

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 1, 2021

**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.**

On February 1, 2021, Arbutus Biopharma Corporation (the “Company”) disclosed additional positive safety and efficacy data from its ongoing Phase 1a/1b clinical trial for AB-729 90 mg single-dose in HBV DNA positive subjects, at the 30th Asian Pacific Association for the Study of the Liver (APASL). The Company posted the updated corporate presentation, which includes such additional data, on its website at [www.arbutusbio.com](http://www.arbutusbio.com) (the “Corporate Presentation”). A copy of the Corporate Presentation is filed as Exhibit 99.1 and incorporated herein by reference.

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

<b>Exhibit Number</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Corporate Presentation dated February 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: February 1, 2021

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

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# Corporate Presentation

February 2021

NASDAQ: ABUS

[www.arbutusbio.com](http://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; 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; Arbutus' expectations regarding the timing and clinical development of Arbutus' product candidates including its 2021 key objectives and its clinical collaboration with Assembly Biosciences; 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](http://www.sec.gov) and at [www.sedar.com](http://www.sedar.com). 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.

# Investment Highlights

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

Significant Unmet Medical Need in HBV

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

Goal of HBV Functional Cure

Undetectable HBV DNA and HBsAg delivered through finite duration treatment with a combination of drugs with different modes of action

Broad HBV Portfolio

HBV assets include:  
RNAi  
Capsid Inhibitors  
PD-L1  
HBV RNA Destabilizers

Coronavirus Research Initiative

Focused on direct acting antivirals targeting the viral polymerase and protease

Team with Antiviral Expertise & Proven Track Record

Applying knowledge gained from HIV and HCV success to HBV and Coronaviruses

16 % Ownership in Genevant

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



**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**

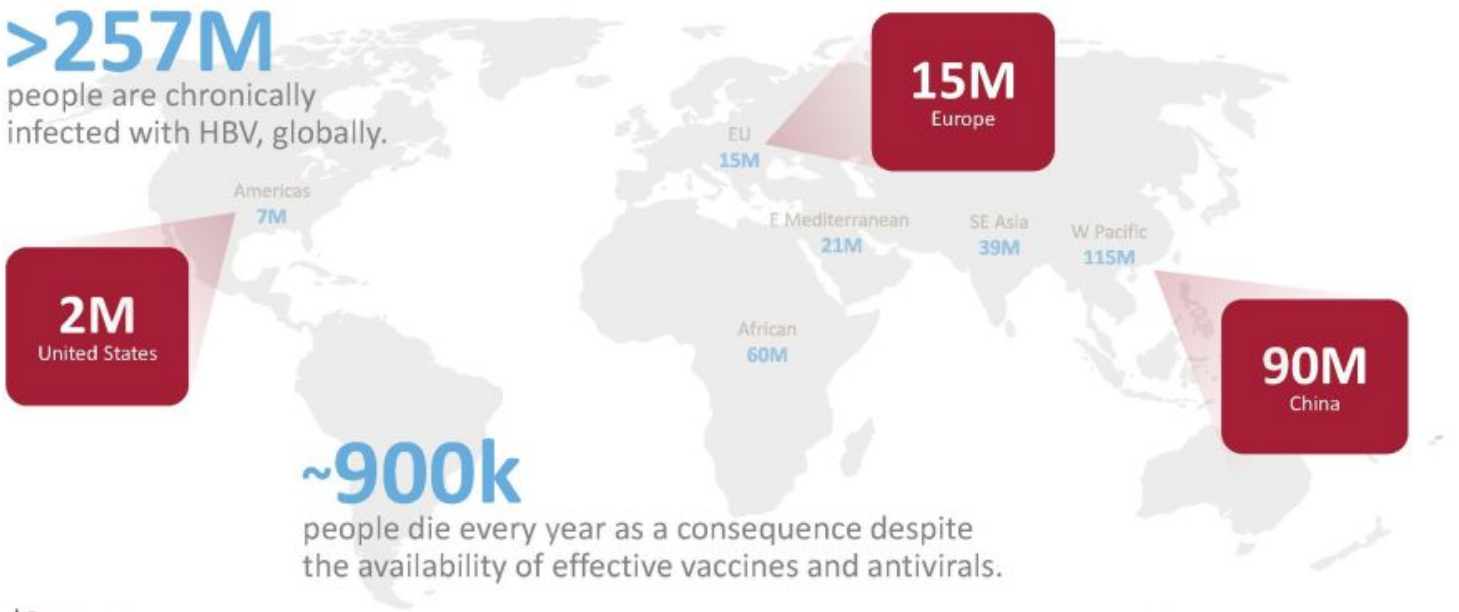
Chief Business Officer



# 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.



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## 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%	+
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

**27M**

**4.5M**

10.5% Diagnosed

1.8% Treated

Low due to sub-optimal SOC cure rate and asymptomatic nature of disease.

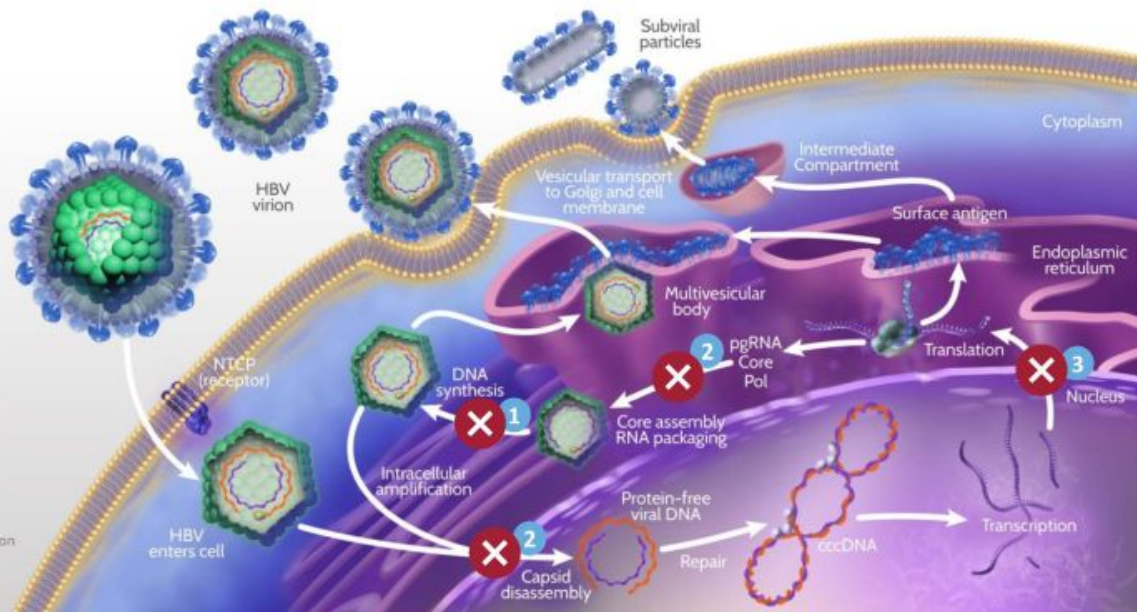
## An HBV curative regimen

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

- 1. Nucleoside Analogue
- 2. Capsid Inhibitor
- 3. RNAi & RNA Destabilizer

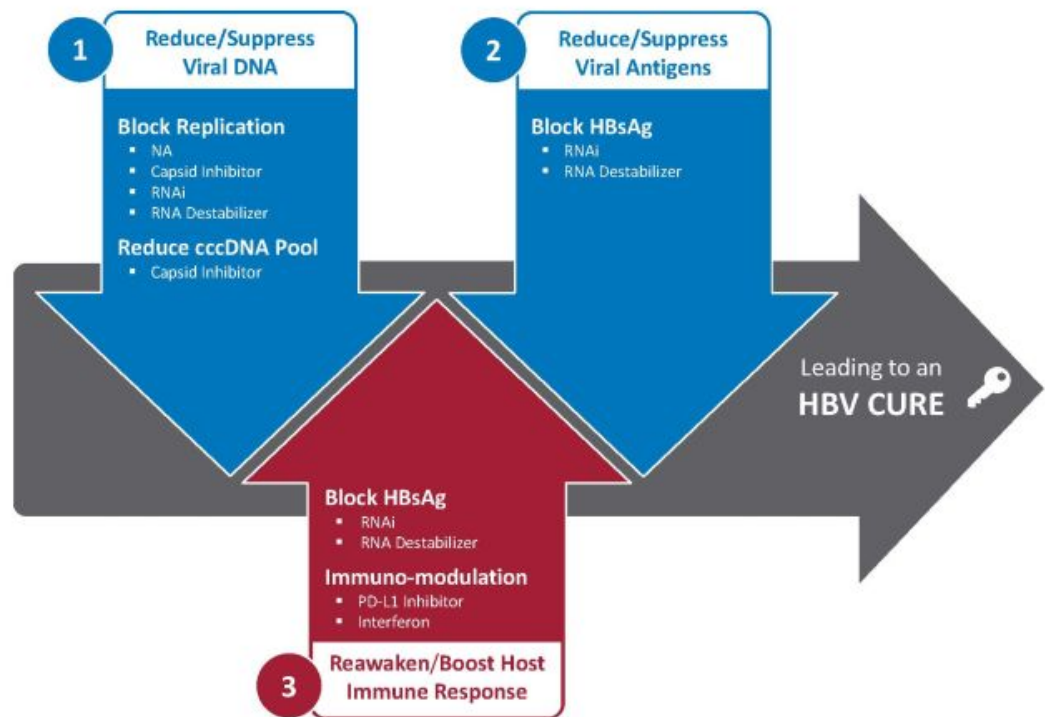


# Keys to Therapeutic Success

Suppress HBV DNA and viral antigens

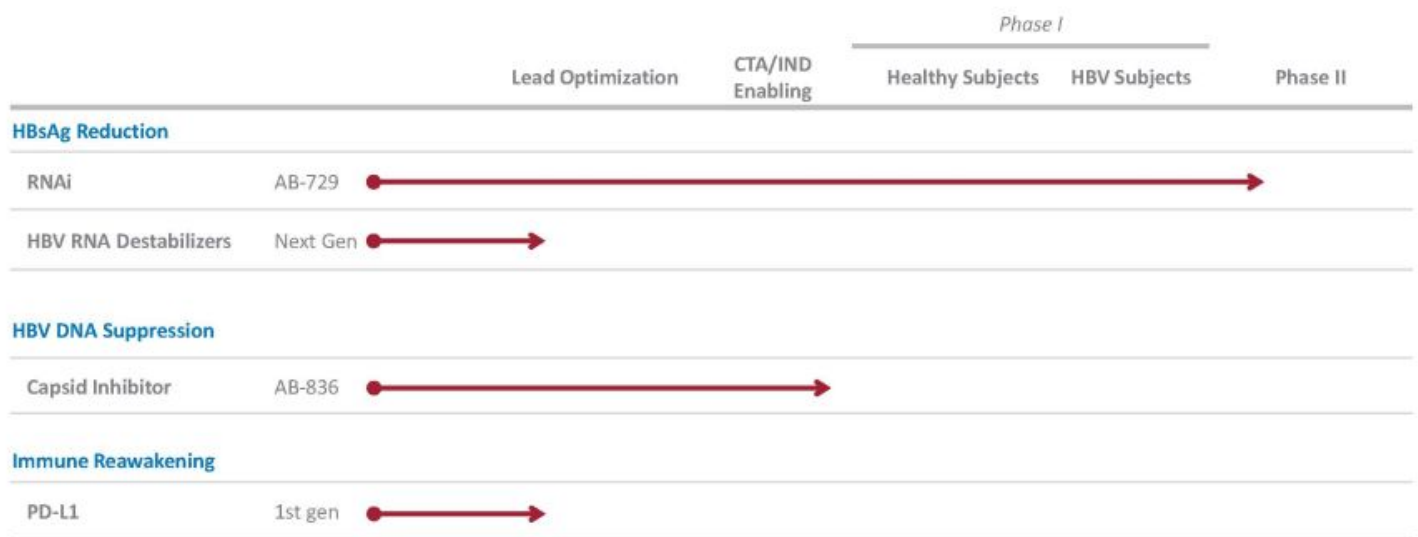
Reawaken host immune response

Therapeutic success will require a combination of agents with complementary MOAs



MOA: Mechanism of Action | NA: Nucleoside Analogue | HBsAg: HBV Surface Antigen

# 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

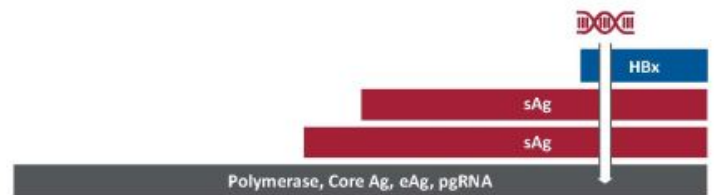
Pan-genotypic activity across HBV genotypes

Demonstrated complementarity with capsid inhibitors

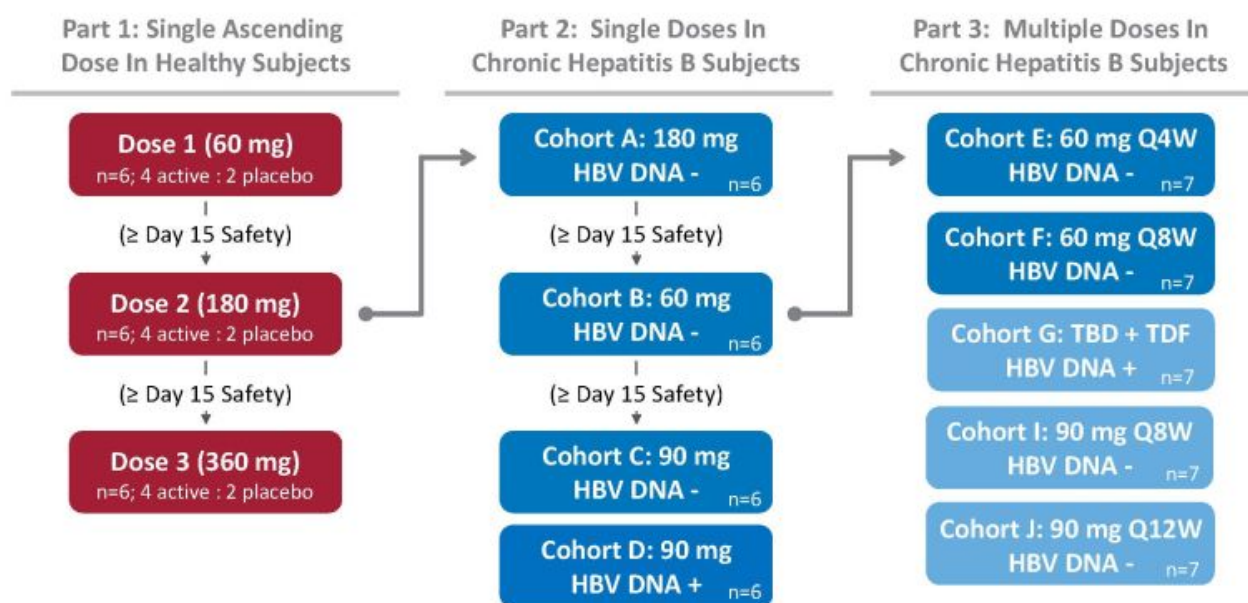
Actively targets the liver

Active against cccDNA derived and integrated HBsAg transcripts

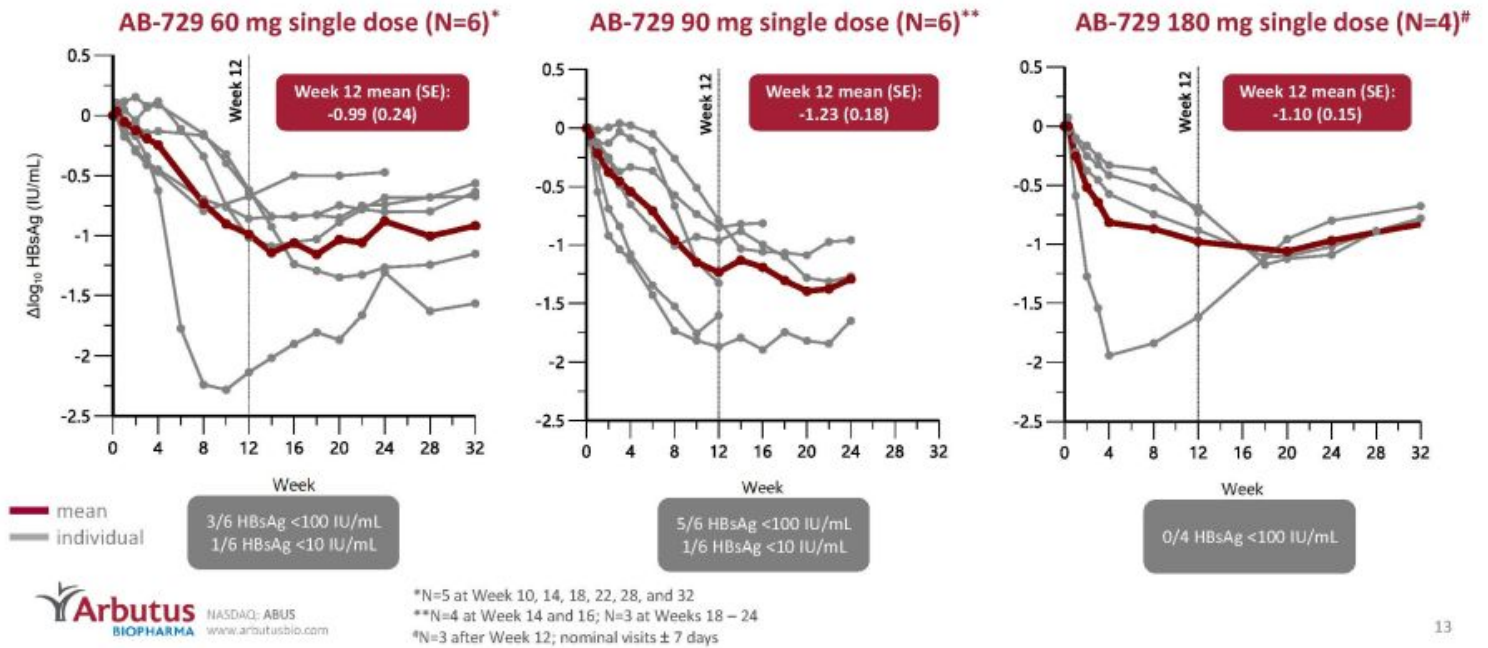
Clean profile in long term preclinical safety studies



# AB-729-001 Study



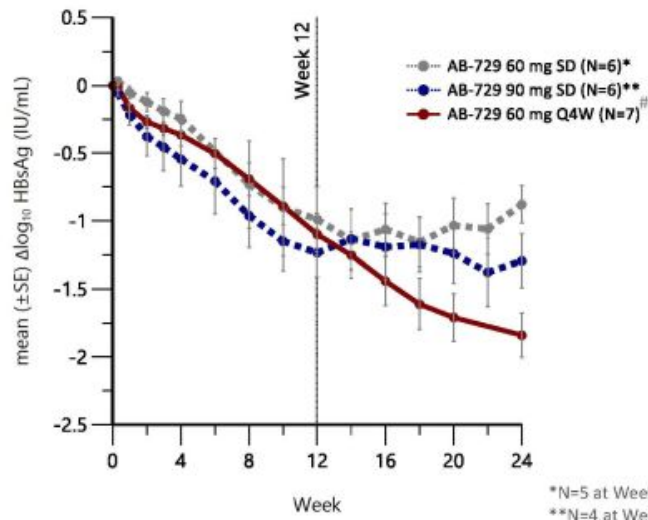
# Single Doses of AB-729 Result in Comparable Mean HBsAg Declines at Week 12 Followed by a Sustained Plateau Phase





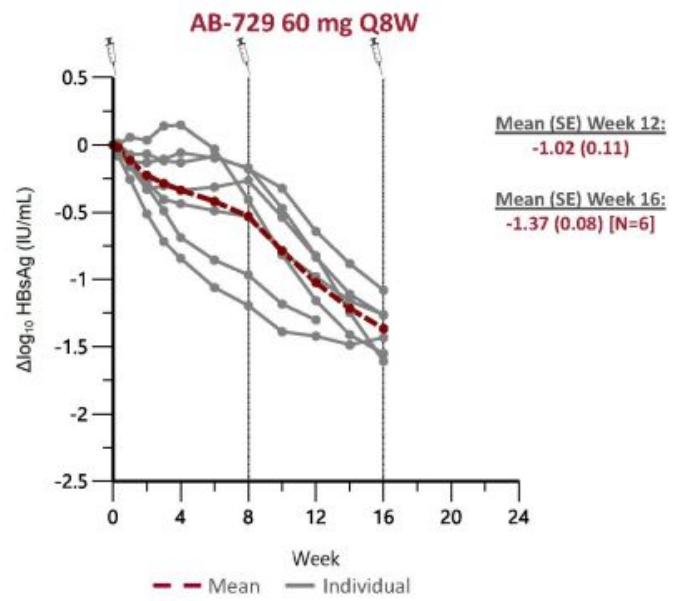
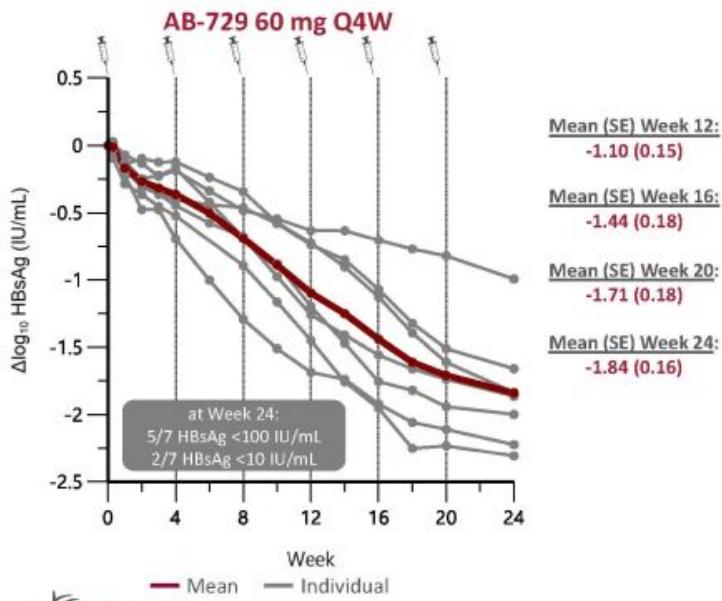
# Repeat Dosing of AB-729 60 mg Every 4 Weeks Results in Continuous Mean HBsAg Declines Beyond Week 12

**Mean ( $\pm$ SE) HBsAg declines across single and repeat dose Cohorts**

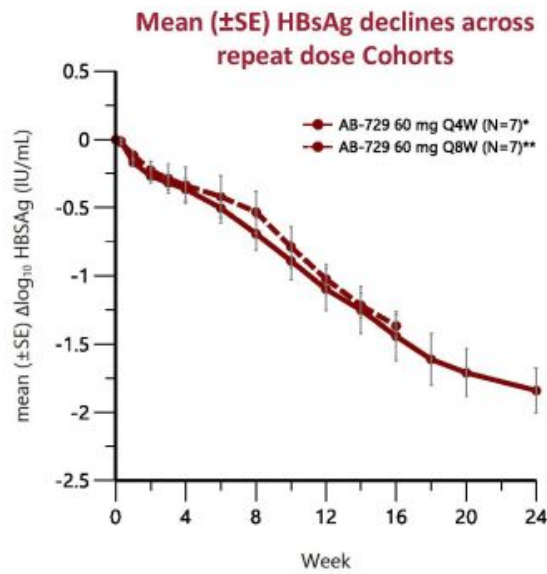


\*N=5 at Week 10, 14, 18 and 22  
 \*\*N=4 at Week 14 - 20; N=3 at Weeks 22 - 24  
 †N=6 at Week 6  
 SD: single dose; Q4W: every 4 weeks

# Repeat Dosing of AB-729 60 mg Every 8 Weeks Results in Comparable Mean HBsAg Declines to 60 mg Every 4 Weeks at Week 16



# Repeat Dosing of AB-729 60 mg Every 8 Weeks Results in Comparable Mean HBsAg Declines to 60 mg Every 4 Weeks at Week 16



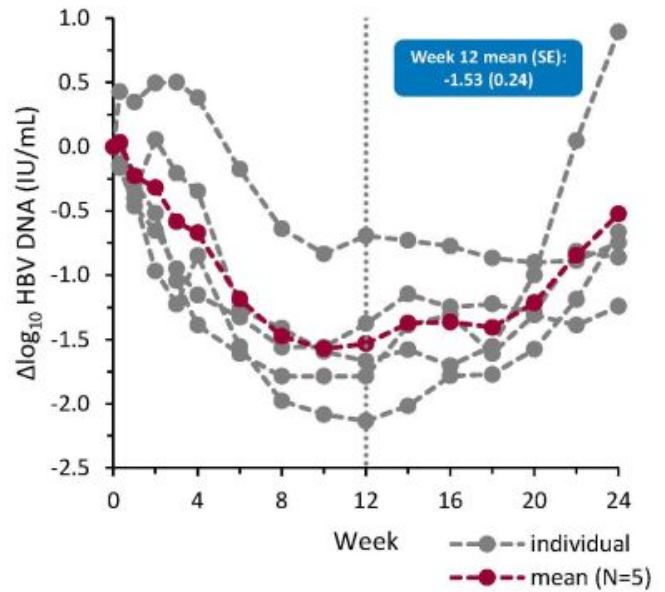
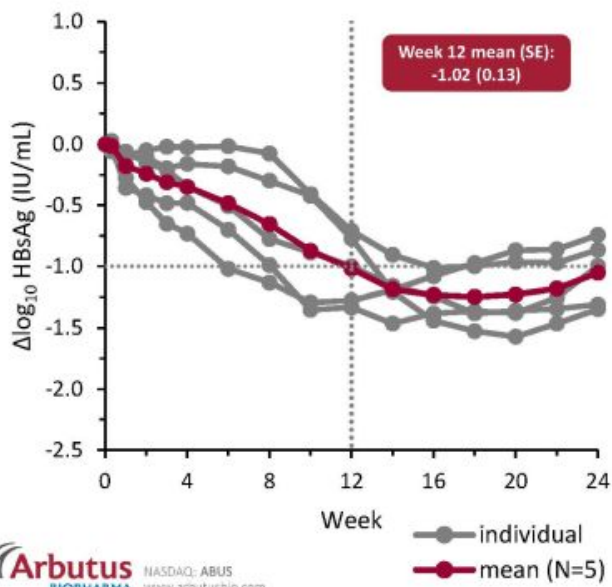
\*N=6 at Week 6

\*\*N=6 at Week 14 - 16

Q4W: every 4 weeks; Q8W: every 8 weeks

# AB-729 90 mg Single Dose Reduces HBsAg and HBV DNA in HBV DNA Positive CHB subjects

These data continue to support dosing intervals of up to 12 weeks



# AB-729 Was Safe and Well Tolerated After Single and Repeat Doses

- No SAEs or discontinuations due to AEs
- No treatment-related Grade 3 or 4 AEs\*
- No Grade 3 or 4 laboratory abnormalities\*
  - Grade 1 and Grade 2 ALT elevations have decreased with continued treatment
- Injection site TEAEs were mild (erythema, pain, pruritis, bruising) or moderate (pain) and transient
- No clinically meaningful changes in ECGs or vital signs
- All subjects in cohort E consented to an additional 6 months of dosing

# AB-729 Clinical Summary

Repeat 60 mg Q4W dosing with AB-729 resulted in a continuous and robust mean HBsAg decline at week 24 (-1.84 log<sub>10</sub> IU/mL, N=7)

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Repeat dosing of AB-729 60 mg every 8 weeks results in comparable mean HBsAg declines relative to 60 mg every 4 weeks at week 16 (-1.44 log<sub>10</sub> IU/mL vs -1.37 log<sub>10</sub> IU/mL, *p*<0.7)

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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
  - These findings support complete target engagement by AB-729
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AB-729 remains generally safe and well tolerated

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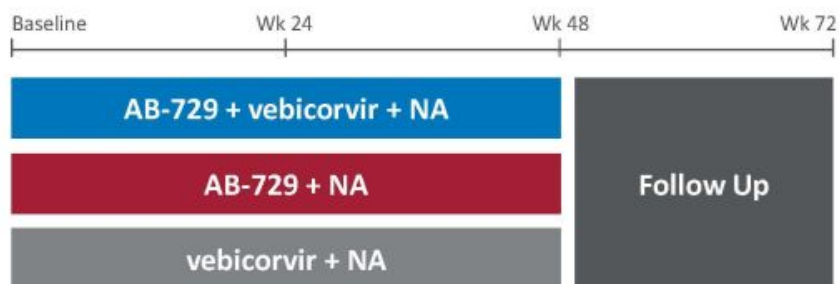
These results support advancing AB-729 to Phase 2 combination studies with AB-729 dosing as infrequently as every 8 or 12 weeks

# 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



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~60 virologically-suppressed subjects with 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

# AB-836

## Capsid Inhibitor

### CTA/IND enabling studies completed

Potential for increased efficacy and enhanced resistance profile

Novel chemical series differentiated from AB-506 and other competitor compounds in the Class II capsid inhibitor space

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Leverages a novel binding site within the core protein dimer-dimer interface

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Improved intrinsic potency with  $EC_{50} \leq 10$  nM

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Active against NA resistant variants

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Potential to address known capsid resistant variants T33N and I105T

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Provides the potential for low dose and wide therapeutic window

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Projected to be once daily dosing

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Pangenotypic

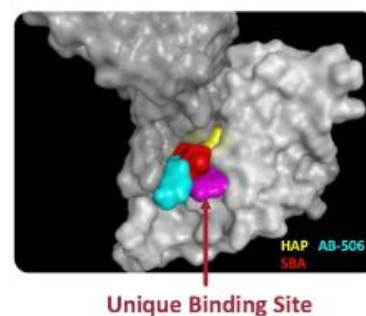
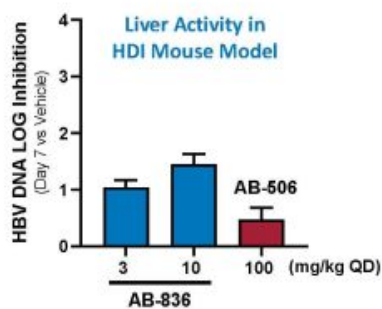
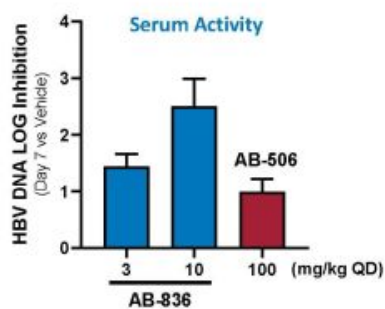
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Combinable with other MOA agents



# AB-836: A Next Generation Capsid Inhibitor

Compound	HBV DNA / 1 <sup>o</sup> Mechanism			cccDNA Formation / 2 <sup>o</sup> Mechanism		Human Serum Shift
	HepDE19 (EC <sub>50</sub> μM)	HBV infected PHH (EC <sub>50</sub> μM)	HBV infected HepG2-NTCP-C4 (EC <sub>50</sub> μM)	Core I105T Mutation (EC <sub>50</sub> mM)	HBV infected HepG2-NTCP-C4 (HBsAg EC <sub>50</sub> μM)	(FC in EC <sub>50</sub> 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



# Next Gen RNA Destabilizer Program

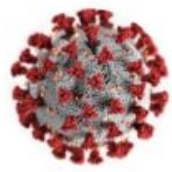
**Offers a novel mechanism of action** to reduce HBsAg and other viral proteins and viral RNA

**Continuing active research** and development of a next generation small molecule

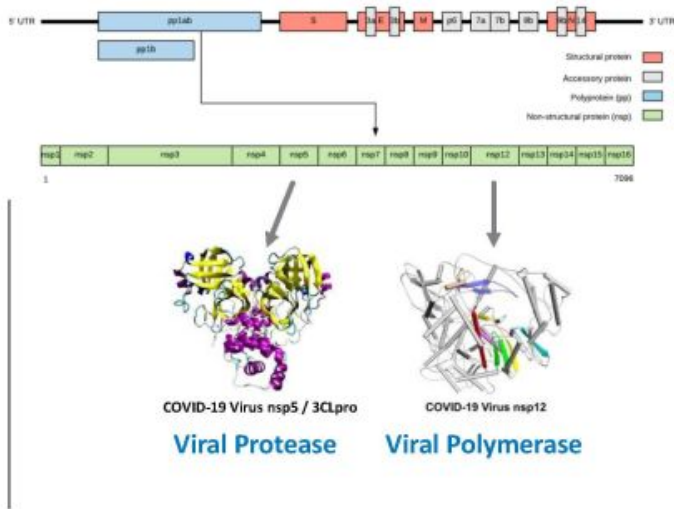
**We believe this approach offers potential** for an oral HBsAg reducing agent and all oral combination therapy

# Coronavirus Strategy

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



**+RNA Virus**  
**31 kb Genome**  
**nsp5 protease & nsp12 polymerase**  
 essential enzymes for replication



**Long term commitment**  
**Pan-coronavirus focused**  
**Small Molecule Direct-Acting Antivirals**

Directed Effort

- nsp12 Viral Polymerase - nucleos(t)ides
- nsp5 Main Viral Protease - de novo design

Screening Effort

- Proprietary library screening through COVID R&D consortium

## 2021 Key Objectives

Cash balance of ~ \$123M (unaudited) as Dec 31, 2020, cash runway into mid-2022

Objective	Anticipated Timing 2021
Additional data from AB-729 90 mg single-dose in HBV DNA positive subjects	1H ✓
Additional data from AB-729 60 mg multi-dose (4 wk / 8 wk dosing intervals)	1H / 1H
Initial data from AB-729 90 mg multi-dose (8 wk / 12 wk dosing intervals)	1H / 2H
Initial data from AB-729 90 mg multi-dose (8 wk dosing interval) in HBV DNA positive subjects	1H
Initiate a Phase 2a combination clinical trial to evaluate AB-729 in combination with Assembly Biosciences' lead core/capsid inhibitor candidate vebicorvir (VBR) and an NrtI	1H
Initiate two Phase 2a combination clinical trials in HBV subjects; both including AB-729, with one or more approved or investigational agents	2H
Initiate a Phase 1a/b clinical trial of AB-836, our next-generation oral capsid inhibitor	1H