

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): September 15, 2020

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

<u>British Columbia, Canada</u> (State or other jurisdiction of incorporation)	<u>001-34949</u> (Commission File Number)	<u>98-0597776</u> (IRS Employer Identification No.)
<u>701 Veterans Circle Warminster, Pennsylvania</u> (Address of principal executive offices)		<u>18974</u> (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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 September 15, 2020, Arbutus Biopharma Corporation (the "Company") issued a press release announcing positive 90 mg AB-729 single-dose week 12 data in patients with chronic hepatitis B infection. A copy of the press release is filed herewith as Exhibit 99.1 and is incorporated by reference herein.

On September 15, 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	Press release, dated September 15, 2020
99.2	Corporate Presentation, dated September 15, 2020
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: September 15, 2020

By: /s/ David C. Hastings

Name: David C. Hastings

Title: Chief Financial Officer



Arbutus Announces AB-729 90 mg Single-Dose Week 12 Data in Chronic Hepatitis B Subjects Demonstrating Significant and Continuous Reductions in HBsAg

Mean HBsAg reduction of 1.23 log₁₀ IU/mL at week 12 with a favorable safety and tolerability profile

WARMINSTER, Pa., -- 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 continued positive data from an ongoing Phase 1a/1b clinical trial (AB-729-001) with AB-729, its proprietary GalNAc delivered RNAi compound. These new data demonstrate that in chronic HBV subjects, a single subcutaneous injection of 90 mg of AB-729 resulted in a mean HBsAg reduction of 1.23 log₁₀ IU/mL at week 12.

William Collier, President and Chief Executive Officer of Arbutus, stated, "The 90 mg single-dose 12-week data coupled with our previously disclosed 60 mg single-dose 12-week data mean that we now have two doses which have demonstrated meaningful reductions in HBsAg with a favorable safety and tolerability profile. We are currently dosing chronic HBV subjects in four multi-dose cohorts using both the 60 mg (every 4- and 8-weeks) and 90 mg (every 8- and 12-weeks) doses to determine the optimal dosing regimen for AB-729. We believe AB-729 will potentially offer people with chronic HBV a well-tolerated low dose treatment with a minimum of injections."

Arbutus expects to present initial results from its ongoing Phase 1a/1b clinical trial for the 60 mg multi-dose cohorts, the 90 mg single-dose cohort in HBV DNA positive subjects, as well as longer-term follow up of the 60 and 90 mg single-dose cohorts, at an upcoming scientific meeting later this year. In addition to the ongoing 60 mg multi dose cohorts with subjects dosed at 4- and 8-weeks, the Company has also initiated 90 mg multi-dose cohorts with subjects dosed at 8- and 12-week intervals.

Mean HBsAg changes from baseline:

	60 mg Single-Dose Cohort (B) (N=6)	90 mg Single-Dose Cohort (C) (N=6)
Week 12 (day 84) mean log ₁₀ IU/mL (Standard Error of the Mean)	-0.99 (0.24)	-1.23 (0.18)

Dr. Gaston Picchio, Chief Development Officer of Arbutus, stated, "The mean HBsAg decline seen in the 90 mg single-dose cohort is consistent with that seen in prior single-dose cohorts. Importantly, the data demonstrate consistent efficacy and a favorable safety profile at this intermediate dose. These findings support the continued evaluation of the 90 mg dose in the multi-dose portion of our ongoing clinical trial."

Summary of clinical trial design

AB-729-001 is an ongoing first-in-human clinical trial consisting of three parts:

In Part 1, three cohorts of healthy subjects were randomized 4:2 to receive single-doses (60 mg, 180 mg or 360 mg) of AB-729 or placebo.

In Part 2, non-cirrhotic, HBeAg positive or negative, chronic HBV subjects (N=6) on a background of nucleos(t)ide therapy with HBV DNA below the limit of quantitation received single-doses (60 mg to 180 mg) of AB-729. An additional cohort in Part 2 included 90 mg single-dose of AB-729 in HBV DNA positive chronic HBV subjects.

In Part 3, chronic HBV subjects, HBV DNA negative first and HBV DNA positive later, are receiving multi-doses of AB-729 for up to six months.

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. In an ongoing single- and multi-dose Phase 1a/1b clinical trial, AB-729 demonstrated positive safety and tolerability data and meaningful reductions in hepatitis B surface antigen.

About HBV

Chronic hepatitis B virus (HBV) infection is a debilitating disease of the liver that afflicts over 250 million people worldwide with up to 90 million people in China, as estimated by the World Health Organization. HBV is a global epidemic that affects more people than hepatitis C virus (HCV) and HIV infection combined—with a higher morbidity and mortality rate. HBV is a leading cause of chronic liver disease and need for liver transplantation, and up to one million people worldwide die every year from HBV-related causes.

The current standard of care for patients with chronic HBV infection is life-long suppressive treatment with medications that reduce, but do not eliminate, the virus, resulting in very low cure rates. There is a significant unmet need for new therapies to treat HBV.

About Arbutus

Arbutus Biopharma Corporation is a publicly traded (Nasdaq: ABUS) biopharmaceutical company 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, please visit www.arbutusbio.com.

COVID-19

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.

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 Arbutus' expectations regarding the timing and clinical development of its product candidates; the potential for AB-729 to be a well-tolerated low dose treatment for HBV with a minimum of injections; Arbutus' expectation to present AB-729 60 mg multi-dose data and 90 mg single-dose data in HBV DNA positive subjects, as well as longer-term follow up of the 60 and 90 mg single-dose cohorts at an upcoming scientific meeting later this year; and Arbutus' expectations regarding the effect of the COVID-19 pandemic on its business.

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 drug 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 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 and Media

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Investor Relations Consultant
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Corporate Presentation

September 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 laws. All statements that are not historical facts are hereby identified as forward-looking statements for this purpose and include, among others, statements relating to: the potential market opportunity for HBV; Arbutus' ability to meet a significant unmet medical need; the sufficiency of Arbutus' cash and cash equivalents to extend into mid-2022; the potential for AB-729 to be a well-tolerated low dose treatment for HBV with a minimum of injections; Arbutus' expectation to present AB-729 60 mg multi-dose data and 90 mg single-dose data in HBV DNA positive subjects, as well as longer-term follow up of the 60 and 90 mg single-dose cohorts at an upcoming scientific meeting later this year; Arbutus' objective to complete IND enabling studies for AB-836 in the 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 I105T; the potential for AB-836 to be once daily dosing; our expectations regarding the timing and clinical development of Arbutus' product candidates; the timeline to a combination cure for HBV; Arbutus' coronavirus strategy; Arbutus' expectations regarding its technology licensed to Genevant; 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 timely 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 including uncertainties and contingencies related to the ongoing COVID-19 pandemic. 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 any 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 future development of the tested drug candidate; changes in Arbutus' 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; and market shifts may require a change in strategic focus; and the ongoing COVID-19 pandemic could significantly disrupt our clinical development programs. A more complete discussion of the risks and uncertainties facing Arbutus appears in Arbutus' Annual Report on Form 10-K, Quarterly Report on Form 10-Q and Arbutus' periodic disclosure filings which are available at www.sec.gov and at www.sedar.com.

Investment Highlights

Therapeutic focus – curing chronic Hepatitis B Virus (HBV) Infection

Significant Unmet Medical Need in HBV	Goal of HBV Functional Cure	Broad HBV Portfolio	Coronavirus Research Initiative	Team with Antiviral Expertise & Proven Track Record	16 % Ownership in Genevant
Global HBV prevalence double that of HCV, potential for larger market opportunity	Undetectable HBV DNA and HBsAg delivered through finite duration treatment with a combination of drugs with different modes of action	HBV assets include: RNAi Capsid Inhibitors PD-L1 HBV RNA Destabilizers	Focused on direct acting antivirals targeting the viral polymerase and protease	Applying knowledge gained from HIV and HCV success to HBV and Coronaviruses	Rights to potential future royalties and sublicense revenues for LNP Technology

Proven Leadership Team

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

 **Arbutus** BIOPHARMA
 NASDAQ: ABUS
 www.arbutusbio.com



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. McElhaugh

Chief Business Officer



HBV Presents a Significant Unmet Medical Need

>257M

people are chronically infected with HBV, globally.



~900k

people die every year as a consequence despite the availability of effective vaccines and antivirals.

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.

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



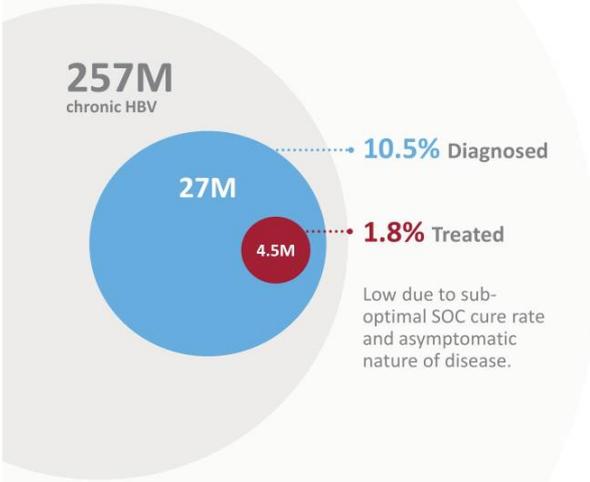
STANDARD OF CARE THERAPIES FOR CHRONIC HBV

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

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

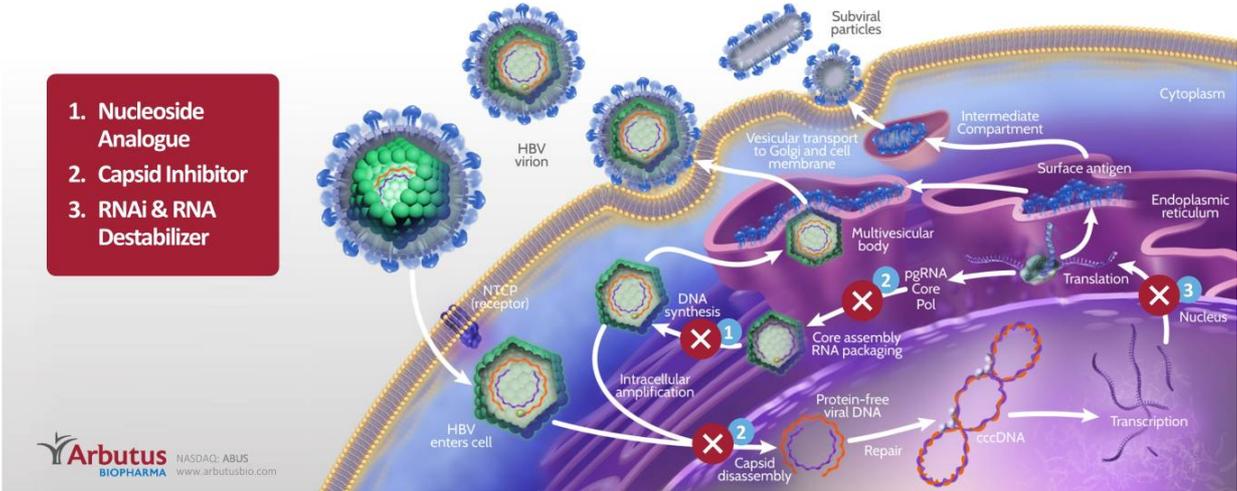
Compelling Growth Opportunity in the **HBV Market**



An HBV curative regimen would substantially increase **diagnosis** and **treatment** rates to unlock significant **market growth opportunities**.

HBV Lifecycle Illustrates Key Points for Intervention

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

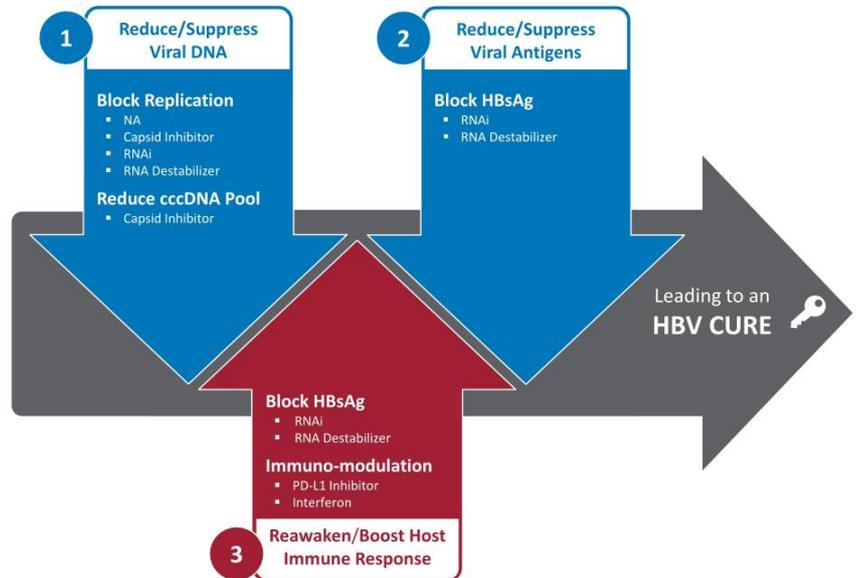


Keys to Therapeutic Success

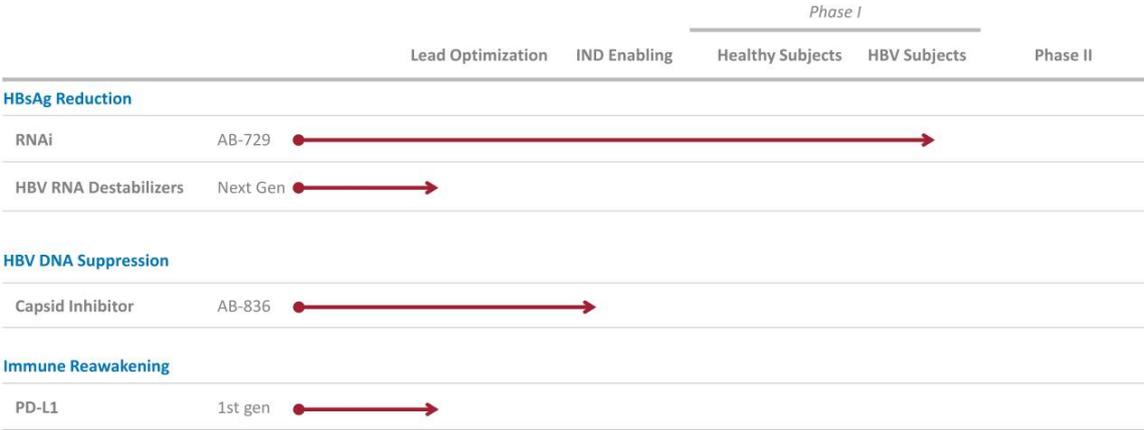
Suppress HBV DNA and viral antigens

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

Demonstrated complementarity with capsid inhibitors

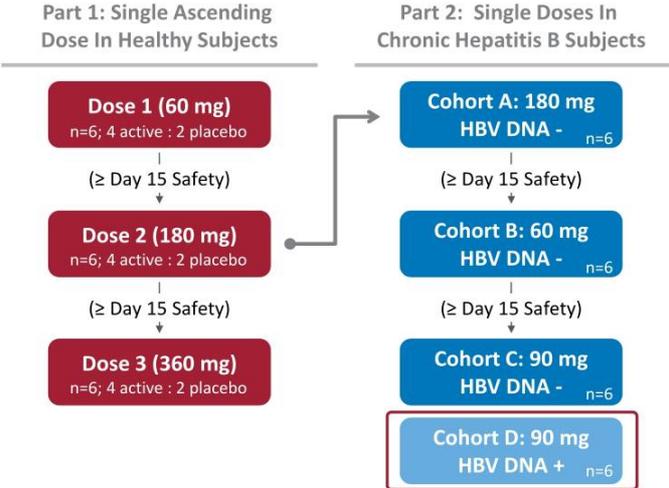
Actively targets the liver

Active against cccDNA derived and integrated HBsAg transcripts

Clean profile in long term preclinical safety studies

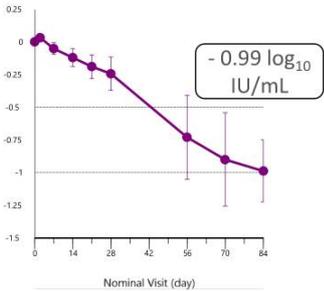


AB-729-001 Study Design

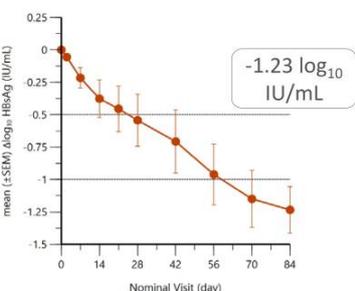


Comparable Mean HBsAg Declines with a Single 60 mg, 90 mg or 180 mg Dose of AB-729 at Week 12

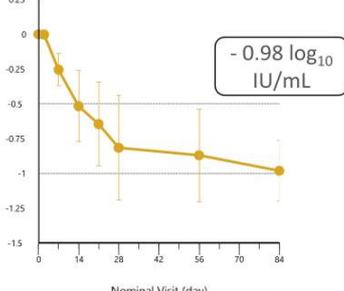
AB-729 60 mg (N=6)



AB-729 90 mg (N=6)



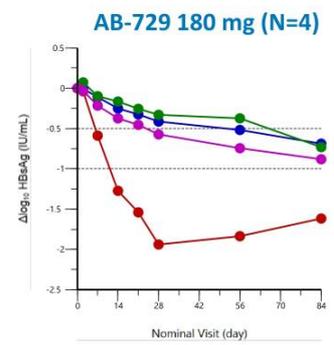
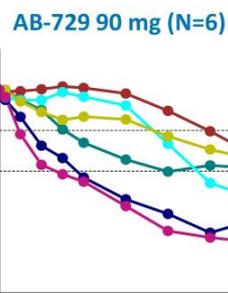
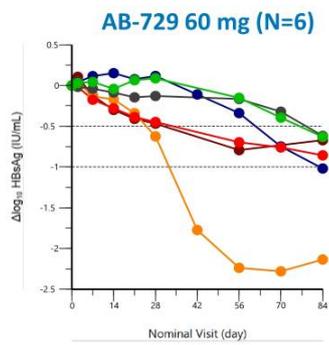
AB-729 180 mg (N=4)



All Subjects Responded in the 60 mg, 90mg and 180 mg Single-Dose Cohorts

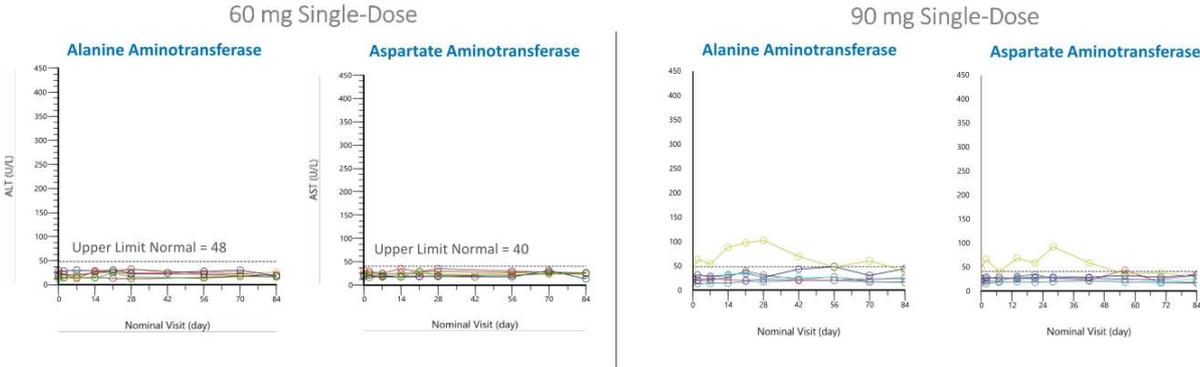
60 mg Cohort: Minimum HBsAg decline of -0.62 log₁₀ and maximum HBsAg decline of -2.14 log₁₀ at week 12

90 mg Cohort: Minimum HBsAg decline of -0.79 log₁₀ and maximum HBsAg decline of -1.87 log₁₀ at week 12



AB-729 was Generally Safe and Well Tolerated

ALT/AST levels in the 60 mg and 90 mg Single-Dose Cohorts



AB-729

RNAi Therapeutic

In September 2020,
Arbutus announced
additional positive single-
dose Phase 1a/1b clinical
trial results for AB-729



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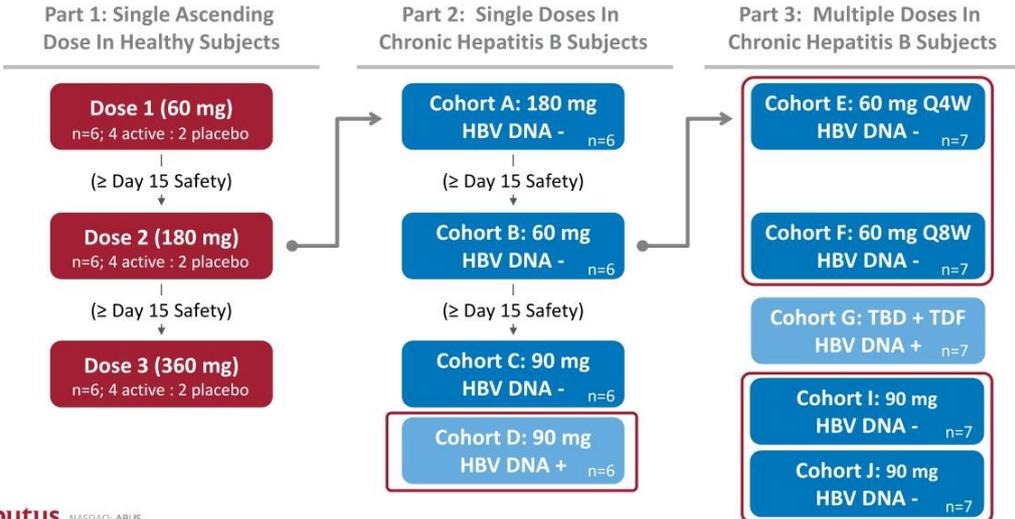
Continuous HBsAg declines
with a single 60 mg or 90
mg dose through week 12
with mean HBsAg declines
of 0.99 and 1.23 log,
respectively, consistent
with the 180 mg cohort at
week 12.

**Demonstrated favorable
safety profile**
through 12 week follow
up period in the 60 mg
and 90 mg single-dose
cohorts.

**All subjects responded to
therapy** with everyone
achieving at least a -0.62 log
and -0.79 log reduction in
HBsAg at week 12 in the 60 mg
and 90 mg dose groups,
respectively. Maximum
declines of -2.14 log and -1.87
log in the 60 mg and 90 mg
dose groups, respectively.

**AB-729 may provide a
competitive advantage**
through low dose and
reduced frequency
of injections.

AB-729-001 Study



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 interface

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

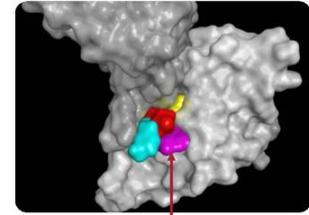
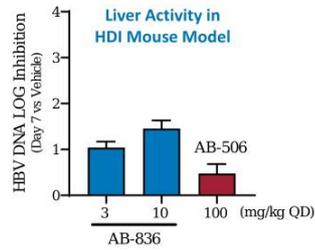
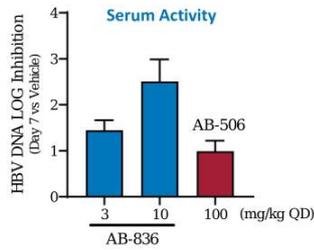
Projected to be once daily dosing

Pangenotypic

Combinable with other MOA agents

AB-836: A Next Generation Capsid Inhibitor

Compound	HBV DNA / 1 ^o Mechanism				cccDNA Formation / 2 ^o Mechanism	Human Serum Shift
	HepDE19 (EC ₅₀ μM)	HBV infected PHH (EC ₅₀ μM)	HBV infected HepG2-NTCP-C4 (EC ₅₀ μM)	Core I105T Mutation (EC ₅₀ mM)	HBV infected HepG2-NTCP-C4 (HBsAg EC ₅₀ μM)	(FC in EC ₅₀ in 40% Human Serum)
AB-506	0.077	0.032	0.101	1.26	1.430	6x
AB-836	0.010	0.002	0.012	0.118	0.196	2x



Unique Binding Site

Next Gen RNA Destabilizer Program

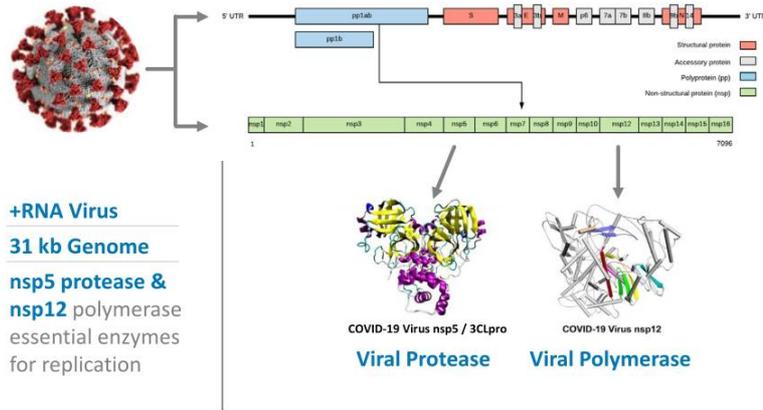
Offers a novel mechanism of action to reduce HBsAg and other viral proteins and viral RNA

Continuing active research and development of a next generation small molecule

We believe this approach offers potential for an oral HBsAg reducing agent and all oral combination therapy

Coronavirus Strategy

Leveraging our proven expertise and capabilities in antiviral drug discovery and development



Long term commitment

Pan-coronavirus focused

Small Molecule Direct-Acting Antivirals

Directed Effort

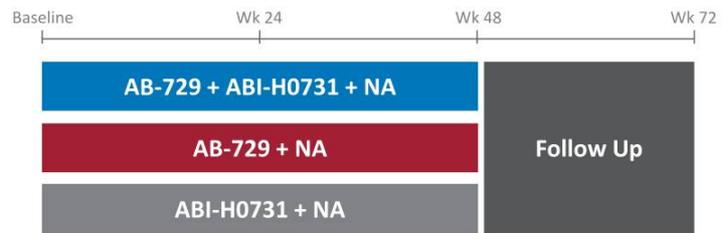
- nsp12 Viral Polymerase - nucleosid(t)es
- nsp5 Main Viral Protease - denovo design

Screening Effort

- Proprietary library screening through COVID R&D consortium

AB-729 Clinical Collaboration with Assembly Biosciences

Provides accelerated **AB-729 combination proof of concept (POC)** with a Capsid Inhibitor and NA with the potential for functional cure



~60 virologically-suppressed subjects with HBeAg negative or HBeAg positive chronic HBV infection

Projected initiation 1H 2021

Equal sharing of expertise and costs for this POC open-label trial

No financial requirements or restrictions and no business requirements or restrictions

NA: Nucleoside Analogue | HBeAg: HBV e Antigen

Key Objectives for 2020

Cash balance of \$115M as July 31, 2020, cash runway into mid-2022

Objective	Anticipated Timing
AB-729 preliminary phase 1a/1b single-dose data	✓ Late 1Q 2020
AB-729 additional week 12 60 mg single-dose data	✓ May 2020
AB-729 week 12 single-dose 90 mg data	✓ Sep 2020
Initiate two AB-729 90 mg multi-dose cohorts (8 and 12 wk intervals)	✓ 2H 2020
AB-729 multi-dose 60 mg data (4 and 8 wk dosing intervals)	2020 Fall Scientific Meeting
AB-729 week 12 single-dose 90 mg data (in HBV DNA Positive Subjects)	2020 Fall Scientific Meeting
Longer Term AB-729 follow-up 60 mg and 90 mg single dose cohorts	2020 Fall Scientific Meeting
Complete AB-836 IND enabling studies	2H 2020

