### 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): May 5, 2022

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  $\Box$ 

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 2.02. Results of Operations and Financial Condition.

On May 5, 2022, Arbutus Biopharma Corporation (the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 2022 and certain other information. A copy of the press release is furnished as Exhibit 99.1 hereto and is incorporated by reference herein.

#### Item 8.01. Other Events.

On May 5, 2022, 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**

<u>99.1</u>	Press release dated May 5, 2022
<u>99.2</u>	Corporate Presentation dated May 5, 2022
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: May 5, 2022

By: <u>/s/ David C. Hastings</u> David C. Hastings Chief Financial Officer

### Arbutus Reports First Quarter 2022 Financial Results and Provides Corporate Update

#### Key milestones across our chronic hepatitis B virus (cHBV) and pan-coronavirus programs remain on track

#### Well positioned financially with a projected cash runway into the second quarter of 2024

#### Conference Call and Webcast Today at 8:45 AM ET

WARMINSTER, Pa., May 05, 2022 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS), a clinical-stage biopharmaceutical company leveraging its extensive virology expertise to develop novel therapeutics that target specific viral diseases, today reports its first quarter 2022 financial results and provides pipeline updates.

"In the first quarter of 2022, we continued to advance our efforts to develop a functional cure for hepatitis B and to develop novel treatment options for coronavirus infections, including SARS-CoV-2," said William Collier, Arbutus' President and Chief Executive Officer. "We are on-track to achieve our goal of reporting data later this year from four clinical trials with chronically infected HBV patients being treated with either AB-729, our RNAi therapeutic, or AB-836, our next generation oral capsid inhibitor. Furthermore, our IND-enabling studies with our oral PD-L1 inhibitor, AB-101, and our oral RNA destabilizer, AB-161, are moving forward and we expect these to be completed in the second half of 2022. Additionally, we have had seven abstracts accepted at the EASL International Liver Congress™, which include some of these data."

Mr. Collier continued, "With respect to our research efforts to develop a nsp5 main protease (M<sup>pro</sup>) and nsp12 viral polymerase for SARS-CoV-2 and future coronavirus outbreaks, we are on-track to initiate IND-enabling studies for a nsp5 M<sup>pro</sup> candidate later this year. Lead optimization activities are continuing for a nsp12 viral polymerase candidate. Financially, we are well-positioned to continue advancing all our current clinical programs through important data milestones with a projected cash runway into the second quarter of 2024."

#### **Anticipated Milestones in 2022:**

- Dose first patient in the AB-729-202 Phase 2a clinical trial evaluating AB-729, in combination with VTP-300, Vaccitech plc's (Vaccitech) therapeutic vaccine and nucleos(t)ide analogue therapy (NA), in cHBV patients in the first half of 2022.
- Present new on-treatment data as well as long-term off-treatment data for cHBV patients in the AB-729-001 clinical trial at a medical conference later this year.
- Report initial data from the AB-729-201 Phase 2a clinical trial evaluating AB-729 in combination with ongoing NA therapy and short courses of PEG-IFNα-2a in cHBV patients in the second half of 2022.
- Report initial data from the Phase 2a clinical trial evaluating AB-729 in combination with vebicorvir (VBR), Assembly Biosciences, Inc.'s (Assembly) lead HBV core inhibitor (capsid inhibitor), and an NA in cHBV patients in the second half of 2022.
- Report data set from the AB-836-001 clinical trial evaluating multiple doses of AB-836 in cHBV patients in the first half of 2022.
- Complete IND-enabling studies for two oral compounds (PD-L1 inhibitor, AB-101 and RNA destabilizer, AB-161) to treat HBV in the second half of 2022.
- Advance an oral compound that inhibits the SARS-CoV-2 nsp5 main protease into IND enabling studies in the second half of 2022.
- Continue to explore a potential oncology indication with our oral PD-L1 program.

#### Financial Results

#### Cash, Cash Equivalents and Investments

As of March 31, 2022, the Company had cash, cash equivalents and investments in marketable securities of \$221.8 million, as compared to \$191.0 million as of December 31, 2021.

During the three months ended March 31, 2022, the Company received a \$40.0 million (net of withholding taxes) upfront payment from Qilu Pharmaceutical Co., Ltd. ("Qilu") related to a technology transfer and license agreement for AB-729 in greater China, \$15.0 million of gross proceeds from Qilu's equity investment and \$0.3 million of net proceeds from the issuance of common shares under Arbutus's "at-the-market" offering program. These cash inflows were partially offset by \$23.4 million of cash used in operations. The Company expects a net cash burn between \$90 to \$95 million in 2022, not including the \$55 million of proceeds received from Qilu, and believes its cash runway will be sufficient to fund operations into the second quarter of 2024.

#### Revenue

Revenues were \$12.6 million for the three months ended March 31, 2022 compared to \$2.1 million for the same period in 2021. The increase of \$10.5 million was due primarily to \$9.6 million of revenue recognition from the Company's license agreement with Qilu based on employee labor hours expended by the Company during the first quarter of 2022 to perform its manufacturing obligations under the license agreement.

#### Net Loss

For the three months ended March 31, 2022, the Company's net loss attributable to common shares was \$15.8 million, or a loss of \$0.11 per basic and diluted common share, as compared to a net loss attributable to common shares of \$19.6 million, or a loss of \$0.21 per basic and diluted common share, for the three months ended March 31, 2021. Net loss attributable to common shares for the three months ended March 31, 2021 included \$3.2 million of non-cash expense for the accrual coupon on the Company's convertible preferred shares, which converted into 22.8 million common shares in October 2021.

#### **Operating Expenses**

Research and development expenses were \$18.5 million for the three months ended March 31, 2022 compared to \$13.8 million for the same period in 2021. The increase of \$4.7 million was due primarily to an increase in expenses related to the Company's multiple, ongoing AB-729 Phase 2a clinical trials, including its collaborations with Assembly and Vaccitech, an increase in expenses for its ongoing AB-836-001 clinical trial, and an increase in expenses for its early stage development programs, including AB-101 and AB-161. General and administrative expenses were \$4.9 million for the three months ended March 31, 2022 compared to \$3.9 million for the same period in 2021. This increase was due primarily to increases in professional fees, employee compensation and non-cash stock-based compensation expense.

#### **Outstanding Shares**

As of March 31, 2022, the Company had approximately 148.7 million common shares issued and outstanding, as well as approximately 15.7 million stock options outstanding. Roivant Sciences Ltd. owned approximately 26% of the Company's outstanding common shares as of March 31, 2022.

### **COVID-19 Impact**

The COVID-19 pandemic has resulted in and will likely continue to result in significant disruptions to businesses. Measures implemented around the world in attempts to slow the spread of COVID-19 have had, and will likely continue to have, a major impact on clinical development, at least in the near-term, including shortages and delays in the supply chain and prohibitions in certain countries on enrolling subjects and patients 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 materially impact our plans and timelines in the future.

#### UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF LOSS (in thousands, except share and per share data)

	 Three Months Ended March 31,		
	2022		2021
Revenue			
Revenue from collaborations and licenses	\$ 11,218	\$	1,154
Non-cash royalty revenue	 1,363		959
Total revenue	12,581		2,113
Operating expenses			
Research and development	18,462		13,782
General and administrative	4,892		3,878
Change in fair value of contingent consideration	 201		129
Total operating expenses	23,555		17,789
Loss from operations	(10,974)		(15,676)
Other income (loss)			
Interest income	159		39
Interest expense	(506)		
Foreign exchange (losses) gains	-		28
Total other loss	(347)		(705)
Net loss before income tax expense	(11,321)		(16,381)
Income tax expense	 (4,444)		-
Net loss	\$ (15,765)	\$	(16,381)
Dividend accretion of convertible preferred shares	-		(3,212)
Net loss attributable to common shares	\$ (15,765)	\$	(19,593)
Net loss per common share			
Basic and diluted	\$ (0.11)	\$	(0.21)
Weighted average number of common shares			. ,
Basic and diluted	148,428,326		93,434,378

### UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS (in thousands)

	March 31, 2022			December 31, 2021	
Cash, cash equivalents and marketable securities, current	\$	165,477	\$	155,317	
Accounts receivable and other current assets		7,221		5,344	
Total current assets		172,698		160,661	
Property and equipment, net of accumulated depreciation		5,664		5,983	
Investments in marketable securities, non-current		56,318		35,688	
Right of use asset		2,007		2,092	
Other non-current assets		190		61	
Total assets	\$	236,877	\$	204,485	

Accounts payable and accrued liabilities	\$ 8,715	\$ 10,838
Deferred revenue	23,255	-
Lease liability, current	439	383
Total current liabilities	 32,409	 11,221
Liability related to sale of future royalties	15,439	16,296
Deferred revenue, non-current	15,585	-
Contingent consideration	5,499	5,298
Lease liability, non-current	2,100	2,231
Total stockholders' equity	165,845	169,439
Total liabilities and stockholders' equity	\$ 236,877	\$ 204,485

### UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW

(in thousands)

	Three Months Ended March 31,			March 31,
		2022		2021
Net loss	\$	(15,765)	\$	(16,381)
Non-cash items		1,642		2,222
Change in deferred license revenue		38,840		-
Other changes in working capital		(4,098)		(3,722)
Net cash provided by (used in) operating activities		20,619		(17,881)
Net cash (used in) provided by investing activities		(60,056)		18,221
Issuance of common shares pursuant to Share Purchase Agreement		10,973		-
Cash provided by other financing activities		512		26,874
Net cash provided by financing activities		11,485		26,874
Effect of foreign exchange rate changes on cash and cash equivalents		-		(44)
(Decrease) Increase in cash and cash equivalents		(27,952)		27,170
Cash and cash equivalents, beginning of period		109,282		52,251
Cash and cash equivalents, end of period		81,330		79,421
Investments in marketable securities		140,465		52,540
Cash, cash equivalents and marketable securities, end of period	\$	221,795	\$	131,961

### **Conference Call and Webcast Today**

Arbutus will hold a conference call and webcast today, Thursday, May 5, 2022, at 8:45 AM Eastern Time to provide a corporate update. You can access a live webcast of the call through the Investors section of Arbutus' website at www.arbutusbio.com. Alternatively, you can dial (866) 393-1607 or (914) 495-8556 and reference conference ID: 6287124.

An archived webcast will be available on the Arbutus website after the event. Alternatively, you may access a replay of the conference call by calling (855) 859-2056 or (404) 537-3406, and reference conference ID: 6287124.

#### About AB-729

AB-729 is an RNA interference (RNAi) therapeutic specifically designed to reduce all HBV viral proteins and antigens, including hepatitis B surface antigen, which is thought to be a key prerequisite to enable reawakening of a patient's immune system to respond to the virus. AB-729 targets hepatocytes using Arbutus' novel covalently conjugated N-acetylgalactosamine (GalNAc) delivery technology that enables subcutaneous delivery. Clinical data generated thus far has shown single- and multi-doses of AB-729 to be generally safe and well-tolerated while providing meaningful reductions in hepatitis B surface antigen and hepatitis B DNA. AB-729 is currently in multiple Phase 2a clinical trials.

#### About AB-836

AB-836 is a next generation oral hepatitis B virus (HBV) capsid inhibitor that interacts with HBV core protein, which in turn is required for viral replication. The current standard-of-care therapy for HBV is primarily nucleos(t)ide analogues that inhibit the viral polymerase and significantly reduce, but do not eliminate viral replication. AB-836 in combination with nucleos(t)ide analogues is designed to completely eliminate viral replication in infected cells by preventing the assembly of functional viral capsids. In addition, AB-836 has been shown to inhibit the replenishment of covalently closed circular DNA (cccDNA), the viral genetic reservoir which the virus needs to replicate itself. Preliminary data from an on-going Phase 1a/1b clinical trial has shown that AB-836 is generally safe and well-tolerated and provides robust antiviral activity.

#### About HBV

Hepatitis B is a potentially life-threatening liver infection caused by the hepatitis B virus (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 290 million people worldwide suffer from chronic HBV infection, while other estimates indicate that approximately 2.4 million people in the United States suffer from chronic HBV infection. Approximately 820,000 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 (Nasdaq: ABUS) is a clinical-stage biopharmaceutical company leveraging its extensive virology expertise to develop novel therapeutics that target specific viral diseases. Our current focus areas include Hepatitis B virus (HBV), SARS-CoV-2, and other coronaviruses. In HBV, we are developing an RNAi therapeutic, oral capsid inhibitor, oral PD-L1 inhibitor, and oral RNA destabilizer that we intend to combine to provide a functional cure for patients with chronic HBV by suppressing viral replication, reducing surface antigen and reawakening the immune system. We believe our lead compound, AB-729, is the only RNAi therapeutic with evidence of immune re-awakening, and is currently being evaluated in multiple phase 2 clinical trials. We have an ongoing drug discovery and development program directed to identifying novel, orally active agents for treating coronavirus (including SARS-CoV-2). We are also exploring oncology applications for our internal PD-L1 portfolio. For more information, 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 our future development plans for our product candidates; the expected cost, timing and results of our clinical development plans and clinical trials with respect to our product candidates; our expectations with respect to the release of data from our clinical trials and the expected timing thereof; our expectations and goals for our collaborations with third parties and any potential benefits related thereto; the potential for our product candidates to achieve success in clinical trials; and our expected financial condition, including the anticipated duration of cash runways and timing regarding needs for additional capital.

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 and patent litigation matters.

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 product 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; uncertainties associated with litigation generally and patent litigation specifically; Arbutus and its collaborators may never realize the expected benefits of the collaborations; 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

May 5, 2022

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 for the anticipated durations; the expected cost, timing and results of Arbutus' clinical development plans and clinical trials, including its clinical collaborations with third parties; the potential for Arbutus' product candidates to achieve their desired or anticipated outcomes; Arbutus' expectations regarding the timing and clinical development of Arbutus' product candidates, including its articulated clinical objectives; the timeline to a combination cure for HBV; Arbutus' coronavirus strategy; Arbutus' expectations regarding its technology licensed to third parties; the expected timing and payments associated with strategic and/or licensing agreements; the patent infringement lawsuit against Moderna; and other statements relating to Arbutus' 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 and patent litigation matters. 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; uncertainties associated with litigation generally and patent litigation specifically; market shifts may require a change in strategic focus; the parties may never realize the expected benefits of the collaborations; 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, Quarterly Report on Form 10-Q and Arbutus' periodic disclosure filings which are available 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**

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 compounds include: RNAi Capsid Inhibitors PD-L1 Inhibitors HBV RNA Destabilizer	Focused on direct acting antivirals targeting the viral polymerase and protease	Extensive knowledge gained from HIV and HCV success being applied to HBV and Coronaviruses	Rights to potential future royalties and sublicense revenues for patented LNP Technology; Filed patent infringement lawsuit against Moderna
Arbutus NASDAQ: A	ABUS tusbio.com HCV: Hepatitis C \	/irus   HIV Human Immunodeficiend	y Virus		3

### Proven Leadership Team

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





## **Broad Pipeline**



### **HBV Presents a Significant Unmet Medical Need**



### Significant Opportunity

### to Improve HBV Cure Rates

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

\*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	Trate of Undetectable HBV DNA
HBV DNA Undetectable (<60-80 IU/ml)	7-19%	67-90%	76-93%	Trate of HBsAg Loss
HBsAg Loss	~3-7%	~1-2%	~1-3%	HIGHER CURES RATES

Achievable HBV Cure Rates with Current SOC

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

7

### **Compelling Growth Opportunity in the HBV Market**



SOC: Standard Of Care Sources: Hepatitis B Fact Sheet, WHO <u>https://www.who.int/news-room/fact-sheets/detail/hepatitis-b</u> Hep B Foundation link: <u>https://www.hepb.org/what-is-hepatitis-b/what-is-hepb/facts-and-figures/</u>

An HBV curative regimen

market growth opportunities.

would substantially increase diagnosis

and treatment rates to unlock significant

8

### A Combination of Agents with Complementary MOA is Needed for HBV Cure



### 3-Pronged Approach to Therapeutic Success

### Suppress HBV DNA

**Reduce** viral antigens

Boost host immune response

Therapeutic success will require a combination of agents with complementary MOAs





### **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 Phase 1a/1b Clinical Trial

### Part 1 & 2: Single-ascending dose

#### AB-729

monotherapy (90mg single-dose) resulted in robust HBsAg and HBV DNA declines in HBV DNA+ patients



E: 60mg Q4W HBV DNA-F: 60mg Q8W HBV DNA-G: 90mg Q8W + TDF HBV DNA+

HBV DNA+
I: 90mg Q8W HBV DNA-
J: 90mg Q12W HBV DNA-

K: 90mg Q8W HBV DNA-, HBeAg+ only

	HBV DNA-				HBV DNA+
Baseline Measure <sup>#</sup>	Cohort E <sup>‡</sup> (N=7)	Cohort F (N=7)	Cohort I (N=6)^	Cohort J (N=7)	Cohort G (N=7)
Age in years, mean (range)	45.1 (33 - 63)	44.0 (31 - 59)	45.7 (38 – 54)	44.3 (35 - 61)	43.9 (34 – 50)
Male gender, n (%)	4 (57%)	4 (57%)	4 (67%)	5 (71%)	3 (43%)
BMI, mean (SD)	27.7 (5.0)	23.7 (2.2)	25.5 (3.1)	28.7 (4.8)	23.8 (4.0)
Race, n (%)					
Asian	1 (14%)	5 (71%)	5 (83%)	4 (57%)	6 (86%)
Black	0	1 (14%)	0	0	0
White	6 (86%)	1 (14%)	1 (17%)	3 (43%)	1 (14%)
ALT (U/L), mean (SD)	22.4 (10.5)	23.4 (15.2)	26.0 (10.2)	20.1 (7.2)	32.7 (15.8)
HBV eAg negative, n (%)	7 (100%)	6 (71%)°	5 (83%)	4 (57%)	7 (100%)
HBsAg (IU/mL), mean (range)	5,372 (584 - 11,761)	5,354 (667 – 18,605)	4,691 (338 – 19,017)	6,911 (309 – 25,345)	1,818 (277 – 4,723)

\*Genotype not determined: <sup>1</sup>Subjects switched to AB-729 60 mg 012W for the estension phase; ^ N = 6 due to one subject meeting exclusion criteria on Day 1 and a replacement subject receiving an incorrect dose on Day 1; both entered follow up and were excluded from the analysis; <sup>6</sup>One subject counted as HBeAg negative was identified as "HBeAg borderine" (baseline HBeAg = 0.18 BJ/mL, LEOQ = 0.11 IU/mL)



HBV: Hepatitis B Virus | TDF: tenofovir disoproxil fumarate | cHBV: chronic HBV

# HBsAg Suppression at levels <100 IU/mL Maintained up to 28 Weeks off AB-729 Treatment



### AB-729 dosed at 90mg Q8W or Q12W Reduces HBsAg in both **DNA- and DNA+ Patients**



### Mean (SE) Baseline HBsAg Response Similar Regardless of **AB-729** Dose and Dosing Intervals to Date

HBV DNA-					HBV DNA+
Visit	Cohort E 60mg Q4W <sup>I</sup> (n=7)	Cohort F 60mg Q8W (n=7)	Cohort I 90mg Q8W (n=6)	Cohort J 90mg Q12W (n=7)	Cohort G 90mg Q8W (n=7)
Baseline	3.51 (0.20)	3.53 (0.17)	3.36 (0.23)	3.37 (0.28)	3.14 (0.14)
Week 12	-1.10 (0.15)	-1.02 (0.11)	-1.30 (0.19)	-1.06 (0.31)	-1.56 (0.32)
Week 24	-1.84 (0.16)	-1.57 (0.09)	-1.79 (0.22)	-1.56 (0.25)	-1.82 <sup>#</sup> (0.29)
Week 40	-1.84 (0.19)	-1.78 (0.10)	-1.93 (0.25)	-1.89 <sup>^</sup> (0.35)	-2.03+ (0.33)
Week 44	-1.81 (0.17)	-1.88 (0.13)	-2.16 (0.31)	-1.86 <sup>^</sup> (0.38)	
Week 48	-1.89 (0.18)	-1.90 (0.14)			
Off Treatm	ent (# weeks post l	ast dose)			
Week 16	-1.74 (0.20)	-1.76 (0.19)			
Week 20	-1.61 (0.20)	-1.55* (0.28)			
Week 24	-1.54 (0.19)				



NOTE: Mean (SE) values presented only if n>3; there are no statistically significant differences between cohorts (data not shown); \*n=5; \*n=6, one patient in Cohort J chose not to extend treatment; \*6 of 7 patients had HBV DNA <LLOQ by Week 8, the 7th patient became <LLOQ at Week 16; \*n=6 Data Presented at AASLD 2021

15

### AB-729-001 Safety Summary

- AB-729 generally safe and well-tolerated after single and repeat doses
- No treatment-related SAEs or discontinuations due to AEs
- No treatment-related Grade 3 or 4 AEs<sup>\*</sup>
- No treatment-related Grade 3 or 4 laboratory abnormalities<sup>\*</sup>
  - Grade 1 and Grade 2 ALT elevations have improved or stabilized with continued treatment
- Injection site TEAEs were mostly mild (erythema, pain, bruising, pruritis)
- No clinically meaningful changes in ECGs or vital signs



\* 1 patient (Cohort A) with rapid decline in HBsAg of ~2.0 log10 IU/mL had an unrelated Gr 2 AE of food poisoning resulting in unrelated transient Grade 3 AEs of ALT/AST elevation (without bilirubin changes)

### AB-729-001 Clinical Trial Key Takeaways

- AB-729 dosed 60mg every 4 wks and every 8 wks and 90mgs every 8 wks and 12 wks resulted in robust and comparable HBsAg declines
  - AB-729 monotherapy (90mg single-dose) resulted in robust HBsAg and HBV DNA declines in HBV DNA + patients
- Long-term dosing with AB-729 resulted in 74% of patients reaching <100 IU/mL of HBsAg, a clinically relevant threshold which could inform when to stop all therapies
  - HBsAg suppression at levels of <100 IU/mL maintained up to 28 weeks off AB-729 treatment</p>
- Preliminary data suggest that long-term suppression of HBsAg with AB-729 results in increased HBV-specific immune response\*
- AB-729 was safe and well-tolerated through 40-48 weeks of dosing



### Next Steps – Combine AB-729 with Different Compounds in Phase 2a to Inform Future Clinical Trials

- Enrollment on-going in a Phase 2a combination trial with ongoing NA therapy and short courses of Peg-IFNα-2a in cHBV patients
- Two Phase 2a proof-of-concept clinical collaborations are on-going or expected to initiate shortly to accelerate key combination data
  - Assembly Biosciences, Inc. enrollment complete
  - Vaccitech plc clinical trial expected to initiate in 1H 2022



### AB-729-201: Phase 2a POC Clinical Trial

AB-729 in combination with ongoing NA therapy and short courses of Peg-IFNα-2a in cHBV patients





Multi-center, open-label Phase 2a

Primary objective: evaluate safety and tolerability of AB-729 in combination with Peg-IFNa-2a in patients with NA-suppressed cHBV

After 24-weeks follow-up, patients may elect to stop NA therapy. Those patients that stop NA therapy will be followed for an additional 48 weeks.

POC: Proof of Concept



### Provides accelerated AB-729 combination POC

with Assembly's capsid inhibitor and a NA



,	AB-729 + vebicorvir + NA		
	AB-729 + NA		Follow Up (24-weeks)
	vebicorvir + NA		
Baseline	Wk 24	Wk 48	

### Phase 2 clinical trial fully enrolled

n=  $\sim$ 60 virologically-suppressed patients with chronic HBV infection

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

NA: Nucleoside Analogue



### **POC Phase 2a clinical trial**

Evaluating AB-729 in combination with Vaccitech's immunotherapeutic, VTP-300, and a NA



Evaluate safety, pharmacokinetics, immunogenicity and anti-viral activity of triple combination - AB-729, VTP-300 and an NA compared to double combinations of AB-729 with an NA and VTP-300 with an NA

Expected to initiate clinical trial in first half of 2022

Full rights retained by the Companies of their respective product candidates and all costs split equally

Assuming positive results parties intend to undertake a larger Phase 2b clinical trial

### AB-729 Strategic Collaboration

### 🕓 QILU PHARMACEUTICAL

### Exclusive Licensing\* and Strategic Partnership

Develop, manufacture and commercialize AB-729 in mainland China, Hong Kong, Macau and Taiwan

> \*ABUS retains the non-exclusive right to develop and manufacture in the Qilu territory for exploiting AB-729 in the rest of the world



Goal - to bring AB-729 to the largest HBV patient population and to tap into one of the largest and most promising healthcare markets worldwide

Arbutus has received \$40M upfront payment and \$15M equity investment, and is eligible for up to \$245M in commercialization and milestone payments and double-digit tiered royalties up to low twenties percent on annual sales

Qilu Pharmaceutical – one of the leading pharmaceutical companies in China, provides development, manufacturing and commercialization expertise to this partnership

## **AB-836** Next Generation Capsid Inhibitor

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 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

Demonstrates high liver concentrations in multiple species

Once daily dosing

Pan-genotypic

Combinable with other MOA agents

### **AB-836: Next Generation Capsid Inhibitor**



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

24

### AB-836-001 Phase 1a/1b Clinical Trial



### AB-836 Phase 1a/1b Clinical Trial Preliminary Data

# Parts 1 & 2: Single and multi-doses of AB-836 in healthy subjects

- Safety:
  - No deaths or SAEs
  - 1 subject (50mg once daily) discontinued on day 13 due to AE of agitation
  - All but 3 AEs were mild (Grade 2 headache, agitation and bronchitis), one assessed as drug related (Grade 1 rash)
  - No clinically significant abnormalities in clinical laboratory tests, ECGs, vital signs or physical exams noted.



# Part 3: 50mg and 100mg of AB-836 once daily for 28 days in patients with cHBV

### Safety:

- No deaths or AEs
- 1 patient had transient increase in ALT from baseline Grade 1 to Grade 3 that resolved with continued dosing
- No clinical abnormalities in ECGs, vital signs or physical exams
- Efficacy (Cohort G 100 mg QD):
  - Provides robust antiviral activity mean (SE) log<sub>10</sub> change from baseline of -3.1 (0.5) at Day 28 (n=4)

Part 3 of the trial continues to enroll patients

### **AB-161: Next Generation Oral RNA Destabilizer**

Next generation small molecule that circumvents non-clinical safety findings with first generation molecule Offers a novel mechanism of action to reduce HBsAg and other viral proteins and viral RNA We believe this approach offers potential for an **oral HBsAg reducing agent** and all oral combination therapy

AB-161 is currently in IND-enabling studies



### **AB-101: Oral PD-L1 Inhibitor for HBV Immune Reactivation**

### Rationale

- HBV immune tolerance is a critical driver of cHBV infection
- PD-1:PD-L1 checkpoint axis plays a key role in immune tolerization in cHBV
- PD-L1 expression upregulated during HBV infection
- PD-1 upregulated on HBVspecific T- and B-cells
- Inhibition associated with HBsAg loss in some cHBV patients

### Small-Molecule Inhibitor Approach

- Allows controlled checkpoint blockade
- Enables oral dosing
- Designed to reduce systemic safety issues seen with Abs

### AB-101

- Blocks PD-L1/PD1 interaction at sub-nM concentrations
- Activates HBV-specific immune responses in T-cells from CHB patients in vitro
- Novel MOA identified
- Demonstrates a robust checkpoint mediated in vivo effect
- Improves HBV-specific T- and B-cell responses ex vivo

#### AB-101 is currently in IND-enabling studies



PD-L1: Programmed death-ligand 1 | PD-1: Programmed death ligand protein DAAs: Direct acting antivirals | Abs: Antibodies | MOA: Mechanism of action

### AB-101: Small-Molecule Oral PD-L1 Inhibitor for HBV

### AB-101 is highly potent with demonstrated activity against cells from chronic HBV patients



cHBV patient T-cells

AB-101 reinvigorates HBV-specific



N= cells from 9 cHBV patients \*p<-0.05

PBMC: Peripheral Blood Mononuclear Cells

### **Coronavirus Strategy**

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



### **Pan-Coronavirus Focused**

Long Term Commitment

### Small Molecule Direct-Acting Antivirals

### X-Chem/Proteros Collaboration

- Proprietary DEL library screening and structural biology for M<sup>PRO</sup> inhibitor discovery
- First milestone reached; several unique compound series that inhibit nsp5 protease identified
- Advancing to lead optimization stage

### 2022 Key Milestones

### Cash balance of \$221.8M as of March 31, 2022, cash runway into Q2 2024

Milestone	Anticipated Timing 2022
AB-836, next generation oral capsid inhibitor: Data from Phase 1a/1b clinical trial in patients with chronic HBV	1H
AB-729, RNAi therapeutic: Initiate a triple combination Phase 2a POC clinical trial with VTP-300 (Vaccitech) and a NA	1H
AB-729: Follow-up data (long-term on- and off-treatment) from Phase 1a/1b, evaluating multiple doses and dosing schedules	1H/2H
AB-729: Initial data from Phase 2a combination trial with NA therapy and Peg-IFN $\alpha$ -2a	2H
AB-729: Initial data from Phase 2a combination trial with VBR (Assembly) and a NA	2H
AB-101, oral PD-L1 inhibitor compound: Complete IND-enabling studies	2H
AB-161, next generation oral RNA destabilizer: Complete IND-enabling studies	2H
COVID M <sup>pro</sup> : Advance clinical candidate that inhibits the SARS-CoV-2 nsp5 main protease into IND-enabling studies	2Н



31

# Thank You

NASDAQ: ABUS

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