



Arbutus Reports Fourth Quarter and Year End 2019 Financial Results, Confirms 2020 Corporate Objectives and Provides Pipeline Update

March 5, 2020

Conference Call and Webcast Scheduled Today at 8:45 AM ET

WARMINSTER, Pa., March 05, 2020 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS), a Hepatitis B Virus (HBV) therapeutic solutions company, today reports its fourth quarter and year end 2019 financial results, confirms 2020 corporate objectives and provides pipeline update.

"Arbutus is focused on developing a portfolio of medicines with different mechanisms of action that we believe could provide a functional cure for people with chronic hepatitis B," said William Collier, Arbutus' President and Chief Executive Officer. "Our key objectives for 2020 are to complete and report results from the Phase 1a/b clinical trial of AB-729, our proprietary subcutaneous RNAi agent, and rapidly advance our next-generation oral capsid inhibitor, AB-836, through IND-enabling studies by year end.

Mr. Collier added, "We remain on track to announce preliminary safety and efficacy results from multiple single-dose cohorts in the Phase 1a/1b clinical trial for AB-729 later this month."

Pipeline Update

AB-729

- AB-729 is an RNA interference (RNAi) therapeutic targeted to hepatocytes using Arbutus' novel covalently conjugated N-acetylgalactosamine (GalNAc) delivery technology that enables subcutaneous delivery. AB-729 inhibits viral replication and reduces all HBV antigens, including hepatitis B surface antigen (HBsAg), in preclinical models. Reducing HBsAg is thought to be a key prerequisite to enable reawakening of a patient's immune system to respond to the virus.
- Arbutus is currently conducting a single- and multiple-dose Phase 1a/1b clinical trial for AB-729 to determine the safety, tolerability, pharmacokinetics, and pharmacodynamics of AB-729 in healthy volunteers and in subjects with chronic hepatitis B (CHB) infection.
- Preliminary safety data in single-dose cohorts of healthy subjects and safety and efficacy data in single-dose cohorts of subjects with CHB infection are expected later this month. Additional single-dose data and preliminary multi-dose data are expected in the second half of 2020.

AB-836

- AB-836 is an oral HBV capsid inhibitor. HBV core protein assembles into a capsid structure, which is required for viral replication. The current standard-of-care therapy for HBV, primarily nucleoside analogues that work by inhibiting the viral polymerase, significantly reduce virus replication, but not completely. Capsid inhibitors inhibit replication by preventing the assembly of functional viral capsids. They also have been shown to inhibit the uncoating step of the viral life cycle thus reducing the formation of new covalently closed circular DNA (cccDNA), the viral reservoir which resides in the cell nucleus.
- In January 2020, Arbutus selected AB-836 as its next-generation oral capsid inhibitor. AB-836 is a novel chemical series differentiated from Arbutus' previously discontinued capsid inhibitor candidate, AB-506, and other competitor compounds in the capsid inhibitor space. AB-836 has the potential for increased potency and an enhanced resistance profile compared to AB-506, our previous generation capsid inhibitor that was discontinued in October 2019. Arbutus anticipates completing IND-enabling studies by the end of 2020.

Early R&D Programs

- Arbutus continues a focused discovery effort on follow-on compounds for its current HBV pipeline, including the development of oral RNA-destabilizers that have shown compelling anti-viral effects in multiple HBV preclinical models. Arbutus is now focused on advancing a next-generation oral HBV specific RNA-destabilizer with chemical scaffolds distinct from AB-452 through lead optimization. Arbutus also has compounds in lead optimization that are potentially capable of reawakening patients' HBV-specific immune response by inhibiting PD-L1.

Cash Position and 2020 Cash Guidance

- Arbutus ended the year with \$90.8 million in cash, cash equivalents and short-term investments which the Company believes is sufficient to fund operations into mid-2021. Arbutus expects to utilize between \$54 to \$58 million of cash and investments to fund operations in 2020.

Financial Results

Cash, Cash Equivalents and Investments

Arbutus had cash, cash equivalents and short-term investments totaling \$90.8 million as of December 31, 2019, as compared to \$124.6 million as of December 31, 2018. The decreased cash balance was due primarily to the \$71.0 million used in operating activities during the year ended December 31, 2019, partially offset by \$18.5 million in net proceeds from the sale of Arbutus' portion of a royalty entitlement on net sales of Alnylam Pharmaceuticals, Inc.'s ONPATTRO™ (Patisiran) in the third quarter of 2019 and \$18.6 million of net proceeds from the issuance of shares under Arbutus' ATM program. Included in the \$71.0 million used in operating activities is a \$5.9 million payment in the third quarter of 2019 for an award rendered in an arbitration proceeding with the University of British Columbia. Subsequent to year end, Arbutus has received an additional \$12.3 million of net proceeds from the issuance of shares under Arbutus' ATM program during the first quarter of 2020 through March 4, 2020.

Net Loss

Net loss attributable to common shares for the year ended December 31, 2019, including non-cash charges of \$43.8 million related to the impairment of an in-process research and development ("IPR&D") intangible asset and \$22.5 million for the impairment of goodwill described further below, was \$164.9 million (\$2.89 basic and diluted loss per common share) as compared to \$67.2 million (\$1.21 basic and diluted loss per common share) in 2018. Net loss attributable to common shares also included non-cash expense for the accrual of coupon on the Company's convertible preferred shares of \$11.1 million in 2019 and \$10.1 million in 2018, as well as non-cash equity losses associated with our investment in Genevant Sciences Ltd.'s ("Genevant") of \$22.5 million in 2019 and non-cash equity gains of \$19.3 million in 2018. Genevant is a company launched with Roivant Sciences Ltd., Arbutus largest shareholder, in April 2018.

ONPATTRO Royalty Entitlement

Arbutus has a royalty entitlement on global net sales of ONPATTRO™ (Patisiran) for the lipid nanoparticle delivery (LNP) technology licensed by Arbutus to Alnylam for this product. ONPATTRO is an RNAi therapeutic for the treatment of hereditary ATTR (hATTR) amyloidosis that has been approved by the U.S. Food and Drug Administration and the European Medicines Agency. In July 2019, Arbutus sold this royalty entitlement to OCM IP Healthcare Portfolio LP, an affiliate of the Ontario Municipal Employees Retirement System (collectively, OMERS), effective as of January 1, 2019, for \$20 million in gross proceeds before advisory fees. OMERS will retain this royalty entitlement until it has received \$30 million in royalties, at which point 100% of this royalty entitlement will revert to Arbutus. OMERS has assumed the risk of collecting up to \$30 million of future royalty payments from Alnylam and Arbutus is not obligated to reimburse OMERS if they fail to collect any such future royalties. Arbutus recognized the \$20 million of gross proceeds from this transaction as a liability, net of transaction costs. The Company is amortizing the liability to non-cash interest expense and will continue to recognize the royalty revenue that Alnylam pays to OMERS as non-cash royalty revenue.

In addition to the royalty entitlement from the Alnylam LNP license agreement, Arbutus is also receiving a second, lower royalty entitlement on global net sales of ONPATTRO originating from a settlement agreement and subsequent license agreement with Acuitas Therapeutics. The royalty entitlement from Acuitas has been retained by Arbutus and is not part of the royalty entitlement sale to OMERS.

Operating Expenses

Research and development expenses were \$57.6 million for the year ended December 31, 2019 compared to \$57.9 million in 2018. Research and development expenses for the year ended December 31, 2019 included costs associated with the Company's Phase 1a/1b clinical trial for its RNAi agent (AB-729), Phase 1a/1b clinical trial for its oral capsid inhibitor (AB-506), which was discontinued in October 2019, and toxicology studies for its HBV RNA Destabilizer (AB-452), which was discontinued in February 2020. General and administrative expenses were \$17.7 million in 2019 compared to \$16.0 million in 2018. The increase in general and administrative expenses was due primarily to severance related to our former President and Chief Executive Officer's departure from the Company in June 2019, partially offset by a decrease in professional fees. In accordance with the terms of his legacy employment agreement, our former President and Chief Executive Officer received \$2.3 million in cash severance and the Company recognized \$1.1 million of non-cash stock-based compensation expense for accelerated vesting of his stock options.

Additionally, the Company recorded a charge of \$6.3 million in 2019 related to an arbitration award from the Company's arbitration with the University of British Columbia.

Impairment of IPR&D Intangible Assets and Goodwill

The Company has historically carried IPR&D and goodwill from its acquisition of technologies and business combination as assets. All acquired IPR&D intangible assets relate to the Company's cccDNA program. During the year ended December 31, 2019, the Company recorded a \$43.8 million non-cash impairment expense to reduce the carrying value of its IPR&D intangible assets to zero. The Company also recognized a corresponding income tax benefit of \$12.7 million related to the decrease in its deferred tax liability associated with the IPR&D intangible assets. The impairment was due to an indefinite delay in further development of the Company's cccDNA program while the Company focuses on its other development programs.

Goodwill represents the excess of purchase price over the value assigned to the net tangible and identifiable intangible assets in connection with the business combination that formed Arbutus. The Company assessed changes in circumstances to determine if it was more likely than not that the fair value of the Company was below its carrying amount. Due to a sustained decrease in the Company's share price during the year, the Company's market capitalization was reduced below the book value of its net assets and the Company concluded that its fair value was below its carrying amount by an amount in excess of the carrying value of the goodwill. As a result, during the third quarter of 2019, the Company recorded a \$22.5 million non-cash impairment expense to reduce the carrying value of its goodwill asset to zero.

Outstanding Shares

The Company had 64,780,314 common shares issued and outstanding as of December 31, 2019. In addition, the Company had approximately 8.6

million stock options outstanding and 1.164 million convertible preferred shares outstanding, which (including the annual 8.75% coupon) will be mandatorily convertible into approximately 23 million common shares on October 18, 2021.

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

	Year Ended December 31,	
	2019	2018
Revenue		
Revenue from collaborations and licenses	\$ 4,355	\$ 5,945
Non-cash revenue	1,656	—
Total revenue	<u>6,011</u>	<u>5,945</u>
Operating expenses		
Research and development	57,601	57,934
General and administrative	17,727	16,002
Depreciation	2,028	2,181
Site consolidation	156	4,797
Impairment of intangible assets	43,836	14,811
Impairment of goodwill	22,471	—
Arbitration	6,266	—
Loss from operations	<u>(144,074)</u>	<u>(89,780)</u>
Other income (loss)		
Interest income	2,111	3,047
Interest expense	(2,108)	(226)
Equity investment gains (losses)	(22,522)	19,322
Increase in fair value of contingent consideration	173	7,298
Foreign exchange gains (losses)	41	(1,003)
Total other income (loss)	<u>(22,305)</u>	<u>28,438</u>
Income tax benefit	12,656	4,282
Net loss ⁽¹⁾	<u>\$ (153,723)</u>	<u>\$ (57,060)</u>
Dividend accretion of convertible preferred shares	(11,149)	(10,091)
Net loss attributable to common shares	<u>\$ (164,872)</u>	<u>\$ (67,151)</u>
Net loss per common share		
Basic and diluted	\$ (2.89)	\$ (1.21)
Weighted average number of common shares		
Basic and diluted	57,093,454	55,304,083

(1) Net loss for the year ended December 31, 2019 included \$66.3 million of non-cash expenses related to the impairments of an IPR&D intangible asset and goodwill, partially offset by a corresponding income tax benefit of \$12.7 million related to the decrease in a deferred tax liability associated with the IPR&D intangible asset. Net loss for the year ended December 31, 2018 included \$14.8 million of non-cash expense related to the impairment of an IPR&D intangible asset, partially offset by a corresponding income tax benefit of \$4.3 million related to the decrease in a deferred tax liability associated with the IPR&D intangible asset.

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	December 31, 2019	December 31, 2018
Cash and cash equivalents	\$ 31,799	\$ 36,942
Investments in marketable securities	59,035	87,675
Accounts receivable and other current assets	2,994	4,612
Total current assets	<u>93,828</u>	<u>129,229</u>
Investment in Genevant	—	22,224
Property and equipment, net of accumulated depreciation	8,676	10,145
Right of use asset	2,738	—
Intangible assets	—	43,836
Goodwill	—	22,471
Other non-current assets	293	—
Total assets	<u>\$ 105,535</u>	<u>\$ 227,905</u>
Accounts payable and accrued liabilities	\$ 7,098	\$ 9,429
Site consolidation accrual	137	1,331
Liability-classified options	253	479

Lease liability, current	340	—
Total current liabilities	7,828	11,239
Liability related to sale of future royalties	18,992	—
Deferred rent and inducements, non-current	—	645
Contingent consideration	2,953	3,126
Lease liability, non-current	3,018	—
Deferred tax liability	—	12,661
Total stockholders' equity	72,744	200,234
Total liabilities and stockholders' equity	\$ 105,535	\$ 227,905

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW
(in thousands)

	Year ended December 31,	
	2019	2018
Net loss for the period	\$ (153,723)	\$ (57,060)
Deferred income tax benefit	(12,661)	(4,282)
Impairment of intangible assets and goodwill	66,307	14,811
Net equity investment loss (gain)	22,522	(19,557)
Other non-cash items	8,774	2,497
Changes in working capital	(2,225)	(4,275)
Net cash used in operating activities	(71,006)	(67,866)
Net cash provided by (used in) investing activities	28,338	(4,127)
Net cash provided by financing activities	37,457	55,646
Effect of foreign exchange rate changes on cash and cash equivalents	68	(1,003)
Decrease in cash and cash equivalents	\$ (5,143)	\$ (17,350)
Cash and cash equivalents, beginning of period	36,942	54,292
Cash and cash equivalents, end of period	\$ 31,799	\$ 36,942
Short-term investments	59,035	87,675
Total cash, cash equivalents and short-term investments, end of period	\$ 90,834	\$ 124,617

Conference Call Today

Arbutus will hold a conference call and webcast today, Thursday, March 5, 2020 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 5084457.

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 5084457.

About Arbutus

Arbutus Biopharma Corporation is a publicly traded (Nasdaq: ABUS) biopharmaceutical company dedicated to discovering, developing and commercializing a cure for patients suffering from chronic Hepatitis B infection. Arbutus is developing multiple drug candidates, each of which have the potential to improve upon the standard of care and contribute to a curative combination regimen. 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 expectation that certain preliminary safety and efficacy data from the Phase 1a/1b clinical trial for AB-729 will be available in the first quarter of 2020 with additional preliminary data available in the second half of 2020; our expectation to complete IND-enabling studies for AB-836 by the end of 2020; our expectation to advance a next-generation oral HBV specific RNA-destabilizer into lead optimization; the sufficiency of our cash and cash equivalents to extend into mid-2021; our expectation to use approximately \$54 to \$58 million of cash and investments to fund operations in 2020; and the potential for our drug candidates to improve upon the standard of care and contribute to a curative combination regimen for chronic HBV.

With respect to the forward-looking statements contained in this press release, Arbutus has made numerous assumptions regarding, among other things: the timely receipt of expected payments; the effectiveness and timeliness of preclinical 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.

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 drug candidate; changes in Arbutus'

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; and 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.

Contact Information

Investors and Media

William H. Collier
President and CEO
Phone: 604-419-3200
Email: ir@arbutusbio.com

Pam Murphy
Investor Relations Consultant
Phone: 604-419-3200
Email: ir@arbutusbio.com



Source: Arbutus Biopharma Corporation