



Arbutus Reports Second Quarter 2020 Financial Results and Provides Corporate Update

August 7, 2020

Phase 1a/1b clinical trial for AB-729, a subcutaneously delivered RNAi agent, remains on track with results from additional cohorts expected in the second half of 2020

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

Actively screening multiple new molecular entities in recently initiated COVID-19 research program

Cash runway guidance extended into mid-2022

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

WARMINSTER, Pa., Aug. 07, 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 second quarter 2020 financial results and provides a corporate update.

William Collier, President and Chief Executive Officer of Arbutus, stated, "Despite the challenging conditions resulting from the COVID-19 pandemic, we continue to make steady progress in our Phase 1a/1b clinical trial of AB-729, a subcutaneously delivered RNAi agent, and have recently initiated an additional AB-729 90 mg single-dose cohort in HBV DNA positive subjects. We also intend to initiate two 90 mg multi-dose cohorts in the second half of this year."

Mr. Collier added, "Importantly, in March and May of this year we announced positive preliminary results from this trial, and we look forward to providing additional clinical updates in the second half of 2020. We anticipate these updates will include data from 60 mg multi-dose cohorts with dosing intervals every four and eight weeks and 90 mg single-dose week 12 data in HBV DNA negative and positive subjects. We continue to believe AB-729 is a potent RNAi agent capable of reducing HBsAg plasma levels."

Pipeline Update

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 (HBsAg), in preclinical models. Reducing HBsAg is thought to be essential to enable the reawakening of a patient's immune system so that it can respond to the virus.
- 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.
- Preliminary positive safety data in single-dose cohorts of healthy subjects and safety and efficacy data in the 60 mg and 180 mg single-dose cohorts in subjects with chronic HBV infection were reported in [March 2020](#). Additional follow-on week 12 data for the 60 mg single-dose cohort were reported in [May 2020](#). The data demonstrate the robust activity of AB-729 and, at week 12, the 60 mg single-dose achieved equivalent reductions in HBsAg as the 180 mg single-dose and did so while remaining generally safe and well tolerated with no abnormal transaminase values in any of the six subjects.

Mean HBsAg changes from baseline:

	60 mg Single-Dose Cohort (N=6)	180 mg Single-Dose Cohort (N=4)
Day 29 mean log ₁₀ IU/mL (Standard Error of the Mean)	-0.24 (0.13)	-0.8 (0.38)
Week 12 (day 84) mean log ₁₀ IU/mL (Standard Error of the Mean)	-0.99 (0.24)	-0.98 (0.22)

- Arbutus is dosing two 60 mg multi-dose cohorts of subjects with chronic HBV infection with dosing intervals of every four and eight weeks, respectively. Arbutus is also dosing subjects in a 90 mg single-dose cohort. Results from these cohorts are expected in the second half of 2020. We also intend to initiate two 90 mg multi-dose cohorts in the second half of this year.

- Arbutus has also initiated an additional AB-729 90 mg single-dose cohort in HBV DNA positive subjects with results expected in the second half of 2020.

AB-836: Oral Capsid Inhibitor

- 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.
- In January 2020, Arbutus selected AB-836 as its next-generation oral capsid inhibitor. AB-836 is from a novel chemical series differentiated from Arbutus' second generation capsid inhibitor candidate, AB-506, as well as competitor compounds. AB-836 has the potential for increased potency and an enhanced resistance profile as compared to AB-506. Arbutus continues to expect completion of 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 next-generation oral RNA-destabilizers with chemical scaffolds distinct from Arbutus' prior generation HBV RNA destabilizer candidate, AB-452, through lead optimization. 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.

Research Efforts to Combat COVID-19 and Future Coronavirus Outbreaks

- Earlier this year, the Company initiated an internal research program to identify new small molecule antiviral medicines to treat COVID-19 and future coronavirus outbreaks. Dr. Michael Sofia, Arbutus' Chief Scientific Officer, who was awarded the Lasker-DeBakey Award for his discovery of sofosbuvir, brings extensive antiviral drug discovery experience to this new program. Arbutus has also joined forces with the [COVID R&D consortium](#) to further support and expedite efforts to address the COVID-19 pandemic. At this time, Arbutus' COVID-19 research program will focus on the discovery and development of new molecular entities that address specific viral targets including the nsp12 viral polymerase and the viral protease. These targets are essential viral proteins which Arbutus has experience in targeting. The Company is actively screening multiple new oral molecular entities. The establishment of the COVID-19 effort does not impact Arbutus' current cash burn guidance for 2020 of \$54 to \$58 million.

Genevant Sciences Ltd. Update

On July 23, 2020, the United States Patent and Trademark Office before the Patent Trial and Appeal Board (PTAB) announced their decision in Moderna Therapeutics, Inc.'s challenge of the validity of U.S. Patent 8,058,069 ("the '069 Patent"). In this decision, the PTAB determined no challenged claims were unpatentable. While Arbutus is the patent holder, this patent has been licensed to Genevant. The '069 Patent was included in this license agreement between Genevant and Arbutus. Arbutus is gratified by the recent decision of the PTAB, upholding the validity of one of the patents protecting Arbutus' LNP technology that Arbutus licensed to Genevant. This decision reinforces Arbutus' continuing belief in the potential of this technology.

Arbutus is entitled to receive tiered low single digit royalties on future sales of Genevant products covered by the licensed patents. If Genevant sub-licenses the intellectual property licensed by Arbutus to Genevant, Arbutus would receive upon the commercialization of a product developed by such sub-licensee the lesser of (i) twenty percent of the revenue received by Genevant for such sublicensing and (ii) tiered low single digit royalties on product sales by the sublicensee.

On July 31, 2020, Roivant recapitalized Genevant through an equity investment and conversion of previously issued convertible debt securities held by Roivant. 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.

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 negatively impact our plans and timelines in the future.

Financial Results

Cash, Cash Equivalents and Investments

Arbutus had cash, cash equivalents and investments totaling \$84.0 million as of June 30, 2020, as compared to \$90.8 million as of December 31, 2019. During the six months ended June 30, 2020, Arbutus used \$24.3 million in operating activities, which was partially offset by \$17.4 million of net proceeds from the issuance of common shares under Arbutus's ATM program. During July 2020, Arbutus fully utilized the remaining availability under the ATM program resulting in an additional \$36.5 million of net proceeds from the issuance of 9.5 million common shares. The Company believes its ending second quarter cash, cash equivalents and investments of \$84.0 million plus the additional \$36.5 million of proceeds received under the ATM program during July 2020 are sufficient to fund the Company's operations into mid-2022 versus prior guidance of mid-2021.

Net Loss

Net loss attributable to common shares for the three months ended June 30, 2020 was \$17.1 million (\$0.25 basic and diluted loss per common share) as compared to \$26.1 million (\$0.46 basic and diluted loss per common share) in 2019. Net loss attributable to common shares for the three months ended June 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. Additionally, net loss attributable to common shares for the three months ended June 30, 2019 included \$3.3 million of non-cash equity losses associated with our investment in Genevant Sciences Ltd. ("Genevant"), a company launched with Roivant Sciences Ltd., Arbutus's largest shareholder, in April 2018.

Operating Expenses

Research and development expenses were \$10.5 million for the three months ended June 30, 2020 compared to \$12.7 million in 2019. The decrease in research and development expenses for the three months ended June 30, 2020 versus the same period in 2019 was due primarily to lower clinical expenses. General and administrative expenses were \$3.6 million for the three months ended June 30, 2020 compared to \$8.2 million in 2019. The decrease in general and administrative expenses was due primarily to the departure of the Company's former President and Chief Executive Officer in June 2019 and a decrease in legal fees. In accordance with the terms of his legacy employment agreement, the Company's former President and Chief Executive Officer received \$2.3 million in cash severance and the Company recognized \$1.1 million of non-cash stock-based compensation expense for accelerated vesting of his stock options in 2019.

Outstanding Shares

The Company had approximately 71.3 million common shares issued and outstanding as of June 30, 2020. During July 2020, Arbutus issued an additional 9.5 million common shares under the ATM program. In addition, the Company had approximately 11.0 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 23.0 million common shares on October 18, 2021.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue				
Collaborations and licenses	\$ 825	\$ 398	\$ 1,660	\$ 814
Non-cash royalty revenue	689	255	1,345	518
Total Revenue	1,514	653	3,005	1,332
Operating expenses				
Research and development	10,465	12,740	20,881	27,452
General and administrative	3,566	8,189	7,119	12,601
Depreciation and amortization	501	505	1,001	1,014
Change in fair value of contingent consideration	116	130	228	255
Site consolidation	7	(266)	64	(149)
Loss from operations	(13,141)	(20,645)	(26,288)	(39,841)
Other income (loss)				
Interest income	200	606	545	1,206
Interest expense	(1,099)	(2)	(2,140)	(14)
Foreign exchange gain (loss)	(47)	60	(65)	68
Equity investment loss	—	(3,334)	—	(7,985)
Total other loss	(946)	(2,670)	(1,660)	(6,725)
Net loss	\$ (14,087)	\$ (23,315)	\$ (27,948)	\$ (46,566)
Dividend accretion of convertible preferred shares	(2,995)	(2,762)	(5,973)	(5,477)
Net loss attributable to common shares	\$ (17,082)	\$ (26,077)	\$ (33,921)	\$ (52,043)
Loss per share				
Basic and diluted	\$ (0.25)	\$ (0.46)	\$ (0.49)	\$ (0.92)
Weighted average number of common shares				
Basic and diluted	69,604,726	56,805,583	68,656,566	56,275,795

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	<u>June 30, 2020</u>	<u>December 31, 2019</u>
Cash and cash equivalents	\$ 45,899	\$ 31,799
Investments in marketable securities, current	36,489	59,035
Accounts receivable and other current assets	3,148	2,994
Total current assets	85,536	93,828
Property and equipment, net of accumulated depreciation	7,741	8,676
Investments in marketable securities, non-current	1,600	—
Right of use asset	2,575	2,738
Other non-current assets	173	293
Total assets	\$ 97,625	\$ 105,535
Accounts payable and accrued liabilities	\$ 5,813	\$ 7,235
Liability-classified options	150	253
Lease liability, current	364	340
Total current liabilities	6,327	7,828
Liability related to sale of future royalties	19,739	18,992
Contingent consideration	3,181	2,953
Lease liability, non-current	2,867	3,018
Total stockholders' equity	65,511	72,744
Total liabilities and stockholders' equity	\$ 97,625	\$ 105,535

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW
(in thousands)

	<u>Six Months Ended June 30,</u>	
	<u>2020</u>	<u>2019</u>
Net loss	\$ (27,948)	\$ (46,566)
Non-cash items	5,114	13,936
Changes in working capital	(1,420)	(1,555)
Net cash used in operating activities	(24,254)	(34,185)
Net cash provided by investing activities	20,970	71,005
Net cash provided by financing activities	17,440	5,015
Effect of foreign exchange rate changes on cash and cash equivalents	(56)	95
Increase in cash and cash equivalents	\$ 14,100	\$ 41,930
Cash and cash equivalents, beginning of period	31,799	36,942
Cash and cash equivalents, end of period	\$ 45,899	\$ 78,872
Investments in marketable securities	38,089	16,410
Cash, cash equivalents and investments, end of period	\$ 83,988	\$ 95,282

Conference Call and Webcast Today

Arbutus will hold a conference call and webcast today, Friday, August 7, 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 4974547.

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 4974547.

About Arbutus

Arbutus Biopharma Corporation is a publicly traded (Nasdaq: ABUS) biopharmaceutical company 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 negative and positive subjects will be available in the second half of 2020 and that IND-enabling studies for AB-836 will be complete by the end of 2020; Arbutus' planned 2020 cash burn guidance; the potential safety and efficacy of Arbutus' product candidates, including the potential for AB-836 to have increase potency and an enhanced resistance profile compared to AB-506; Arbutus' expectations regarding its internal and external research efforts to combat COVID-19 and future coronavirus outbreaks; Arbutus' expectation to dose two 90 mg multi-dose cohorts in the second half of this year; the expected sufficiency of Arbutus' ending second quarter cash, cash equivalents and investments plus additional proceeds received under Arbutus' ATM program during July 2020 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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