



Arbutus Reports Third Quarter 2020 Financial Results and Provides Corporate Update

November 5, 2020

Results from an ongoing Phase 1a/1b clinical trial for Arbutus' AB-729, a subcutaneously delivered RNAi agent, in subjects with chronic hepatitis B virus (HBV) infection, to be presented at the upcoming American Association for the Study of Liver Disease (AASLD) Conference

Clinical collaboration with Assembly Biosciences, Inc. established to evaluate Arbutus' AB-729 in combination with vebicorvir, Assembly's oral core/capsid inhibitor

AB-836, Arbutus' oral capsid inhibitor, remains on track for completion of CTA/IND-enabling studies by the end of 2020

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

WARMINSTER, Nov. 05, 2020 (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 reports its third quarter 2020 financial results and provides a corporate update.

William Collier, President and Chief Executive Officer of Arbutus, stated, "Arbutus is focused on discovering and developing a functional cure with a finite treatment duration for chronic HBV by developing a combination of agents, with different mechanisms of action, that target distinct parts of the virus lifecycle. To this end, we continue to make steady progress in our ongoing Phase 1a/1b clinical trial of our lead clinical candidate, AB-729, a subcutaneously delivered RNAi agent. AB-729 is currently being dosed in chronic HBV subjects in four multi-dose cohorts using both the 60 mg dose every 4- and 8-weeks and the 90 mg dose every 8- and 12-weeks."

"Based upon the clinical data generated thus far, AB-729 has demonstrated meaningful reductions in HBsAg with a favorable safety and tolerability profile. We look forward to presenting additional results from the ongoing Phase 1a/1b clinical trial as part of an oral presentation at the upcoming AASLD conference in November."

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.
- Arbutus is currently dosing two 60 mg multi-dose cohorts of subjects with chronic HBV infection with dosing intervals of every four and eight weeks, respectively. Results from the 60 mg multi-dose cohort with a dosing interval of every four weeks and additional follow-up data on the 60 mg and 90 mg single-dose cohorts are expected to be disclosed as part of an oral presentation at the upcoming AASLD conference in November.
- Separately, results from the 60 mg multi-dose cohort with a dosing interval of every eight weeks and a 90 mg single-dose cohort in HBV DNA positive subjects are expected in the fourth quarter of 2020.
- In [September 2020](#), Arbutus reported additional data from its ongoing Phase 1a/1b clinical trial for AB-729. The clinical data generated thus far demonstrate the robust activity of AB-729 and, at week 12, the 60 mg and 90 mg single-doses achieved meaningful reductions in HBsAg while remaining generally safe and well tolerated.

Mean HBsAg changes from baseline:

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

- Arbutus is also currently dosing two 90 mg multi-dose cohorts of subjects with dosing intervals of every eight and twelve weeks, respectively.

AB-836: Oral Capsid Inhibitor

- In January 2020, Arbutus selected AB-836 as its next-generation oral capsid inhibitor. AB-836 is from a novel chemical series differentiated from competitor compounds with the potential for increased efficacy and an enhanced resistance

profile. Arbutus continues to expect completion of CTA/IND-enabling studies by the end of 2020.

Early HBV R&D Programs

- Arbutus' drug discovery efforts are focused on follow-on compounds for its current HBV pipeline, including the development of oral RNA-destabilizers that have shown compelling antiviral effects in multiple HBV preclinical models. Arbutus is now focused on advancing through lead optimization next-generation oral RNA-destabilizers with chemical scaffolds distinct from Arbutus' prior generation HBV RNA destabilizer candidate. Arbutus also has several oral anti-PD-L1 inhibitors in lead optimization that are potentially capable of reawakening the immune response to HBV in infected patients.

Clinical Collaboration with Assembly Biosciences, Inc.

- In August 2020, the Company entered into a clinical collaboration agreement with Assembly Biosciences, Inc. (Assembly) to evaluate Arbutus' AB-729 clinical candidate in combination with Assembly's lead hepatitis B virus (HBV) core/capsid inhibitor candidate vebicorvir (VBR) and standard-of-care nucleos(t)ide reverse transcriptase inhibitor (Nrtl) therapy for the treatment of patients with chronic HBV infection. This collaboration will include a randomized, multi-center, open-label Phase 2 clinical trial that will explore the safety, pharmacokinetics, and antiviral activity of the triple combination of AB-729, VBR, and an Nrtl compared to the double combinations of VBR with an Nrtl and AB-729 with an Nrtl. This trial is expected to initiate in the first half of 2021 and enroll approximately 60 virologically-suppressed patients with chronic HBV infection.

Dr. Gaston Picchio, Chief Development Officer of Arbutus, stated, "This clinical collaboration in which both companies share expertise and costs has the potential to provide proof of concept data regarding the safety and efficacy of combining two promising drug candidates and to expedite efforts to advance a much needed HBV treatment regimen."

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 has also joined forces with the COVID R&D consortium to further support and expedite efforts to address the COVID-19 pandemic.

Genevant Sciences Ltd. Update

- On July 31, 2020, Genevant Sciences Ltd. (Genevant) was recapitalized through an equity investment and conversion of previously issued convertible debt securities held by Roivant Sciences Ltd. (Roivant), Arbutus' largest shareholder. Arbutus participated in the recapitalization of Genevant with an equity investment of \$2.5 million. Following the recapitalization, Arbutus owns approximately 16% of the common equity of Genevant. Arbutus' entitlement to receive future royalties or sublicensing revenue from Genevant remains unchanged.
- As previously disclosed, in April 2018 Arbutus entered into an agreement with Roivant to launch Genevant, a company focused on the discovery, development, and commercialization of a broad range of RNA-based therapeutics enabled by Arbutus' lipid nanoparticle ("LNP") and ligand conjugate delivery technologies. Arbutus licensed exclusive rights to its LNP and ligand conjugate delivery platforms to Genevant for RNA-based applications outside of HBV, except to the extent certain rights had already been licensed to other third parties

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 also likely continue to result in significant disruptions to businesses. A number of countries and other jurisdictions around the world have implemented extreme measures to try and slow the spread of the virus. These measures include the closing of businesses and requiring people to stay in their homes, the latter of which raises uncertainty regarding the ability to travel to hospitals in order to participate in clinical trials. Additional measures that have had, and will likely continue to have, a major impact on clinical development, at least in the near-term, include shortages and delays in the supply chain, and prohibitions in certain countries on enrolling subjects in new clinical trials. While we have been able to progress with our clinical and pre-clinical activities to date, it is not possible to predict if the COVID-19 pandemic will negatively impact our plans and timelines in the future.

Financial Results

Cash, Cash Equivalents and Investments

Arbutus had cash, cash equivalents and investments totaling \$118.3 million as of September 30, 2020, as compared to \$90.8 million as of December 31, 2019. During the nine months ended September 30, 2020, Arbutus used \$36.4 million in operating activities and made a \$2.5 million equity investment in Genevant. These cash outflows were offset by \$66.1 million of net proceeds from the issuance of common shares under Arbutus's ATM program. The Company believes its ending third quarter cash, cash equivalents and investments of \$118.3 million are sufficient to fund the Company's operations into mid-2022.

Net Loss

Net loss attributable to common shares for the three months ended September 30, 2020 was \$21.8 million (\$0.27 basic and diluted loss per common share) as compared to \$85.3 million (\$1.50 basic and diluted loss per common share) for the three months ended September 30, 2019. Net loss attributable to common shares for the three months ended September 30, 2019 included: i) non-cash impairment charges of \$43.8 million for an in-process research and development ("IPR&D") intangible asset and \$22.5 million for goodwill to reduce their carrying values to zero, as well as a corresponding income tax benefit of \$12.7 million related to the decrease in the deferred tax liability associated with the IPR&D intangible assets; and ii) a \$6.5 million expense related to an arbitration award from the Company's arbitration with the University of British Columbia.

Net loss attributable to common shares for the three months ended September 30, 2020 and 2019 included non-cash expense for the accrual of coupon on the Company's convertible preferred shares of \$3.0 million and \$2.8 million, respectively, and non-cash expense for a proportionate share of Genevant's net losses of \$2.5 million in the third quarter of 2020 and \$3.5 million in the third quarter of 2019.

Operating Expenses

Research and development expenses were \$12.1 million for the three months ended September 30, 2020 compared to \$17.7 million in 2019. The decrease in research and development expenses for the three months ended September 30, 2020 versus the same period in 2019 was due primarily to lower clinical expenses in 2020. General and administrative expenses were \$4.1 million for the three months ended September 30, 2020 compared to \$3.2 million for the same period in 2019. This increase was due primarily to increased compensation-related expenses and an increase in insurance premiums.

Outstanding Shares

The Company had approximately 84.6 million common shares issued and outstanding as of September 30, 2020. In addition, the Company had approximately 10.9 million stock options outstanding and 1.164 million convertible preferred shares outstanding, which (including the 8.75% annual interest in the form of additional preferred shares) will be mandatorily convertible into approximately 23.0 million common shares on October 18, 2021.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue				
Collaborations and licenses	\$ 827	\$ 2,600	\$ 2,487	\$ 3,414
Non-cash royalty revenue	696	461	2,041	979
Total Revenue	1,523	3,061	4,528	4,393
Operating expenses				
Research and development	12,065	17,731	32,946	45,183
General and administrative	4,065	3,249	11,184	15,850
Depreciation and amortization	490	507	1,491	1,521
Change in fair value of contingent consideration	120	(376)	348	(121)
Site consolidation	—	182	64	33
Impairment of intangible assets	—	43,836	—	43,836
Impairment of goodwill	—	22,471	—	22,471
Arbitration	—	6,486	—	6,486
Loss from operations	(15,217)	(91,025)	(41,505)	(130,866)
Other income (loss)				
Interest income	100	503	645	1,709
Interest expense	(1,074)	(1,100)	(3,214)	(1,114)
Foreign exchange gain (loss)	(19)	(25)	(84)	43
Equity investment loss	(2,545)	(3,512)	(2,545)	(11,497)
Total other loss	(3,538)	(4,134)	(5,198)	(10,859)
Loss before income taxes	\$ (18,755)	\$ (95,159)	\$ (46,703)	\$ (141,725)
Income tax benefit	—	12,656	—	12,656
Net loss	\$ (18,755)	\$ (82,503)	\$ (46,703)	\$ (129,069)
Dividend accretion of convertible preferred shares	(3,027)	(2,792)	(9,000)	(8,269)
Net loss attributable to common shares	\$ (21,782)	\$ (85,295)	\$ (55,703)	\$ (137,338)
Loss per share				
Basic and diluted	\$ (0.27)	\$ (1.50)	\$ (0.77)	\$ (2.43)
Weighted average number of common shares				
Basic and diluted	79,487,444	56,850,172	72,342,070	56,469,358

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS (in thousands)

	September 30, 2020	December 31, 2019
Cash and cash equivalents	\$ 96,918	\$ 31,799
Investments in marketable securities, current	21,378	59,035
Accounts receivable and other current assets	\$ 2,946	2,994
Total current assets	121,242	93,828
Property and equipment, net of accumulated depreciation	7,262	8,676
Right of use asset	2,491	2,738
Other non-current assets	109	293
Total assets	\$ 131,104	\$ 105,535
Accounts payable and accrued liabilities	\$ 6,913	\$ 7,235
Liability-classified options	317	253
Lease liability, current	378	340
Total current liabilities	7,608	7,828
Liability related to sale of future royalties	20,117	18,992
Contingent consideration	3,301	2,953
Lease liability, non-current	2,733	3,018
Total stockholders' equity	97,345	72,744
Total liabilities and stockholders' equity	\$ 131,104	\$ 105,535

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW
(in thousands)

	Nine Months Ended September 30,	
	2020	2019
Net loss	\$ (46,703)	\$ (129,069)
Impairment of intangible assets and goodwill	—	66,307
Deferred income tax benefit	—	(12,661)
Other non-cash items	10,365	19,764
Changes in working capital	(90)	(1,996)
Net cash used in operating activities	(36,428)	(57,655)
Net cash provided by investing activities	35,067	87,160
Net cash provided by financing activities	66,536	23,564
Effect of foreign exchange rate changes on cash and cash equivalents	(56)	71
Increase in cash and cash equivalents	\$ 65,119	\$ 53,140
Cash and cash equivalents, beginning of period	31,799	36,942
Cash and cash equivalents, end of period	\$ 96,918	\$ 90,082
Investments in marketable securities	21,378	—
Cash, cash equivalents and investments, end of period	\$ 118,296	\$ 90,082

Conference Call and Webcast Today

Arbutus will hold a conference call and webcast today, Thursday, November 5, 2020 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 or directly at [Live Webcast](#). Alternatively, you can dial (866) 393-1607 or (914) 495-8556 and reference conference ID 7161816.

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 7161816.

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

Chronic hepatitis B virus (HBV) infection is a debilitating disease of the liver that afflicts over 250 million people worldwide with up to 90 million people in China, as estimated by the World Health Organization. HBV is a global epidemic that affects more people than hepatitis C virus (HCV) and HIV infection combined—with a higher morbidity and mortality rate. HBV is a leading cause of chronic liver disease and need for liver transplantation, and up to one million people worldwide die every year from HBV-related causes. The current standard of care for patients with chronic HBV infection is life-long suppressive treatment with medications that reduce, but do not eliminate, the virus, resulting in very low cure rates. There is a significant unmet need for new therapies to treat HBV.

About Arbutus

Arbutus Biopharma Corporation is a publicly traded (Nasdaq: ABUS) biopharmaceutical company 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, 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 Arbutus’ expectations regarding the timing and clinical development of its product candidates, including Arbutus’ expectations that results from the multi-dose 60 mg cohorts and single-dose 90 mg cohorts in HBV DNA positive subjects will be disclosed as part of an oral presentation at the upcoming ASSLD conference in November, that results from the 60 mg multi-dose cohort with a dosing interval of every eight weeks and a 90 mg single-dose cohort in HBV DNA positive subjects are expected in the fourth quarter of 2020, and that CTA/IND-enabling studies for AB-836 will be complete by the end of 2020; Arbutus’ expectation to initiate a Phase 2 clinical trial for AB-729, VBR and an Nrtl in the first half of 2021 and enroll approximately 60 virologically-suppressed patients with chronic HBV infection; Arbutus’ planned 2020 cash burn guidance; the potential safety and efficacy of Arbutus’ product candidates; Arbutus’ expectations regarding its internal and external research efforts to combat COVID-19 and future coronavirus outbreaks; the expected sufficiency of Arbutus’ ending third quarter cash, cash equivalents and investments are sufficient to fund operations into mid-2022; Arbutus’ expectations regarding its technology licensed to Genevant and Arbutus’ expectations regarding the effect of the COVID-19 pandemic on its business.

With respect to the forward-looking statements contained in this press release, Arbutus has made numerous assumptions regarding, among other things: the 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.

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; 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, 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.

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