

# **Arbutus Announces Corporate Update and Year-End 2017 Financial Results**

March 14, 2018

ARB-1467 Phase II Combination Study Beginning in 1Q18
Two New Drug Candidates Planned to Enter Clinical Development in 2H18
Over \$200M in CashAvailable to Fund Development of HBV Assets
Company to Host a Corporate Update Conference Call Today at 4:30 PM ET

VANCOUVER, British Columbia and WARMINSTER, Pa., March 14, 2018 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq:ABUS), an industry-leading Hepatitis B Virus (HBV) therapeutic solutions company, today announced its year-end 2017 audited financial results and provided a corporate update.

"I'm excited by the progress that Arbutus is making on delivering a cure for chronic HBV using a drug combination approach," said Dr. Mark J. Murray, Arbutus' President and CEO. "This year we plan to introduce into clinical development two new small molecule drug candidates which will put us firmly on the path to a proprietary combination therapy for HBV. In 2017, we advanced our RNAi agent, ARB-1467, to the stage of enabling a combination study with tenofovir and pegylated interferon. We begin 2018 from a strong financial position with over \$200 million in cash on a proforma basis, sufficient to fund our HBV development plans well beyond 2019. This year we look forward to beginning to receive a royalty from Alnylam based on patisiran sales enabled by our LNP intellectual property estate. This asset represents a meaningful source of runway extending capital to Arbutus, as well as further validating our LNP technology in the potentially first approved RNAi therapy. We will present data on our clinical programs in 2018 as we continue to move each asset closer to inclusion in future combination studies."

### **Clinical HBV Pipeline Update**

Phase II Combination Study of ARB-1467 to be initiated in 1Q18. This 30-week, multi-dose, triple combination study will evaluate bi-weekly doses of ARB-1467 and daily tenofovir, followed by the addition of weekly pegylated interferon for predefined treatment responders at 6 weeks and will conclude with a 24-week post-treatment follow-up period. The study aims to maximize HBsAg loss and to evaluate the importance of immune stimulation in patients who have achieved low HBV DNA and HBsAg levels. This study is the first of its kind for an RNAi agent in chronic HBV patients. We hope this study will inform the design of future combination studies. Interim on-treatment results from this study are expected in the second half of 2018, followed by final results in 2019.

AB-506 to enter clinical development. The Company has both first-and-next-generation capsid inhibitors in development. AB-423, the first-generation capsid inhibitor, was generally safe and well tolerated in its recently completed Phase 1 studies. AB-506, the next-generation capsid inhibitor, showed striking potency and improved PK in preclinical studies. Arbutus will continue to focus on rapidly advancing AB-506 into clinical testing before proceeding with additional clinical evaluation of AB-423. Arbutus plans to file an Investigational New Drug (IND)/Clinical Trial Application (CTA) in mid-2018 (pending successful IND/CTA-enabling studies) for AB-506, which has the potential to be a 'best-in-class' capsid inhibitor based on its favorable drug-like properties and potent inhibition of HBV replication. This molecule has the potential for once-daily oral dosing, making it an ideal candidate for inclusion in a combination regimen. Results from additional preclinical studies of AB-506 drug combinations with compounds acting through different mechanisms, will be presented in 2018. Based on comparative clinical data, Arbutus will select one of its capsid inhibitors for development as part of a proprietary drug combination.

AB-452 to enter clinical development. Arbutus plans to file an IND/CTA in mid-2018 (pending successful IND/CTA-enabling studies) for AB-452, an HBV RNA destabilizer with novel and broad activity in destabilizing HBV RNAs and reducing HBsAg. In 2017, Arbutus presented preclinical data showing that AB-452 has synergistic effects when combined with two of Arbutus' proprietary HBV RNAi agents in vitro. This molecule also has the potential for once-daily oral dosing, which is ideal for inclusion in drug combinations. Results from additional preclinical studies of AB-452 drug combinations with different mechanisms will be presented in 2018.

## **Corporate Highlights and Developments**

- Alnylam announced positive Phase III results for its LNP-enabled patisiran product in 2017. Alnylam has since completed a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) and a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for patisiran, which could result in regulatory approval in the second half of 2018. Arbutus is owed low-to-mid single digit royalties tiered based on global sales of patisiran and could receive its first royalty payment in late-2018. The Company anticipates that this royalty could provide meaningful runway extending capital to fund our HBV development programs.
- Litigation with Acuitas Therapeutics (Acuitas) was settled before trial, terminating Acuitas' right to use or further sublicense Arbutus' LNP technology. Arbutus' LNP represents the most clinically validated delivery technology suitable for RNAi, mRNA therapeutics, and gene editing applications. With the settlement of the Acuitas litigation, Arbutus has now consolidated its LNP intellectual property estate. This is a major milestone which establishes Arbutus as the owner and only source of this industry-leading technology platform with the ability to develop a full range of applications.
- Arbutus and Roivant Sciences (Roivant) entered into an Exclusivity Agreement, extended to April 15, 2018, to negotiate
  the terms of a proposal and a structure for the joint development, not including HBV indications, of Arbutus' nucleic
  acid-based delivery platforms (Lipid Nanoparticle (LNP) and GalNAc technologies) through a new company that would
  jointly own, manage, and develop these technologies. Arbutus will fully retain its patisiran royalty entitlement and rights to

- the LNP and GalNAc technologies for applications in HBV.
- Arbutus closed the second of two tranches of Preferred Shares issued to Roivant for aggregate gross proceeds of US\$116.4 million. In addition to the capital, the Roivant relationship provides Arbutus the opportunity to leverage Roivant's infrastructure and human capital to further advance its HBV and non-HBV assets.
- Arbutus initiated a site consolidation to focus its operations in its Warminster, PA site and will close its Burnaby, BC site
  June 1, 2018. This is expected to result in increased operational efficiency, a more flexible variable cost structure, and
  additional preservation of the Company's cash reserves. The Company's LNP technology group remains intact.

#### **Upcoming Milestones in 2018**

- 1Q18: Commence a 30-week Phase II triple combination study of ARB-1467, tenofovir, and pegylated interferon.
- 2H18: Alnylam expects initial regulatory approval for patisiran (Arbutus to receive royalties on sales).
- 1H18: Nominate a clinical candidate for IND/CTA-enabling studies of a lead GalNAc conjugate to enable subcutaneous delivery of an RNAi therapeutic that targets HBV.
- Mid-2018: Submit AB-506 IND/CTA-regulatory filing to enable Phase I clinical study start (pending approvals).
- Mid-2018: Submit AB-452 IND/CTA-regulatory filing to enable Phase I clinical study start (pending approvals).
- 2H18: Interim on-treatment results from triple combination study of ARB-1467, tenofovir, and pegylated interferon.

#### **Financial Results**

## Cash, Cash Equivalents and Investments

As of December 31, 2017, Arbutus had cash, cash equivalents, short-term investments and restricted investments totaling \$139.0 million, as compared to \$143.2 million at December 31, 2016. On October 16, 2017, the Company closed Tranche 1 of a strategic financing for the issue and sale of 500,000 Series A participating convertible preferred shares to Roivant for gross proceeds of \$50.0 million. On January 12, 2018, the Company closed the Tranche 2 issue and sale of 664,000 Series A participating convertible preferred shares to Roivant for gross proceeds of \$66.4 million, following receipt of the approval of Arbutus' shareholders on January 11, 2018. On a proforma basis, including the Tranche 2 proceeds the Company's cash balance was \$205.4 million at the start of 2018.

#### **Net Loss**

For the year ended December 31, 2017, the net loss was \$84.4 million (\$1.56 basic and diluted loss per common share) as compared to a net loss of \$384.2 million (\$7.24 basic and diluted loss per common share) for 2016. The decrease in net loss is primarily due to an impairment of \$29.0 million (net of taxes) of intangible assets in 2017 compared to an impairment of \$286.4 million (net of taxes) of intangible assets and goodwill in 2016.

## **Non-GAAP Net Loss**

The non-GAAP net loss for 2017 was \$59.9 million (\$1.09 loss per common share) as compared to a non-GAAP net loss of \$65.8 million (\$1.24 per common share) for 2016. The non-GAAP net loss for 2017 has been adjusted to exclude:

- non-cash compensation expense of \$8.0 million in connection with certain share repurchase provisions arising from the merger with Arbutus Inc. in March 2015;
- a non-cash recovery in deferred tax liability of \$12.5 million on intangible asset balance sheet value related to reduced U.S. federal taxes; and
- a non-cash net impairment charge related to intangible assets of \$23.9 million (\$40.8 million less deferred taxes of \$16.9 million) as described below.

### Revenue

Revenue was \$10.7 million in 2017 as compared to \$1.5 million in 2016.

In March 2017, Arbutus signed a License Agreement with Alexion that granted them exclusive use of the Company's proprietary lipid nanoparticle (LNP) technology in one of Alexion's rare disease programs. In July 2017, Arbutus received notice of termination from Alexion for the LNP license agreement. Revenue recorded in 2017 included the upfront license payment, as well as services provided to Alexion related to technology development, manufacturing and regulatory support for the advancement of Alexion's mRNA product candidate.

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. Revenue recognized in 2017 relates to the earned portion of the upfront license fee, as well as services provided to Gritstone.

In addition, Arbutus has ongoing license agreements with Alnylam and Spectrum, under which Arbutus is eligible to receive commercial royalties.

Revenue in 2016 related primarily to the Dicerna license and collaboration that was terminated in November 2016.

## Research, Development, Collaborations and Contracts Expenses

Research, development, collaborations and contracts expenses were \$62.7 million in 2017 as compared to \$61.3 million in 2016.

R&D expenses remained consistent during 2017 and 2016. The Company's R&D expenses predominantly relate to its HBV programs during both periods. Arbutus initiated a Phase I clinical trial for AB-423 in Q1 2017 and continues to incur costs related to the Company's clinical trials for ARB-1467 as well as costs for IND enabling studies for the Company's recent candidate nominations - a next-generation capsid inhibitor (AB-506) and an HBV RNA destabilizer (AB-452). The Company also continues to incur costs related to research and preclinical studies for the Company's other

HBV programs.

#### **General and Administrative**

General and administrative expenses were \$16.1 million in 2017 as compared to \$39.4 million in 2016.

G&A expenses decreased in 2017 compared to 2016 due to a decrease in non-cash compensation expense related to the expiry of repurchase rights effective Q2 2016 related to the departure of two of the four former Arbutus Inc. founders in June 2016. As a result of this change, the Company's quarterly non-cash compensation G&A expense decreased to \$1.5 million per quarter. The repurchase right provisions expired in Q3 2017, and no further compensation expense was recorded thereafter. Arbutus recorded a total of \$4.0 million in non-cash G&A compensation expense in 2017 compared to \$26.0 million in 2016.

## Impairment of Intangible Assets and Goodwill

During the year-ended December 31, 2017, the Company recorded a total impairment charge of \$40.8 million and a corresponding income tax benefit of \$16.9 million against its identified intangible assets, for the discontinuance of STING activities which represented the remainder of the intangible asset in the Immune Modulators drug class.

For the year ended December 31, 2016, the Company recorded a net impairment charge of \$148.2 million on intangible assets (\$253.2 million less deferred taxes of \$105.0 million). \$91.5 million net of taxes was recorded in the second quarter for the discontinuance of the ARB-1598 program in the Immune Modulator drug class after extensive research and analysis, as well as a delay for additional exploration of the biology of the cccDNA Sterilizer drug class. A further \$56.7 million net of tax was recorded in the fourth quarter as a result of a change in the estimated cost of capital and resulting discount rate used in the annual impairment assessment. This change in discount rate was made to address the sustained discrepancy between the market capitalization and the carrying value of the Company's intangible assets.

On December 31, Arbutus performed an annual impairment analysis for goodwill. No impairment was recorded for goodwill in 2017. The Company recorded an impairment of \$138.2 million in 2016 resulting from its reassessment of the discount rate.

## **Outstanding Shares**

At March 6, 2018, we had 55.1 million common shares issued and outstanding. In addition, we had outstanding 5.4 million options and 1.2 million Series A participating convertible preferred shares outstanding, which will be mandatorily convertible into 22.6 million common shares on October 18, 2021. Assuming the convertible preferred shares were converted as of March 6, 2018, we would have had 83.1 million common shares outstanding at March 6, common shares outstanding at March 6, 2018.

#### Other Income (Losses)

The Company continues to incur substantial expenses and to hold a portion of its cash and investment balances in Canadian dollars, and as such, will remain subject to risks associated with foreign currency fluctuations. During 2017, Arbutus recorded a foreign exchange gain of \$2.3 million, which is primarily an unrealized gain related to an appreciation in the value of the Company's Canadian dollar funds from the previous period, when converted to the Company's functional currency of U.S. dollars.

Contingent consideration is a liability assumed by the Company from acquiring Arbutus Inc. in March 2015. In 2017, Arbutus recorded an increase in the fair value of contingent consideration of \$1.4 million. In general, increases in the fair value of the contingent consideration are related to the progress of the Company's programs as they get closer to triggering contingent payments.

# UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

(in millions)

	December 31, 2017	December 31, 2016
Cash and cash equivalents	\$ 54.3	\$ 23.4
Short-term investments	72.1	107.1
Accounts receivable	0.4	0.3
Other current assets	2.6	1.8
Restricted investments	12.6	12.6
Property and equipment, net	12.2	6.9
Intangible assets	58.6	99.4
Goodwill	24.4	24.4
Total assets	\$ 237.2	\$ 275.9
Accounts payable and accrued liabilities	10.7	9.8
Total deferred revenue	2.7	0.0
Deferred lease inducements, net of current portion	0.7	0.0
Warrant liability	_	0.1
Liability-classified options	1.2	0.6
Loan payable	12.0	12.0
Contingent consideration	10.5	9.1
Deferred tax liability	16.9	41.3
Total stockholders' equity	182.5	203.0

## UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW

(in millions)

	December 31, 2017	December 31, 2016
Net loss for the period	\$ (84.4	) \$ (384.2 )
Net cash used in operating activities	(48.6	<b>)</b> (57.9
Net cash provided by (used in) investing activities	27.8	(99.1)
Net cash provided by financing activities	49.3	12.6
Effect of foreign exchange rate changes on cash & cash equivalents	2.4	1.0
Net increase (decrease) in cash and cash equivalents	\$ 30.9	\$ (143.4 )
Cash and cash equivalents, beginning of period	23.4	166.8
Cash and cash equivalents, end of period	\$ 54.3	\$ 23.4

## UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in millions)

	December 31, 2017	December 31, 2016
Total revenue	\$ 10.7	\$ 1.5
Operating expenses		
Research, development, collaborations and contracts	62.7	61.3
General and administrative	16.1	39.4
Depreciation of property and equipment	2.0	1.1
Impairment of intangible assets	40.8	253.2
Impairment of goodwill	0.0	138.2
Loss from operations	(110.9	<b>)</b> (491.7 )
Other income (losses)	2.2	2.5
Income tax benefit	24.3	105.0
Net loss	\$ (84.4	<b>)</b> \$ (384.2 )

## UNAUDITED GAAP TO NON-GAAP RECONCILIATION: NET LOSS AND NET LOSS PER SHARE

(in millions)

	December 31, 2017	December 31, 2016
GAAP net loss	\$ (84.4	) \$ (384.2 )
Adjustment:		
Compensation expense of expired repurchase provision rights	8.0	32.0
Recovery in deferred tax liability related to reduced U.S. federal taxes	(12.5	) 0.0
Impairment of intangible assets (net of tax benefit)	29.0	148.2
Impairment of goodwill	0.0	138.2
Non-GAAP net loss	\$ (59.9	) \$ (65.8 )
GAAP net loss per common share	\$ (1.56	) \$ (7.24 )
Non-GAAP net loss per common share	\$ (1.09	) \$ (1.24 )

#### **Use of Non-GAAP Financial Measures**

The Company's consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States (U.S. GAAP) on a basis consistent for all periods presented. In addition to the results reported in accordance with U.S. GAAP, the Company provides additional measures that are considered "non-GAAP" financial measures under applicable SEC rules. These non-GAAP financial measures should not be viewed in isolation or as a substitute for GAAP net loss and basic and diluted net loss per common share.

The Company evaluates items on an individual basis, and considers both the quantitative and qualitative aspects of the item, including (i) its size and nature, (ii) whether or not it relates to the Company's ongoing business operations, and (iii) whether or not the Company expects it to occur as part of its normal business on a regular basis. In the year ended December 31, 2017, the Company's non-GAAP net loss and non-GAAP net loss per common share excludes the compensation expense related to the expiration of repurchase provision rights connected with certain common shares issued as part of total consideration for the acquisition of Arbutus Inc. The Company believes that the exclusion of this item provides management and investors with supplemental measures of performance that better reflect the underlying economics of the Company's business. In addition, the Company believes the exclusion of this item is important in comparing current results with prior period results and understanding projected operating performance.

## **Conference Call Today**

Arbutus will hold a conference call and webcast today, Wednesday, March 14, 2018 at 1:30 PM Pacific Time (4:30 PM Eastern Time) to provide a corporate update. A live webcast of the call can be accessed through the Investor section of Arbutus' website at <a href="https://www.arbutusbio.com">www.arbutusbio.com</a>. Or, alternatively, to access the conference call, please dial 1-914-495-8556 or 1-866-393-1607.

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 1-404-537-3406 or 1-855-859-2056 and referencing conference ID 8777644.

#### **About Arbutus**

Arbutus Biopharma Corporation is a biopharmaceutical company dedicated to discovering, developing and commercializing a cure for patients suffering from chronic HBV infection. For more information, visit <a href="https://www.arbutusbio.com">www.arbutusbio.com</a>.

### 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 delivering a cure for chronic HBV using a drug combination approach; consolidating the business to more efficiently focus on our mission of delivering a cure for HBV; presenting data on our clinical programs in 2018; the structure and timing of a trial for ARB-1467, with interim on-treatment results expected in the 2H18 followed by final results in 2019; rapidly advancing AB-506 into clinical testing before proceeding with additional clinical evaluation of AB-423; an IND (or equivalent) filing for AB-506 in mid-2018; AB-506's potential to be a 'best-in-class' capsid inhibitor; results from additional preclinical studies of AB-506 drug combinations together with different mechanisms, being presented in 2018; an IND (or equivalent) filing for AB-452 in mid-2018, its potential for once-daily oral dosing, and results from additional preclinical studies of AB-452 drug combinations with different mechanisms being presented in 2018; the joint development of Arbutus' nucleic acid-based delivery platforms with Roivant; regulatory approval for patisiran in the second half of 2018; milestone and royalty payments from Moderna; the site consolidation resulting in increased efficiency, a more flexible variable cost structure, and additional preservation of the Company's cash reserves; the Company's LNP technology group remaining intact; and nominating a clinical candidate for IND/CTA-enabling studies of a lead GalNAc conjugate in 1H18.

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 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: expected payments, financings, and royalties may not be as large or as timely as expected, if at all; anticipated pre-clinical 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; the site consolidation may not result in the level of anticipated benefits, if at all; 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 <a href="www.sedar.com">www.sedar.com</a> and at <a href="www.sec.gov">www.sec.gov</a>. 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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