



## Arbutus Reports Second Quarter 2021 Financial Results and Provides Corporate Update

August 5, 2021

**New data on AB-729, Arbutus' proprietary subcutaneously delivered RNAi agent, highlighted in four abstracts at the EASL International Liver Congress™; all AB-729 abstracts selected for best of ILC™**

**Announced two additional proof-of-concept clinical collaborations to evaluate AB-729 in combination with agents from Vaccitech plc and Antios Therapeutics, Inc.**

**Announced U.S. Food and Drug Administration (FDA) authorization to proceed with an Investigational New Drug (IND) application in a Phase 2a clinical trial to investigate the safety and anti-viral activity of AB-729 in combination with ongoing nucleos(t)ide analog (NA) therapy and short courses of Peg-IFN $\alpha$ -2a in subjects with chronic HBV**

**Presentation at EASL of pre-clinical data for AB-836, Arbutus' proprietary oral capsid inhibitor, suggests the potential for increased efficacy and an enhanced resistance profile relative to previous generation capsid inhibitors**

**Conference Call and Webcast Scheduled Today at 8:45 AM ET**

WARMINSTER, Pa., Aug. 05, 2021 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS), a clinical-stage biopharmaceutical company primarily focused on discovering, developing and commercializing a cure for people with chronic hepatitis B virus (HBV) infection, as well as therapies to treat coronaviruses (including COVID-19), today reports its second quarter 2021 financial results and provides a corporate update.

William Collier, President and Chief Executive Officer of Arbutus, stated, "We had a productive second quarter, particularly in advancing our efforts to position AB-729 as a potential cornerstone therapy in future HBV combination regimens. Our recently announced proof-of-concept clinical collaborations with Vaccitech plc and Antios Therapeutics, Inc. to evaluate AB-729 with other agents reflects this objective as does our planned Phase 2a clinical trial to evaluate AB-729 in combination with Peg-IFN $\alpha$ -2a."

Mr. Collier added, "Looking ahead, we expect a productive second half of 2021 including: additional data from the ongoing Phase 1a/1b clinical trial with AB-729, specifically 90 mg multi-dose data (dosing interval every 12 weeks) in HBV DNA negative subjects and 90 mg multi-dose data (dosing interval every 8 weeks) in HBV DNA positive subjects, initiation of two Phase 2a proof-of-concept clinical trials for AB-729, and initial Phase 1a/1b data from our proprietary oral capsid inhibitor, AB-836."

### Pipeline Update

#### AB-729

- Arbutus is currently conducting a single- and multi-dose Phase 1a/1b clinical trial to determine the safety, tolerability, pharmacokinetics, and pharmacodynamics of AB-729 in healthy subjects and in subjects with chronic HBV infection. The Company presented three posters and a late breaker oral presentation at the 2021 EASL conference highlighting the most recent data from this clinical trial. AB-729 continues to demonstrate robust mean HBsAg reduction across all doses and dosing intervals with a favorable safety and tolerability profile, followed by a sustained plateau phase:

#### Mean (range) change in HBsAg with repeat dosing of AB-729:

Visit	Cohort E AB-729 60 mg Q4W	Cohort F AB-729 60 mg Q8W	Cohort I AB-729 90 mg Q8W	p value between Cohorts
Week 16	-1.44 (-0.71 to -1.95)	-1.39 (-1.61 to -1.08)	-1.63 (-0.89 to -2.44)	$p \geq 0.4$
Week 24	-1.84 (-0.99 to -2.31)	-1.57 (-1.24 to -2.01)	-1.79 (-1.22 to -2.46)	$p \geq 0.2$
Week 32	-1.84 (-0.94 to -2.36)	-1.68 (-1.37 to -2.15)	---	$p = 0.5$
Week 40	-1.84 (-0.88 to -2.47)	-1.78* (-1.40 to -2.14)	---	$p = 0.7$
Week 44	-1.81* (-0.93 to -2.43)	-1.87* (-1.32 to -2.34) [N=6]	---	$p = 0.8$
Week 48	-1.89* (-0.91 to -2.44)	---	---	---

† subjects switched to AB-729 60 mg Q12W after Week 20 dose

\* Data updated since EASL ILC™ presentation

- The efficacy and safety data for AB-729 derived from up to one year of dosing support our view that 60 mg every 8 weeks

is an appropriate dose to move forward in the upcoming Phase 2a clinical trials.

- Additionally, based on 3/5 evaluable subjects, long term dosing with AB-729 demonstrated increased HBV-specific immune responses, providing support for combination therapy including immunomodulatory agents.
- Arbutus expects to provide additional data from ongoing cohorts of the Phase 1a/1b clinical trial in the second half of 2021, including initial data for a 90 mg every 12 weeks cohort in HBV DNA negative subjects and initial data in a 90 mg every 8 weeks cohort in HBV DNA positive subjects.
- In July 2021, Arbutus received authorization from the U.S. Food and Drug Administration to proceed with its Investigational New Drug (IND) application for AB-729 in a Phase 2 proof-of-concept clinical trial to evaluate AB-729 in combination with ongoing NA therapy and short courses of Peg-IFN $\alpha$ -2a in subjects with chronic HBV infection. This clinical trial is expected to initiate in the second half of 2021.
- To further support AB-729 as a potential cornerstone therapeutic in future HBV combination regimens, Arbutus has entered into several clinical collaborations to evaluate AB-729 in combination with other agents:
  - Through a collaboration with Assembly Biosciences, Inc. (“Assembly”), subjects are being enrolled in a Phase 2 proof-of-concept clinical trial with a triple combination of AB-729, Assembly’s lead HBV core inhibitor (capsid inhibitor) product candidate, vebicorvir (“VBR”), and nucleos(t)ide analog (“NA”) therapy for the treatment of people with chronic HBV.
  - In July 2021, we entered into a clinical collaboration with Vaccitech plc (“Vaccitech”) to evaluate a triple combination of AB-729 with Vaccitech’s proprietary immunotherapeutic, VTP-300, and standard-of-care NA therapy for the treatment of subjects with chronic HBV infection. We expect to file a Clinical Trial Application (CTA) in the second half of 2021 and initiate the clinical trial in early 2022.
  - In June 2021, we entered into a clinical collaboration with Antios Therapeutics, Inc. (“Antios”) to evaluate a triple combination of AB-729, Antios’ proprietary active site polymerase inhibitor nucleotide (ASPIN), ATI-2173, and Viread (tenofovir disoproxil fumarate), for the treatment of subjects with chronic HBV infection. This clinical trial is expected to initiate in the second half 2021.

#### **AB-836: Oral Capsid Inhibitor**

- In January 2020, Arbutus selected AB-836, from a novel chemical series, as its next-generation oral capsid inhibitor. At EASL, Arbutus presented pre-clinical data suggesting the potential for increased efficacy and an enhanced resistance profile relative to previous generation capsid inhibitors. Arbutus completed CTA/IND-enabling studies in the fourth quarter of 2020 and initiated a Phase 1a/1b clinical trial for AB-836 in the first quarter of 2021. Initial data from healthy volunteers and HBV subjects from this clinical trial is expected in second half of 2021.

#### **HBV Discovery Programs**

- Arbutus’ drug discovery efforts are focused on follow-on compounds for its current HBV pipeline. Arbutus expects to continue to advance its research in its oral PD-L1 inhibitor and RNA-destabilizer programs.

#### **Research Efforts to Combat COVID-19 and Future Coronavirus Outbreaks**

- Based on its extensive antiviral drug discovery experience, Arbutus has established an internal research program to identify new small molecule antiviral medicines to treat COVID-19 and future coronavirus outbreaks. This effort, led by Dr. Michael Sofia, Arbutus’ Chief Scientific Officer, is focused on the discovery and development of new molecular entities that address specific viral targets including the nsp12 viral polymerase and the nsp5 viral protease. These targets are essential viral proteins which Arbutus has experience in targeting. Arbutus recently entered into a discovery research and license agreement with X-Chem, Inc. and Proteros biostructures GmbH focused on the discovery of novel inhibitors targeting the SARS-CoV-2 nsp5 main protease (Mpro). The agreement is designed to accelerate the development of pan-coronavirus agents to treat COVID-19 and potential future coronavirus outbreaks.

#### **Financial Results**

##### **Cash, Cash Equivalents and Investments**

Arbutus had cash, cash equivalents and investments totaling \$121.3 million as of June 30, 2021, as compared to \$123.3 million as of December 31, 2020. During the six months ended June 30, 2021, Arbutus used \$31.9 million in operating activities, which was offset by \$30.7 million of net proceeds from the issuance of common shares under Arbutus’s “at-the-market” offering program. The Company believes its cash, cash equivalents and

investments of \$121.3 million as of June 30, 2021 are sufficient to fund the Company's operations through the third quarter of 2022.

### Net Loss

Net loss attributable to common shares for the three months ended June 30, 2021 was \$22.7 million (\$0.23 basic and diluted loss per common share) as compared to \$17.1 million (\$0.25 basic and diluted loss per common share) for the three months ended June 30, 2020. Net loss attributable to common shares for the three months ended June 30, 2021 and 2020 included non-cash expense for the accrual of coupon on the Company's convertible preferred shares of \$3.3 million and \$3.0 million, respectively.

### Operating Expenses

Research and development expenses were \$15.4 million for the three months ended June 30, 2021 compared to \$10.5 million in the same period in 2020. The increase in research and development expenses for the three months ended June 30, 2021 versus the same period in 2020 was due primarily to higher expenses for the Company's clinical development and discovery programs, including activities under our collaboration with Assembly and internal research efforts to treat COVID-19 and future coronavirus outbreaks, both of which initiated in mid-2020. General and administrative expenses were \$4.4 million for the three months ended June 30, 2021 compared to \$3.6 million for the same period in 2020. This increase was due primarily to increases in non-cash stock-based compensation expense and professional fees.

### Outstanding Shares

The Company had approximately 97.7 million common shares issued and outstanding as of June 30, 2021. In addition, the Company had approximately 13.3 million stock options outstanding and 1.164 million convertible preferred shares outstanding, which (including the annual 8.75% coupon) will be mandatorily convertible into approximately 23 million common shares on October 18, 2021.

### COVID-19 Impact

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 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
<b>Revenue</b>				
Collaborations and licenses	\$ 1,185	\$ 825	\$ 2,339	\$ 1,660
Non-cash royalty revenue	1,144	689	2,103	1,345
<b>Total Revenue</b>	<b>2,329</b>	<b>1,514</b>	<b>4,442</b>	<b>3,005</b>
<b>Operating expenses</b>				
Research and development	15,396	10,465	28,766	20,881
General and administrative	4,445	3,566	8,292	7,119
Depreciation	436	501	879	1,001
Change in fair value of contingent consideration	694	116	823	228
Site consolidation	—	7	—	64
<b>Loss from operations</b>	<b>(18,642)</b>	<b>(13,141)</b>	<b>(34,318)</b>	<b>(26,288)</b>
<b>Other income (loss)</b>				
Interest income	31	200	70	545
Interest expense	(763)	(1,099)	(1,535)	(2,140)
Foreign exchange gain (loss)	(13)	(47)	15	(65)
<b>Total other loss</b>	<b>(745)</b>	<b>(946)</b>	<b>(1,450)</b>	<b>(1,660)</b>
<b>Net loss</b>	<b>(19,387)</b>	<b>(14,087)</b>	<b>(35,768)</b>	<b>(27,948)</b>
Dividend accretion of convertible preferred shares	(3,266)	(2,995)	\$ (6,478)	\$ (5,973)
<b>Net loss attributable to common shares</b>	<b>\$ (22,653)</b>	<b>\$ (17,082)</b>	<b>\$ (42,246)</b>	<b>\$ (33,921)</b>
<b>Loss per share</b>				
<b>Basic and diluted</b>	<b>\$ (0.23)</b>	<b>\$ (0.25)</b>	<b>\$ (0.44)</b>	<b>\$ (0.49)</b>
Weighted average number of common shares				
<b>Basic and diluted</b>	<b>96,869,805</b>	<b>69,604,726</b>	<b>95,153,545</b>	<b>68,656,566</b>

## UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	<u>June 30, 2021</u>	<u>December 31, 2020</u>
Cash, cash equivalents and marketable securities, current	\$ 78,379	\$ 123,268
Accounts receivable and other current assets	5,087	4,436
<b>Total current assets</b>	<b>83,466</b>	<b>127,704</b>
Property and equipment, net of accumulated depreciation	6,779	6,927
Investments in marketable securities, non-current	42,906	—
Right of use asset	2,225	2,405
Other non-current assets	—	44
<b>Total assets</b>	<b>\$ 135,376</b>	<b>\$ 137,080</b>
Accounts payable and accrued liabilities	\$ 8,352	\$ 8,901
Liability-classified options	132	250
Lease liability, current	357	390
<b>Total current liabilities</b>	<b>8,841</b>	<b>9,541</b>
Liability related to sale of future royalties	18,982	19,554
Contingent consideration	4,249	3,426
Lease liability, non-current	2,475	2,593
Total stockholders' equity	100,829	101,966
<b>Total liabilities and stockholders' equity</b>	<b>\$ 135,376</b>	<b>\$ 137,080</b>

**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW**  
(in thousands)

	<u>Six Months Ended June 30,</u>	
	<u>2021</u>	<u>2020</u>
Net loss	\$ (35,768)	\$ (27,948)
Other non-cash items	5,005	5,114
Changes in working capital	(1,127)	(1,420)
<b>Net cash used in operating activities</b>	<b>(31,890)</b>	<b>(24,254)</b>
<b>Net cash (used in) provided by investing activities</b>	<b>(20,526)</b>	<b>20,970</b>
<b>Net cash provided by financing activities</b>	<b>31,163</b>	<b>17,440</b>
Effect of foreign exchange rate changes on cash and cash equivalents	(44)	(56)
<b>(Decrease) increase in cash and cash equivalents</b>	<b>(21,297)</b>	<b>14,100</b>
Cash and cash equivalents, beginning of period	52,251	31,799
<b>Cash and cash equivalents, end of period</b>	<b>30,954</b>	<b>45,899</b>
Investments in marketable securities	90,331	38,089
<b>Cash, cash equivalents and marketable securities, end of period</b>	<b>\$ 121,285</b>	<b>\$ 83,988</b>

**Conference Call and Webcast Today**

Arbutus will hold a conference call and webcast today, Thursday, August 5, 2021 at 8:45 AM Eastern Time to provide a corporate update. You can access a live webcast of the call, which will include presentation slides, through the Investors section of Arbutus' website at [www.arbutusbio.com](http://www.arbutusbio.com) or directly at [Live Webcast](#). Alternatively, you can dial (866) 393-1607 or (914) 495-8556 and reference conference ID 2719108.

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 2719108.

**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. Based upon clinical data generated thus far in an ongoing single- and multi-dose Phase 1a/1b clinical trial, AB-729 has demonstrated positive safety and tolerability data and meaningful reductions in hepatitis B surface antigen.

**About AB-836**

AB-836 is an oral HBV capsid inhibitor. HBV core protein assembles into a capsid structure, which is required for viral replication. The current standard-of-care therapy for HBV, primarily nucleos(t)ide analogues that work by inhibiting the viral polymerase, significantly reduce virus replication, but not completely. Capsid inhibitors inhibit replication by preventing the assembly of functional viral capsids. They also have been shown to inhibit the uncoating step of the viral life cycle thus reducing the formation of new covalently closed circular DNA (cccDNA), the genetic reservoir which the virus uses to replicate itself.

**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 focused on discovering, developing and commercializing a cure for people with chronic hepatitis B virus (HBV) infection. The Company is advancing multiple product candidates with distinct mechanisms of action that it believes have the potential to provide a new 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, visit [www.arbutusbio.com](http://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 AB-729 and AB-836, including our expectations that in the second half of 2021 we will (a) have additional data from the ongoing Phase 1a/1b clinical trial with AB-729, (b) initiate two Phase 2a proof-of-concept clinical trials for AB-729, and (c) have initial Phase 1a/1b data for AB-836; our expectation to file a CTA in the second half of 2021 and initiate another proof-of-concept clinical trial in early 2022; our expectations and goals for our collaborations with third parties and any potential benefits related thereto; the potential for AB-836 to have increased efficacy and an enhanced resistance profile; our expected cash runway through the third quarter of 2022; and our expectations regarding the impact of the COVID-19 pandemic on our business and clinical trials.

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 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; 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](http://www.sedar.com) and at [www.sec.gov](http://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.

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