Arbutus Reports Second Quarter 2023 Financial Results and Corporate Update

August 3, 2023

Regulatory approval received in New Zealand to advance AB-101, our oral PD-L1 inhibitor, into a Phase 1 clinical trial with dosing to begin this quarter

AB-729 (imdusiran), in combination with pegylated interferon alfa-2a, in a Phase 2a clinical trial, was generally well tolerated and appears to result in continued HBsAg declines in some patients

First patient dosed in additional arm of Phase 2a clinical trial combining imdusiran, VTP-300, NA therapy and nivolumab – advancing towards goal of further stimulating host HBV-associated immunity

Cash runway into the first quarter of 2025

Conference Call and Webcast Today at 8:45 AM ET

WARMINSTER, Pa., Aug. 03, 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 second quarter 2023 financial results and provided a corporate update.

"In the second quarter of 2023, we achieved two important milestones in our Phase 2a clinical trials that support our efforts in developing AB-729 (imdusiran), our lead RNAi therapeutic, as a cornerstone therapy in a functional cure treatment regimen for HBV," said William Collier, Arbutus President and Chief Executive Officer. "First, we reported data from our Phase 2a clinical trial showing that imdusiran in combination with interferon, is well tolerated and appears to result in continued HBsAg declines in some patients. Second, we made solid progress towards our goal of further stimulating host HBV-associated immunity, as we dosed the first patient in the additional treatment arm of the ongoing Phase 2a trial assessing the addition of low-dose nivolumab, a PD-1 monoclonal antibody, to VTP-300 and imdusiran."

Mr. Collier continued, "Regarding our early-stage HBV assets, we are now prepared to move AB-101 forward into a Phase 1 clinical trial in New Zealand, which we expect to initiate this quarter, and AB-161, our oral RNA destabilizer, is in an on-going Phase 1 clinical trial. Additionally, we are on-track to complete IND-enabling studies with our coronavirus M^{pro} inhibitor candidate, AB-343, as well as initiate IND-enabling studies for a coronavirus nsp12 inhibitor candidate in the second half of this year."

Pipeline Updates and Key Milestones

Imdusiran (AB-729, RNAi Therapeutic)

- At the European Association for the Study of the Liver (EASL) Congress, we presented data from our on-going Phase 2a clinical trial (AB-729-201), evaluating the safety, tolerability and antiviral activity of the combination of imdusiran and pegylated interferon alfa-2a (IFN) in patients with chronic hepatitis B virus (cHBV). Preliminary data suggests that the addition of IFN to imdusiran was generally well tolerated and appears to result in continued HBsAg declines in some patients. The mean HBsAg decline from baseline during the imdusiran lead-in phase was 1.6 $\log_{10}$ at week 24 of treatment which is comparable to what was previously seen in other imdusiran clinical trials. Four patients reached HBsAg below the lower limit of quantitation (LLOQ) at some point during IFN treatment. We plan to provide a further update on this clinical trial when we have additional meaningful patient data.
- We have completed enrollment in the first group of our Phase 2a clinical trial (AB-729-202) that is evaluating imdusiran, nucleos(t)ide analogue (NA) therapy and Vaccitech's HBV antigen-specific immunotherapeutic, VTP-300. Preliminary data from patients in the clinical trial are expected in the second half of 2023.

  We recently expanded the AB-729-202 clinical trial to enroll 20 patients who will receive imdusiran (60mg every 8 weeks) plus NA therapy for 24 weeks followed by VTP-300 plus up to two doses of low-dose nivolumab (Opdivo®). In June 2023, we announced that the first patient received the first dose of imdusiran in this additional arm. Preliminary data from this additional treatment arm are expected in 2024.

AB-161 (Oral RNA destabilizer)

- The Phase 1 clinical trial with AB-161 is on-going with single-ascending dose data 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. Recently reported preclinical data showed that AB-161 provides robust anti-HBV activity including suppression of HBV RNA and HBsAg production *in vitro* and *in vivo*.

AB-101 (Oral PD-L1 Inhibitor)

- In April 2023, AB-101 was placed on clinical hold by the U.S. Food and Drug Administration (FDA) during the Investigational New Drug (IND) application review process prior to dosing subjects. In July 2023, the New Zealand Medicine and Medical Device Safety Authority (Medsafe) approved our CTA application for a Phase 1 clinical trial in New Zealand for AB-101, and we believe the protocol approved by Medsafe adequately addresses the clinical trial design and safety monitoring issues raised by the FDA. We are planning to initiate the Phase 1 clinical trial this quarter. We are developing AB-101 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

- We are continuing to conduct IND-enabling studies with AB-343 and are on track to complete those studies in the second half of 2023.
- We are continuing to direct our research efforts to identifying an nsp12 viral polymerase inhibitor 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 inhibitor clinical candidate and initiate IND-enabling studies in the second half of 2023.

Corporate Updates

- In July 2023, we announced that Melissa V. Rewolinski, PhD was appointed to the Board of Directors. Melissa brings to the Board more than 20 years of strategic, operational and drug development experience within the pharmaceutical industry.
- In July 2023, we announced the promotion of Karen Sims, MD, PhD to Chief Medical Officer. Karen is a board-certified infectious disease physician with more than 12 years of industry experience in conducting and overseeing early stage through global Phase 2 clinical trials. She joined Arbutus in April 2017 and has held positions of increasing seniority, including most recently as Vice President, Clinical Development, before being promoted to Chief Medical Officer.
- In July 2023, we also announced the appointment of Christopher Naftzger as General Counsel and Chief Compliance Officer. Chris succeeds Dr. Elizabeth Howard who will continue in an advisory role with respect to the on-going patent infringement litigations. Chris brings more than 25 years of legal experience, including over a decade of experience serving in senior in-house counsel positions with life science companies.

Financial Results

Cash, Cash Equivalents and Investments

As of June 30, 2023, we had cash, cash equivalents and investments in marketable securities of $163.5 million compared to $184.3 million as of December 31, 2022. During the six months ended June 30, 2023, we used $46.9 million in operating activities, which was partially offset by $24.6 million of net proceeds from the issuance of common shares under our “at-the-market” offering program. We expect our 2023 net cash burn to range from between $90 to $95 million, excluding any proceeds received from our “at the market program”. We believe our cash runway will be sufficient to fund our operations into the first quarter of 2025.

Revenue

Total revenue was $4.7 million for the three months ended June 30, 2023 compared to $14.2 million for the same period in 2022. The decrease of $9.5 million for the 2023 period was due primarily to lower revenue recognition from our license agreement with Qilu compared to the 2022 period based on lower employee labor hours expended by us in the 2023 period compared to the 2022 period to perform our manufacturing obligations under the license agreement.

Operating Expenses

Research and development expenses were $17.7 million for the three months ended June 30, 2023 compared to $22.9 million for the same period in 2022. The decrease of $5.2 million was due primarily to a decrease in expenses for drug supply manufacturing for our imdusiran, AB-101 and AB-161 clinical trials, as well as a decrease in expenses related to our AB-836 Phase 1a/1b clinical trial, which was discontinued in the fourth quarter of 2022. These were partially offset by an increase in expenses for our coronavirus program, including drug supply manufacturing. General and administrative expenses were $6.0 million for the three months ended June 30, 2023, compared to $5.2 million for the same period in 2022. This increase was due primarily to increases in non-cash stock-based compensation expense and professional fees.

Net Loss

For the three months ended June 30, 2023, our net loss was $17.1 million, or a loss of $0.10 per basic and diluted common share, as compared to a net loss of $14.2 million, or a loss of $0.10 per basic and diluted common share, for the three months ended June 30, 2022.

Outstanding Shares

As of June 30, 2023, we had approximately 166.9 million common shares issued and outstanding, as well as approximately 20.2 million stock options and unvested restricted stock units outstanding. Roivant Sciences Ltd. owned approximately 23% of our outstanding common shares as of June 30, 2023.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Revenue				
Collaborations and licenses	$ 3,885	$ 12,556	$ 9,394	$ 23,774
Non-cash royalty revenue	766	1,685	1,944	3,048
Total revenue	**4,651**	**14,241**	**11,338**	**26,822**
Operating expenses				
Research and development	17,692	22,942	35,967	41,404
General and administrative	5,980	5,200	11,532	10,092
Change in fair value of contingent consideration	(636)	208	(363)	409
Total operating expenses	**23,036**	**28,350**	**47,136**	**51,905**
Loss from operations	(18,385)	(14,109)	(35,798)	(25,083)
Other income (loss)				
Interest income	1,461	396	2,729	555
Interest expense	(171)	(482)	(369)	(988)
Foreign exchange gain	1	3	5	3
Total other income (loss)	1,291	(83)	2,365	(430)
Loss before income taxes	(17,094)	(14,192)	(33,433)	(25,513)
Income tax expense	—	—	—	(4,444)
Net loss	**$ (17,094)**	**$ (14,192)**	**$ (33,433)**	**$ (29,957)**
Net loss per common share				
Basic and diluted	$ (0.10)	$ (0.10)	$ (0.20)	$ (0.20)
Weighted average number of common shares				
Basic and diluted	166,063,284	148,750,048	163,855,661	148,589,711

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	June 30, 2023	December 31, 2022
Cash, cash equivalents and marketable securities, current	$ 152,484	$ 146,913
Accounts receivable and other current assets	6,316	4,226
Total current assets	158,800	151,139
Property and equipment, net of accumulated depreciation	5,370	5,070
Investments in marketable securities, non-current	11,057	37,363
Right of use asset	1,585	1,744
Other non-current assets	11	103
Total assets	**$ 176,823**	**$ 195,419**
Accounts payable and accrued liabilities	$ 8,805	$ 16,029
Deferred license revenue, current	15,327	16,456
Lease liability, current	397	372
Total current liabilities	24,529	32,857
Liability related to sale of future royalties	8,787	10,365
Deferred license revenue, non-current	—	5,999
Contingent consideration	7,168	7,531
Lease liability, non-current	1,646	1,815
Total stockholders' equity	134,693	136,852
Total liabilities and stockholders' equity	**$ 176,823**	**$ 195,419**

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Six Months Ended June 30,	
	2023	**2022**
Net loss	$ (33,433)	$ (29,957)
Non-cash items	2,911	3,154

Change in deferred license revenue	(7,128)	27,815
Other changes in working capital	(9,210)	(686)
Net cash (used in) provided by operating activities	**(46,860)**	**326**
Net cash provided by (used in) investing activities	18,119	(73,886)
Issuance of common shares pursuant to Share Purchase Agreement	—	10,973
Issuance of common shares pursuant to the Open Market Sale Agreement	24,604	268
Cash provided by other financing activities	555	357
Net cash provided by financing activities	25,159	11,598
Effect of foreign exchange rate changes on cash and cash equivalents	3	—
Decrease in cash and cash equivalents	(3,579)	(61,962)
Cash and cash equivalents, beginning of period	30,776	109,282
Cash and cash equivalents, end of period	27,197	47,320
Investments in marketable securities	136,344	153,329
Cash, cash equivalents and marketable securities, end of period	**$ 163,541**	**$ 200,649**

Conference Call and Webcast Today

Arbutus will hold a conference call and webcast today, Thursday, August 3, 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 imdusiran (AB-729)

Imdusiran 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. Imdusiran 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 imdusiran to be generally safe and well-tolerated, while also providing meaningful reductions in hepatitis B surface antigen and hepatitis B DNA. Imdusiran 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, imdusiran (AB-729), is the only RNAi therapeutic with evidence of immune re-awakening. Imdusiran 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; statements regarding our plans for AB-101 in light of the FDA's clinical hold; 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 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; it may take considerable time and expense to resolve the clinical hold that has been placed on AB-101 by the FDA, and no assurance can be given that the FDA will remove the clinical hold; Arbutus and its collaborators may never realize the expected benefits of the collaborations; and market shifts may require a change in strategic focus.

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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