

November 5, 2015

# **Arbutus Announces Third Quarter 2015 Financial Results**

VANCOUVER, British Columbia and DOYLESTOWN, Pa., Nov. 5, 2015 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq:ABUS), an industry-leading therapeutic solutions company focused on developing a cure for chronic hepatitis B virus infection (HBV), today announced its third quarter 2015 unaudited financial results and provided a corporate update.

"We are excited to advance the development of our lead HBV candidate, TKM-HBV, to a Phase II, multi-dosing, clinical trial that will measure hepatitis B surface antigen (HBsAg) reduction in HBV infected patients," said Dr. Mark J. Murray, Arbutus' President and CEO. "We are also accelerating the development of our other promising HBV candidates, in particular, those that target cccDNA formation and core protein/capsid assembly."

# **Recent Company Highlights**

- Arbutus announced progression of TKM-HBV to Phase II studies in HBV infected patients based on results from a Phase I single ascending dose study. The TKM-HBV product candidate that will be studied in Phase II will be referred to as ARB-1467.
- Arbutus presented preclinical HBV data at the 2015 International Meeting on Molecular Biology of Hepatitis B Viruses, held on October 4-8, 2015. The presentations were titled: 1) "Profiling the Effects of TKM-HBV on cccDNA in Humanized Chimeric Mouse Model of HBV"; 2) "TKM-HBV, a Novel RNA Interference Treatment for Chronic Hepatitis B, Mediates Global Viral Antigen Reductions through a Well-Defined Mechanism of Action"; and 3) "Novel Inhibitors of HBV cccDNA Formation Exhibit Synergistic Effects with Nucleoside and Nucleotide Analog."
- Arbutus announced plans to present at the 2015 American Association for the Study of Liver Diseases (AASLD) Liver Meeting held on November 13-17, 2015. The titles of Arbutus' accepted abstracts are: 1) "TKM-HBV, a Novel RNA Interference Treatment for Chronic Hepatitis B, Rapidly Reduces Surface Antigen and other Viral Proteins in Both Intrahepatic and Peripheral Compartments"; 2) "TKM-HBV, a Novel RNA Interference Treatment for Chronic Hepatitis B, has a Complementary Mode of Action to Current Standard of Care Nucleos(t)ide Analogs"; and 3) "Development of a Direct RNA Interference Therapy for Hepatitis Delta Virus Infection."

#### **Upcoming Pipeline Milestones**

- 4Q15: Initiate phase II, multi-dose efficacy study of TKM-HBV in chronically infected patients
- 2016: HBsAg reduction data from TKM-HBV Phase II trial (final data in 2H16)
- 2016: Initiate clinical immune biomarker study for CYT-003 in HBV chronically infected patients
- 2H16: File IND (or equivalent) for cccDNA formation inhibitor
- 1 2H16: File IND (or equivalent) for core protein/capsid assembly inhibitor
- 1 2017: Initiate combination studies including two or more Arbutus HBV product candidates

#### **Financial Results**

#### **Cash, Cash Equivalents and Investments**

As at September 30, 2015, Arbutus had an aggregate balance in cash and investments of \$206.1 million, as compared to \$112.2 million at December 31, 2014. On March 25, 2015, Arbutus completed an underwritten public offering of 7,500,000 common shares, at a price of \$20.25 per share, resulting in net proceeds of \$142.2 million. The Company plans to use these proceeds to develop and advance its product candidates through clinical trials, as well as for working capital and general corporate purposes.

#### Cash used in operating activities

Arbutus is revising its guidance for 2015 cash used in operating activities to \$50 million. Results to-date reflect \$38.2 million of cash used in operating activities.

#### **Non-GAAP Net Loss**

The non-GAAP net loss for the three months and nine months ended September 30, 2015 was \$15.7 million (\$0.31 loss per common share) and \$37.3 million (\$0.86 loss per common share), respectively. The non-GAAP net loss has been adjusted to exclude:

- non-cash compensation expense of \$5.7 million for the three month period and \$11.0 million for the nine month period included in research, development, collaborations and contracts expenses and general and administrative expenses in connection to certain share repurchase provisions related to the merger with Arbutus Inc., described below.
- in both the three and nine month periods ended September 30, 2015, a non-cash estimated impairment charge of \$38.0 million on intangible assets related to the discontinuance of the cyclophilins program OCB-030, net of deferred income taxes of \$15.2 million.

### Net loss

The net loss for Q3 2015 was \$29.0 million (\$0.57 per common share) as compared to a net loss of \$8.6 million (\$0.39 per common share) for Q3 2014. The net loss for the nine-months ended September 30, 2015 was \$55.9 million (\$1.28 per common share) as compared to a net loss of \$32.7 million (\$1.53 per common share) for the nine-months ended September 30, 2014.

#### Revenue

Revenue was \$4.1 million for Q3 2015 as compared to \$4.4 million for Q3 2014.

Under the DoD contract to develop TKM-Ebola, Arbutus is being reimbursed for costs incurred, including an allocation of overheads, and is being paid an incentive fee. In October, the Company received formal notification from the DoD that, due to an unclear development path for TKM-Ebola and TKM-Ebola-Guinea, the Ebola Manufacturing and Ebola-Guinea IND submission statements of work had been terminated, subject to the completion of certain post-termination obligations. For this contract, Arbutus recorded \$2.0 million in revenue in Q3 2015 as compared to \$1.5 million in Q3 2014. The increase is largely related to the release of deferred revenue as the Company is near completion of the TKM-Ebola portion of the contract, which is expected to complete by the end of 2015, at which point the contract close out procedures will commence.

Under the Monsanto contract, Arbutus earns revenue from research and collaboration activities, as well as license fees related to Monsanto's use of the Company's delivery technology and related intellectual property in agriculture. In 2015, Monsanto made a total of \$1.8 million in payments for research services under the arrangement. Arbutus recorded \$1.0 million in aggregate Monsanto revenue in Q3 2015.

In November 2014, Arbutus entered into a collaboration with Dicerna for the use of its technology to develop, manufacture, and commercialize products related to the treatment of PH1. Arbutus recorded \$1.0 million in revenue in respect of the Dicerna collaboration in Q3 2015.

#### **Research, Development, Collaborations and Contracts Expenses**

Research, development, collaborations and contracts expenses were \$16.4 million in Q3 2015 as compared to \$9.3 million in Q3 2014.

Arbutus increased research activities related to HBV assets in Q3 2015, following the merger with Arbutus Inc. (formerly OnCore BioPharma, Inc.).

#### **General and Administrative**

General and administrative expenses were \$7.7 million in Q3 2015 as compared to \$1.8 million in Q3 2014.

The increase in general and administrative expenses was largely due to an increase in compensation expense with the growth in employee base to support the expanded portfolio of product candidates, and, in particular, a non-cash compensation expense related to share repurchase rights. As a result of the expiry of share repurchase rights included in the consideration paid for Arbutus Inc. (formerly OnCore), in Q3 2015, the Company recorded \$5.7 million of incremental non-cash compensation expense. Of this amount, \$4.3 million has been included in general and administration expense, and \$1.4 million has been included in research and development, collaborations and contracts expenses.

#### **Acquisition Costs**

During 2015, Arbutus incurred \$9.7 million in costs related to the merger with Arbutus Inc., which was completed on March 4, 2015.

### Impairment of intangible assets

In Q3 2015, Arbutus recorded an estimated impairment charge of \$38.0 million based on the Company's decision to discontinue the cyclophilin program, OCB-030, after extensive preclinical evaluations which concluded that cyclophilins do not play a meaningful role in HBV biology.

# Other Income (Losses)

In Q3 2015, Arbutus recorded a foreign exchange gain of \$11.8 million with the appreciation in value of U.S. dollar funds from the prior period, as compared to a foreign exchange gain of \$3.1 million in Q3 2014.

The aggregate decrease in fair value of the Company's common share purchase warrants was \$2.0 million in Q3 2015 as compared to an increase in the fair value of common share purchase warrants outstanding of \$5.1 million in Q3 2014. The decrease is a result of a decrease in the Company's share price from the previous reporting date, and vice versa for Q3 2014.

# **About Arbutus**

Arbutus Biopharma Corporation is a biopharmaceutical company dedicated to discovering, developing and commercializing a cure for patients suffering from chronic HBV infection. Our strategy is to target the three pillars necessary to develop a curative regimen for HBV: suppressing HBV replication within liver cells, stimulating and reactivating the body's immune system so that it can mount an effective defense against the virus and, eliminating the reservoir of viral genomic material known as covalently closed circular DNA, or cccDNA that is the source of HBV persistence. Our portfolio of assets includes a broad pipeline of drug candidates for use in combination to develop a cure for HBV. To support continuous discovery of potential novel drug candidates and technologies, Arbutus has a research collaboration agreement with the Baruch S. Blumberg Institute that provides exclusive rights to in-license any intellectual property generated through the relationship. The Baruch S. Blumberg Institute was established in 2003 by the Hepatitis B Foundation.

Arbutus is headquartered in Vancouver, BC, Canada with offices in Doylestown, PA, USA. For more information, visit <u>www.arbutusbio.com</u>.

#### **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 developing a cure for HBV; advancing the development of TKM-HBV (ARB-1467) to a Phase II clinical trial in the fourth quarter of 2015; HBsAg reduction data from the TKM-HBV trial in 2016 (and final data in the second half of 2016); the initiation of a clinical immune biomarker study for CYT-003 in 2016; fling an IND (or equivalent) for cccDNA formation inhibitor in the second half of 2016; filing an IND (or equivalent) for core protein/capsid assembly inhibitor in the second half of 2016; initiating combination studies including two or more Arbutus HBV product candidates in 2017; and planned use of proceeds from our March 2015 underwritten public offering.

With respect to the forward-looking statements contained in this press release, Arbutus has made numerous assumptions regarding, among other things: the effectiveness 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 contained herein. Known risk factors include, among others: 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; 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 <u>www.sedar.com</u> and at <u>www.sec.gov</u>. 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.

#### UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

(in millions)

#### September 30, 2015 December 31, 2014

Cash and cash equivalents	\$ 181.1	\$ 72.2
Short -term investments	15.0	40.0
Accounts receivable	2.2	1.9
Other current assets	1.8	2.3
Long-term investments	10.0	
Property and equipment, net	2.3	1.8
Intangible assets	353.6	
Goodwill	156.6	
Total assets	\$ 722.6	\$ 118.2
Accounts payable and accrued liabilities	7.5	9.3
Total deferred revenue	11.7	15.8
Warrant liability	1.5	5.1
Contingent consideration	6.7	
Deferred tax liability	141.4	
Total stockholders' equity	553.8	88.0
Total stockholders' equity		

# UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (in millions)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Total revenue	\$ 4.1	\$ 4.4	\$ 12.2	\$ 10.6
Operating expenses				
Research, development, collaborations and contracts	16.4	9.3	20.2	26.8
General and administrative	7.7	1.8	10.4	5.6
Depreciation of property and equipment	0.2	0.1	0.3	0.4
Acquisition costs			9.6	
Impairment of intangible assets	38.0		38.0	
Loss from operations	(58.1)	(6.8)	(90.6)	(22.2)
Other income (losses)	14.0	(1.8)	19.5	(10.4)
Income tax benefit	15.2		15.2	
Net loss	\$ (29.0)	\$ (8.6)	\$ (55.9)	\$ (32.7)
Cumulative translation adjustment	(10.1)	(4.8)	19.3	(3.2)
Comprehensive loss	\$ (39.1)	\$ (13.4)	\$ (75.1)	\$ (35.9)

UNAUDITED GAAP TO NON-GAAP RECONCILIATION: NET LOSS AND NET LOSS PER SHARE (in millions, except per share amounts)

	Ended September 30		Ended September 30	
	2015	2014	2015	2014
GAAP net loss	\$ (29.0)	(8.6)	(55.9)	(32.7)
Adjustment:				
Compensation expense of expiring repurchase provision rights	5.7		11.0	
Impairment on intangible assets (net of tax benefit)	22.8		22.8	
Non-GAAP net loss	<u>\$ (15.7)</u>	\$ (8.6)	<u>\$ (37.3)</u>	<u>\$ (32.7)</u>
GAAP net loss per common share	\$ (0.57)	\$ (0.39)	\$ (1.28)	\$ (1.53)
Non-GAAP net loss per common share	\$ (0.31)	\$ (0.39)	\$ (0.86)	\$ (1.53)

#### **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 three and nine months period ended September 30, 2015, 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. (formerly OnCore BioPharma, Inc.) and impairment on intangible assets (net of tax benefit). The Company believes that the exclusion of these items 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 these items is important in comparing current results with prior period results and understanding projected operating performance.

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