

**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): March 16, 2021

Arbutus Biopharma Corporation

(Exact name of registrant as specified in its charter)

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

001-34949
(Commission File Number)

98-0597776
(I.R.S. Employer Identification No.)

701 Veterans Circle
Warminster, Pennsylvania 18974
(Address of Principal Executive Offices) (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 communications 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 communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications 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

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 March 16, 2021, Arbutus Biopharma Corporation (the "Company") issued a press release announcing that it has received regulatory approval to initiate a Phase 1a/1b clinical trial with AB-836, an oral capsid inhibitor for the treatment of chronic hepatitis B infection. A copy of the press release is filed herewith as Exhibit 99.1 and is incorporated by reference herein.

On March 16, 2021, 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 March 16, 2021
99.2	Corporate Presentation dated March 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: March 16, 2021

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

Arbutus Receives Regulatory Approval to Initiate a Phase 1a/1b Clinical Trial with AB-836, an Oral Capsid Inhibitor for the Treatment of Chronic Hepatitis B Infection

WARMINSTER, Pa., March 16, 2021 (GLOBE NEWSWIRE) -- 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 announced that it has received regulatory approval to initiate a Phase 1a/1b clinical trial with AB-836, its proprietary oral capsid inhibitor for the treatment of HBV infection.

“We are pleased that we have received regulatory approval to proceed with our Phase 1a/1b clinical trial for AB-836, and we expect to begin dosing shortly. Initiation of this trial is an important step towards potential future proprietary combinations with AB-729 and other mechanisms,” said William Collier, President and Chief Executive Officer of Arbutus.

Dr. Michael Sofia, Chief Scientific Officer of Arbutus, added, “Based on pre-clinical studies with AB-836, which is derived from a novel chemical series in this class, we believe it has the potential for improved clinical efficacy and safety as well as a favorable resistance profile relative to earlier generation capsid inhibitors. In addition, we believe that the strong potency of AB-836 as shown in *in vitro* testing should allow active engagement of the second mechanism of inhibiting cccDNA replenishment at clinically relevant doses.”

About AB-836

AB-836 is an oral capsid inhibitor for the treatment of chronic hepatitis B infection. It is from a novel chemical series that is differentiated from competitor compounds and has the potential for increased efficacy and an enhanced resistance profile. AB-836 binds to a novel site within the core protein dimer-dimer interface and has shown in *in vitro* testing to be active against nucleotide analog resistant variants and also has the potential to address certain known capsid resistant variants. AB-836 has been shown in *in vitro* studies to be active against nucleoside resistant variants and therapeutically relevant activity against key core protein resistant variants I105T and T33N. AB-836 is anticipated to be combinable with other drugs having different mechanisms of action for treating HBV, including AB-729, and is also anticipated to be dosed once daily.

About HBV

Hepatitis B is a potentially life-threatening liver infection caused by HBV. HBV can cause chronic infection which leads to a higher risk of death from cirrhosis and liver cancer. Chronic HBV infection represents a significant unmet medical need. The World Health Organization estimates that over 250 million people worldwide suffer from chronic HBV infection, while other estimates indicate that approximately 2 million people in the United States suffer from chronic HBV infection. Approximately 900,000 people die every year from complications related to chronic HBV infection despite the availability of effective vaccines and current treatment options.

About Arbutus

Arbutus Biopharma Corporation is a publicly traded (Nasdaq: ABUS) biopharmaceutical company primarily 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.

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 the Company’s expectation to begin dosing in a Phase 1a/1b clinical trial for AB-836 shortly; the Company’s belief that AB-836 has the potential for improved clinical efficacy and safety as well as a favorable resistance profile relative to earlier generation capsid inhibitors; the Company’s belief regarding the strong potency of AB-836 and its ability to allow active engagement of the second mechanism of inhibiting cccDNA replenishment at clinically relevant doses; AB-836’s potential to address certain known capsid resistant variants; and the Company’s anticipation for AB-836 to be combinable with other drugs having different mechanisms of action for treating HBV and to be dosed once daily.

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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Corporate Presentation

March 2021

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 through the third quarter of 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 clinical objectives with respect to AB-729 and AB-836 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 and at 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

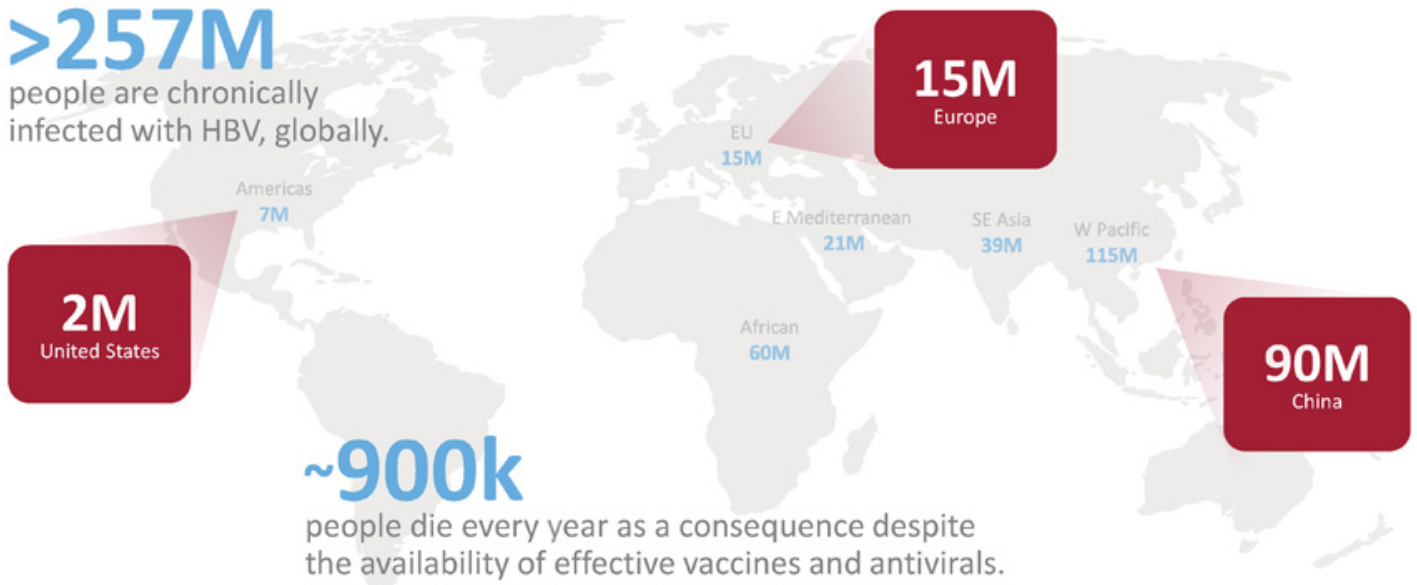
Chief Business Officer



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.

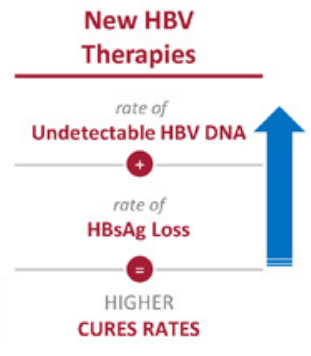
*undetectable HBsAg and HBV DNA 6 months after end-of-treatment accepted as a functional cure.



STANDARD OF CARE THERAPIES FOR CHRONIC HBV

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

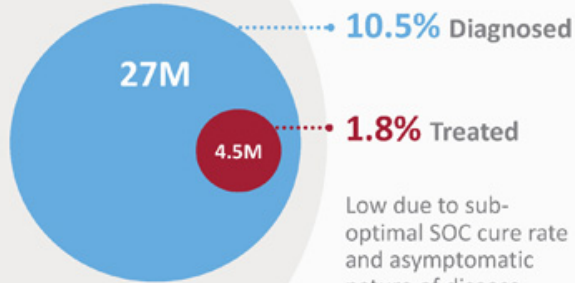
Achievable **HBV Cure Rates** with Current SOC



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**

257M
chronic HBV

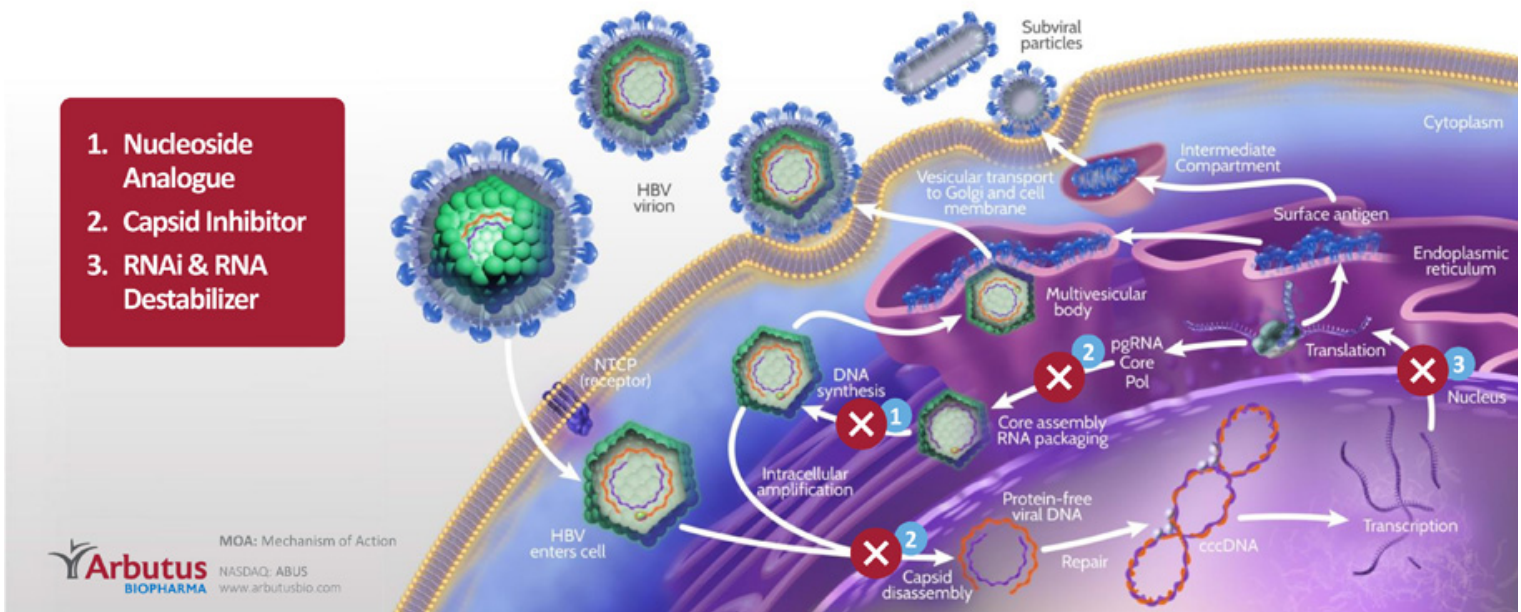


Low due to sub-optimal SOC cure rate and asymptomatic nature of disease.

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**

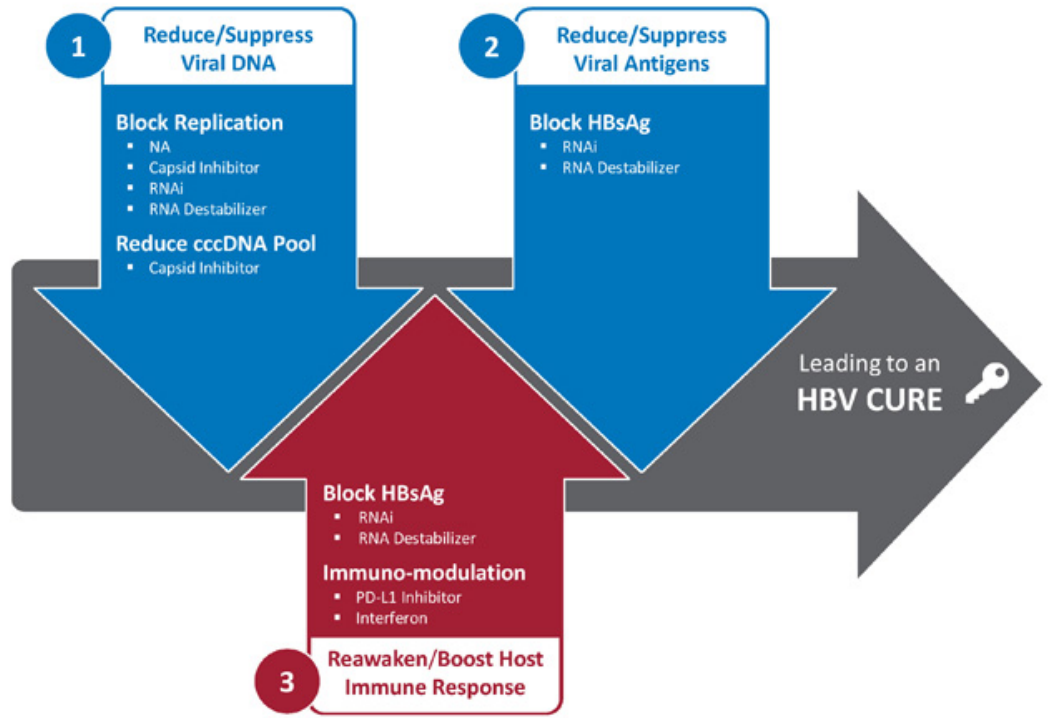


Keys to Therapeutic Success

Suppress HBV DNA and viral antigens

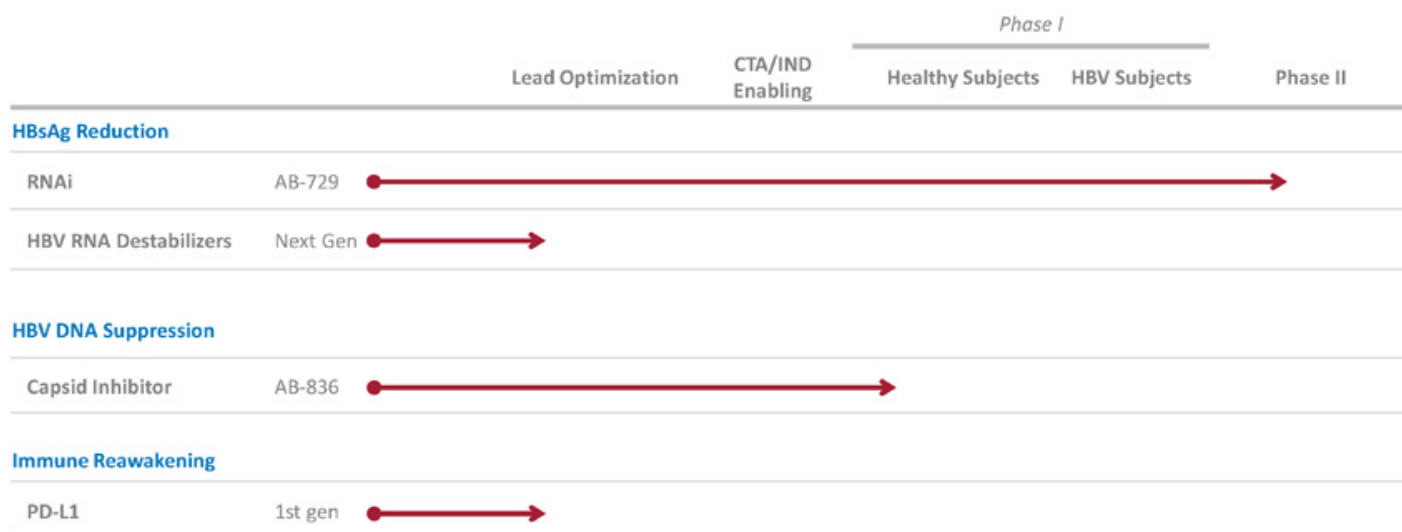
Reawaken host immune response

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

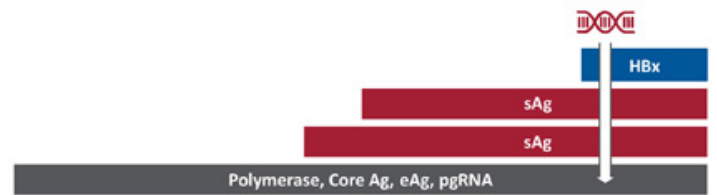
Pan-genotypic activity across HBV genotypes

Demonstrated complementarity with capsid inhibitors

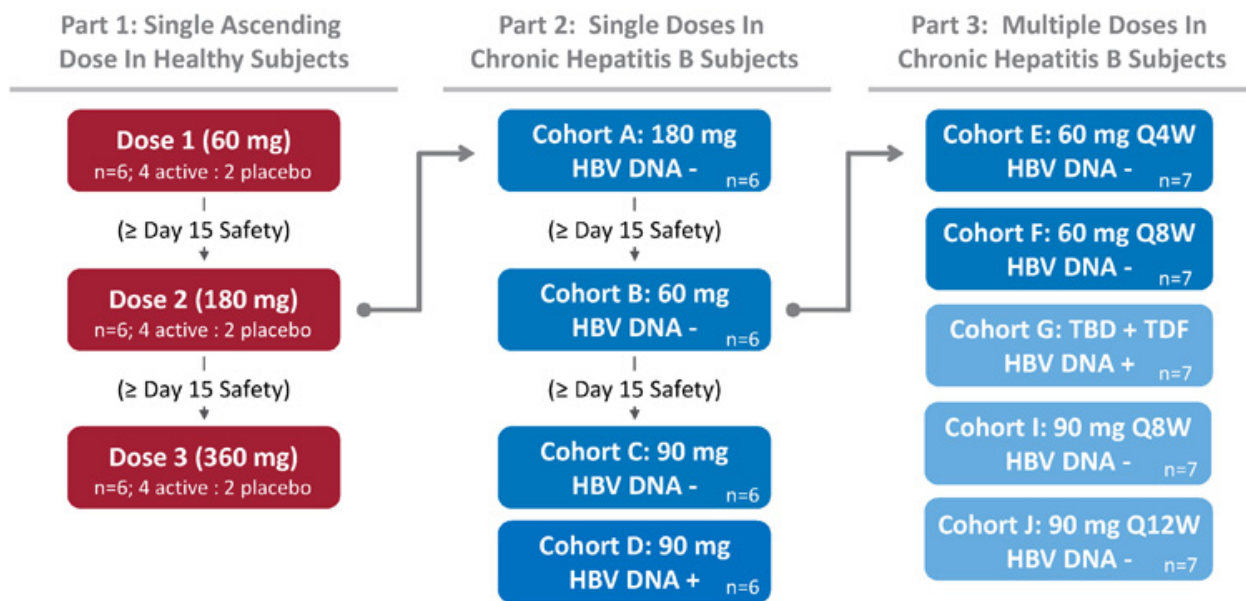
Actively targets the liver

Active against cccDNA derived and integrated HBsAg transcripts

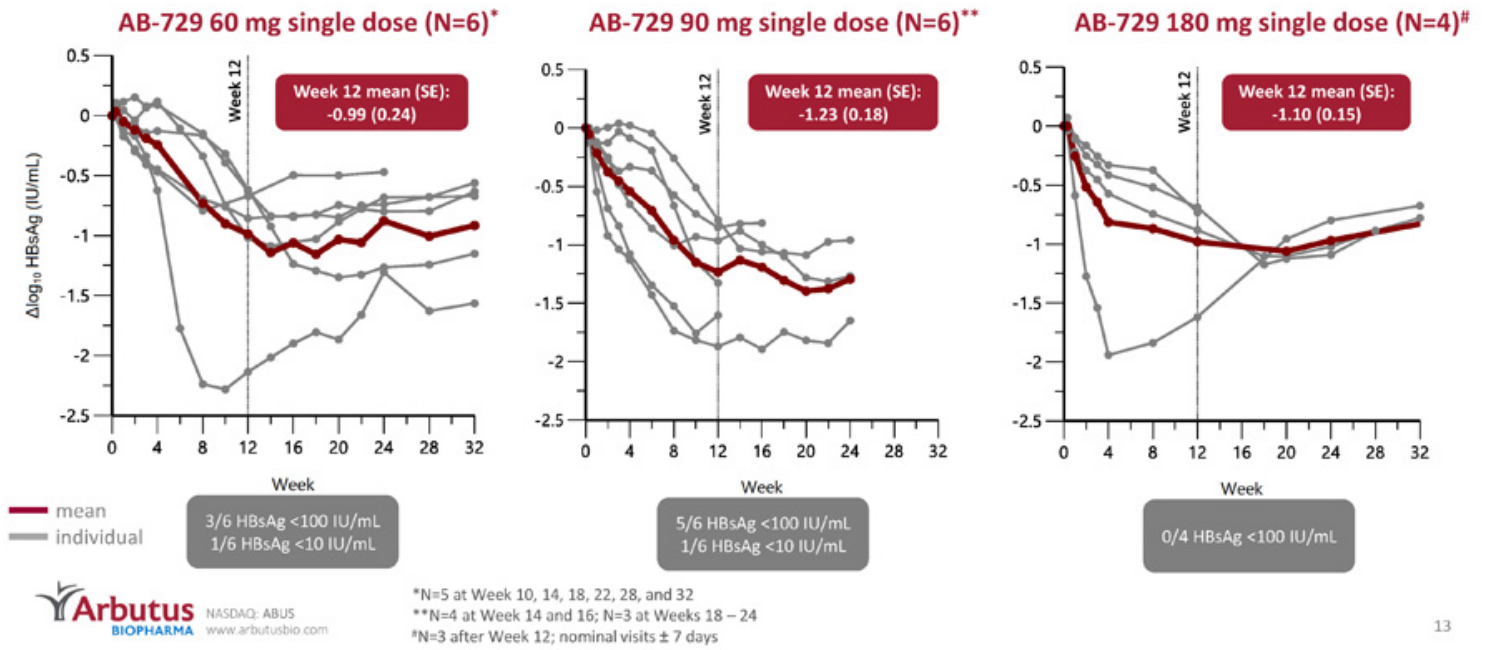
Clean profile in long term preclinical safety studies



AB-729-001 Study

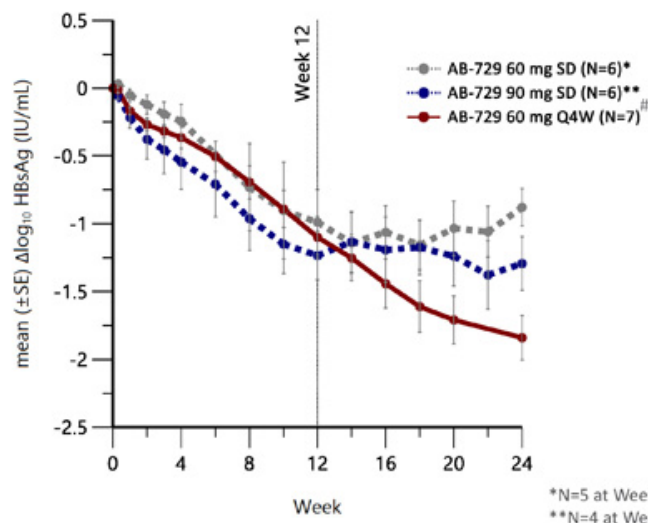


Single Doses of AB-729 Result in Comparable Mean HBsAg Declines at Week 12 Followed by a Sustained Plateau Phase



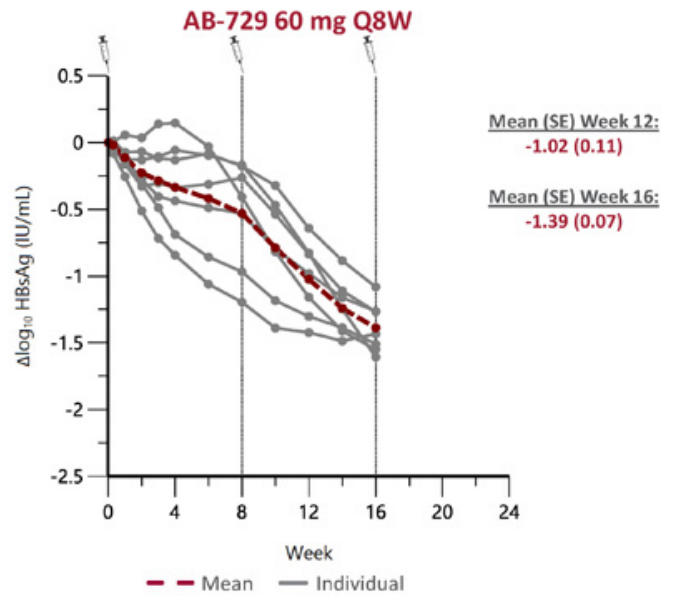
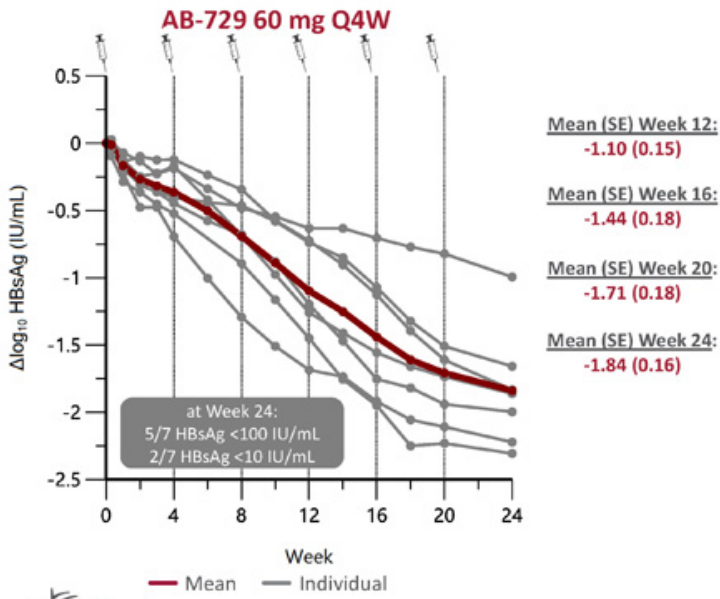
Repeat Dosing of AB-729 60 mg Every 4 Weeks Results in Continuous Mean HBsAg Declines Beyond Week 12

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

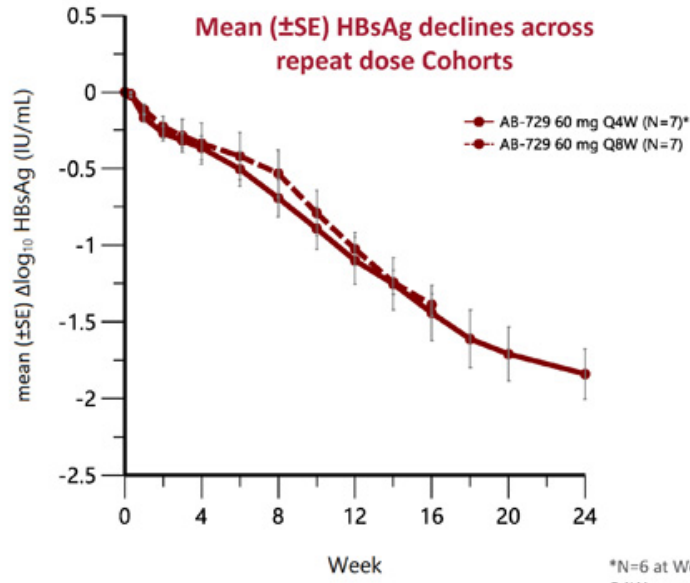


*N=5 at Week 10, 14, 18 and 22
**N=4 at Week 14 - 20; N=3 at Weeks 22 - 24
#N=6 at Week 6
SD: single dose; Q4W: every 4 weeks

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

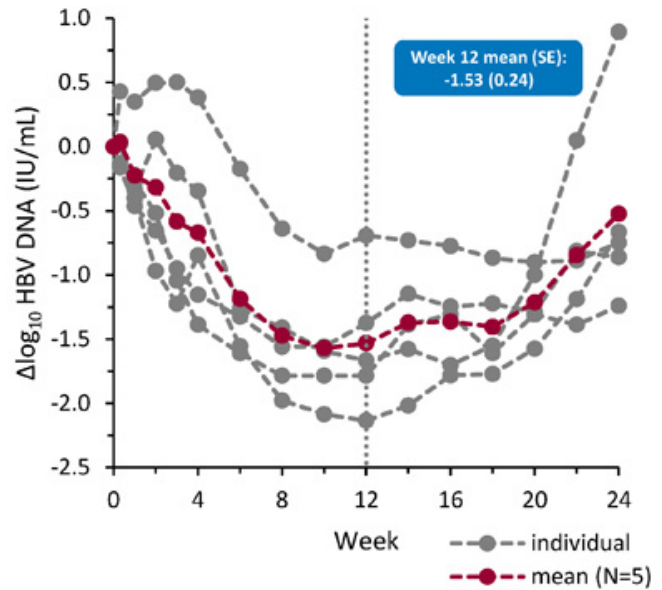
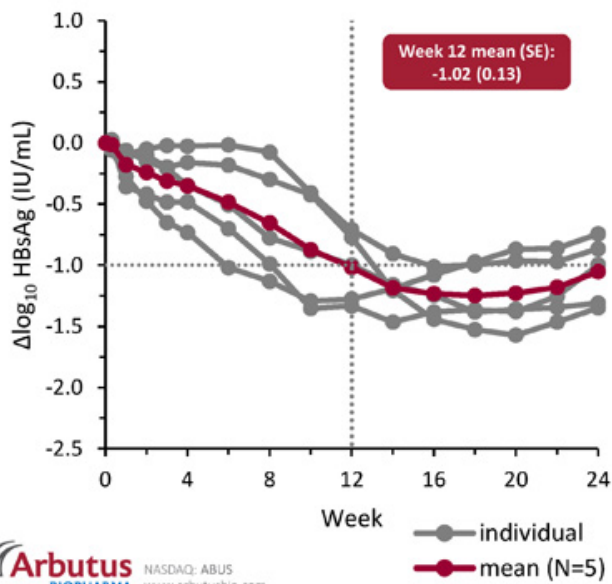


Repeat Dosing of AB-729 60 mg Every 8 Weeks Results in Comparable Mean HBsAg Declines to 60 mg Every 4 Weeks at Week 16



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 log₁₀ IU/mL, N=7)

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 log₁₀ IU/mL vs -1.37 log₁₀ IU/mL, *p*<0.7)

In HBV DNA positive CHB subjects, a single 90 mg AB-729 dose resulted in robust mean HBsAg (-1.02 log₁₀ IU/mL) and HBV DNA (-1.53 log₁₀ 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
-

AB-729 remains generally safe and well tolerated

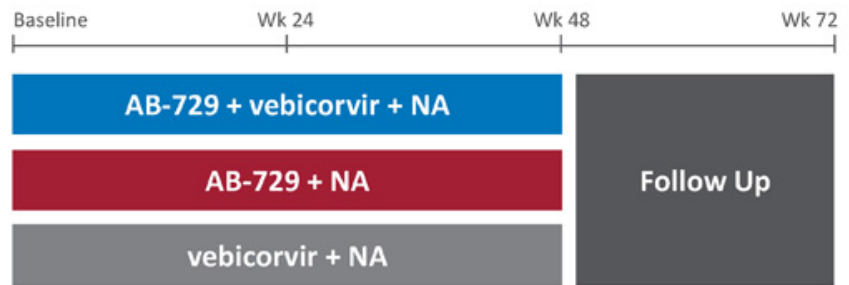
These results support advancing AB-729 to Phase 2 combination studies with AB-729 dosing as infrequently as every 8 or 12 weeks

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



NASDAQ: ABUS
www.arbutusbio.com



Initiated Phase 2 Clinical Trial Feb 2021

~60 virologically-suppressed subjects with chronic HBV infection

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

In March 2021, received regulatory approval to initiate Phase 1a/1b clinical trial

Potential for increased efficacy and enhanced resistance profile relative to earlier generation capsid inhibitors



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 $EC_{50} \leq 10$ 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

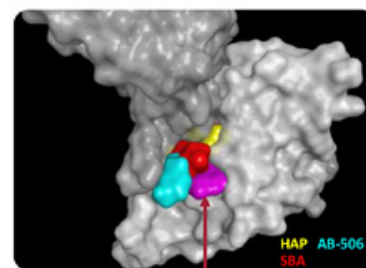
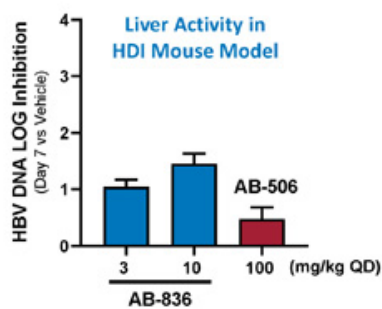
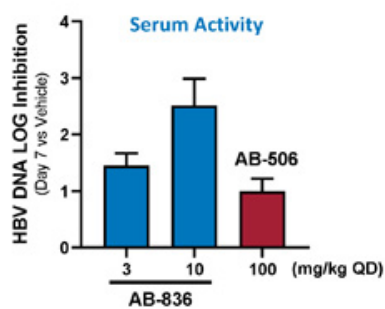
Projected to be once daily dosing

Pangenotypic

Combinable with other MOA agents

AB-836: A Next Generation Capsid Inhibitor

Compound	HBV DNA / 1 ^o Mechanism			Core I105T Mutation (EC ₅₀ mM)	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)		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

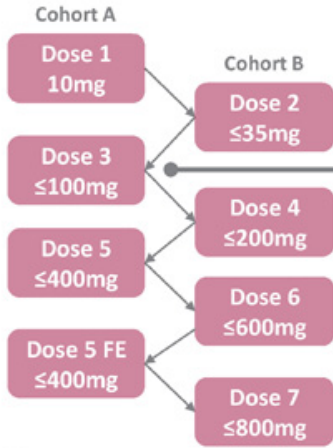


Unique Binding Site

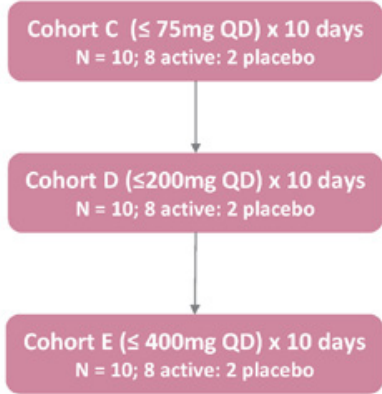
AB-836-001 Study

Part 1: Single Ascending Dose In Healthy Subjects

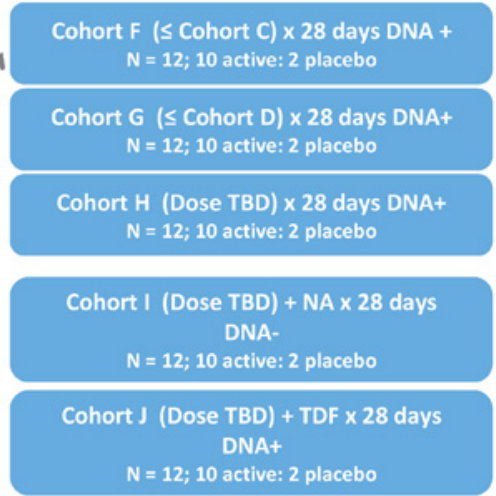
Alternating Cohorts A and B
n=8/cohort; 6 active: 2 placebo



Part 2: Multiple Ascending Dose in Healthy Subjects



Part 3: Multiple Doses In Chronic Hepatitis B Subjects



Next Gen RNA Destabilizer Program

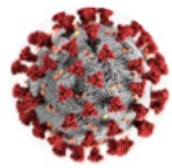
Offers a novel mechanism of action to reduce HBsAg and other viral proteins and viral RNA

Continuing active research and development of a next generation small molecule

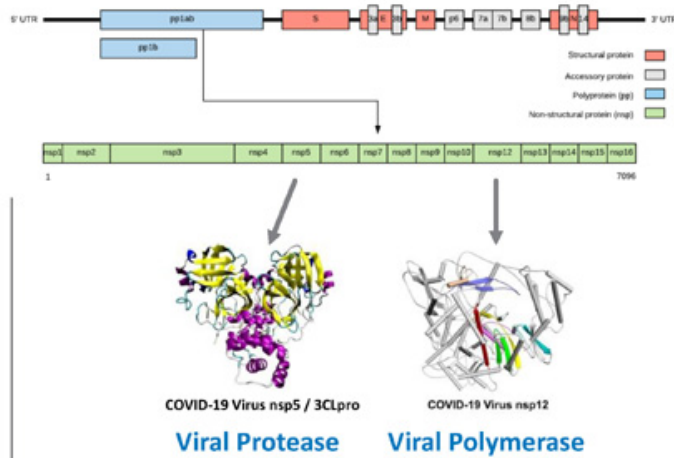
We believe this approach offers potential for an oral HBsAg reducing agent and all oral combination therapy

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 as December 31, 2020, cash runway through 3Q 2022

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