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

wasiiiigtoii,	<b>D.C.</b>	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): May 6, 2019

#### **Arbutus Biopharma Corporation**

(Exact Name of Registrant as Specified in Charter)

**British Columbia, Canada** (State or Other Jurisdiction of Incorporation)

**001-34949** (Commission File Number)

**98-0597776** (I.R.S. Employer Identification Number)

701 Veterans Circle, Warminster, Pennsylvania 18974

(Address of Principal Executive Offices) (Zip Code)

(604) 419-3200

(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:

o)
2)
(17 CFR 240.14d-2(b))
(17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). 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. [ ]

Securities registered pursuant to Section 12(b) of the Act:

Common Shares, no par value ABUS	The Nasdaq Stock Market LLC

#### Item 2.02. Results of Operations and Financial Condition.

On May 6, 2019, Arbutus Biopharma Corporation issued a press release announcing its financial results for the three months ended March 31, 2019 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

**Exhibit No. Description** 

99.1 Press Release dated May 6, 2019

#### 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: May 6, 2019 By: /s/ David C. Hastings David C. Hastings Chief Financial Officer

### Arbutus Reports First Quarter 2019 Financial Results and Provides Corporate Update

• Top-line safety and efficacy results from an interim analysis of the initial Phase 1a/1b clinical trial of AB-506, a proprietary oral capsid inhibitor, expected in July 2019

#### Conference Call and Webcast Scheduled Today at 4:30 PM ET

WARMINSTER, Pa., May 06, 2019 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS), an industry-leading Hepatitis B Virus (HBV) therapeutic solutions company, today reports its first quarter 2019 financial results and provides a corporate update.

"Arbutus is committed to the development of an effective combination regimen to achieve an HBV cure. We continue to believe that the development of a cure for chronic HBV can best be achieved by employing a combination of therapeutic agents with complementary mechanisms of action," said Dr. Mark J. Murray, President and Chief Executive Officer of Arbutus. "Our pipeline, of proprietary therapeutic agents that target HBV replication and HBsAg expression could in combination, lead to a cure."

### Recent Clinical Accomplishments and Key Corporate Objectives AB-506

- In a Phase 1a/1b clinical trial, AB-506, Arbutus' oral capsid inhibitor, successfully progressed through the healthy volunteer portion and is currently being administered in two dose levels to HBV patients in the 28-day multiple dose portion of the trial. Top-line results of an interim analysis from this Phase 1a/1b clinical trial are expected in July 2019 at which time we expect to disclose information on clinical safety in healthy volunteers and safety and efficacy data in chronically infected HBV patients at both dose levels. We intend to present more detailed information on the trial at an upcoming scientific conference towards the end of 2019.
- A Phase 2a dose-finding and long-term safety trial of AB-506 with an approved nucleoside analogue is planned to initiate late in the second half of the year to support the use of AB-506 in future combination registration trials.

#### **AB-729**

• AB-729, an RNAi agent which blocks HBsAg expression that is administered subcutaneously and is intended to be dosed monthly, has successfully completed IND-enabling studies in support of the single ascending dosing portion of a Phase 1a/1b clinical trial which the Company filed as part of a Clinical Trial Application. On May 3<sup>rd</sup>, a regulatory authority requested that the Company complete its ongoing 3- and 6-month toxicology studies before commencing the single ascending portion of the Phase 1a/1b clinical trial, which was planned for this quarter. As a result of this request, the clinical trial start will be delayed. We will explore options to accelerate its initiation based on the currently available toxicology study duration and update the market when the clinical trial start date is fixed.

#### **RNA Destabilizer Program**

- Arbutus remains committed to the development of oral RNA-destabilizers that have shown compelling anti-viral effects in multiple HBV preclinical models. AB-452, Arbutus' lead oral RNA-destabilizer is being evaluated in a series of in vitro and in vivo studies to further characterize the compound, its mechanism of action, safety and pharmacokinetic profile before deciding whether to initiate clinical trials. Following careful assessment of the nonclinical safety findings that led to pausing the entry of AB-452 into human clinical studies, we have concluded that the nonclinical safety study resulted in several confounding observations which included clinical observations with no histological correlation, a lack of dose response regarding some key findings and an unexplained vehicle effect. Because of these confounding observations, we have determined that repeating the 90-day preclinical safety study in two species is appropriate before making a go/no-go decision. We expect that the results of this study will allow us to make that decision early in 2020.
- In parallel, the Company is advancing several follow-on compounds, with distinct chemical scaffolds, into the lead optimization stage, with a goal of having a 2<sup>nd</sup> generation candidate nominated for development by the end of 2019.

Dr. Michael J. Sofia, Arbutus' Chief Scientific Officer, stated, "We continue to believe that oral RNA destabilizers represent a very relevant and important therapeutic approach to treating HBV. We also believe we continue to have the most advanced program of this kind in the HBV field and that success here could be very significant for HBV patients, as well as for Arbutus."

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

• The Company continues a robust discovery effort focused on follow on compounds for its current pipeline, including further advancements in the Company's capsid inhibitors and RNA destabilizers as well as discovery efforts focused on reawakening HBV patients' immune response and novel HBV-specific targets such as compounds targeting PD-L1 and HBV cccDNA.

#### **ONPATTRO Royalty Entitlement**

ONPATTRO is an RNAi therapeutic that has been developed for the treatment of hereditary ATTR (hATTR) amyloidosis, and has been approved by the FDA and the EMA. Arbutus has a royalty entitlement on global sales of ONPATTRO for the LNP technology licensed by Arbutus to Alnylam for this product. The Company began recognizing royalty income in 2018. The royalty rate is tiered, based on product sales, and in the low to mid-single digits.

#### **Financial Results**

#### Cash, Cash Equivalents and Investments

Arbutus had cash, cash equivalents and short-term investments totaling \$110.6 million as of March 31, 2019, as compared to \$124.6 million as of December 31, 2018. The \$14.0 million decrease for the three months ended March 31, 2019 was due primarily to \$16.5 million of cash used in operating activities partially offset by \$2.6 million of proceeds from the issuance of shares under its ATM program. We believe our cash and investments balance is sufficient to fund operations into 2020.

#### **Operating Expenses**

Research and development expenses for the three months ended March 31, 2019 were \$14.8 million compared to \$13.9 million for the three months ended March 31, 2018. Research and development expenses for the three months ended March 31, 2019 included costs associated with the Company's Phase 1a/1b clinical trial for its lead capsid inhibitor (AB-506), pre-clinical studies for its RNAi agent (AB-729), and characterization activities for its HBV RNA Destabilizer (AB-452). General and Administrative expenses for the three months ended March 31, 2019 were \$4.4 million compared to \$3.7 million for the three months ended March 31, 2018.

#### **Equity investment loss**

The Company recorded a loss of \$4.7 million in the first quarter of 2019 for its proportionate share of Genevant's net loss, a company launched with Roivant Sciences Ltd. There was no comparable amount for the first quarter of 2018. Financial results of Genevant are recorded on a one-quarter lag basis. The Company currently owns approximately 40% of the common equity of Genevant as of March 31, 2019.

#### **Net Loss**

For the three months ended March 31, 2019, net loss attributable to common shares was \$26.0 million (\$0.47 basic and diluted loss per common share) as compared to \$19.8 million (\$0.36 basic and diluted loss per common share) for the three months ended March 31, 2018. Net loss attributable to common shares for the three months ended March 31, 2019 included \$2.7 million of non-cash expense for the accrual of coupon on its convertible preferred shares. The increase in net loss is due primarily to the equity investment loss in Genevant.

#### **Outstanding Shares**

The Company had approximately 55.7 million common shares issued and outstanding as of March 31, 2019. In addition, the Company had approximately 7.7 million 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. Assuming the outstanding options and convertible preferred shares were fully converted, the Company would have had approximately 86 million common shares outstanding as of March 31, 2019.

#### UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF LOSS

(in millions, except share and per share data)

	Three Months Ended			
		Marc	h 31,	
		2019		2018
Total revenue	\$	0.7	\$	1.4
Operating expenses:				
Research and development		14.8		13.9
General and administrative		4.4		3.7
Depreciation and amortization		0.5		0.6
Site consolidation		0.1		1.6
Loss from operations		(19.1)		(18.4)
Other income (loss)				
Interest income (expense), net		0.6		0.7
Foreign exchange gain (loss)		_		(0.5)
Equity investment loss		(4.7)		_

Decrease (increase) in fair value of contingent consideration	(0.1)	0.8
Total other income	(4.2)	1.0
Net loss	\$ (23.3)	\$ (17.4)
Accrual of coupon on convertible preferred shares	(2.7)	(2.3)
Net loss attributable to common shares	\$ (26.0)	\$ (19.8)
Loss per share Basic and diluted	\$ (0.47)	\$ (0.36)
Weighted average number of shares Basic and diluted	55,740,121	55,071,964

## UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS (in millions)

	March 31, 2019		December 31, 2018		
	 2019		2010		
Cash and cash equivalents	\$ 84.0	\$	36.9		
Short-term investments	26.6		87.7		
Accounts receivable and other current assets	1.8		4.6		
Investment in Genevant	17.7		22.2		
Property and equipment, net	9.7		10.2		
Right of use asset	3.1		_		
Intangible assets	43.8		43.8		
Goodwill	 22.5		22.5		
Total assets	\$ 209.2	\$	227.9		
Accounts payable and accrued liabilities	6.8		9.5		
Site consolidation accrual	1.0		1.3		
Liability-classified options	0.4		0.5		
Lease liability, current	0.6		_		
Deferred rent and inducements, non-current			0.6		
Contingent consideration	3.2		3.1		
Lease liability, non-current	3.3		_		
Deferred tax liability	12.7		12.7		
Total stockholders' equity	 181.2		200.2		
Total liabilities and stockholders' equity	\$ 209.2	\$	227.9		

## UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW (in millions)

	5	Three Months Ended March 31,			
	2	019		2018	
Net loss for the period  Net cash used in operating activities  Net cash provided by (used in) investing activities  Net cash provided by financing activities  Effect of foreign exchange rate changes on cash & cash equivalents	\$	(23.3) (16.5) 61.0 2.5 (0.0)	\$	(17.4) (20.0) (75.7) 54.4 (0.5)	
Net (decrease) increase in cash, cash equivalents and restricted investments  Cash, cash equivalents and restricted investments, beginning of period	\$	47.0 37.0	\$	(41.8) 54.3	

Cash, cash equivalents and restricted investments, end of period	\$	84.0	\$ 12.5
Short-term investments		26.6	160.1
Total cash, cash equivalents, restricted	-		
cash and short-term investments, end			
of period	\$	110.6	\$ 172.6

#### **Conference Call Today**

Arbutus will hold a conference call and webcast today, Monday, May 6, 2019 at 4:30 PM Eastern Time (1:30 PM Pacific Time) to provide a corporate update. You can access a live webcast of the call through the Investors section of Arbutus' website at www.arbutusbio.com. Alternatively, you can dial (866) 393-1607 or (914) 495-8556 and reference conference ID 9448718.

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 9448718.

#### **About Arbutus**

Arbutus Biopharma Corporation is a publicly traded (Nasdaq: ABUS) biopharmaceutical company dedicated to discovering, developing and commercializing a cure for patients suffering from chronic Hepatitis B infection. Arbutus is developing multiple drug candidates, each of which have the potential to improve upon the standard of care and contribute to a curative combination regimen. 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 belief that our pipeline of proprietary therapeutic agents that target HBV replication and HBsAg expression could lead to an HBV cure; our expectation for top-line safety and efficacy results from an interim analysis of the initial Phase 1a/1b clinical trial of AB-506 in July 2019 and our intention to present more detailed information on the trial at an upcoming scientific conference towards the end of 2019; our expectation to make a decision regarding AB-452 clinical development in early 2020; our expectation to initiate a Phase 2a dose-finding and long-term safety trial of AB-506 late in the second half of 2019; the trajectory for inclusion of AB-506 in a multi-drug combination regimen with AB-729 in 2020; our goal to have a second generation candidate nominated by the end of 2019; our expectations regarding the initiation, timing and completion of preclinical studies and clinical trials; the sufficiency of our cash and cash equivalents to extend into 2020; and the potential for our drug candidates to improve upon the standard of care and contribute to a curative combination regimen for chronic HBV.

With respect to the forward-looking statements contained in this press release, Arbutus has made numerous assumptions regarding, among other things: the timely receipt of expected payments; the effectiveness and timeliness of preclinical 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.

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 drug candidate; Arbutus may not receive the necessary regulatory approvals for the clinical development of Arbutus' products; economic and market conditions may worsen; and 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 and Arbutus' continuous 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**

Mark J. Murray President and CEO Phone: 604-419-3200 Email: ir@arbutusbio.com

Media
Pam Murphy
Investor Relations Consultant
Phone: 604-419-3200

Email: ir@arbutusbio.com