Arbutus Reports First Quarter 2023 Financial Results and Corporate Update

May 4, 2023

Additional AB-729 off-treatment data highlighted in an oral presentation at the Global Hepatitis Summit 2023

Dosed first subject in Phase 1 clinical trial with oral RNA Destabilizer, AB-161

Filed patent infringement lawsuit against Pfizer and BioNTech seeking compensation for use of unlicensed patented technologies in COVID-19 mRNA-LNP vaccines

Strong financial position – cash runway extends into the first quarter of 2025

Conference Call and Webcast Today at 8:45 AM ET

WARMINSTER, Pa., May 04, 2023 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS) ("Arbutus" or the "Company"), a clinical-stage biopharmaceutical company leveraging its extensive virology expertise to develop novel therapeutics that target specific viral diseases, today reported first quarter 2023 financial results and provided a corporate update.

"In the first quarter of 2023, we made meaningful progress advancing our pipeline of HBV and coronavirus assets to address large global market opportunities," said William Collier, Arbutus' President and Chief Executive Officer. "We reported data from our lead HBV-focused RNAi therapeutic, AB-729, showing low levels of HBsAg and HBV DNA in most patients persisting for at least a year and a half after their last dose of AB-729. In addition, we dosed the first healthy subject in our Phase 1 clinical trial with AB-161, our oral RNA destabilizer, for which we expect data in the second half of this year. We continue to advance our coronavirus programs and expect to initiate a Phase 1 clinical trial with our M^{pro} inhibitor candidate, AB-343, as well as IND-enabling studies for an nsp12 inhibitor candidate in the second half of this year."

Pipeline Updates and Key Milestones

AB-729 (RNAi Therapeutic)

- At the Global Hepatitis Summit in April, we reported in an oral presentation additional off-treatment data from the patients in our Phase 1b clinical trial (AB-729-001) who have discontinued both AB-729 and nucleos(t)ide analogue (NA) therapy. These seven remaining patients continue to maintain low HBV DNA levels off all therapy, and HBsAg levels remain below baseline (-0.8 to -1.6 $\log_{10}$) up to one and a half years after the last dose of AB-729.
- We are continuing to evaluate the safety and tolerability of AB-729 in combination with ongoing NA therapy and short courses of PEG-IFNα-2a (IFN) in 43 patients with chronic hepatitis B virus (cHBV) infection in a Phase 2a clinical trial (AB-729-201). Preliminary data from the lead-in phase of the trial further validated AB-729's capacity to reduce HBsAg. We expect to announce preliminary data from patients receiving the combination of AB-729, NA therapy and IFN in the second quarter of 2023.
- We are continuing to evaluate AB-729, NA therapy and Vaccitech's HBV antigen-specific immunotherapeutic, VTP-300, in a Phase 2a clinical trial (AB-729-202). Once enrollment is complete in the initial portion of this trial, we will begin enrolling 20 patients in an additional arm of the trial. These patients will receive AB-729 (60mg every 8 weeks) plus NA therapy for 24 weeks, followed by VTP-300 plus one to two low doses of nivolumab (Opdivo®). We expect preliminary data from patients who receive AB-729, NA therapy and VTP-300 in the second half of 2023, and we expect to dose the first patient in the additional arm receiving AB-729, NA therapy, VTP-300 and nivolumab in the second quarter of 2023.

AB-161 (Oral RNA destabilizer)

- In March, we dosed the first healthy subject in our Phase 1 clinical trial with AB-161. The single-ascending dose data is expected in the second half of 2023. AB-161 is our next-generation oral HBV-specific RNA destabilizer, which is being developed as part of a potential all-oral treatment regimen to functionally cure HBV.
- At the Global Hepatitis Summit in April, we presented preclinical data showing that AB-161 provides robust anti-HBV activity including suppression of HBV RNA and HBsAg production *in vitro* and *in vivo*. The differentiated anti-HBV mode of action of AB-161 compared to other classes of HBV inhibitors, suggest that AB-161 may be an important component in combination to provide a functional cure for cHBV.

AB-101 (Oral PD-L1 Inhibitor)

- In April, we received verbal communication from the U.S. Food and Drug Administration (FDA) that the AB-101 Investigational New Drug (IND) application has been placed on clinical hold. For purposes of clarity, the Phase 1 clinical trial had not been initiated and we had not dosed any patients with AB-101. The FDA indicated they will provide an official

clinical hold letter to Arbutus within 30 days of the verbal communication. Based on this communication, we no longer intend to report initial data from the single-ascending dose portion of a Phase 1 clinical trial in the second half of 2023. We are developing AB-101, our oral PD-L1 inhibitor, to reawaken and boost the immune system of patients with cHBV. Preclinical data generated thus far indicates that AB-101 is highly potent and mediates activation and reinvigoration of HBV-specific T-cells from cHBV patients.

COVID-19 and Pan-Coronavirus Programs

- At the 36th International Conference on Antiviral Research in March, we presented pre-clinical data for AB-343, our lead coronavirus drug candidate that inhibits the main protease (M^{pro}). The antiviral potency, selectivity and favorable pharmacokinetic data support the further development of AB-343 as a potential ritonavir-free oral treatment for COVID-19 and other human coronaviruses. We are currently conducting IND-enabling studies with AB-343, and on completion, we expect to initiate a Phase 1 clinical trial in the second half of 2023.
- We are continuing to direct our research efforts to identifying an nsp12 viral polymerase clinical candidate. Such a candidate could potentially be combined with AB-343 to achieve better patient treatment outcomes and for use in prophylactic settings. We expect to nominate an nsp12 clinical candidate and initiate IND-enabling studies in the second half of 2023.

Financial Results

Cash, Cash Equivalents and Investments

As of March 31, 2023, we had cash, cash equivalents and investments in marketable securities of $178.5 million compared to $184.3 million as of December 31, 2022. During the three months ended March 31, 2023, we used $27.3 million in operating activities, which was partially offset by $19.9 million of net proceeds from the issuance of common shares under our “at-the-market” offering program. Based on AB-101's IND being placed on clinical hold by the FDA and a resulting shift in the timing of our AB-101 Phase 1 clinical trial, we are reducing our 2023 cash burn guidance from between $95 to $100 million to between $90 to $95 million. We believe our cash runway will be sufficient to fund our operations into the first quarter of 2025.

Revenue

Total revenue was $6.7 million for the three months ended March 31, 2023 compared to $12.6 million for the same period in 2022. The decrease of $5.9 million was due primarily to less revenue recognition from our license agreement with Qilu compared to last year based on employee labor hours expended by us to perform our manufacturing obligations under the license agreement.

Operating Expenses

Research and development expenses were $18.3 million for the three months ended March 31, 2023 compared to $18.5 million for the same period in 2022. The decrease of $0.2 million was due primarily to a decrease in expenses for our AB-836 Phase 1a/1b clinical trial, which was discontinued in the fourth quarter of 2022, partially offset by an increase in expenses for our coronavirus program and other early-stage development programs.

Net Loss

For the three months ended March 31, 2023, our net loss was $16.3 million, or a loss of $0.10 per basic and diluted common share, as compared to a net loss of $15.8 million, or a loss of $0.11 per basic and diluted common share, for the three months ended March 31, 2022. Net loss for the three months ended March 31, 2022 included $4.4 million of income tax expense for withholding taxes paid to the Chinese taxing authority by Qilu on our behalf in connection with the upfront license fee Qilu paid us.

Outstanding Shares

As of March 31, 2023, we had approximately 165.1 million common shares issued and outstanding, as well as approximately 19.7 million stock options and unvested restricted stock units outstanding. Roivant Sciences Ltd. owned approximately 23% of our outstanding common shares as of March 31, 2023.

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

	Three Months Ended March 31,	
	2023	**2022**
Revenue		
Collaborations and licenses	$ 5,509	$ 11,218
Non-cash royalty revenue	1,178	1,363
Total revenue	6,687	12,581
Operating expenses		
Research and development	18,275	18,462
General and administrative	5,552	4,892
Change in fair value of contingent consideration	273	201

Total operating expenses	24,100	23,555
Loss from operations	(17,413)	(10,974)
Other income (loss)		
Interest income	1,268	159
Interest expense	(198)	(506)
Foreign exchange gain	4	—
Total other income (loss)	1,074	(347)
Loss before income taxes	(16,339)	(11,321)
Income tax expense	—	(4,444)
Net loss	$ (16,339)	$ (15,765)
Net loss per common share		
Basic and diluted	$ (0.10)	$ (0.11)
Weighted average number of common shares		
Basic and diluted	161,643,404	148,428,326

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	March 31, 2023	December 31, 2022
Cash, cash equivalents and marketable securities, current	$ 146,728	$ 146,913
Accounts receivable and other current assets	6,126	4,226
Total current assets	152,854	151,139
Property and equipment, net of accumulated depreciation	4,853	5,070
Investments in marketable securities, non-current	31,790	37,363
Right of use asset	1,665	1,744
Other non-current assets	62	103
Total assets	$ 191,224	$ 195,419
Accounts payable and accrued liabilities	$ 9,653	$ 16,029
Deferred license revenue, current	15,055	16,456
Lease liability, current	446	372
Total current liabilities	25,154	32,857
Liability related to sale of future royalties	9,384	10,365
Deferred license revenue, non-current	3,296	5,999
Contingent consideration	7,804	7,531
Lease liability, non-current	1,671	1,815
Total stockholders' equity	143,915	136,852
Total liabilities and stockholders' equity	$ 191,224	$ 195,419

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Three Months Ended March 31,	
	2023	2022
Net loss	$ (16,339)	$ (15,765)
Non-cash items	1,372	1,642
Change in deferred license revenue	(4,104)	38,840
Other changes in working capital	(8,230)	(4,098)
Net cash (used in) provided by operating activities	(27,301)	20,619
Net cash provided by (used in) investing activities	16,678	(60,056)
Issuance of common shares pursuant to Share Purchase Agreement	—	10,973
Issuance of common shares pursuant to the Open Market Sale Agreement	19,862	268
Cash provided by other financing activities	555	244
Net cash provided by financing activities	20,417	11,485
Effect of foreign exchange rate changes on cash and cash equivalents	4	-
Increase (decrease) in cash and cash equivalents	9,798	(27,952)
Cash and cash equivalents, beginning of period	30,776	109,282
Cash and cash equivalents, end of period	40,574	81,330

Investments in marketable securities	137,944	153,500
Cash, cash equivalents and marketable securities, end of period	$ 178,518	$ 234,830

Conference Call and Webcast Today

Arbutus will hold a conference call and webcast today, Thursday, May 4, 2023, 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

AB-101 is our lead oral PD-L1 inhibitor candidate that we believe will allow for controlled checkpoint blockade and enable oral dosing, while minimizing the systemic safety issues typically seen with checkpoint antibody therapies. 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. Preclinical data generated thus far indicates that AB-101 mediates activation and reinvigoration of HBV-specific T-cells from cHBV patients. We believe AB-101, when used in combination with other approved and investigational agents, could potentially lead to a functional cure in HBV chronically infected patients. We are also exploring oncology applications for our internal PD-L1 portfolio.

About AB-161

AB-161 is our next generation oral small molecule RNA destabilizer, specifically designed to target the liver. Mechanistically, RNA destabilizers target the host proteins PAPD5/7, which are involved in regulating the stability of HBV RNA transcripts. In doing so, RNA destabilizers lead to the selective degradation of HBV RNAs, thus reducing HBsAg levels and inhibiting viral replication. To provide a proprietary all-oral treatment regimen for patients with cHBV, we believe inclusion of a small molecule RNA destabilizer is key.

About AB-343

AB-343 is our lead coronavirus drug candidate that inhibits the SARS-CoV-2 main protease (M^{pro}), a validated target for the treatment of COVID-19 and potential future coronavirus outbreaks. In our pre-clinical research conducted to date, AB-343 has shown pan-coronavirus antiviral activity, no reduction in potency against known SARS-CoV-2 variants, robust activity against SARS-CoV-2 M^{pro} resistant strains, and a favorable drug-drug interaction profile with no need for ritonavir boosting. We see an opportunity to pursue a potential combination therapeutic strategy focusing on M^{pro} and nsp12 viral polymerase targets to reduce hospitalizations, achieve better patient treatment outcomes and provide pre-exposure prophylactic therapy.

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 Coronaviruses

Coronaviruses are a large family of viruses that range from the common cold to more severe diseases such as severe acute respiratory syndrome (SARS), Middle East respiratory syndrome (MERS), and COVID-19. COVID-19 has caused approximately 7.2 million deaths globally according to an analysis by the Institute for Health Metrics and Evaluation (IHME). As we strive to identify and develop new antiviral small molecules to treat COVID-19 and future coronavirus outbreaks, we have focused our research efforts on two essential targets critical for replication across all coronaviruses – nsp5 protease and nsp12 polymerase.

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. AB-729 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 coronaviruses, (including SARS-CoV-2), for which we have nominated a compound and have begun IND-enabling pre-clinical studies. In addition, we are also 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 our anticipated net cash burn, 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.

Contact Information

Investors and Media
Lisa M. Caperelli
Vice President, Investor Relations
Phone: 215-206-1822
Email: lcaperelli@arbutusbio.com