



Arbutus Reports Third Quarter 2022 Financial Results and Provides Corporate Update

November 9, 2022

Financially strong with a projected cash runway into the second quarter of 2024

HBsAg and HBV DNA remain at low levels with no evidence of clinical relapse up to 44 weeks after discontinuing AB-729, our RNAi therapeutic, and NA therapy

On-track to achieve multiple additional milestones before year end

Conference call and webcast today at 8:45 AM ET

WARMINSTER, Pa., Nov. 09, 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 third quarter 2022 financial results and provides corporate updates.

"This quarter we continued to advance our pipeline of clinical and preclinical programs in support of our mission to develop a functional cure for patients with chronic hepatitis B virus (CHBV) and to treat COVID-19 and future coronavirus outbreaks," said William Collier, Arbutus' President and Chief Executive Officer. "We reported at AASLD off-treatment data which showed that AB-729 treatment results in long-lasting control of HBV biomarker levels. We continue to believe that AB-729 can be a cornerstone agent in a potential curative combination treatment for CHBV based on the body of data supporting its impact on HBV markers and immune activation properties, safety profile and convenient dosing schedule."

Mr. Collier continued, "Looking ahead, we are on-track to achieve our remaining 2022 milestones including reporting data from our Phase 2 clinical trial evaluating AB-729 with interferon, completing IND-enabling studies with AB-161, our RNAi destabilizer, and AB-101, our PD-L1 inhibitor, and nominating a compound that inhibits the SARS-CoV-2 nsp5 main protease and has pan-coronavirus inhibitor properties."

Pipeline Updates:

AB-729 (RNAi Therapeutic)

- Presented additional off-treatment data from AB-729-001 at the AASLD Liver Meeting, showing that HBsAg levels remained well below pre-trial levels in nine of nine patients who were eligible and elected to stop therapy, suggestive of immunological control, with no patient meeting protocol-defined criteria to restart NA therapy.
- The Phase 2a clinical trial evaluating AB-729 in combination with NA therapy and short courses of Peg-IFN α -2a (AB-729-201) in CHBV patients is continuing. The Company is on-track to report initial data this quarter.
- Enrollment is on-going in the AB-729-202 Phase 2a clinical trial evaluating AB-729, in combination with VTP-300, Vaccitech plc's (Vaccitech) therapeutic vaccine, and NA, in CHBV patients.
- Presented preliminary data from the Phase 2a clinical trial evaluating AB-729 and NA in combination with vebicorvir (VBR), Assembly Biosciences, Inc.'s first generation HBV core inhibitor (capsid inhibitor), at AASLD showing that the combination of VBR+AB-729+NA does not result in greater on-treatment improvements in markers of active HBV infection as compared to AB-729+NA alone. The addition of VBR did not negatively impact the reduction of HBsAg, in the triple combination arm.

AB-101 (Oral PD-L1 Inhibitor)

- At AASLD, presented preclinical data in mice infected with HBV showing that combination treatment with AB-101 and an HBV targeting GalNAc-siRNA agent resulted in activation and increased frequency of HBV-specific T-cells and greater anti-HBsAg antibody production. The Company is on-track to complete IND-enabling studies for AB-101 this year.

AB-161 (Oral RNA Destabilizer)

- At the Discovery on Target Conference, presented preclinical data showing that AB-161 reduced HBV RNA and HBsAg in multiple preclinical models, with favorable liver centricity and lack of observed peripheral neuropathy. The Company is conducting the remaining IND-enabling studies which are expected to be complete by the end of the year.

AB-836 (Oral Capsid Inhibitor)

- Discontinued development of AB-836 based on additional ALT elevations seen in the new healthy volunteer arm of the AB-836-001 clinical trial.

COVID-19 and Pan-Coronavirus Programs

- The Company is on-track to nominate a lead candidate that inhibits the SARS-CoV-2 nsp5 main protease (M^{pro}) this year and then advance that compound into IND-enabling studies.

- The Company is continuing lead optimization activities for an nsp12 viral polymerase candidate.

Financial Results

Cash, Cash Equivalents and Investments

As of September 30, 2022, the Company had cash, cash equivalents and investments in marketable securities of \$190.2 million, as compared to \$191.0 million as of December 31, 2021.

During the nine months ended September 30, 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 in the Company and \$9.2 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 \$62.4 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

Total revenue was \$6.0 million for the three months ended September 30, 2022 compared to \$3.3 million for the same period in 2021. The increase of \$2.7 million was due primarily to \$2.3 million of revenue recognition from the Company's license agreement with Qilu based on employee labor hours expended by the Company during the three months ended September 30, 2022 to perform its manufacturing obligations under the license agreement.

Operating Expenses

Research and development expenses were \$20.1 million for the three months ended September 30, 2022, compared to \$16.7 million for the same period in 2021. The increase of \$3.4 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, and an increase in expenses for its early-stage development programs, including AB-101 and AB-161. General and administrative expenses were \$3.5 million for the three months ended September 30, 2022, compared to \$4.2 million for the same period in 2021. This decrease was due primarily to an arbitrator's award of \$0.5 million during the three months ended September 30, 2022 for recovery of costs and attorneys' fees related to an arbitration matter with the University of British Columbia.

Net Loss

For the three months ended September 30, 2022, the Company's net loss attributable to common shares was \$17.6 million, or a loss of \$0.12 per basic and diluted common share, as compared to a net loss attributable to common shares of \$24.2 million, or a loss of \$0.24 per basic and diluted common share, for the three months ended September 30, 2021. Net loss attributable to common shares for the three months ended September 30, 2021 included \$5.1 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.

Outstanding Shares

As of September 30, 2022, the Company had approximately 152.7 million common shares issued and outstanding, as well as approximately 15.9 million stock options outstanding. Roivant Sciences Ltd. owned approximately 25% of the Company's outstanding common shares as of September 30, 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 the Company 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 the Company's 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,	
	2022	2021	2022	2021
Revenue				
Collaborations and licenses	\$ 3,607	\$ 1,480	\$ 27,381	\$ 3,819
Non-cash royalty revenue	2,345	1,860	5,393	3,963
Total Revenue	5,952	3,340	32,774	7,782
Operating expenses				
Research and development	20,055	16,709	61,459	46,290
General and administrative	3,493	4,183	13,585	12,539
Change in fair value of contingent consideration	215	856	624	1,679
Total operating expenses	23,763	21,748	75,668	60,508
Loss from operations	(17,811)	(18,408)	(42,894)	(52,726)
Other income (loss)				
Interest income	694	27	1,249	97
Interest expense	(429)	(762)	(1,417)	(2,297)

Foreign exchange loss	(21)	(15)	(18)	-
Total other income (loss)	<u>244</u>	<u>(750)</u>	<u>(186)</u>	<u>(2,200)</u>
Loss before income taxes	<u>(17,567)</u>	<u>(19,158)</u>	<u>(43,080)</u>	<u>(54,926)</u>
Income tax expense	-	-	(4,444)	-
Net loss	<u>(17,567)</u>	<u>(19,158)</u>	<u>(47,524)</u>	<u>(54,926)</u>
Dividend accretion of convertible preferred shares	-	(5,087)	-	(11,565)
Net loss attributable to common shares	<u>\$ (17,567)</u>	<u>\$ (24,245)</u>	<u>\$ (47,524)</u>	<u>\$ (66,491)</u>
Loss per share				
Basic and diluted	\$ (0.12)	\$ (0.24)	\$ (0.32)	\$ (0.68)
Weighted average number of common shares				
Basic and diluted	150,995,191	101,286,351	149,385,999	97,174,253

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	September 30, 2022	December 31, 2021
Cash, cash equivalents and marketable securities, current	\$ 134,718	\$ 155,317
Accounts receivable and other current assets	<u>6,418</u>	<u>5,344</u>
Total current assets	141,136	160,661
Property and equipment, net of accumulated depreciation	5,241	5,983
Investments in marketable securities, non-current	55,436	35,688
Right of use asset	1,821	2,092
Other non-current assets	<u>167</u>	<u>61</u>
Total assets	<u>\$ 203,801</u>	<u>\$ 204,485</u>
Accounts payable and accrued liabilities	\$ 12,268	\$ 10,838
Deferred revenue	14,878	-
Lease liability, current	<u>360</u>	<u>383</u>
Total current liabilities	27,506	11,221
Liability related to sale of future royalties	12,316	16,296
Deferred revenue, non-current	10,585	-
Contingent consideration	5,922	5,298
Lease liability, non-current	1,955	2,231
Total stockholders' equity	<u>145,517</u>	<u>169,439</u>
Total liabilities and stockholders' equity	<u>\$ 203,801</u>	<u>\$ 204,485</u>

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW
(in thousands)

	Nine Months Ended September 30,	
	2022	2021
Net loss	\$ (47,524)	\$ (54,926)
Non-cash items	3,429	7,080
Change in deferred license revenue	25,463	-
Other changes in working capital	<u>266</u>	<u>(80)</u>
Net cash used in operating activities	(18,366)	(47,926)
Net cash used in investing activities	(87,624)	(4,557)
Issuance of common shares pursuant to Share Purchase Agreement	10,973	-
Cash provided by other financing activities	<u>9,757</u>	<u>78,115</u>
Net cash provided by financing activities	20,730	78,115
Effect of foreign exchange rate changes on cash and cash equivalents	<u>(18)</u>	<u>-</u>
(Decrease) increase in cash and cash equivalents	(85,278)	25,632
Cash and cash equivalents, beginning of period	<u>109,282</u>	<u>52,251</u>
Cash and cash equivalents, end of period	24,004	77,883
Investments in marketable securities	<u>166,150</u>	<u>74,054</u>
Cash, cash equivalents and marketable securities, end of period	<u>\$ 190,154</u>	<u>\$ 151,937</u>

Conference Call and Webcast Today

Arbutus will hold a conference call and webcast today, Wednesday, November 9, 2022, at 8:45 AM Eastern Time to provide a corporate update. To

dial-in for the conference call by phone, please register using the following link: [Registration Link](#). A live webcast of the conference call can be accessed through the Investors section of Arbutus' website at www.arbutusbio.com.

An archived webcast will be available on the Arbutus website after the event.

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 enabling subcutaneous delivery. Clinical data generated thus far has shown single- and multi-doses of AB-729 to be generally safe and well-tolerated, while also providing meaningful reductions in hepatitis B surface antigen and hepatitis B DNA. AB-729 is currently in multiple Phase 2a clinical trials.

About AB-101

Immune checkpoints such as PD-1/PD-L1 play an important role in the induction and maintenance of immune tolerance and in T-cell activation. We have identified a class of small molecule oral PD-L1 inhibitors that we believe will allow for controlled checkpoint blockade, enable oral dosing, and mitigate systemic safety issues typically seen with checkpoint antibody therapies. Our lead oral PD-L1 inhibitor candidate, AB-101, is currently in IND-enabling studies. We believe AB-101, when used in combination with other approved and investigational agents, could potentially allow us to realize our mission of achieving a functional cure for HBV chronically infected patients. We are also exploring oncology applications for our internal PD-L1 portfolio.

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. To address HBV, we are developing a RNAi therapeutic, an oral PD-L1 inhibitor, and an oral RNA destabilizer to potentially identify a combination regimen with the aim of providing 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. It is currently being evaluated in multiple phase 2 clinical trials. We also have an ongoing drug discovery and development program directed to identifying novel, orally active agents for treating coronavirus (including SARS-CoV-2). In addition, we are 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.

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