



## Arbutus Reports 2018 Third Quarter Financial Results and Provides Corporate Update

November 7, 2018

*- AB-506, a second-generation capsid inhibitor, advanced to HBV patient portion of Phase 1a/1b clinical trial*

*- ONPATTRO™ (patisiran) approved by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), triggering a royalty stream to Arbutus*

### **Third Quarter Conference Call and Webcast Scheduled Today at 4:30 PM ET**

WARMINSTER, Pa., Nov. 07, 2018 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS), an industry-leading Hepatitis B Virus (HBV) therapeutic solutions company, today reports its 2018 third quarter financial results and provides a corporate update.

"Arbutus is committed to developing a cure for chronic Hepatitis B by employing a combination of therapeutic agents, acting in concert," said Dr. Mark J Murray, President and Chief Executive Officer of Arbutus. "We are currently focused on the combination AB-506, our second-generation capsid inhibitor designed to block HBV DNA replication and AB-729, our second-generation RNAi agent designed to reduce HBsAg."

Dr. Murray added, "We believe a combination of these two agents, with their distinct antiviral mechanisms, combined with an approved nucleoside, has the potential to offer HBV patients a more effective, durable and finite treatment regimen."

### **Recent Updates and Upcoming Clinical Milestones**

- Phase 1a/1b clinical trial of AB-506, Arbutus' second generation oral capsid inhibitor, successfully progressed through healthy volunteers into the 28 day HBV patient phase. Top-line results of the phase 1a/1b clinical trial are expected in the second quarter of 2019. AB-506 is designed to inhibit HBV DNA replication with a mode of action complementary to nucleoside analogues. AB-506 is also designed to inhibit the formation of new cccDNA, the viral structure which resides in the cell nucleus.
- The company is actively developing orally delivered RNA-destabilizers that have shown compelling anti-viral effects in multiple preclinical models. Based on recent nonclinical safety findings with our lead RNA-destabilizer, AB-452, we have delayed the planned initiation of a Phase 1a/1b clinical trial to devote additional time to further characterize the compound before potentially initiating clinical trials. While further characterizing these recent AB-452 observations, we are advancing backup compounds.
- Arbutus is developing a second-generation RNAi agent, AB-729, a subcutaneously-administered GalNAc conjugate, targeting HBV replication and HBsAg antigen production. In preclinical models AB-729 exhibits potent and durable reductions in HBsAg. This agent is expected to enter clinical trials in Q2 2019 and may subsequently be combined with AB-506.
- ARB-1467, one of our early LNP delivered, intravenous administered, RNAi agents targeting HBV, is currently in a 30-week trial in HBV patients, in combination with tenofovir and PEG-IFN. To date, six HBV patients have enrolled and been treated. Two of these patients have met the predetermined criteria to proceed into the PEG-IFN treatment phase of the trial. The results from this proof-of-concept trial suggest that this regimen has the potential to drive HBsAg levels to undetectable in some patients thus confirming our hypothesis that a combination of multiple mechanisms will be required to improve clinical outcomes for HBV patients. While the trial remains open to enrollment, the Company does not plan to advance this program beyond this trial. We intend to present results from this trial in a future scientific meeting.
- Dr. Gaston Picchio, formerly Janssen's Infectious Diseases & Vaccines VP Hepatitis Disease Area Leader, has joined as Arbutus' Chief Development Officer and adds antiviral drug development expertise.
- James Meyers and Myrtle Potter were appointed to the Arbutus Board of Directors, replacing Herbert Conrad and Dr. William Symonds. Dr. Symonds remains with Arbutus as Chairman of its Clinical Advisory Board.

### **ONPATTRO Royalty Entitlement**

ONPATTRO is an RNAi therapeutic that has been developed for the treatment of hereditary ATTR (hATTR) amyloidosis, and has been approved by the FDA and the EMA. Arbutus has a royalty entitlement on global sales of ONPATTRO for the LNP technology licensed by Arbutus to Alnylam for this product.

### **Financial Results**

## Cash, Cash Equivalents and Investments

As of September 30, 2018, Arbutus had cash, cash equivalents and short-term investments totaling \$142.0 million, as compared to \$139.0 million in cash and cash equivalents, short-term investments, and restricted investments at December 31, 2017. The increased cash balance was the result of \$66.4 million of gross proceeds received in Q1 2018 from the second tranche of Series A participating convertible preferred shares ("Preferred Shares") issued to Roivant, offset by the repayment of a \$12.6 million promissory note to Wells Fargo and cash used in operations.

## Net Loss

For Q3 2018, net loss attributable to common shares was \$27.0 million (\$0.49 basic and diluted loss per common share) as compared to \$11.6 million (\$0.21 basic and diluted loss per common share) for Q3 2017. The Company recorded a non-cash expense for the impairment of intangible assets of \$14.8 million (\$10.5 million net of tax benefit) in Q3 2018 for the indefinite deferral of further development of its AB-423 program, due to the successful progression of its AB-506 program.

## Revenue

Revenue was \$1.6 million in Q3 2018 as compared to \$6.9 million in Q3 2017.

In October 2017, Arbutus entered into a license agreement with Gritstone that entitles Gritstone to research, develop, manufacture and commercialize products with the Company's LNP technology in exchange for an upfront license payment and potential future milestone and royalty payments. In April 2018, as part of the license agreement for Arbutus' delivery technologies, Genevant gained the right to receive 50% of future revenues from Gritstone. As Genevant is now the principal provider of services to Gritstone, the Company is now recording revenues from Gritstone on a net basis. Arbutus received a milestone payment from Gritstone of \$2.5 million, of which Arbutus recorded its share, \$1.25 million, as revenue in Q3 of 2018.

The \$6.9 million in revenue in Q3 2017 was primarily related to the release of deferred revenue from an Alexion up-front payment. Upon review of its portfolio in July 2017, Alexion decided to discontinue development of mRNA therapeutics and therefore the LNP license with Arbutus.

## Research, Development, Collaborations and Contracts Expenses

Research, development, collaborations and contracts expenses increased to \$16.6 million in Q3 2018 from \$15.5 million in Q3 2017. Program R&D expenses have increased as Arbutus' pipeline expands and advances into the clinic. In the first half of 2018 the Company initiated a Phase I clinical trial in healthy volunteers for AB-506 (capsid inhibitor) and has progressed this trial into HBV patients in Q4 2018. Given the progression of AB-506, the Company decided to indefinitely defer additional clinical evaluation of AB-423 in favor of focusing on the next generation capsid agent. In Q3 2018, Arbutus continued to incur costs related to its clinical programs including IND/CTA-enabling work and CTA regulatory filings for AB-452 (HBV RNA Destabilizer), pre-IND/CTA work on AB-729 (GalNAc-RNAi), as well as the ongoing clinical trial of ARB-1467 in combination with nucs and interferon. In addition, Arbutus continues to incur research costs related to discovery and pre-clinical programs.

## General and Administrative

General and administrative expenses were \$2.6 million in Q3 2018, as compared to \$3.7 million in Q3 2017. General and administrative expenses decreased in Q3 2018 compared to Q3 2017 due primarily to a decrease in non-cash compensation expense related to the expiry in Q3 2017 of repurchase rights connected with certain common shares issued as part of the total consideration for the acquisition of Arbutus Inc.

## Decrease in fair value of contingent consideration

Contingent consideration is a liability assumed by the Company from its acquisition of Enantigen in October 2014. Under the stock purchase agreement, Arbutus Inc. agreed to pay certain amounts to Enantigen's selling stockholders upon the achievement of certain triggering events related to Enantigen's two programs in pre-clinical development related to HBV therapies. In Q3 2018 the Company recorded a non-cash decrease in this contingent consideration of \$5.8 million. This was primarily due to the Company's decision to indefinitely defer clinical development of AB-423 thereby reducing the probability of achieving future development milestones, as well as a recalibration in the expected timing of future sales milestones, resulting in a reduction in the estimated fair value of the liability.

## Equity investment loss

On April 11, 2018, the Company entered into an agreement with Roivant Sciences ("Roivant") to launch Genevant Sciences ("Genevant"), a jointly-owned company focused on the discovery, development, and commercialization of a broad range of RNA-based therapeutics enabled by Arbutus' proprietary lipid nanoparticle ("LNP") and ligand conjugate delivery technologies. The Company determined that since the agreement stipulates that significant decisions relating to the management of Genevant must be shared between the Principal Shareholders (being the Company and Roivant), the Company does not control Genevant but does exercise significant influence over it and, will therefore, account for its investment in Genevant using the equity method. On April 11, 2018, the Company and Roivant each received a 50% ownership interest in Genevant. As a result of the subsequent investment in Genevant completed in June 2018 by Roivant and other parties, the Company owned approximately 40% of the common equity of Genevant as of September 30, 2018.

The Company's proportionate share of the Genevant's loss was \$2.8 million in Q3 2018. Financial results of Genevant are recorded on a one-quarter lag basis.

## Outstanding Shares

The Company had 55.5 million common shares issued and outstanding at September 30, 2018. In addition, the Company had 6.7 million options outstanding and 1.164 million Series A participating convertible preferred shares outstanding, which (including the annual 8.75% coupon) will be mandatorily convertible into 22.6 million common shares on October 18, 2021. Assuming the outstanding options and convertible preferred shares were fully converted, the Company would have had 84.8 million common shares outstanding at September 30, 2018.

	September 30, 2018		December 31, 2017	
Cash and cash equivalents	\$	21.9	\$	54.3
Short-term investments		120.1		72.1
Accounts receivable		0.5		0.4
Other current assets		1.5		2.6
Restricted investments		—		12.6
Investment in Genevant		24.7		—
Property and equipment, net		10.4		12.2
Intangible assets		43.8		58.6
Goodwill		22.5		24.4
<b>Total assets</b>	<b>\$</b>	<b>245.4</b>	<b>\$</b>	<b>237.2</b>
Accounts payable and accrued liabilities		8.5		10.7
Total deferred revenue		0.6		2.7
Liability-classified options		2.7		1.2
Loan payable		—		12.0
Site consolidation accrual		0.7		—
Deferred lease inducements, net of current portion		0.7		0.7
Contingent consideration		4.2		10.5
Deferred tax liability		12.7		16.9
Total stockholders' equity		215.3		182.5
<b>Total liabilities and stockholders' equity</b>	<b>\$</b>	<b>245.4</b>	<b>\$</b>	<b>237.2</b>

**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW**  
(in millions)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Net loss for the period	\$ (24.5)	\$ (11.6)	\$ (38.8)	\$ (48.5)
Net cash used in operating activities	(13.2)	(15.7)	(50.8)	(38.3)
Net cash provided by (used in) investing activities	24.4	5.3	(48.9)	27.1
Net cash provided by financing activities	0.4	0.1	55.5	0.4
Effect of foreign exchange rate changes on cash & cash equivalents	0.1	1.3	(0.8)	2.6
<b>Net (decrease) increase in cash, cash equivalents and restricted investments</b>	<b>\$ 11.7</b>	<b>\$ (9.0)</b>	<b>\$ (45.0)</b>	<b>\$ (8.2)</b>
Cash, cash equivalents and restricted investments, beginning of period	10.2	24.2	66.9	23.4
<b>Cash, cash equivalents and restricted investments, end of period</b>	<b>\$ 21.9</b>	<b>\$ 15.2</b>	<b>\$ 21.9</b>	<b>\$ 15.2</b>

**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF LOSS**  
(in millions)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
<b>Total revenue</b>	<b>\$ 1.6</b>	<b>\$ 6.9</b>	<b>\$ 4.3</b>	<b>\$ 8.2</b>
Operating expenses				
Research, development, collaborations and contracts	16.6	15.5	46.9	44.9
General and administrative	2.6	3.7	10.1	12.6
Depreciation of property and equipment	0.5	0.6	1.7	1.4
Site consolidation	(0.5)	—	3.7	—
Impairment of intangible assets	14.8	—	14.8	—
<b>Loss from operations</b>	<b>(32.4)</b>	<b>(12.9)</b>	<b>(72.9)</b>	<b>(50.7)</b>

Other income (loss)				
Interest income	0.8	0.3	2.3	1.1
Interest expense	—	(0.1)	(0.1)	(0.2)
Foreign exchange (loss) gain	0.1	1.2	(0.7)	2.5
Gain on investment	—	—	24.9	—
Equity investment loss	(2.8)	—	(2.8)	—
Increase in fair value of warrant liability	—	—	—	(0.02)
Decrease (increase) in fair value of contingent consideration	5.6	(0.2)	6.3	1.1
Total other income	3.7	1.3	29.8	2.2
Income tax benefit	4.3	—	4.3	—
<b>Net loss</b>	<b>\$ (24.4)</b>	<b>\$ (11.6)</b>	<b>\$ (38.8)</b>	<b>\$ (48.5)</b>
Accrual of coupon on convertible preferred shares	(2.6)	—	(7.4)	—
<b>Net loss attributable to common shares</b>	<b>\$ (27.0)</b>	<b>\$ (11.6)</b>	<b>\$ (46.3)</b>	<b>\$ (48.5)</b>

## Conference Call Today

Arbutus will hold a conference call and webcast today, Wednesday, November 7, 2018 at 4:30 PM Eastern Time (1:30 PM Pacific 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](http://www.arbutusbio.com). Alternatively, you can dial 1-866-393-1607 or 1-914-495-8556 and reference conference ID 2628189.

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 1-855-859-2056 or 1-404-537-3406, and reference conference ID 2628189.

## 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](http://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 expectations for AB-729 to enter the clinic in Q2 of 2019 and subsequently be combined with AB-506; the timing of expected top-line results of the Phase 1a/1b clinical trial of AB-506 in Q2 of 2019; our expectations regarding the initiation, timing and completion of preclinical studies and clinical trials; 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 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; 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 and Arbutus' continuous disclosure filings, which are available at [www.sedar.com](http://www.sedar.com) and at [www.sec.gov](http://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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Source: Arbutus Biopharma Corporation