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): February 10, 2020 Arbutus Biopharma Corporation

(Exact name of registrant as specified in charter)

British Columbia, Canada	001-34949	98-0597776	
(State or other jurisdiction of incorporation)	(Commission File Number)	sion (IRS Employer ber) Identification No.	
701 Veterans Circle Warminster, Pennsylvania		18974	
(Address of principal executive offices)		(Zip Code)	
	(267) 469-0914		

(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 Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communication 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 o

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. o

Item 8.01. Other Events.

On February 10, 2020, Arbutus Biopharma Corporation (the "Company") issued a press release announcing its decision to discontinue AB-452 and pursue development of a next generation HBV specific oral RNA-destabilizer. A copy of the press release is filed herewith as Exhibit 99.1 and is incorporated by reference herein.

Also on February 10, 2020, the Company posted an updated corporate presentation on its website at www.arbutusbio.com. A copy of the presentation is filed herewith as Exhibit 99.2 and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number

Description

99.1 99.2 Press Release, dated February 10, 2020. Corporate Presentation, dated February 10, 2020.

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: February 10, 2020

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



Arbutus Announces Decision to Discontinue AB-452 and to Pursue Development of a Next Generation HBV Specific Oral RNA-Destabilizer

Arbutus expects to announce AB-729 Preliminary Phase 1a/1b Data late Q12020

WARMINSTER, Pa., - February 10, 2020 - Arbutus Biopharma Corporation (Nasdaq: ABUS), announced today its decision to discontinue AB-452, its first generation orally available hepatitis B (HBV) specific RNA-destabilizer, and to continue research and development of a next generation oral HBV RNA-destabilizer. In October 2018, Arbutus announced its decision to delay the initiation of a planned 28-day Phase 1a/1b clinical trial for AB-452 in order to further evaluate the safety of the compound. This decision was based on findings in 90-day preclinical safety studies in two species. Since that time Arbutus has extensively reviewed and further characterized these preclinical findings, including repeating the 90-day safety studies.

Michael J. Sofia, Ph.D., Chief Scientific Officer of Arbutus, added, "After reviewing all the data from the preclinical studies, and in consultation with external regulatory and pre-clinical experts, we have decided to not move AB-452 forward. We continue to believe, however, that the HBV RNA destabilizer mechanism of action is very compelling and has the potential to lead to an oral therapy. We intend to vigorously pursue next generation compounds in this area."

Arbutus also reiterated its earlier guidance for both AB-729 and AB-836. AB-729 is a subcutaneously delivered RNAi agent which has been shown in preclinical models to reduce viral antigens, including hepatitis B surface antigen (HBsAg) expression, and to inhibit HBV replication. In July 2019, the Company initiated a single and multiple dose Phase 1a/1b clinical trial for AB-729, designed to investigate the safety, tolerability, pharmacokinetics, and pharmacodynamics of AB-729 in healthy volunteers and in subjects with chronic hepatitis B (CHB) infection. Preliminary safety data in single-dose cohorts of healthy subjects and safety and efficacy data in single-dose cohorts of subjects with CHB infection are expected late this quarter. For AB-836, Arbutus' next generation capsid inhibitor, the Company expects to complete investigational new drug enabling studies by the end of the year.



The Company believes that this compound has the potential for increased efficacy and an enhanced resistance profile relative to its previous generation capsid inhibitor, AB-506.

William H. Collier, President and Chief Executive Officer of Arbutus, stated, "Arbutus remains committed to developing a range of medicines with differing mechanisms of action that can be used in combination for treatment of chronic HBV infection. The Company is on track to deliver on its key pipeline objectives for 2020; we look forward to announcing our preliminary safety and efficacy data for AB-729 later this quarter and to completing IND enabling studies for AB-836 by the end of the year."

About Oral RNA-Destabilizers

Small molecule HBV RNA destabilizers are orally active agents that cause the destabilization and ultimate degradation of HBV RNAs. These agents result in the reduction of HBsAg, HBeAg, pgRNA, and core protein in both whole cell systems and animal models. They have the potential to selectively impact HBV versus other RNA or DNA viruses and demonstrate pangenotypic characteristics. HBV RNA destabilizers have demonstrated additive effects in combination with other mechanism of action anti-HBV agents.

About AB-729

AB-729 is a 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 (HBsAg) in preclinical models. Reducing HBsAg is thought to be a key prerequisite to enable reawakening of a patient's immune system to respond to the virus.

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 nucleoside 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 viral reservoir which resides in the cell nucleus.

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 (HBV) 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 <u>www.arbutusbio.com</u>.

Forward-Looking Statements and Information

This press release contains forward-looking statements within the meaning of 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 expectations regarding the timing and clinical development of our product candidates; our expectation to announce AB-729 preliminary Phase 1a/1b data late in the first quarter of 2020; our belief that the HBV RNA destabilizer mechanism of action is very compelling and has the potential to lead to an oral therapy; our intention to vigorously pursue additional next generation compounds; our guidance for AB-729 and AB-836, including our expectation to complete investigational new drug enabling studies by the end of the year; our belief that AB-836 has the potential for increased efficacy and an enhanced resistance profile relative to AB-506; and our belief that we are on track to deliver on our key pipeline objectives for 2020.

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 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: delays in the selection of and the advancement of an additional capsid inhibitor compound into lead optimization, 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, 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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Singularly Focused on HBV

February 2020

NASDAQ: ABUS

www.arbutusbio.com

Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and Canadian securities la statements that are not historical facts are hereby identified as forward-looking statements for this purpose and include, among others, statements relating potential for HBV to have a larger market opportunity than HCV; our ability to meet a significant unmet medical need; the sufficiency of our cash and cash equival extend into mid 2021; our expected cash burn rate for 2020; our expectation for AB-729 for preliminary results from our Phase I trial to be available late in the first c of 2020; the potential for an oral HBsAg reducing agent and potential all oral combination therapy; our objective to complete IND enabling studies for AB-836 second half of 2020; the potential for AB-836 to be low dose with a greater therapeutic window and to address known capsid resistant variants T33N and 110. potential for AB-836 to be once daily dosing; our expectations regarding the timing and clinical development of our product candidates; the timeline to a combinatic for HBV; and other statements relating to our future operations, future financial performance, future financial condition, prospects or other future events.

With respect to the forward-looking statements contained in this presentation, Arbutus has made numerous assumptions regarding, among other things: the receipt of expected payments; the effectiveness and timeliness of preclinical studies and clinical trials, and the usefulness of the data; the timeliness of reg approvals; the continued demand for Arbutus' assets; and the stability of economic and market conditions. While Arbutus considers these assumptions to be rease these assumptions are inherently subject to significant business, economic, competitive, market and social uncertainties and contingencies. Forward-looking state herein involve known and unknown risks, uncertainties and other factors that may cause the actual results, events or developments to be materially different from future results, events or developments expressed or implied by such forward-looking statements. Such factors include, among others: anticipated pre-clinical and 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 development of the tested drug candidate; changes in Arbutus' strategy regarding its product candidates and clinical development activities; Arbutus may not rece necessary regulatory approvals for the clinical development of Arbutus' products; economic and market conditions may worsen; and market shifts may require a chastrategic focus. A more complete discussion of the risks and uncertainties facing Arbutus appears in Arbutus' Annual Report on Form 10-K and Arbutus' periodic dis filings which are available at www.sec.gov and at www.sedar.com.

The forward-looking statements made in connection with this presentation represent our views only as of the date of this presentation (or any earlier date indic such statement). While we may update certain forward-looking statements from time to time, we specifically disclaim any obligation to do so, even if new infor becomes available in the future.



HBV Presents a Significant Unmet Medical Need



Significant Opportunity

to Improve HBV Cure Rates

HBV cures are achievable with today's SOC in **<5% of patients**. **Sustained** HBsAg and HBV DNA loss after end-of-treatment* is rare.

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*undetectable HBsAg and HBV DNA 6 months after end-of-treatment accepted as a functional cure..



STANDARD OF CARE THERAPIES FOR CHRONIC HBV

	PegIFN	Entecavir	Tenofovir	New HBV Therapies
Dosing Duration	48-weeks	Chronic	Chronic	rate of Undetectable HBV DNA
HBV DNA Undetectable (<60-80 IU/ml)	7-19%	67-90%	76-93%	rate of HBsAg Loss
HBsAg Loss	~3-7%	~1-2%	~1-3%	HIGHER CURES RATES

Achievable HBV Cure Rates with Current SOC

SOC: Standard Of Care | HBsAg: HBV Surface Antigen | PegIFN: Pegylated Interferon Source: EASL HBV Clinical Practice Guidelines, 2017 - Pegasys, PEG-Intron, Baraclude and Viread Package Inserts

Compelling Growth Opportunity in the HBV Market

257M chronic HBV



would substantially increase **diagnosis** and **treatm** rates to unlock significant **market growth opportunit**

An HBV curative regimen

SOC: Standard Of Care Source: Global Hepatitis Report and Hepatitis B Fact Sheet, WHO (2017) <u>http://www.who.int/mediacentre/factsheets/fs204/en/</u>

Investment Highlights

Singular therapeutic focus - curing chronic Hepatitis B Virus (HBV) Infection



Proven Leadership Team

Successful track records in the discovery, development, and commercialization of multiple antivirals including sofosbuvir, etravirine, rilpivirine, telaprevir and simeprevir





HBV Lifecycle Illustrates Key Points for Intervention

A combination of agents with complementary MOA is needed to cure HBV



Keys to Therapeutic Success

Suppress HBV DNA and viral antigens

Reawaken host immune response

Therapeutic success will require a combination of agents with complementary MOAs





Arbutus HBV Pipeline



AB-729 RNAi Therapeutic

Proprietary GalNAc-conjugate delivery technology provides liver targeting and enables subcutaneous dosing





Single trigger RNAi agent targeting all HBV transcripts

Inhibits HBV replication and lowers all HBV antigens

Pan-genotypic activity across HBV genotypes

Duration of HBsAg reduction supports once per month dosing

Demonstrated complementarity with capsid inhibitors

Phase I initiated in July 2019

Preliminary results in healthy volunteer and HBV subjects expected in late Q1 2020





Strong dose response in AAV mouse model

Stepwise reduction of HBsAg with monthly repeat dose administration





AB-729 Phase 1a/b Study Design

Preliminary results anticipated late Q1 2020

<u>Part 1:</u> Blinded SAD in Healthy Volunteers	<u>Part 2:</u> SAD in HBV Subjects	<u>Part 3:</u> 3 and 6 Month Mult dose in HBV Subject
Starting dose 60 mg	Starting dose selected from Part 1	Dose selected from pa
6 subjects per cohort (4 active, 2 placebo)	6 subjects per cohort	7 subjects per cohort
	CHB on stable NA Rx (HBV DNA neg-), HBeAg pos+ or neg-	CHB on stable NA Rx (H DNA neg-), HBeAg pos neg-
	Naïve CHB, HBeAg pos+ or neg-	Rx Naïve CHB, HBeAg p or neg-



SAD: Single Ascending Dose | HBeAg: Hepatitis B e Antigen | CHB: Chronic Hepatitis B

AB-452 and Next Gen RNA Destabilizer Program

- AB-452 development discontinued following extensive pre-clinical evaluations
- However, we believe this target offers potential for an oral HBsAg reducing agent and potential all oral combination therapy
- Continuing active research and development of a next generation small molecule



AB-836 Capsid Inhibitor

IND enabling studies ongoing

Potential for increased potency and enhanced resistance profile



- Novel chemical series differentiated from AB-506 and other competitor compounds in the Class II capsid inhibitor space
- Leverages a novel binding site within the core protein dimer-dimer interf
- Improved intrinsic potency with EC50 \leq 10 nM
- Active against NA resistant variants
- Potential to address known capsid resistant variants T33N and I105T
- Provides the potential for low dose and wide therapeutic window
- Projected to be once daily dosing
- Pangenotypic
- Combinable with other MOA agents

AB-836: A Next Generation Capsid Inhibitor

	HBV DNA / 1° Mechanism				cccDNA Formation / 2° Mechanism	Human Sei Shift
Compound	HepDE19 (EC ₅₀ μM)	HBV infected РНН (EC ₅₀ µM)	HBV infected HepG2-NTCP-C4 (EC ₅₀ μM)	Core I105T Mutation (EC ₅₀ µM)	HBV infected HepG2-NTCP-C4 (HBsAg EC ₅₀ μM)	(FC in EC₅₀ in Human Seri
AB-506	0.077	0.032	0.101	1.26	1.430	6х
AB-836	0.010	0.002	0.012	0.118	0.196	2x





Unique Binding Site

HAP: Heteroaryldihydropyrimidine | SBA: Sulfamoylbenzamide | PHH: Primary Human Hepatocytes

Key Objectives for 2020

Objective	Anticipated Timing
AB-729 preliminary phase 1a/1b single dose data	Late 1Q 2020
AB-729 multiple dose data	2H 2020
AB-836 complete IND enabling studies	2H 2020



Investment Highlights

Singular therapeutic focus - curing chronic Hepatitis B Virus (HBV) Infection

