Arbutus Reports Second Quarter 2024 Financial Results and Provides Corporate Update

August 1, 2024

End-of-treatment data presented at the EASL Congress from two Phase 2a clinical trials supports advancing imdusiran as a potential cornerstone in a HBV functional cure treatment regimen

IM-PROVE I clinical trial demonstrated undetectable HBsAg in 33% of patients who were treated with 48 weeks of imdusiran and 24 weeks of IFN and in 67% of these patients with baseline HBsAg less than 1000 IU/mL

Prioritizing imdusiran Phase 2b clinical development; eliminating HBV discovery efforts resulting in a reduction in workforce by 40% and extension of expected cash runway into the fourth quarter of 2026

Conference Call and Webcast Today at 8:45 AM ET

WARMINSTER, Pa., Aug. 01, 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 second quarter 2024 financial results and provides a corporate update.

"At the EASL Congress we reported impressive imdusiran data. I'm particularly excited that in the IM-PROVE I clinical trial we saw undetectable HBsAg in 67% of those patients with baseline HBsAg less than 1000 IU/mL who were treated with 48 weeks of imdusiran and 24 weeks of IFN," said Michael J. McElhaugh, Interim President and Chief Executive Officer of Arbutus Biopharma. "In addition, these patients stopped all therapy and in early follow-up have maintained undetectable HBsAg and HBV DNA, a precursor to a functional cure. With these encouraging data, we continue to be optimistic about imdusiran as a potential cornerstone therapeutic in a treatment regimen to functionally cure cHBV."

Mr. McElhaugh continued, "We intend to focus our existing resources on conducting a Phase 2b clinical trial with imdusiran, assuming continued positive data. This has the potential to create a true inflection point for both Arbutus and HBV patients. To ensure we have the resources to conduct such a program, we have made the difficult decision to discontinue our HBV research efforts and reduce our headcount leading to a projected cash runway into the fourth quarter of 2026. I want to express my sincere gratitude to those impacted by the workforce reduction for their invaluable contributions to our mission and their dedication to helping HBV patients."

Clinical Development Update

Imdusiran (AB-729, RNAi Therapeutic)

- At the EASL Congress in June, end-of-treatment data was presented from IM-PROVE I (AB-729-201), a Phase 2a clinical trial 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. The data showed that 33.3% (n=4/12) of patients in Cohort A1 receiving 48 weeks of imdusiran combined with a short course of IFN (24-weeks) and NA therapy, achieved undetectable HBsAg at the end-of-treatment that was maintained in 100% of these patients 24 weeks after completing imdusiran and IFN treatment. Undetectable HBsAg was achieved in 67% of those patients with HBsAg less than 1000 IU/mL at baseline. A total of six patients who received 24 weeks of IFN (n=4 Cohort A1; n=2 Cohort A2) seroconverted, with HBsAg loss accompanied by high titers of anti-HBsAg antibodies. All six of these patients have stopped NA therapy, with two of those patients reaching 12 weeks off all therapy with sustained undetectable levels of HBsAg and HBV DNA. The combination of imdusiran and IFN in this clinical trial was generally safe and well-tolerated.
- Also at the EASL Congress in June, end-of treatment data was presented from the IM-PROVE II (AB-729-202) Phase 2a clinical trial evaluating the safety and immunogenicity of imdusiran, NA therapy and Barinthus Bio's VTP-300, an HBV antigen-specific immunotherapy. The data showed that at 24-weeks post-end of treatment with imdusiran and VTP-300, statistical significance ($p<0.05$) was achieved in HBsAg levels between the treatment arm (n=5) and placebo (n=6). In addition, more patients maintained HBsAg thresholds of <100 IU/mL and <10 IU/mL when administered VTP-300 vs. placebo at 24-weeks post end-of-treatment. The combination of imdusiran and VTP-300 in this clinical trial was generally safe and well-tolerated.
- IM-PROVE II includes an additional cohort of 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. Arbutus is on-track to report preliminary end-of-treatment data from this additional cohort in the second half of 2024.
- Arbutus has terminated its Phase 2a clinical trial evaluating the safety, tolerability and antiviral activity of imdusiran and NA therapy in combination with intermittent low doses of durvalumab, an approved anti-PD-L1 monoclonal antibody (IM-PROVE III, AB-729-203) prior to dosing any participants. This decision was based on a prioritization of resources and the projected availability of clinical data from this 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. Part 1 of the clinical trial has enrolled four sequential cohorts of eight healthy subjects each (6 active:2 placebo) to date, each receiving a single dose of AB-101 at increasing dose levels up to 25 mg or placebo. Data from Part 1 of this trial showed that AB-101 was generally well-tolerated with evidence of dose-dependent receptor occupancy. In the 25 mg cohort, all five evaluable subjects showed evidence of receptor occupancy between 50-100%. Arbutus has moved into Part 2 of this clinical trial which evaluates multiple-ascending doses of AB-101 in healthy subjects and expects to report preliminary data in the second half of this year.

Corporate Updates

- The Company has made the decision to streamline the organization to focus its efforts on advancing the clinical development of imdusiran and AB-101, and is therefore ceasing all discovery efforts and discontinuing its IM-PROVE III clinical trial. In taking these steps to streamline the organization, Arbutus is implementing a reduction in its workforce of 40%, primarily affecting the discovery and general and administrative functions. As a result, Arbutus will incur a one-time restructuring charge of approximately $3.0 - $4.0 million that will be recorded in the third quarter of 2024. With these organizational changes and its ongoing cost management efforts, the Company now expects its current cash, cash equivalents and investments in marketable securities will be sufficient to fund operations into the fourth quarter of 2026.

LNP Litigation Update

- Next steps in the lawsuit against Moderna include expert reports and expert depositions. A trial date has been set for April 21, 2025, and is subject to change.
- The lawsuit against Pfizer/BioNTech is ongoing and a date for a claim construction hearing has not been set.

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's and Pfizer/BioNTech's COVID-19 vaccines would not have been successful.

Financial Results

Cash, Cash Equivalents and Investments

As of June 30, 2024, the Company had cash, cash equivalents and investments in marketable securities of $148.5 million compared to $132.3 million as of December 31, 2023. During the six months ended June 30, 2024, the Company used $33.8 million in operating activities, which was offset by $44.1 million of net proceeds from the issuance of common shares under its "at-the-market" offering program (ATM Program). The Company expects its 2024 cash burn to range from $63 million to $67 million. With the organizational changes announced today, the Company believes its cash, cash equivalents and investments in marketable securities will be sufficient to fund its operations into the fourth quarter of 2026.

Revenue

Total revenue was $1.7 million for the three months ended June 30, 2024 compared to $4.7 million for the same period in 2023. The decrease of $3.0 million was due primarily to: i) a decrease in license revenue recognized under our licensing agreement with Qilu Pharmaceutical; and ii) a decrease in license royalty revenue from Alnylam due to lower sales of ONPATTRO in 2024 compared to 2023.

Operating Expenses

Research and development expenses were $15.6 million for the three months ended June 30, 2024 compared to $17.7 million for the same period in 2023. The decrease of $2.1 million was due primarily to the discontinuation of the Company's coronavirus and AB-161 programs in September 2023 as part of its efforts to focus on its lead HBV product candidates, partially offset by an increase in clinical expenses for the Company's AB-101 Phase 1a/1b clinical trial and its multiple imdusiran Phase 2a clinical trials. General and administrative expenses were $7.5 million for the three months ended June 30, 2024 compared to $6.0 million for the same period in 2023. The increase of $1.5 million was due primarily to higher litigation costs, partially offset by a decrease in compensation-related expenses.

Net Loss

For the three months ended June 30, 2024, the Company's net loss was $19.8 million, or a loss of $0.11 per basic and diluted common share, as compared to a net loss of $17.1 million, or a loss of $0.10 per basic and diluted common share, for the three months ended June 30, 2023.

Outstanding Shares

As of June 30, 2024, the Company had approximately 188.7 million common shares issued and outstanding. In addition, the Company had approximately 20.5 million stock options and unvested restricted stock units outstanding as of June 30, 2024. Roivant Sciences Ltd. owned approximately 21% of our outstanding common shares as of June 30, 2024.

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

	Three Months Ended March 31,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Revenue				
Collaborations and licenses	$ 1,155	$ 3,885	$ 2,094	$ 9,394
Non-cash royalty revenue	571	766	1,164	1,944
Total revenue	**1,726**	**4,651**	**3,258**	**11,338**
Operating expenses				
Research and development	15,551	17,692	30,954	35,967
General and administrative	7,547	5,980	12,859	11,532
Change in fair value of contingent consideration	211	(636)	391	(363)
Total operating expenses	**23,309**	**23,036**	44,204	47,136
Loss from operations	(21,583)	(18,385)	(40,946)	(35,798)
Other income				
Interest income	1,829	1,461	3,374	2,729
Interest expense	(34)	(171)	(78)	(369)
Foreign exchange gain	(8)	1	(21)	5
Total other income	1,787	1,291	3,275	2,365
Net loss	$ **(19,796)**	**$ (17,094)**	$ **(37,671)**	**$ (33,433)**
Loss per share				
Basic and diluted	$ (0.11)	$ (0.10)	$ (0.21)	$ (0.20)
Weighted average number of common shares				
Basic and diluted	188,041,489	166,063,284	181,842,519	163,855,661
Comprehensive loss				
Unrealized gain on available-for-sale securities	63	166	113	1,020
Comprehensive loss	$ **(19,733)**	**$ (16,928)**	$ **(37,558)**	**$ (32,413)**

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	June 30, 2024	**December 31, 2023**
Cash, cash equivalents and marketable securities, current	$ 141,986	$ 126,003
Accounts receivable and other current assets	6,234	6,024
Total current assets	**148,220**	**132,027**
Property and equipment, net of accumulated depreciation	4,059	4,674
Investments in marketable securities, non-current	6,527	6,284
Right of use asset	1,237	1,416
Total assets	**$ 160,043**	**$ 144,401**
Accounts payable and accrued liabilities	$ 11,108	$ 10,271
Deferred license revenue, current	11,034	11,791
Lease liability, current	453	425
Total current liabilities	**22,595**	**22,487**
Liability related to sale of future royalties	5,859	6,953
Contingent consideration	7,991	7,600
Lease liability, non-current	1,144	1,343
Total stockholders' equity	122,454	106,018
Total liabilities and stockholders' equity	**$ 160,043**	**$ 144,401**

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Six Months Ended June 30,	
	2024	**2023**
Net loss	$ (37,671)	$ (33,433)

Non-cash items	3,973	2,911
Change in deferred license revenue	(757)	(7,128)
Other changes in working capital	656	(9,210)
Net cash used in operating activities	**(33,799)**	**(46,860)**
Net cash provided by investing activities	**21,523**	**18,119**
Issuance of common shares pursuant to the Open Market Sale Agreement	44,124	24,604
Cash provided by other financing activities	4,676	555
Net cash provided by financing activities	**48,800**	**25,159**
Effect of foreign exchange rate changes on cash and cash equivalents	(21)	3
Increase/(decrease) in cash and cash equivalents	36,503	(3,579)
Cash and cash equivalents, beginning of period	26,285	30,776
Cash and cash equivalents, end of period	62,788	27,197
Investments in marketable securities	85,725	136,344
Cash, cash equivalents and marketable securities, end of period	$ **148,513**	**$ 163,541**

Conference Call and Webcast Today

Arbutus will hold a conference call and webcast today, Thursday, August 1, 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 250 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 with distinct mechanisms of action, which can potentially 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; 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; our expectations regarding our organizational changes; the potential for our product candidates to achieve success in clinical trials; our expectations regarding our pending litigation matters; 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 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; Arbutus may not realize the anticipated benefits from the organizational changes; Arbutus may incur additional unexpected expenses in connection with the organizational changes; Arbutus may experience additional employee turnover as a result of the organizational changes; uncertainties associated with litigation generally and patent litigation specifically; and Arbutus and its collaborators may never realize the expected benefits of the collaborations; 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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