Arbutus Reports Fourth Quarter and Year End 2022 Financial Results and Corporate Update

March 2, 2023

Significant progress made advancing proprietary programs in chronic HBV and Coronavirus

AB-729 data from multiple Phase 2a combination clinical trials expected in 2023

Initial Phase 1 data for oral PD-L1, AB-101, and oral RNA Destabilizer, AB-161, expected in the second half of 2023

Initiate Phase 1 clinical trial for oral M^{pro} coronavirus candidate, AB-343, expected in the second half of 2023

Strengthened financial position – cash runway into Q4 2024

Conference Call and Webcast Today at 8:45 AM ET

WARMINSTER, Pa., March 02, 2023 (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 reported fourth quarter and year end 2022 financial results and provided a corporate update.

"In 2022 we focused on three key initiatives: exploring several combination therapies with AB-729, our RNAi therapeutic, as a potential cornerstone agent in a functional cure for hepatitis B virus; advancing our preclinical HBV compounds AB-101, our oral PD-L1 inhibitor, and AB-161, our oral RNA destabilizer; and identifying a clinical candidate that inhibits the SARS-CoV-2 nsp5 main protease," said William Collier, Arbutus' President and Chief Executive Officer. "With promising AB-729 data in-hand and plans to initiate phase 1 clinical trials with AB-101, AB-161 and our newly nominated pan-coronavirus M^{pro} compound, AB-343, we achieved our 2022 corporate objectives and are now well-positioned to further execute on these strategic initiatives to deliver multiple clinical milestones this year. The need for a functional cure for patients with cHBV and alternatives to treat COVID-19 and future coronavirus outbreaks remains urgent, and we look forward to advancing our pipeline to address these large global market opportunities."

Pipeline Updates and Key Milestones

AB-729 (RNAi Therapeutic)

- In the first half of 2023, we anticipate announcing additional off-treatment data from those patients in our Phase 1b clinical trial, AB-729-001, who have discontinued both AB-729 and nucleos(t)ide analogue (NA) therapy. Recently, one of the patients has met the protocol-defined HBV DNA criteria to restart their NA therapy. We are continuing to follow the seven patients who remain off-treatment.
- To assess AB-729 as a potential cornerstone agent in a functional cure for cHBV, we are conducting a Phase 2a clinical trial, AB-729-201, evaluating 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 cHBV infection. 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 first half of 2023.
- We are conducting a Phase 2a clinical trial, AB-729-202, evaluating AB-729, NA therapy and Vaccitech's antigen-specific immunotherapeutic, VTP-300. We have recently amended the clinical trial to include an additional arm with an approved PD-1 inhibitor, nivolumab (Opdivo®). Upon regulatory approval of the amendment, 20 patients will receive AB-729 (60mg every 8 weeks) plus NA therapy for 24 weeks, followed by VTP-300 plus a low dose of nivolumab in conjunction with the booster dose(s) only while remaining on their NA therapy. At week 48, all patients will be evaluated for eligibility to discontinue NA therapy and will be followed for an additional 24-48 weeks. We expect to dose the first patient in the amended arm in the first half of 2023 and announce preliminary data from patients who receive AB-729, NA and VTP-300 in the second half of 2023.
- Through our collaboration with Assembly Biosciences Inc., (Assembly), we are conducting a Phase 2a proof-of-concept clinical trial evaluating AB-729 in combination with Assembly's first-generation HBV core inhibitor, vebicorvir (VBR) and NA therapy. Preliminary data from sixty-five patients in the trial showed that the addition of VBR did not positively or negatively impact the reduction of HBsAg in the triple arm combination. Accordingly, we have mutually agreed to discontinue the clinical trial following completion of the final, on-treatment visit at week 48.

AB-101 (Oral PD-L1 Inhibitor)

- To reawaken and boost the immune system of patients with cHBV, we are developing AB-101, our oral PD-L1 inhibitor. 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. We expect to initiate a Phase 1 healthy subject clinical trial with AB-101 in the first half of 2023 with data from the single-ascending dose portion of this trial expected in the second half of 2023.

AB-161 (Oral RNA destabilizer)

- AB-161 is our next-generation oral HBV specific RNA destabilizer, which is being developed to create an all-oral treatment regimen to functionally cure HBV. Preclinical data generated thus far shows that AB-161 is effective as a once-daily dose in reducing HBsAg in an HBV mouse model. We expect to initiate a Phase 1 healthy subject clinical trial with AB-161 in the first half of 2023 with single-ascending dose data expected in the second half of 2023.

COVID-19 and Pan-Coronavirus Programs

- We have nominated, AB-343 as our lead coronavirus drug candidate that inhibits the main protease (M^{pro}). In pre-clinical research conducted thus far, 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 expect to complete IND-enabling studies and initiate a Phase 1 clinical trial with AB-343 in the second half of 2023.
- Our research efforts directed to identifying an nsp12 viral polymerase clinical candidate are continuing. 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 a nsp12 clinical candidate and initiate IND-enabling studies in the second half of 2023.

Financial Results

Cash, Cash Equivalents and Investments

As of December 31, 2022, we had cash, cash equivalents and investments in marketable securities of $184.3 million as compared to $191.0 million as of December 31, 2021.

During the year ended December 31, 2022, we 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 us and $20.3 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 $79.4 million of cash used in operations. We expect a net cash burn between $95 to $100 million in 2023 and believe our cash runway will be sufficient to fund our operations into the fourth quarter of 2024.

Revenue

Total revenue was $39.0 million for the year ended December 31, 2022 compared to $11.0 million for the same period in 2021. The increase of $28.0 million was due primarily to $26.0 million of revenue recognition from our license agreement with Qilu based on employee labor hours expended by us during 2022 to perform our manufacturing obligations under the license agreement.

Operating Expenses

Research and development expenses were $84.4 million for the year ended December 31, 2022 compared to $65.5 million for the same period in 2021. The increase of $18.9 million was due primarily to an increase in expenses related to our multiple ongoing AB-729 Phase 2a clinical trials, an increase in expenses for our early-stage development programs, including AB-101 and AB-161, and an increase in compensation costs due to hiring several new employees for our research and development team in early 2022, partially offset by a decrease in expenses for our AB-836 Phase 1a/1b clinical trial, which we discontinued during the fourth quarter of 2022.

Net Loss

For the year ended December 31, 2022, our net loss attributable to common shares was $69.5 million, or a loss of $0.46 per basic and diluted common share, as compared to a net loss of $88.4 million, or a loss of $0.83 per basic and diluted common share, for the year ended December 31, 2021. Net loss attributable to common shares for the year ended December 31, 2021 included $12.1 million of non-cash expense for the accrual of coupon on our convertible preferred shares, which converted into 22.8 million common shares in October 2021.

Outstanding Shares

As of December 31, 2022, we had approximately 157.5 million common shares issued and outstanding, as well as approximately 15.5 million stock options outstanding. Roivant Sciences Ltd. owned approximately 25% of our outstanding common shares as of December 31, 2022.

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

	Year ended December 31,	
	2022	**2021**
Revenue		
Collaborations and licenses	$ 31,366	$ 4,880
Non-cash royalty revenue	7,653	6,108
Total revenue	39,019	10,988
Operating expenses		
Research and development	84,408	65,502
General and administrative	17,834	17,136

Change in fair value of contingent consideration	2,233	1,872
Total operating expenses	104,475	84,510
Loss from operations	(65,456)	(73,522)
Other income (loss)		
Interest income	2,192	127
Interest expense	(1,726)	(2,857)
Foreign exchange (losses) gains	(22)	5
Total other income (loss)	444	(2,725)
Loss before income taxes	(65,012)	(76,247)
Income tax expense	(4,444)	—
Net loss	(69,456)	(76,247)
Items applicable to preferred shares		
Dividend accretion of convertible preferred shares	—	(12,139)
Net loss attributable to common shares	$ (69,456)	$ (88,386)
Net loss per common share		
Basic and diluted	$ (0.46)	$ (0.83)
Weighted average number of common shares		
Basic and diluted	150,939,337	106,242,452

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	December 31, 2022	December 31, 2021
Cash, cash equivalents and marketable securities, current	$ 146,913	$ 155,317
Accounts receivable and other current assets	4,226	5,344
Total current assets	151,139	160,661
Property and equipment, net of accumulated depreciation	5,070	5,983
Investments in marketable securities, non-current	37,363	35,688
Right of use asset	1,744	2,092
Other non-current assets	103	61
Total assets	$ 195,419	$ 204,485
Accounts payable and accrued liabilities	$ 16,029	$ 10,838
Deferred license revenue, current	16,456	—
Lease liability, current	372	383
Total current liabilities	32,857	11,221
Liability related to sale of future royalties	10,365	16,296
Deferred license revenue, non-current	5,999	—
Contingent consideration	7,531	5,298
Lease liability, non-current	1,815	2,231
Total stockholders' equity	136,852	169,439
Total liabilities and stockholders' equity	$ 195,419	$ 204,485

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW
(in thousands)

	Twelve Months Ended December 31,	
	2022	2021
Net loss	$ (69,456)	$ (76,247)
Non-cash items	4,857	7,790
Change in deferred license revenue	22,455	—
Other changes in working capital	6,788	925
Net cash used in operating activities	(35,356)	(67,532)
Net cash used in investing activities	(74,942)	(12,678)
Issuance of common shares pursuant to Share Purchase Agreement	10,973	—
Issuance of common shares pursuant to the Open Market Sales Agreement	20,324	134,665
Cash provided by other financing activities	517	2,571
Net cash provided by financing activities	31,814	137,236
Effect of foreign exchange rate changes on cash and cash equivalents	(22)	5

(Decrease) increase in cash and cash equivalents	(78,506)	57,031
Cash and cash equivalents, beginning of period	109,282	52,251
Cash and cash equivalents, end of period	30,776	109,282
Investments in marketable securities	153,500	81,723
Cash, cash equivalents and marketable securities, end of period	$ 184,276	$ 191,005

Conference Call and Webcast Today

Arbutus will hold a conference call and webcast today, Thursday, March 2, 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 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 robust pan-coronavirus antiviral activity, no reduction in potency against known SARS-CoV-2 variants, and 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.

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