

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 3, 2019 (September 30, 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

(IRS Employer
Identification No.)

**701 Veterans Circle
Warminster, Pennsylvania**

(Address of principal executive offices)

18974

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

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

Common Shares, without par value

Trading Symbol(s)

ABUS

Name of each exchange on which registered

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.

In July 2019, Arbutus Biopharma Corporation (“Arbutus” or “Company”) announced preliminary results from a Phase 1a/1b clinical trial of AB-506, the Company’s second generation capsid inhibitor, in healthy subjects and two cohorts of chronic hepatitis B (“CHB”) infected subjects. As Arbutus has also previously reported, no serious adverse events (“SAEs”) or clinically significant safety findings were observed in healthy subjects (N=33), with alanine aminotransferase (“ALT”) levels and other liver function tests remaining normal throughout the 10 days of dosing in healthy subjects.

Arbutus further reported, however, that in two cohorts of CHB subjects, four CHB subjects (two in each of the cohorts) experienced Grade 4 ALT flares, which returned to baseline levels upon AB-506 discontinuation or completion of the 28-day treatment period. Aspartate aminotransferase values were also elevated to a lesser degree, however, none of the subjects met the criteria for drug induced liver injury as bilirubin values and liver synthetic function remained normal. All four ALT flares occurred after the subjects experienced a >2 log decline in hepatitis B virus DNA from baseline.

To further investigate the nature of the ALT flares, the Company initiated a healthy subjects study testing 28 days of dosing. Before completing the study, the Company observed two cases of acute hepatitis. Consequently, the Company immediately stopped the clinical trial and decided to discontinue all further development of AB-506.

As a result of its decision to discontinue further development of AB-506, Arbutus no longer expects to initiate a combination study of AB-506 and AB-729 in the second half of 2020.

On October 3, 2019, Arbutus posted an updated corporate presentation on its website at www.arbutusbio.com. A copy of the presentation is filed herewith as Exhibit 99.1 and is incorporated by reference herein.

Forward-Looking Statements and Information

This Current Report on Form 8-K 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 report include statements about the Company’s expectations regarding the timing and clinical development of its product candidates.

There are known and unknown risks and uncertainties which could cause the Company’s 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 risks and uncertainties include, among others: changes in the Company’s strategy regarding its product candidates and clinical development activities; anticipated pre-clinical studies and clinical trials may be more costly or take longer to complete than anticipated; 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 the Company appears in the Company’s Annual Report on Form 10-K, the Company’s Quarterly Reports on Form 10-Q and the Company’s 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 the Company 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.

Item 9.01. Financial Statements and Exhibits.**(d) Exhibits.**

| Exhibit Number | Description |
|----------------|---|
| 99.1 | Corporate presentation dated October 3, 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: October 3, 2019

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



Singularly Focused on HBV

October 2019

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 laws. Forward-looking statements that are not historical facts are hereby identified as forward-looking statements for this purpose and include, among others, statements relating to: our 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 equivalents to extend into the second half of 2020; our ability to develop a curative regimen for HBV and unlock significant market growth opportunities; our expectations regarding the timing and clinical development of our product candidates; our expectation for AB-729 for preliminary results from our Phase I trial to be available in the first quarter of 2020; the timeline to a combination cure for HBV; and other statements relating to our future operations, future financial performance, future financial condition, future 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 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. Forward-looking statements herein involve known and unknown risks, uncertainties and other factors that may cause the actual results, events or developments to be materially different from the future results, events or developments expressed or implied by such forward-looking statements. Such factors include, among others: anticipated pre-clinical 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 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' periodic disclosure 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 indicated in 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 information becomes available in the future.



Investment Highlights

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

Significant unmet medical need in **HBV**

Global HBV prevalence double that of HCV, potential for larger market opportunity

Team with antiviral **expertise & proven track record**

Applying knowledge gained from HIV and HCV success to find **HBV cure through proprietary drug combinations**

Broad **HBV Portfolio**

HBV assets generating pre clinical and clinical data

Financial Position

\$95M cash at 6/30/19 excludes \$20M gross proceeds received from Onpattro royalty monetization in July 2019 and \$5.9M arbitration payment to UBC in Sept 2019
Cash runway into 2H 2020

Goal of **Functional Cure**

Goal of functional cure through finite duration treatment with **combination of different mechanisms of action**

Proven Leadership Team

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



William H. Collier

President and CEO



Michael J. Sofia, PhD

Chief Scientific Officer



Gaston Picchio, PhD

Chief Development Officer



David C. Hastings

Chief Financial Officer



Elizabeth Howard, PhD, JD

EVP, General Counsel and Chief Compliance Officer



Michael J. McElhugh

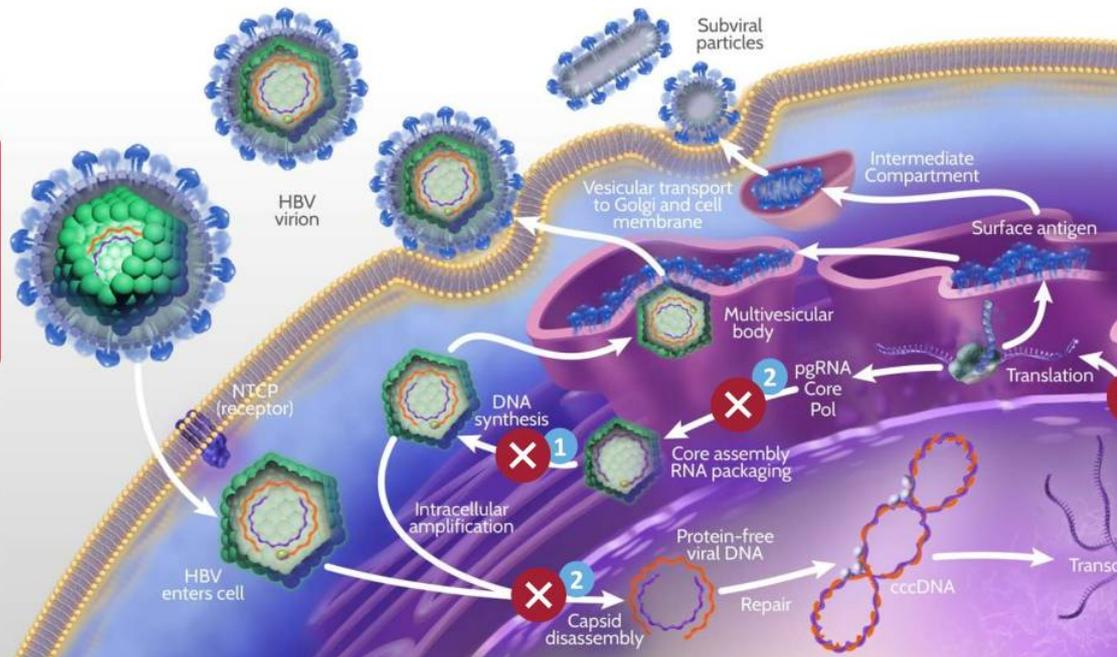
Chief Business Officer



HBV Lifecycle Illustrates Key Points for Intervention

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

- 1 – Nucleoside Analogue
- 2 – Capsid Inhibitor
- 3 – AB-729
- 3 – RNA Destabilizer

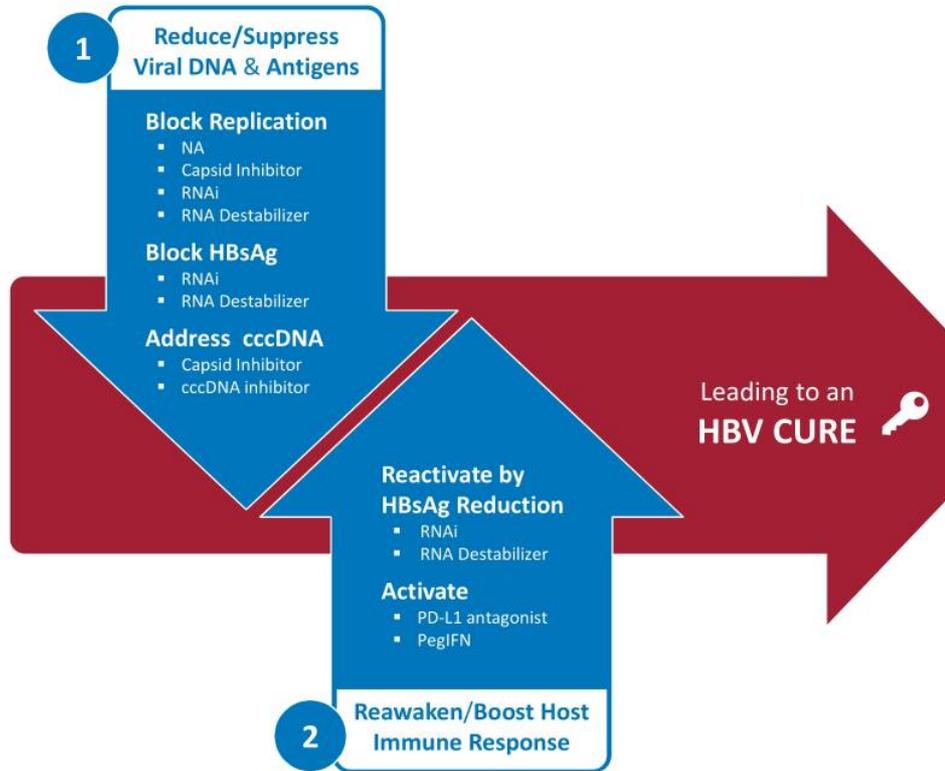


Keys to Therapeutic Success

Suppress HBV DNA and viral antigens

Reawaken host immune response

Therapeutic success will require a combination of agents with complementary MOAs.



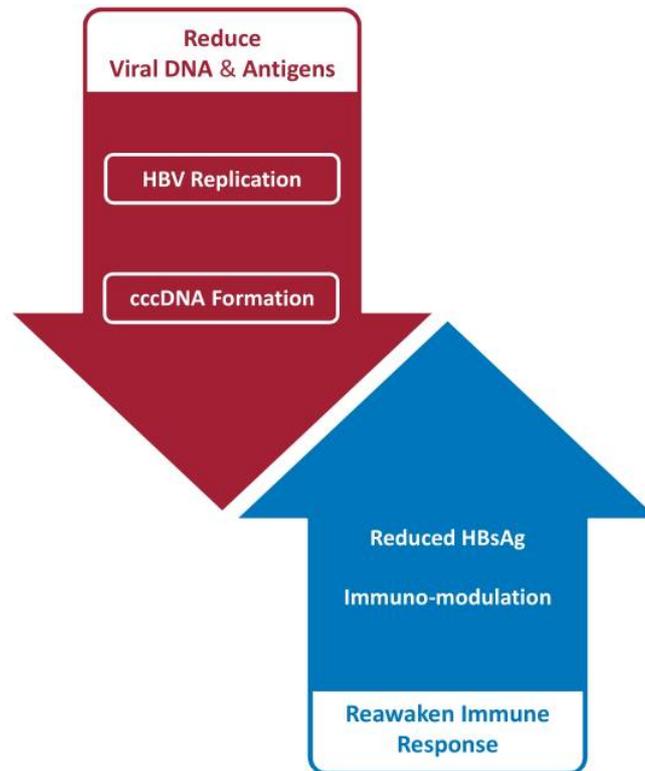
MOA: Mechanism Of Action | NA: Nucleoside Analogue | PegIFN: Pegylated Interferon | HBsAg: HBV Surface Antigen

Arbutus HBV Pipeline



Capsid Inhibitor: Blocking HBV Replication

Driving HBV DNA to undetectable, in the serum **and in the liver** is a key to therapeutic success in HBV



AB-506

Capsid Inhibitor

[Press Release](#)



Arbutus Announces Decision to Discontinue Development of AB-506, an Oral Capsid Inhibitor for the Treatment of Chronic Hepatitis

William H. Collier, President and Chief Executive Officer of Arbutus, stated, "We have observed two cases of acute hepatitis in our Phase 1a 28-day clinical trial in healthy volunteers. Consequently, the clinical trial and further development of AB-506 have been stopped."

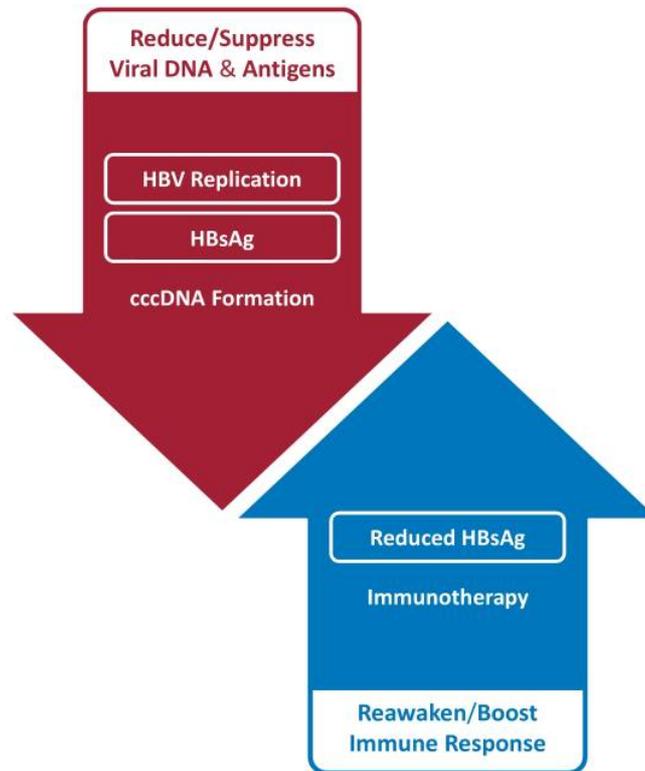
"The two subjects are experiencing resolution of their acute hepatitis. We will continue to follow them and the other study participants, as safety is our highest priority at Arbutus," said Gaston Picchio, Ph.D., Chief Development Officer of Arbutus. "We intend to present results from the AB-506 Phase 1a/1b clinical trial along with further details regarding the two cases of acute hepatitis at an appropriate scientific meeting later in 2019."

Michael J. Sofia, Ph.D., Chief Scientific Officer of Arbutus, added, "While we are disappointed in these recent clinical findings, we have a number of oral follow-up capsid inhibitor compounds with distinct chemical scaffolds that we believe have potential to contribute to the inhibition of HBV replication as part of a combination regimen. Our objective is to select one of several lead compounds for IND-enabling studies by December of this year."

Driving Down HBsAg Is A Key to Therapeutic Success in HBV

HBsAg is responsible for
immune exhaustion

Replication inhibitors do not
block HBsAg production



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

- Potent HBsAg reduction in preclinical models

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 expected Q1 2020**



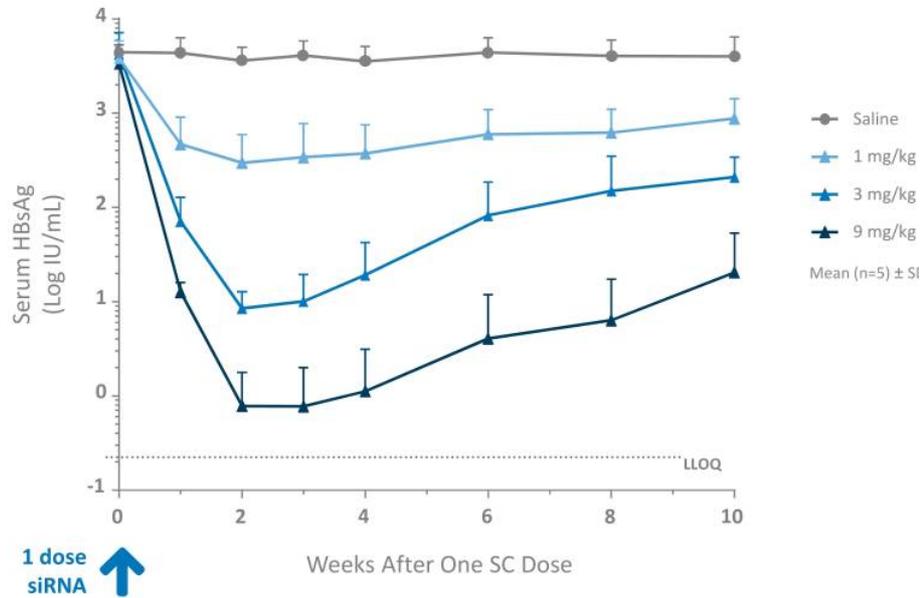
AB-729

In Vivo Single Dose Response & Duration

Clear dose response
in AAV mouse model

Achieves maximum
HBsAg reduction possible
in this model

Duration supports
a clinical dosing frequency
of **once per month**

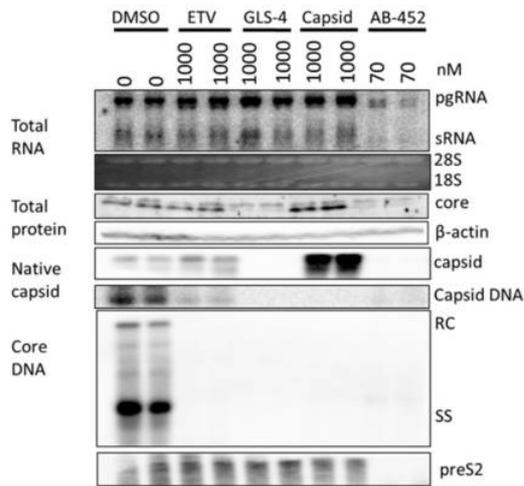


AB-729 also reduces HBV RNA, HBV DNA and e-antigen

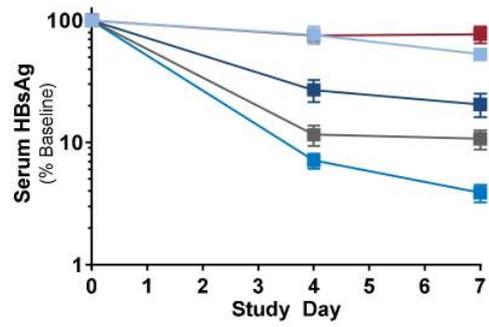
Lee, A., Et al, EASL 2019, Abstract FRI-184

Small Molecule HBV RNA Destabilizers

HBV RNA reduction leads to interference in viral gene expression, DNA replication, and virion assembly

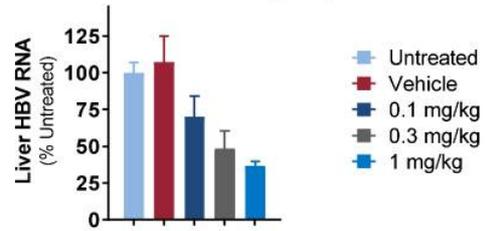


AAV mouse model
PO dosing



Dose-dependent reduction in HBsAg

HBsAg reduction correlates with reductions in HBV RNAs



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Gotchev, D., et al., AASLD, 2017, Abstract 923
Liu, F., et al., Int HBV Meeting 2018, Sicily

AB-452 and RNA Destabilizer Program

Multiple evaluations underway to support AB-452 and RNA destabilizer program next steps

Completed

- ✓ IND enabling studies and 28 day toxicology
- ✓ AB-452 mechanism of action studies demonstrating AB-452 causes HBV mRNA poly A tail shortening
- ✓ Host protein knock out causes no cellular tox
- ✓ Host gene expression studies indicating that AB-452 has no detectable effect on host cell mRNAs

Ongoing

- *In vitro* target engagement and target-based cell viability evaluations
- Additional, specialized *in vitro* and *in vivo* non-clinical safety assessments
- In depth DMPK evaluations
- 90 day toxicology studies, two species



Multiple small molecule chemotypes under investigation to **maximize program opportunity**

Arbutus HBV Pipeline

