensed patents. If Genevant sub-licenses the intellectual property licensed by us to Genevant, we are entitled to receive, upon the commercialization of a product developed by such sub-licensee, the lesser of (i) twenty percent of the revenue received by Genevant for such sublicensing and (ii) tiered low single-digit royalties on product sales by the sublicensee.

### **Financial Results**

#### **Cash, Cash Equivalents and Investments**

Arbutus had cash, cash equivalents and investments totaling \$123.3 million as of December 31, 2020, as compared to \$90.8 million as of December 31, 2019. During the twelve months ended December 31, 2020, Arbutus used \$51.4 million in operating activities and made a \$2.5 million equity investment in Genevant, which was offset by \$86.3 million of net proceeds from the issuance of common shares under Arbutus' ATM program. Thus far during the first quarter of 2021, Arbutus has received an additional \$24.3 million of net proceeds from the issuance of common shares under its ATM program. Arbutus expects a net cash burn between \$70 to \$75 million in 2021 and therefore the Company believes its cash runway extends through the third quarter of 2022.

#### **Net Loss**

Net loss attributable to common shares for the twelve months ended December 31, 2020 was \$75.9 million (\$1.00 basic and diluted loss per common share) as compared to \$164.9 million (\$2.89 basic and diluted loss per common share) for the twelve months ended December 31, 2019. The decrease in the net loss was due primarily to: i) non-cash impairment charges in 2019 of \$43.8 million for an in-process research and development ("IPR&D") intangible asset and \$22.5 million for goodwill to reduce their carrying values to zero, as well as a corresponding income tax benefit of \$12.7 million related to the decrease in the deferred tax liability associated with the IPR&D intangible assets; ii) a \$20.0 million decrease in non-cash equity losses associated with the Company's investment in Genevant; iii) a \$10.1 million decrease in research and development expenses; and iv) a \$6.3 million expense in 2019 related to an arbitration award from the Company's arbitration with the University of British Columbia.

Net loss attributable to common shares for the twelve months ended December 31, 2020 and 2019 also included non-cash expense for the accrual of coupon on the Company's convertible preferred shares of \$12.1 million and \$11.1 million, respectively.

#### **Operating Expenses**

Research and development expenses were \$47.5 million for the twelve months ended December 31, 2020 compared to \$57.6 million in 2019. The decrease in research and development expenses for the year ended December 31, 2020 versus the same period in 2019 was due primarily to lower clinical expenses in 2020. General and administrative expenses were \$14.7 million for the twelve months ended December 31, 2020 compared to \$17.7 million for the same period in 2019. This decrease was due primarily to \$2.3 million in cash severance and \$1.1 million of non-cash stock-based compensation expense related to our former President and Chief Executive Officer's departure from the Company in June 2019.

#### **Outstanding Shares**

The Company had approximately 89.7 million common shares issued and outstanding as of December 31, 2020. In addition, the Company had approximately 10.7 million stock options outstanding and 1.164 million convertible preferred shares outstanding, which (including the annual 8.75% coupon) will be mandatorily convertible into approximately 23 million common shares on October 18, 2021.

#### **COVID-19 Impact**

In December 2019 an outbreak of a novel strain of coronavirus (COVID-19) was identified in Wuhan, China. This virus continues to spread globally, has been declared a pandemic by the World Health Organization and has spread to nearly every country in the world. The impact of this pandemic has been, and will likely continue to be, extensive in many aspects of society. The pandemic has resulted in and will likely continue to result in significant disruptions to businesses. A number of countries and other jurisdictions around the world have implemented extreme measures to try and slow the spread of the virus. These measures include the closing of businesses and requiring people to stay in their homes, the latter of which raises uncertainty regarding the ability to travel to hospitals in order to participate in clinical trials. Additional measures that have had, and will likely continue to have, a major impact on clinical development, at least in the near-term, include shortages and delays in the supply chain, and prohibitions in certain countries on enrolling subjects in new clinical trials. While we have been able to progress with our clinical and pre-clinical activities to date, it is not possible to predict if the COVID-19 pandemic will negatively impact our plans and timelines in the future.

**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF LOSS**  
(in thousands, except share and per share data)

	Year ended December 31,	
	2020	2019
<b>Revenue</b>		
Collaborations and licenses	\$ 3,519	\$ 4,355
Non-cash royalty revenue	3,395	1,656
<b>Total revenue</b>	6,914	6,011
<b>Operating expenses</b>		
Research and development	47,481	57,601
General and administrative	14,724	17,727
Depreciation	1,978	2,028
Change in fair value of contingent consideration	473	(173)
Site consolidation	64	156
Impairment of intangible assets	—	43,836
Impairment of goodwill	—	22,471
Arbitration	—	6,266
<b>Loss from operations</b>	(57,806)	(143,901)
<b>Other income (loss)</b>		
Interest income	741	2,111
Interest expense	(4,011)	(2,108)
Equity investment loss	(2,545)	(22,522)
Foreign exchange gain (loss)	(124)	41
<b>Total other loss</b>	(5,939)	(22,478)
Income tax benefit	—	12,656
<b>Net loss</b>	\$ (63,745)	\$ (153,723)
Dividend accretion of convertible preferred shares	(12,123)	(11,149)
<b>Net loss attributable to common shares</b>	\$ (75,868)	\$ (164,872)
<b>Loss per share</b>		
Basic and diluted	\$ (1.00)	\$ (2.89)
<b>Weighted average number of common shares</b>		
Basic and diluted	75,835,378	57,093,454

**UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS**  
(in thousands)

	December 31, 2020	December 31, 2019
Cash, cash equivalents and marketable securities, current	\$ 123,268	\$ 90,834
Accounts receivable and other current assets	4,436	2,994
<b>Total current assets</b>	127,704	93,828
Property and equipment, net of accumulated depreciation	6,927	8,676
Right of use asset	2,405	2,738
Other non-current assets	44	293
<b>Total assets</b>	\$ 137,080	\$ 105,535
Accounts payable and accrued liabilities	\$ 8,901	\$ 7,235

Liability-classified options	250	253
Lease liability, current	390	340
<b>Total current liabilities</b>	<b>9,541</b>	<b>7,828</b>
Liability related to sale of future royalties	19,554	18,992
Contingent consideration	3,426	2,953
Lease liability, non-current	2,593	3,018
Total stockholders' equity	101,966	72,744
<b>Total liabilities and stockholders' equity</b>	<b>\$ 137,080</b>	<b>\$ 105,535</b>

**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW**  
(in thousands)

	<b>Year ended December 31,</b>	
	<b>2020</b>	<b>2019</b>
Net loss	\$ (63,745)	\$ (153,723)
Deferred income tax benefit	—	(12,661)
Impairment of intangible assets and goodwill	—	66,307
Net equity investment loss	2,545	22,522
Other non-cash items	9,328	8,774
Changes in working capital	431	(2,225)
Net cash used in operating activities	\$ (51,441)	\$ (71,006)
Net cash provided by (used in) investing activities	(14,909)	28,338
Net cash provided by financing activities	86,746	37,457
Effect of foreign exchange rate changes on cash and cash equivalents	56	68
Increase (decrease) in cash and cash equivalents	\$ 20,452	\$ (5,143)
Cash and cash equivalents, beginning of period	31,799	36,942
Cash and cash equivalents, end of period	\$ 52,251	\$ 31,799
Investments	\$ 71,017	\$ 59,035
<b>Total cash, cash equivalents and investments, end of period</b>	<b>\$ 123,268</b>	<b>\$ 90,834</b>

**Conference Call and Webcast Today**

Arbutus will hold a conference call and webcast today, Thursday, March 4, 2021 at 8:45 AM Eastern Time to provide a corporate update. You can access a live webcast of the call, which will include presentation slides, through the Investors section of Arbutus' website at <http://www.arbutusbio.com> or directly at Live Webcast. Alternatively, you can dial (866) 393-1607 or (914) 495-8556 and reference conference ID 4084504.

An archived webcast will be available on the Arbutus website after the event. Alternatively, you may access a replay of the conference call by calling (855) 859-2056 or (404) 537-3406, and reference conference ID 4084504.

**About AB-729**

AB-729 is an RNA interference (RNAi) therapeutic targeted to hepatocytes using Arbutus' novel covalently conjugated N-acetylgalactosamine (GalNAc) delivery technology that enables subcutaneous delivery. AB-729 inhibits viral replication and reduces all HBV antigens, including hepatitis B surface antigen in preclinical models. Reducing hepatitis B surface antigen is thought to be a key prerequisite to enable reawakening of a patient's immune system to respond to the virus. Based upon clinical data generated thus far in an ongoing single- and multi-dose Phase 1a/1b clinical trial, AB-729 has demonstrated positive safety and tolerability data and meaningful reductions in hepatitis B surface antigen.

**About AB-836**

AB-836 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 nucleos(t)ide analogues that work by inhibiting the viral polymerase, significantly reduce virus replication, but not completely. Capsid inhibitors inhibit replication by preventing the assembly of functional viral capsids. They also have been shown to inhibit the uncoating step of the viral life cycle thus reducing the formation of new covalently closed circular DNA (cccDNA), the genetic reservoir which the virus uses to replicate itself.

**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 represents a significant unmet medical need. The World Health Organization estimates that over 250 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 Arbutus**

Arbutus Biopharma Corporation is a publicly traded (Nasdaq: ABUS) biopharmaceutical company primarily dedicated to discovering, developing and commercializing a cure for people with chronic hepatitis B virus (HBV) infection. The Company is advancing multiple drug product candidates that may be combined into a potentially curative regimen for chronic HBV infection. Arbutus has also initiated a drug discovery and development effort for treating coronaviruses (including COVID-19). For more information, visit [www.arbutusbio.com](http://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 confidence that AB-729 has the potential to be a cornerstone drug in future HBV combination regimens; the potential that AB-729 could potentially be dosed less frequently than every 4 weeks potentially providing a competitive advantage; our expectation to provide additional data from ongoing cohorts of the Phase 1a/1b clinical trial of AB-729 in the first half of 2021, except for initial data from the 90 mg every 12 week cohort which is expected in the second half of 2021; our intention to advance AB-729 into two Phase 2 combination trials with one or more approved or investigational agents in the second half of 2021 with dosing of AB-729 as infrequently as every 8 to 12 weeks; our plans with respect to the Phase 2 proof-of-concept combination clinical trial to evaluate AB-729 in combination with Assembly Biosciences' lead core/capsid inhibitor candidate vebicorvir and a nucleos(t)ide reverse transcriptase inhibitor for the treatment of subjects with chronic HBV infection, including the expected trial design, the expected number and type of patients to be enrolled in the trial and the expected dosing schedule; the potential for AB-836 to have increased efficacy and an enhanced resistance profile; the expected initiation, in the first half of 2021, of a Phase 1a/1b clinical trial of AB-836; the expected continued advancement of our research in the oral PD-LE inhibitor, RNA-destabilizer and coronavirus programs; our expectation regarding the impact of the COVID-19 pandemic on our business and clinical trials; our expected net cash burn between \$70 to \$75 million for 2021; and our expected cash runway through the third quarter of 2022.

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, 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; 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](http://www.sedar.com) and at [www.sec.gov](http://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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