Arbutus Reports Third Quarter 2024 Financial Results and Provides Corporate Update

November 6, 2024

Imdusiran data from IM-PROVE I and IM-PROVE II Phase 2a clinical trials to be presented at upcoming AASLD - The Liver Meeting 2024

Multiple-ascending doses of AB-101 in healthy subjects in the Phase 1a/1b clinical trial were generally safe and well-tolerated with evidence of receptor occupancy

Now dosing cHBV patients with AB-101 in Part 3 of the Phase 1a/1b clinical trial

Cash runway into the fourth quarter of 2026

Conference Call and Webcast Today at 8:45 AM ET

WARMINSTER, Pa., Nov. 06, 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 third quarter 2024 financial results and provides a corporate update.

"We are making significant progress in advancing the development of imdusiran to bring hope to millions of cHBV patients globally," said Michael J. McElhaugh, Interim President and Chief Executive Officer of Arbutus Biopharma. "In June, we shared promising data from our IM-PROVE I Phase 2a clinical trial, showing that some patients treated with imdusiran and interferon were trending towards a functional cure. We look forward to presenting follow-up data from this trial, as well as end-of-treatment data from patients that received nivolumab in addition to imdusiran and VTP-300 in our IM-PROVE II Phase 2a trial, at the upcoming AASLD meeting. Assuming continued positive data, and with a projected cash runway extending into the fourth quarter of 2026, we are well-positioned to advance imdusiran into a Phase 2b clinical trial as a cornerstone in a treatment regimen aimed at functionally curing cHBV."

Mr. McElhaugh continued, "Our proprietary oral PD-L1 checkpoint inhibitor, AB-101, is progressing well, as we continue to see dose-dependent receptor occupancy and have now advanced into dosing cHBV patients in our Phase 1a/1b clinical trial. We look forward to providing updates as this trial progresses."

Clinical Development Update

Imdusiran (AB-729, RNAi Therapeutic)

- End-of-treatment data from the IM-PROVE I Phase 2a clinical trial evaluating the safety, tolerability and antiviral activity of the combination of imdusiran (4 or 6 doses over 24 or 48 weeks, respectively), nucleos(t)ide analogue (NA) therapy and a short course of pegylated interferon alfa-2a (IFN, 12 or 24 weeks) in patients with cHBV was presented at the EASL Congress in June. The data showed that 33.3% (n=4/12) of patients in Cohort A1 receiving 48 weeks (6 doses) of imdusiran combined with 24 weeks of IFN and NA therapy achieved HBsAg loss at the end-of-treatment that was maintained in 100% of these patients 24 weeks after completing imdusiran and IFN treatment. HBsAg loss was achieved and maintained in 67% of those patients with HBsAg less than 1000 IU/mL at baseline. A total of six patients from Cohort A1 (n=4) and Cohort A2 (n=2) seroconverted with HBsAg loss. At the time the data was reported, all six of those patients had stopped all therapy, with two of those patients reaching 12 weeks off all therapy with sustained HBsAg and HBV DNA loss. The combination of imdusiran and IFN in this clinical trial was generally safe and well-tolerated. The Company will present a late-breaker poster with additional follow-up data at the upcoming AASLD-The Liver Meeting 2024 later this month.

- End-of treatment data from the IM-PROVE II Phase 2a clinical trial evaluating the safety and immunogenicity of imdusiran, NA therapy and Barinthus Bio's VTP-300, an HBV antigen-specific immunotherapy was presented at the EASL Congress in June. The data showed that the combination of imdusiran and VTP-300 was generally safe and well-tolerated. At 24-weeks post-end of treatment, statistical significance ($p<0.05$) was achieved in HBsAg levels between the VTP-300 arm (n=5) and placebo (n=6). IM-PROVE II includes an additional cohort of patients who received 4 doses of 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. The Company will present a late-breaker poster with preliminary end-of-treatment data from this additional cohort at the upcoming AASLD - The Liver Meeting 2024 in November.

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 in healthy subjects and patients with cHBV.

- Part 2 of this clinical trial has enrolled to date two sequential cohorts of ten healthy subjects each receiving 10 mg or 25 mg of AB-101 (n=8) or placebo (n=2) daily for 7 days. AB-101 was generally well-tolerated with evidence of dose-dependent receptor occupancy. In the 25 mg cohort, all subjects showed evidence of receptor occupancy, with seven of the eight subjects demonstrating receptor occupancy greater than 70% during the 7-day dosing period.
- Arbutus has moved into Part 3 of this clinical trial which evaluates repeat dosing of AB-101 for 28 days in patients with cHBV and expects to report preliminary data in the first half of next year.

LNP Litigation Update

- Expert reports and expert depositions continue in the Moderna lawsuit. A trial date has been set for September 24, 2025, and is subject to the Court's availability.
- The lawsuit against Pfizer/BioNTech is ongoing and a date for the claim construction hearing has been set for December 18, 2024.

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 September 30, 2024, the Company had cash, cash equivalents and investments in marketable securities of $130.8 million compared to $132.3 million as of December 31, 2023. During the nine months ended September 30, 2024, the Company used $54.5 million in operating activities, which was partially offset by $44.1 million of net proceeds from the issuance of common shares under its "at-the-market" offering program (ATM Program) and $6.1 million of proceeds from the exercise of stock options. The Company did not issue any common shares under its ATM program in the third quarter of 2024. The Company expects its 2024 cash burn to range from $63 million to $67 million. With the organizational changes in the third quarter, 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 $1.3 million for the three months ended September 30, 2024 compared to $4.7 million for the same period in 2023. The decrease of $3.4 million was due primarily to: i) a decrease in license revenue recognized under the Company's 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 $14.3 million for the three months ended September 30, 2024 compared to $20.2 million for the same period in 2023. The decrease of $5.9 million was due primarily to the discontinuation of the Company's coronavirus and AB-161 programs in September 2023, along with related headcount reductions. General and administrative expenses were $4.5 million for the three months ended September 30, 2024 compared to $5.8 million for the same period in 2023. The decrease of $1.3 million was due primarily to decreased employee compensation and non-cash stock-based compensation expenses due to headcount reductions. The Company also incurred a $3.6 million one-time restructuring charge in the third quarter of 2024 related to its decision to cease all discovery efforts, discontinue its IM-PROVE III clinical trial, and reduce headcount to streamline the organization with a focus on advancing the clinical development of imdusiran and AB-101.

Net Loss

The Company's net loss was $19.7 million for the three months ended September 30, 2024 and $20.1 million for the same period in 2023, with a loss per basic and diluted common share of $0.10 and $0.12, respectively.

Outstanding Shares

As of September 30, 2024, the Company had approximately 189.4 million common shares issued and outstanding. In addition, the Company had approximately 18.7 million stock options and unvested restricted stock units outstanding as of September 30, 2024. Roivant Sciences Ltd. owned approximately 21% of the Company's outstanding common shares as of September 30, 2024.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue				
Collaborations and licenses	$ 767	$ 3,935	$ 2,861	$ 13,329
Non-cash royalty revenue	572	723	1,736	2,667
Total revenue	**1,339**	**4,658**	**4,597**	**15,996**
Operating expenses				

Research and development	14,273	20,169	45,227	56,136
General and administrative	4,537	5,842	17,396	17,374
Change in fair value of contingent consideration	344	205	735	(158)
Restructuring	3,625	-	3,625	-
Total operating expenses	**22,779**	**26,216**	**66,983**	**73,352**
Loss from operations	(21,440)	(21,558)	(62,386)	(57,356)
Other income				
Interest income	1,747	1,494	5,121	4,223
Interest expense	(29)	(46)	(107)	(415)
Foreign exchange gain / (loss)	5	6	(16)	11
Total other income	1,723	1,454	4,998	3,819
Net loss	$ **(19,717)**	**$ (20,104)**	$ **(57,388)**	**$ (53,537)**
Loss per share				
Basic and diluted	$ (0.10)	$ (0.12)	$ (0.31)	$ (0.32)
Weighted average number of common shares				
Basic and diluted	188,997,194	167,512,708	184,244,819	165,085,243
Comprehensive loss				
Unrealized gain on available-for-sale securities	218	584	331	1,604
Comprehensive loss	$ **(19,499)**	**$ (19,520)**	$ **(57,057)**	**$ (51,933)**

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	September 30, 2024	December 31, 2023
Cash, cash equivalents and marketable securities, current	$ 127,794	$ 126,003
Accounts receivable and other current assets	4,983	6,024
Total current assets	**132,777**	**132,027**
Property and equipment, net of accumulated depreciation	3,556	4,674
Investments in marketable securities, non-current	2,964	6,284
Right of use asset	1,144	1,416
Total assets	$ **140,441**	**$ 144,401**
Accounts payable and accrued liabilities	$ 7,544	$ 10,271
Deferred license revenue, current	10,911	11,791
Lease liability, current	468	425
Total current liabilities	**18,923**	**22,487**
Liability related to sale of future royalties	5,315	6,953
Contingent consideration	8,335	7,600
Lease liability, non-current	978	1,343
Total stockholders' equity	106,890	106,018
Total liabilities and stockholders' equity	$ **140,441**	**$ 144,401**

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Nine Months Ended September 30,	
	2024	**2023**
Net loss	$ (57,388)	$ (53,537)
Non-cash items	5,453	4,613
Change in deferred license revenue	(880)	(10,349)
Other changes in working capital	(1,720)	(9,371)
Net cash used in operating activities	**(54,535)**	**(68,644)**
Net cash provided by investing activities	**9,537**	**28,548**
Issuance of common shares pursuant to the Open Market Sale Agreement	44,124	26,000
Cash provided by other financing activities	6,451	840
Net cash provided by financing activities	**50,575**	**26,840**
Effect of foreign exchange rate changes on cash and cash equivalents	(16)	11

Increase/(decrease) in cash and cash equivalents	5,561	(13,245)
Cash and cash equivalents, beginning of period	26,285	30,776
Cash and cash equivalents, end of period	31,846	17,531
Investments in marketable securities	98,912	127,145
Cash, cash equivalents and marketable securities, end of period	$ **130,758**	**$ 144,676**

Conference Call and Webcast Today

Arbutus will hold a conference call and webcast today, Wednesday, November 6, 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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