Arbutus Reports First Quarter 2022 Financial Results and Provides Corporate Update

May 5, 2022

Key milestones across our chronic hepatitis B virus (cHBV) and pan-coronavirus programs remain on track

Well positioned financially with a projected cash runway into the second quarter of 2024

Conference Call and Webcast Today at 8:45 AM ET

WARMINSTER, Pa., May 05, 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 first quarter 2022 financial results and provides pipeline updates.

“In the first quarter of 2022, we continued to advance our efforts to develop a functional cure for hepatitis B and to develop novel treatment options for coronavirus infections, including SARS-CoV-2,” said William Collier, Arbutus’ President and Chief Executive Officer. “We are on-track to achieve our goal of reporting data later this year from four clinical trials with chronically infected HBV patients being treated with either AB-729, our RNAi therapeutic, or AB-836, our next generation oral capsid inhibitor. Furthermore, our IND-enabling studies with our oral PD-L1 inhibitor, AB-101, and our oral RNA destabilizer, AB-161, are moving forward and we expect these to be completed in the second half of 2022. Additionally, we have had seven abstracts accepted at the EASL International Liver Congress™, which include some of these data.”

Mr. Collier continued, “With respect to our research efforts to develop a nsp5 main protease (M^{pro}) and nsp12 viral polymerase for SARS-CoV-2 and future coronavirus outbreaks, we are on-track to initiate IND-enabling studies for a nsp5 M^{pro} candidate later this year. Lead optimization activities are continuing for a nsp12 viral polymerase candidate. Financially, we are well-positioned to continue advancing all our current clinical programs through important data milestones with a projected cash runway into the second quarter of 2024.”

Anticipated Milestones in 2022:

- Dose first patient in the AB-729-202 Phase 2a clinical trial evaluating AB-729, in combination with VTP-300, Vaccitech plc’s (Vaccitech) therapeutic vaccine and nucleos(t)ide analogue therapy (NA), in cHBV patients in the first half of 2022.
- Present new on-treatment data as well as long-term off-treatment data for cHBV patients in the AB-729-001 clinical trial at a medical conference later this year.
- Report initial data from the AB-729-201 Phase 2a clinical trial evaluating AB-729 in combination with ongoing NA therapy and short courses of PEG-IFNα-2a in cHBV patients in the second half of 2022.
- Report initial data from the Phase 2a clinical trial evaluating AB-729 in combination with vebicorvir (VBR), Assembly Biosciences, Inc.’s (Assembly) lead HBV core inhibitor (capsid inhibitor), and an NA in cHBV patients in the second half of 2022.
- Report data set from the AB-836-001 clinical trial evaluating multiple doses of AB-836 in cHBV patients in the first half of 2022.
- Complete IND-enabling studies for two oral compounds (PD-L1 inhibitor, AB-101 and RNA destabilizer, AB-161) to treat HBV in the second half of 2022.
- Advance an oral compound that inhibits the SARS-CoV-2 nsp5 main protease into IND enabling studies in the second half of 2022.
- Continue to explore a potential oncology indication with our oral PD-L1 program.

Financial Results

Cash, Cash Equivalents and Investments

As of March 31, 2022, the Company had cash, cash equivalents and investments in marketable securities of $221.8 million, as compared to $191.0 million as of December 31, 2021.

During the three months ended March 31, 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 and $0.3 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 $23.4 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

Revenues were $12.6 million for the three months ended March 31, 2022 compared to $2.1 million for the same period in 2021. The increase of $10.5 million was due primarily to $9.6 million of revenue recognition from the Company's license agreement with Qilu based on employee labor hours expended by the Company during the first quarter of 2022 to perform its manufacturing obligations under the license agreement.

Net Loss

For the three months ended March 31, 2022, the Company's net loss attributable to common shares was $15.8 million, or a loss of $0.11 per basic and diluted common share, as compared to a net loss attributable to common shares of $19.6 million, or a loss of $0.21 per basic and diluted common share, for the three months ended March 31, 2021. Net loss attributable to common shares for the three months ended March 31, 2021 included $3.2 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.

Operating Expenses

Research and development expenses were $18.5 million for the three months ended March 31, 2022 compared to $13.8 million for the same period in 2021. The increase of $4.7 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, an increase in expenses for its ongoing AB-836-001 clinical trial, and an increase in expenses for its early stage development programs, including AB-101 and AB-161. General and administrative expenses were $4.9 million for the three months ended March 31, 2022 compared to $3.9 million for the same period in 2021. This increase was due primarily to increases in professional fees, employee compensation and non-cash stock-based compensation expense.

Outstanding Shares

As of March 31, 2022, the Company had approximately 148.7 million common shares issued and outstanding, as well as approximately 15.7 million stock options outstanding. Roivant Sciences Ltd. owned approximately 26% of the Company's outstanding common shares as of March 31, 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 we have been able to progress with our clinical and pre-clinical activities to date, it is not possible to predict if the COVID-19 pandemic will materially impact our plans and timelines in the future.

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

	Three Months Ended March 31,	
	2022	**2021**
Revenue		
Revenue from collaborations and licenses	$ 11,218	$ 1,154
Non-cash royalty revenue	1,363	959
Total revenue	12,581	2,113
Operating expenses		
Research and development	18,462	13,782
General and administrative	4,892	3,878
Change in fair value of contingent consideration	201	129
Total operating expenses	23,555	17,789
Loss from operations	(10,974)	(15,676)
Other income (loss)		
Interest income	159	39
Interest expense	(506)	(772)
Foreign exchange (losses) gains	-	28
Total other loss	(347)	(705)
Net loss before income tax expense	(11,321)	(16,381)
Income tax expense	(4,444)	-
Net loss	$ (15,765)	$ (16,381)
Dividend accretion of convertible preferred shares	-	(3,212)
Net loss attributable to common shares	$ (15,765)	$ (19,593)
Net loss per common share		
Basic and diluted	$ (0.11)	$ (0.21)
Weighted average number of common shares		
Basic and diluted	148,428,326	93,434,378

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	March 31, 2022	December 31, 2021
Cash, cash equivalents and marketable securities, current	$ 165,477	$ 155,317
Accounts receivable and other current assets	7,221	5,344
Total current assets	172,698	160,661
Property and equipment, net of accumulated depreciation	5,664	5,983
Investments in marketable securities, non-current	56,318	35,688
Right of use asset	2,007	2,092
Other non-current assets	190	61
Total assets	$ 236,877	$ 204,485
Accounts payable and accrued liabilities	$ 8,715	$ 10,838
Deferred revenue	23,255	-
Lease liability, current	439	383
Total current liabilities	32,409	11,221
Liability related to sale of future royalties	15,439	16,296
Deferred revenue, non-current	15,585	-
Contingent consideration	5,499	5,298
Lease liability, non-current	2,100	2,231
Total stockholders' equity	165,845	169,439
Total liabilities and stockholders' equity	$ 236,877	$ 204,485

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW
(in thousands)

	Three Months Ended March 31,	
	2022	2021
Net loss	$ (15,765)	$ (16,381)
Non-cash items	1,642	2,222
Change in deferred license revenue	38,840	-
Other changes in working capital	(4,098)	(3,722)
Net cash provided by (used in) operating activities	20,619	(17,881)
Net cash (used in) provided by investing activities	(60,056)	18,221
Issuance of common shares pursuant to Share Purchase Agreement	10,973	-
Cash provided by other financing activities	512	26,874
Net cash provided by financing activities	11,485	26,874
Effect of foreign exchange rate changes on cash and cash equivalents	-	(44)
(Decrease) Increase in cash and cash equivalents	(27,952)	27,170
Cash and cash equivalents, beginning of period	109,282	52,251
Cash and cash equivalents, end of period	81,330	79,421
Investments in marketable securities	140,465	52,540
Cash, cash equivalents and marketable securities, end of period	$ 221,795	$ 131,961

Conference Call and Webcast Today

Arbutus will hold a conference call and webcast today, Thursday, May 5, 2022, 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: 6287124.

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: 6287124.

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. AB-729 is currently in multiple Phase 2a clinical trials.

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. Preliminary data from an on-going Phase 1a/1b clinical trial has shown that AB-836 is generally safe and well-tolerated and provides robust antiviral activity.

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. In HBV, we are developing an RNAi therapeutic, oral capsid inhibitor, oral PD-L1 inhibitor, and oral RNA destabilizer that we intend to combine to provide 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, and is currently being evaluated in multiple phase 2 clinical trials. We have an ongoing drug discovery and development program directed to identifying novel, orally active agents for treating coronavirus (including SARS-CoV-2). 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 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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