



Arbutus Reports Third Quarter 2021 Financial Results and Provides Corporate Update

November 4, 2021

On-track for multiple data readouts of AB-729 and AB-836 in Q4 2021

First patient dosed in Phase 2a clinical trial combining AB-729, Peg-IFN α -2a and nucleos(t)ide analog (“NA”) therapy

On-track to initiate several proof-of-concept Phase 2a clinical trials with AB-729 as a cornerstone agent in combination with other approved or investigational compounds

Commenced IND enabling studies for Arbutus’ oral PD-L1 program

Cash runway guidance extended into the second quarter of 2023

Conference call and webcast scheduled today at 8:45 AM ET

WARMINSTER, Pa., Nov. 04, 2021 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS), a clinical-stage biopharmaceutical company primarily focused on discovering, developing and commercializing a broad portfolio of wholly-owned assets with different mechanisms of action to provide a cure for people with chronic hepatitis B virus (HBV) infection and to treat coronaviruses (including COVID-19), today reports its third quarter 2021 financial results and provides a corporate update.

William Collier, President and Chief Executive Officer of Arbutus, stated, “We are impressed with the continued development of our proprietary HBV assets that align with our novel three-pronged approach to develop an HBV functional cure by suppressing HBV DNA, reducing HBV surface antigen and boosting the host immune system. We have clinical trials underway assessing our RNAi therapeutic and capsid inhibitor in both healthy subjects and patients with chronic HBV infection and are poised for multiple data readouts in the fourth quarter of this year. We expect these data will further inform the design of future combination clinical trials with AB-729 as a cornerstone agent in HBV treatment.”

Mr. Collier continued, “Importantly, we have now moved forward with IND enabling studies for our internally-discovered oral PD-L1 program intended to address the third arm of our three-prong approach, reawakening the host immune response. In addition, we are continuing to conduct lead optimization activities for our oral RNA destabilizer in HBV and to progress our efforts to identify lead candidates for our pan-coronavirus program. We intend to provide additional updates on these programs early next year.”

Pipeline Update

AB-729 (RNAi Therapeutic)

- Arbutus is conducting a single- and multi-dose Phase 1a/b clinical trial to determine the safety, tolerability, pharmacokinetics, and pharmacodynamics of AB-729 in healthy subjects and patients with chronic HBV infection. Data disclosed to-date show that AB-729 continues to reduce HBsAg across all doses and dosing intervals with a favorable safety and tolerability profile. Additionally, based on 3/5 evaluable patients, long term dosing of AB-729 showed increased HBV-specific immune responses, providing support for combination therapy including immunomodulatory agents.
- Arbutus will be presenting data from additional cohorts in the AB-729 Phase 1a/1b clinical trial at the upcoming AASLD medical conference. The presentation, which was accepted as a late-breaker poster for the conference, will include data in HBV DNA negative patients that received 90 mg dosed every 12 weeks (cohort J) and data in HBV DNA positive patients that received 90 mg dosed every 8 weeks (cohort G). In addition, the company will provide follow-up data from HBV DNA negative patients that received the 60 mg dose every 4 or 8 weeks or the 90 mg dose every 8 weeks (cohort E, F, and I respectively). Key findings include:
 - AB-729 repeat dosing is generally safe and well tolerated.
 - Robust mean declines in HBsAg were sustained with repeat dosing of AB-729, with no meaningful differences observed to date between doses (60 mg or 90 mg) and/or dosing intervals (every 4, 8 or 12 weeks).
 - HBsAg suppression at levels <100 IU/mL is maintained in some patients up to 20 weeks following the last dose of AB-729.
- In-line with our strategy to combine multiple therapies that target different points of the viral replication cycle to develop a curative treatment regimen in HBV, Arbutus has dosed the first patient in its Phase 2a randomized, open-label, proof-of-concept clinical trial designed to evaluate AB-729 in combination with ongoing standard-of-care NA therapy and short courses of Peg-IFN α -2a in 40 patients with chronic HBV infection. The primary objective of the clinical trial is to evaluate the safety and tolerability of AB-729 plus Peg-IFN α -2a in subjects with NA-suppressed chronic HBV infection. After

24-weeks of dosing with AB-729, patients will be randomized into one of four groups to receive either AB-729 plus NA therapy plus Peg-IFN α -2a or NA therapy plus Peg-IFN α -2a for either 24 or 12 weeks. After completion of the assigned interferon treatment period, all patients will remain on NA therapy for the initial 24-week follow-up period, and then discontinue NA treatment, provided they meet certain stopping criteria.

- Also, in line with our strategy, we have entered into separate clinical collaboration agreements with Assembly Biosciences, Inc. (“Assembly”), Vaccitech plc (“Vaccitech”) and Antios Therapeutics, Inc. (“Antios”) to evaluate AB-729 as the cornerstone agent in combination with Assembly’s capsid inhibitor, Vaccitech’s T cell stimulating therapeutic vaccine, and Antios’ active site polymerase inhibitor nucleotide, respectively.
 - Enrollment is on-going in the Phase 2 proof-of-concept triple combination clinical trial evaluating AB-729, vebicorvir (“VBR”), Assembly’s lead HBV core inhibitor (capsid inhibitor), and an NA. Assembly is conducting this clinical trial and expecting initial data in 2022.
 - Arbutus is on-track to file a Clinical Trial Application (CTA) in the fourth quarter of 2021 with plans to initiate a triple combination Phase 2 trial in early 2022 to evaluate AB-729, combined with VTP-300, Vaccitech’s therapeutic vaccine and a NA.
 - In the fourth quarter of 2021, Antios is planning to add a cohort to its on-going Phase 2 clinical trial to evaluate AB-729, ATI-2173, Antios’ proprietary active site polymerase inhibitor nucleotide (ASPIN) and Viread (tenofovir disoproxil fumarate), which is currently approved by the FDA for the treatment of chronic hepatitis B.

AB-836 (Oral Capsid Inhibitor)

- AB-836 is Arbutus’ novel, next generation oral capsid inhibitor with improved intrinsic potency, activity against resistant variants and an enhanced ability to starve replenishment of cccDNA which is responsible for HBV recurrence.
- Arbutus is conducting a double-blind, randomized, placebo-controlled, single and multiple dose Phase 1a/1b clinical trial evaluating the safety, tolerability, pharmacokinetics and pharmacodynamics of AB-836. The Company is on-track to report initial data from healthy subjects and HBV patients in the fourth quarter of 2021.

HBV Discovery Programs

- Arbutus’ drug discovery efforts are focused on developing small molecules to create an all-oral treatment regimen to cure HBV. Research efforts are continuing with the oral RNA-destabilizer program, where Arbutus is currently in late-stage lead optimization.

Oral PD-L1 Program

- Arbutus’ oral PD-L1 program is designed to reawaken the immune system, which Arbutus believes is a key component in developing a cure for HBV. Arbutus has commenced IND-enabling studies for its oral PD-L1 program.

Research Efforts to Combat COVID-19 and Future Coronavirus Outbreaks

- Leveraging its extensive antiviral drug discovery experience, Arbutus is focused on the discovery and development of new pan-coronavirus molecular entities to treat COVID-19 and future coronavirus outbreaks by targeting essential viral proteins including the nsp12 viral polymerase and the nsp5 viral protease. Through its discovery research and license agreement with X-Chem, Inc. and Proteros biostructures GmbH, Arbutus is progressing lead candidates to nomination.

Financial Results

Cash, Cash Equivalents and Investments

Arbutus had cash, cash equivalents and investments in marketable securities totaling \$151.9 million as of September 30, 2021, as compared to \$123.3 million as of December 31, 2020. During the nine months ended September 30, 2021, Arbutus used \$47.9 million in operating activities, which was offset by \$75.4 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 in marketable securities of \$151.9 million as of September 30, 2021 are sufficient to fund the Company’s operations into the second quarter of 2023.

Net Loss

Net loss attributable to common shares for the three months ended September 30, 2021 was \$24.2 million (\$0.24 basic and diluted loss per common share) as compared to \$21.8 million (\$0.27 basic and diluted loss per common share) for the three months ended September 30, 2020. Net loss attributable to common shares for the three months ended September 30, 2021 and 2020 included non-cash expense for the accrual of coupon on the Company’s convertible preferred shares of \$5.1 million and \$3.0 million, respectively.

Operating Expenses

Research and development expenses were \$16.3 million for the three months ended September 30, 2021 compared to \$12.1 million for the same period in 2020. The increase in research and development expenses for the three months ended September 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 the 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 \$4.1 million for the three months ended September 30, 2021 compared to \$4.1 million for the same period in 2020.

Outstanding Shares

As of September 30, 2021, the Company had approximately 110.3 million common shares issued and outstanding, approximately 11.4 million stock options outstanding and 1.164 million convertible preferred shares outstanding. On October 18, 2021, all 1.164 million convertible preferred shares (including the annual 8.75% coupon) converted into 22,833,922 common shares. Following the conversion, Roivant owns approximately 29% of the Company's outstanding common shares.

COVID-19 Impact

In December 2019 an outbreak of a novel strain of coronavirus (COVID-19) was identified in Wuhan, China. This virus 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 Arbutus has been able to progress with its clinical and pre-clinical activities to date, it is not possible to predict if the COVID-19 pandemic will materially impact its plans and timelines in the future.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue				
Collaborations and licenses	\$ 1,480	\$ 827	\$ 3,819	\$ 2,487
Non-cash royalty revenue	1,860	696	3,963	2,041
Total Revenue	3,340	1,523	7,782	4,528
Operating expenses				
Research and development	16,299	12,065	45,065	32,946
General and administrative	4,146	4,065	12,438	11,184
Depreciation	447	490	1,326	1,491
Change in fair value of contingent consideration	856	120	1,679	348
Site consolidation	—	—	—	64
Loss from operations	(18,408)	(15,217)	(52,726)	(41,505)
Other income (loss)				
Interest income	27	100	97	645
Interest expense	(762)	(1,074)	(2,297)	(3,214)
Foreign exchange (loss) gain	(15)	(19)	—	(84)
Equity investment loss	—	(2,545)	—	(2,545)
Total other loss	(750)	(3,538)	(2,200)	(5,198)
Net loss	(19,158)	(18,755)	(54,926)	(46,703)
Dividend accretion of convertible preferred shares	(5,087)	(3,027)	(11,565)	(9,000)
Net loss attributable to common shares	\$ (24,245)	\$ (21,782)	\$ (66,491)	\$ (55,703)
Loss per share				
Basic and diluted	\$ (0.24)	\$ (0.27)	\$ (0.68)	\$ (0.77)
Weighted average number of common shares				
Basic and diluted	101,286,351	79,487,444	97,174,253	72,342,070

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS (in thousands)

	September 30, 2021	December 31, 2020
Cash, cash equivalents and marketable securities, current	\$ 121,403	\$ 123,268
Accounts receivable and other current assets	5,133	4,436
Total current assets	126,536	127,704
Property and equipment, net of accumulated depreciation	6,352	6,927

Investments in marketable securities, non-current	30,534	—
Right of use asset	2,174	2,405
Other non-current assets	—	44
Total assets	\$ 165,596	\$ 137,080
Accounts payable and accrued liabilities	\$ 9,727	\$ 9,151
Lease liability, current	386	390
Total current liabilities	10,113	9,541
Liability related to sale of future royalties	17,883	19,554
Contingent consideration	5,105	3,426
Lease liability, non-current	2,355	2,593
Total stockholders' equity	130,140	101,966
Total liabilities and stockholders' equity	\$ 165,596	\$ 137,080

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW
(in thousands)

	Nine Months Ended September 30,	
	2021	2020
Net loss	\$ (54,926)	\$ (46,703)
Other non-cash items	7,080	10,365
Changes in working capital	(80)	(90)
Net cash used in operating activities	(47,926)	(36,428)
Net cash (used in) provided by investing activities	(4,557)	35,067
Net cash provided by financing activities	78,115	66,536
Effect of foreign exchange rate changes on cash and cash equivalents	—	(56)
Increase in cash and cash equivalents	25,632	65,119
Cash and cash equivalents, beginning of period	52,251	31,799
Cash and cash equivalents, end of period	77,883	96,918
Investments in marketable securities	74,054	21,378
Cash, cash equivalents and marketable securities, end of period	\$ 151,937	\$ 118,296

Conference Call and Webcast Today

Arbutus will hold a conference call and webcast today, Thursday, November 4, 2021 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: 5035306.

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: 5035306.

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.

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.

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 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 (Nasdaq: ABUS) is a clinical-stage biopharmaceutical company primarily focused on discovering, developing and commercializing a broad portfolio of wholly-owned assets with different modes of action to provide a cure for people with chronic hepatitis B virus (HBV) infection. The Company is advancing multiple product candidates with distinct mechanisms of action that suppress viral replication, reduce surface antigen and reawaken the immune system. Arbutus believes this three-prong approach is key to transforming the treatment and developing a

potential cure for chronic HBV infection. Arbutus' HBV product pipeline includes RNA interference (RNAi) therapeutics, oral capsid inhibitors, oral compounds that inhibit PD-L1 and oral HBV RNA destabilizers. In addition, Arbutus has an ongoing drug discovery and development program directed to identifying orally active agents 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 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 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; our expected financial condition, including the anticipated duration of cash runways and timing regarding needs for additional capital; 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 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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