Arbutus Reports Fourth Quarter and Year End 2023 Financial Results and Provides Corporate Update

February 29, 2024

On-track to report key clinical data in 2024 from two on-going Phase 2a clinical trials with imdusiran and the Phase 1a/1b clinical trial with AB-101

Plans to initiate a third Phase 2a clinical trial with imdusiran in first half of 2024

Claim Construction for Moderna LNP litigation occurred on February 8, 2024; trial date set for April 21, 2025

Strong financial position with cash and investments of $132M; cash runway into Q1 2026

Conference Call and Webcast Today at 8:45 am ET

WARMINSTER, Pa., Feb. 29, 2024 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS) ("Arbutus" or the "Company"), a clinical-stage biopharmaceutical company leveraging its extensive virology expertise to develop a functional cure for people with chronic hepatitis B virus (cHBV) infection, today reports fourth quarter and year end 2023 financial results and provides a corporate update.

"I anticipate that 2024 will be a productive year for Arbutus as we continue to advance the development of our HBV assets: imdusiran, our RNAi therapeutic, and AB-101, our oral checkpoint inhibitor," said Michael J. McElhaugh, Interim President and Chief Executive Officer of Arbutus Biopharma. "To date, we have dosed more than 170 HBV patients with imdusiran and continue to see notable and sustained reductions in surface antigen. We believe that a combination therapy that reduces surface antigen, suppresses HBV DNA and boosts the host immune response will be necessary to functionally cure HBV. We are currently evaluating imdusiran with other immune modulators and expect multiple data readouts this year, including the potential to see undetectable surface antigen at end of treatment. These trials, in addition to our plans to initiate an imdusiran + durvalumab clinical trial, will help inform our later stage clinical development program in addition to the dose and dosing duration for AB-101, potentially expediting imdusiran + AB-101 combinations."

2024 Clinical Development Milestones

Imdusiran (AB-729, RNAi Therapeutic)

- AB-729-201 is a Phase 2a clinical trial that is evaluating the safety, tolerability and antiviral activity of the combination of imdusiran, nucleos(t)ide analogue (NA) therapy and pegylated interferon alfa-2a (IFN) in patients with cHBV. Preliminary data presented at the EASL Congress in June 2023 suggest that the addition of IFN to imdusiran was generally well-tolerated and appears to result in continued HBsAg declines in some patients. Arbutus plans to announce end-of-treatment data from this trial in the first half of 2024.
- AB-729-202 is a Phase 2a clinical trial that is evaluating the safety and immunogenicity of imdusiran, NA therapy and Barinthus Bio's (formerly Vaccitech plc) VTP-300, an HBV antigen-specific immunotherapy. Preliminary data presented at AASLD – The Liver Meeting in November 2023 showed that the combination of imdusiran and VTP-300 provided a meaningful reduction of HBsAg levels that are maintained well below baseline. In addition, a subset of patients given imdusiran and then VTP-300 showed early signs of immune activation. Arbutus plans to announce end-of-treatment data from this portion of the trial in the first half of 2024.
- AB-729-202 was amended to include an additional cohort of 20 patients who will receive imdusiran plus NA therapy for 24 weeks followed by VTP-300 plus up to two low doses of nivolumab, an approved anti-PD-1 monoclonal antibody. Preliminary data from this additional cohort are expected in the second half of 2024.
- AB-729-203 is a Phase 2a clinical trial that Arbutus intends to initiate in the first half of 2024 to evaluate the safety, tolerability and antiviral activity of intermittent low doses of durvalumab, an approved anti-PD-L1 monoclonal antibody in combination with imdusiran and NA therapy. Insights gained from this clinical trial and the amended portion of the AB-729-202 clinical trial with nivolumab, may inform dosing for the planned imdusiran plus AB-101 Phase 2 clinical trial.

AB-101 (Oral PD-L1 Inhibitor)

- AB-101-001 is a Phase 1a/1b double-blind, randomized, placebo-controlled clinical trial designed to investigate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of single- and multiple-ascending oral doses of AB-101 for up to 28 days in healthy subjects and patients with cHBV. Arbutus is advancing AB-101 into part two of this clinical trial which involves dosing healthy subjects with multiple-ascending doses of AB-101. Arbutus expects to report preliminary data from the healthy subject portion of this clinical trial, including target engagement and receptor occupancy data, in the first half of 2024.

LNP Litigation Update:

- Arbutus continues to protect and defend its intellectual property, which is the subject of the on-going lawsuits against Moderna and Pfizer/BioNTech. The Company is seeking fair compensation for Moderna's and Pfizer/BioNTech's use of its patented LNP technology that was developed with great effort and at a great expense, without which Moderna and Pfizer/BioNTech's COVID-19 vaccines would not have been successful. With respect to the Moderna lawsuit, fact discovery is on-going and the claim construction hearing occurred on February 8, 2024. According to the Court Scheduling Order, which was issued on March 21, 2023, the court is expected to issue its claim construction order within 60 days of conclusion of the claim construction hearing. Expert testimony and depositions will then follow. A trial date has been set for April 21, 2025 and is subject to the Court's availability. The lawsuit against Pfizer/BioNTech is ongoing and a date for a claim construction hearing has not been set.

Financial Results

Cash, Cash Equivalents and Investments

As of December 31, 2023, the Company had cash, cash equivalents and investments in marketable securities of $132.3 million compared to $184.3 million as of December 31, 2022. During the year ended December 31, 2023, the Company used $85.9 million in operating activities, which was partially offset by $29.9 million of net proceeds from the issuance of common shares under its "at-the-market" offering program. The Company expects its 2024 net cash burn to range from between $63 million to $67 million, excluding any proceeds received from its "at the market" offering program. The Company believes its cash, cash equivalents and investments in marketable securities of $132.3 million as of December 31, 2023, are sufficient to fund its operations into the first quarter of 2026.

Revenue

Total revenue was $18.1 million for the year ended December 31, 2023, compared to $39.0 million for the same period in 2022. The decrease of $20.9 million was due primarily to a decrease in revenue recognition from the Company's license agreement with Qilu, the Company's collaboration partner in China, Hong Kong, Macau and Taiwan, based on a decrease in employee labor hours expended by the Company during 2023 compared to 2022 to perform its manufacturing obligations under the license agreement. Additionally, license royalty revenues decreased in 2023 compared to 2022 due to a decrease in Alnylam's sales of ONPATTRO.

Operating Expenses

Research and development expenses were $73.7 million for the year ended December 31, 2023 compared to $84.4 million for the same period in 2022. The decrease of $10.7 million was due primarily to: (i) a decrease in manufacturing expenses associated with supplying drug for the Company's clinical trials; and (ii) a decrease in clinical expenses due to the discontinuation of the Company's AB-836 program in 2022; partially offset by (iii) an increase in clinical expenses for the Company's ongoing AB-101 Phase 1a/1b clinical trial in 2023. General and administrative expenses were $22.5 million for the year ended December 31, 2023, compared to $17.8 million for the same period in 2022. This increase was due primarily to an increase in legal fees, non-cash stock-based compensation expense and employee compensation costs.

Net Loss

For the year ended December 31, 2023, our net loss was $72.8 million, or a loss of $0.44 per basic and diluted common share, as compared to a net loss of $69.5 million, or a loss of $0.46 per basic and diluted common share, for the year ended December 31, 2022.

Outstanding Shares

As of December 31, 2023, the Company had 169.9 million common shares issued and outstanding, as well as 20.4 million stock options and unvested restricted stock units outstanding. Roivant Sciences Ltd. owned approximately 23% of the Company's outstanding common shares as of December 31, 2023.

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

	Year Ended December 31,	
	2023	**2022**
Revenue		
Collaborations and licenses	$ 14,274	$ 31,366
Non-cash royalty revenue	3,867	7,653
Total revenue	**18,141**	**39,019**
Operating expenses		
Research and development	73,700	84,408
General and administrative	22,475	17,834
Change in fair value of contingent consideration	69	2,233
Total operating expenses	**96,244**	**104,475**
Loss from operations	(78,103)	(65,456)
Other income (loss)		
Interest income	5,688	2,192

Interest expense	(459)	(1,726)
Foreign exchange gain	25	(22)
Total other income	5,254	444
Loss before income taxes	(72,849)	(65,012)
Income tax expense	—	(4,444)
Net loss	**$ (72,849)**	**$ (69,456)**
Net loss per common share		
Basic and diluted	$ (0.44)	$ (0.46)
Weighted average number of common shares		
Basic and diluted	165,960,379	150,939,337

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	December 31, 2023	December 31, 2022
Cash, cash equivalents and marketable securities, current	$ 126,003	$ 146,913
Accounts receivable and other current assets	6,024	4,226
Total current assets	132,027	151,139
Property and equipment, net of accumulated depreciation	4,674	5,070
Investments in marketable securities, non-current	6,284	37,363
Right of use asset	1,416	1,744
Other non-current assets	—	103
Total assets	**$ 144,401**	**$ 195,419**
Accounts payable and accrued liabilities	$ 10,271	$ 16,029
Deferred license revenue, current	11,791	16,456
Lease liability, current	425	372
Total current liabilities	22,487	32,857
Liability related to sale of future royalties	6,953	10,365
Deferred license revenue, non-current	—	5,999
Contingent consideration	7,600	7,531
Lease liability, non-current	1,343	1,815
Total stockholders' equity	106,018	136,852
Total liabilities and stockholders' equity	**$ 144,401**	**$ 195,419**

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Twelve Months Ended December 31,	
	2023	2022
Net loss	$ (72,849)	$ (69,456)
Non-cash items	5,146	4,857
Change in deferred license revenue	(10,664)	22,455
Other changes in working capital	(7,569)	6,788
Net cash used in operating activities	**(85,936)**	**(35,356)**
Net cash provided by (used in) investing activities	50,773	(74,942)
Issuance of common shares pursuant to Share Purchase Agreement	—	10,973
Issuance of common shares pursuant to the Open Market Sale Agreement	29,852	20,324
Cash provided by other financing activities	795	517
Net cash provided by financing activities	30,647	31,814
Effect of foreign exchange rate changes on cash and cash equivalents	25	(22)
Decrease in cash and cash equivalents	(4,491)	(78,506)
Cash and cash equivalents, beginning of period	30,776	109,282
Cash and cash equivalents, end of period	26,285	30,776
Investments in marketable securities	106,002	153,500

Cash, cash equivalents and marketable securities, end of period	**$ 132,287**	**$ 184,276**

Conference Call and Webcast Today

Arbutus will hold a conference call and webcast today, Thursday, February 29, 2024, 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 multiple 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 oral PD-L1 inhibitor candidate that we believe will allow for controlled checkpoint blockade 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 re-activation of exhausted 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 patients chronically infected with HBV. AB-101 is currently being evaluated in a Phase 1a/1b clinical trial.

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 identify and develop novel therapeutics with distinct mechanisms of action, which can be combined to provide a functional cure for patients with chronic hepatitis B virus (cHBV). We believe the key to success in developing a functional cure involves suppressing HBV DNA, reducing surface antigen, and boosting HBV-specific immune responses. Our pipeline of internally developed, proprietary compounds includes an RNAi therapeutic, imdusiran (AB-729), and an oral PD-L1 inhibitor, AB-101. Imdusiran has generated meaningful clinical data demonstrating an impact on both surface antigen reduction and reawakening of the HBV-specific immune response. Imdusiran is currently in two Phase 2a combination clinical trials. AB-101 is currently being evaluated in a Phase 1a/1b clinical trial. 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; our program updates; our belief that checkpoint inhibitors may play a key role in antiviral immune tolerance in cHBV; 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 clinical trial design and 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; our plans with respect to the ongoing patent litigation matters; and our expected financial condition, including the anticipated duration of cash runways, our expectations regarding our 2024 cash burn and the timing regarding our 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; Arbutus' plans to reduce its net cash burn may not materially extend the cash runway and may create a distraction or uncertainty that may adversely affect its operating results, business, or investor perceptions; and risks related to the sufficiency of Arbutus' cash resources and its ability to obtain adequate financing in the future for its foreseeable and unforeseeable operating expenses and capital expenditures.

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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