Arbutus Reports First Quarter 2020 Financial Results, Provides Pipeline Update and Announces New Research Initiative to Identify Novel Antiviral Therapies for the Treatment of Coronavirus Infections

May 11, 2020

Arbutus remains on track to achieve its key 2020 objectives despite COVID-19 challenges

Conference Call and Webcast Scheduled Today at 8:00 AM ET

WARMINSTER, Pa., May 11, 2020 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS), a clinical-stage biopharmaceutical company focused on developing a cure for people with chronic hepatitis B virus (HBV) infection, today reports its first quarter 2020 financial results, provides a pipeline update and announces the establishment of a new research initiative focused on the identification of novel therapies to combat COVID-19.

William Collier, President and Chief Executive Officer of Arbutus, stated, “As we announced in March, preliminary results from an ongoing Phase 1a/1b clinical trial for our lead compound, AB-729, demonstrate that it is a potent RNAi agent capable of reducing HBsAg plasma levels. We are on track to have additional results from the week 12 portion of the 60 mg single-dose cohort in the second quarter of 2020.”

Mr. Collier added, “Despite the challenges of COVID-19, we have not had to alter our objectives for 2020. However, future disruptions related to the COVID-19 pandemic could negatively impact our plans and timelines, including enrolling and monitoring subjects in the trial. We remain focused on developing a portfolio of products, with different mechanisms of action, that when used in combination could result in a functional cure for HBV.”

The Arbutus 2020 objectives include:

- advancing the Phase 1a/1b clinical trial of AB-729, a proprietary GalNAc delivered RNAi compound;
- progressing our next-generation capsid inhibitor AB-836 through IND-enabling studies; and,
- continuing our preclinical research to develop an oral HBV RNA-destabilizer and an oral anti-PD-L1 inhibitor.

Also, during the first quarter, and under the direction of Arbutus’ Chief Scientific Officer, Dr. Michael Sofia, the Company has initiated an internal research program to identify new small molecule antiviral medicines to treat COVID-19 and future coronavirus outbreaks. Dr. Sofia, who was awarded the Lasker-DeBakey Award for his discovery of sofosbuvir, brings extensive antiviral drug discovery experience to this new program. Arbutus has also joined forces with the COVID R&D consortium to further support and expedite efforts to address the COVID-19 pandemic.

The establishment of the COVID-19 effort does not impact Arbutus’ current cash burn guidance for 2020 of $54 to $58 million.

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 essential to enable the reawakening of a patient’s immune system so that it can respond to the virus.
- Arbutus is currently conducting a single- and multi-dose Phase 1a/1b clinical trial to determine the safety, tolerability, pharmacokinetics, and pharmacodynamics of AB-729 in healthy subjects and in subjects with chronic HBV infection.
    - Preliminary positive safety data in single-dose cohorts of healthy subjects and safety and efficacy data in the 60 mg and 180 mg single-dose cohorts in subjects with chronic HBV infection were reported in March.
    - Additional week 12 results for the 60 mg single-dose cohort are expected in the second quarter of 2020.
    - Results from the multi-dose 60 mg and single-dose 90 mg cohorts are expected in the second half of 2020.

AB-836: Oral Capsid Inhibitor

- 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 nucleos(t)ide 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 genetic reservoir which the virus uses to replicate itself.

- In January 2020, Arbutus selected AB-836 as its next-generation oral capsid inhibitor. AB-836 is from a novel chemical series differentiated from Arbutus' second generation capsid inhibitor candidate, AB-506, as well as competitor compounds. AB-836 has the potential for increased potency and an enhanced resistance profile compared to AB-506. Arbutus continues to expect completion of 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 antiviral effects in multiple HBV preclinical models. Arbutus is now focused on advancing next-generation oral RNA-destabilizers with chemical scaffolds distinct from Arbutus' prior generation HBV RNA destabilizer candidate, AB-452, through lead optimization. Arbutus also has several oral anti-PD-L1 inhibitors in lead optimization that are potentially capable of reawakening the immune response to HBV in infected patients.

New Research Efforts Initiated to Combat COVID-19

Dr. Michael Sofia, Chief Scientific Officer of Arbutus stated, "While our core mission at Arbutus is to find a cure for hepatitis B, the magnitude of the coronavirus pandemic is undeniable. Given our proven expertise in the discovery of new antiviral therapies, we feel compelled to work towards the discovery of a new treatment. To that end, we have assembled an internal team of expert scientists, with proven track records in bringing new antiviral medicines to market, to identify novel small molecule therapies to treat COVID-19. We have also recently joined forces with the COVID R&D consortium to further support and expedite efforts to address the SARS-CoV-2 pandemic and any future coronavirus outbreaks."

At this time, Arbutus' COVID-19 research program will focus on the discovery and development of new molecular entities that address specific viral targets including the nsp12 viral polymerase and the viral protease. These targets are essential viral proteins which Arbutus has experience in targeting.

COVID-19

In December 2019 an outbreak of a novel strain of coronavirus (COVID-19) was identified in Wuhan, China. This virus continues to spread globally, has been declared a pandemic by the World Health Organization and has spread to nearly every country in the world. The impact of this pandemic has been, and will likely continue to be, extensive in many aspects of society. The pandemic has resulted in and will likely continue to result in significant disruptions to businesses. A number of countries and other jurisdictions around the world have implemented extreme measures to try and slow the spread of the virus. These measures include the closing of businesses and requiring people to stay in their homes, the latter of which raises uncertainty regarding the ability to travel to hospitals in order to participate in clinical trials. Additional measures that have had, and will likely continue to have, a major impact on clinical development, at least in the near-term, include shortages and delays in the supply chain, and prohibitions in certain countries on enrolling subjects in new clinical trials. While we have been able to progress with our clinical and pre-clinical activities to date, it is not possible to predict if the COVID-19 pandemic will negatively impact our plans and timelines in the future.

Financial Results

Cash, Cash Equivalents and Investments

Arbutus had cash, cash equivalents and investments totaling $88.1 million as of March 31, 2020, as compared to $90.8 million as of December 31, 2019. We believe our ending first quarter cash, cash equivalents and investments of $88.1 million is sufficient to fund operations into mid-2021. Arbutus used $15.5 million in operating activities during the three months ended March 31, 2020. In addition, we received $12.3 million of net proceeds during the three months ended March 31, 2020 from the issuance of common shares under Arbutus's ATM program.

Net Loss

Net loss attributable to common shares for the three months ended March 31, 2020 was $16.8 million ($0.25 basic and diluted loss per common share) as compared to $26.0 million ($0.47 basic and diluted loss per common share) in 2019. Net loss attributable to common shares for the three months ended March 31, 2020 and 2019 included non-cash expense for the accrual of coupon on the Company's convertible preferred shares of $3.0 million and $2.7 million, respectively. Additionally, net loss attributable to common shares for the three months ended March 31, 2019 included $4.7 million of non-cash equity losses associated with our investment in Genevant Sciences Ltd. ("Genevant"), a company launched with Roivant Sciences Ltd., Arbutus's largest shareholder, in April 2018.

Operating Expenses

Research and development expenses were $10.4 million for the three months ended March 31, 2020 compared to $14.7 million in 2019. The decrease in research and development expenses for the three months ended March 31, 2020 versus the same period in 2019 was due primarily to lower clinical expenses. General and administrative expenses were $3.6 million for the three months ended March 31, 2020 compared to $4.4 million in 2019. The decrease in general and administrative expenses was due primarily to a decrease in legal fees and non-cash stock based compensation expense.

Outstanding Shares

The Company had 68,961,395 common shares issued and outstanding as of March 31, 2020. In addition, the Company had approximately 10.6 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)

	Three Months Ended March 31,	
	2020	**2019**
Revenue		
Revenue from collaborations and licenses	$ 835	$ 508
Non-cash royalty revenue	656	171
Total Revenue	1,491	679
Operating expenses		
Research and development	10,416	14,712
General and administrative	3,553	4,412
Depreciation	500	509
Change in fair value of contingent consideration	112	125
Site consolidation	57	117
Loss from operations	(13,147)	(19,196)
Other income (loss)		
Interest income	345	600
Interest expense	(1,041)	(12)
Foreign exchange (losses) / gains	(18)	8
Net equity investment loss	—	(4,651)
Total other loss	(714)	(4,055)
Net loss	$ (13,861)	$ (23,251)
Dividend accretion of convertible preferred shares	(2,978)	(2,715)
Net loss attributable to common shares	$ (16,839)	$ (25,966)
Net loss per common share		
Basic and diluted	$ (0.25)	$ (0.47)
Weighted average number of common shares		
Basic and diluted	67,683,586	55,740,121

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	March 31, 2020	**December 31, 2019**
Cash and cash equivalents	$ 26,416	$ 31,799
Investments in marketable securities, current	58,475	59,035
Accounts receivable and other current assets	3,442	2,994
Total current assets	88,333	93,828
Property and equipment, net of accumulated depreciation	8,176	8,676
Investments in marketable securities, non-current	3,215	—
Right of use asset	2,657	2,738
Other non-current assets	233	293
Total assets	$ 102,614	$ 105,535
Accounts payable and accrued liabilities	$ 3,565	$ 7,235
Liability-classified options	58	253
Lease liability, current	408	340
Total current liabilities	4,031	7,828
Liability related to sale of future royalties	19,375	18,992
Contingent consideration	3,065	2,953
Lease liability, non-current	2,887	3,018
Total stockholders' equity	73,256	72,744
Total liabilities and stockholders' equity	$ 102,614	$ 105,535

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW
(in thousands)

	Three Months Ended March 31,

	2020	2019
Net loss	$ (13,861)	$ (23,251)
Non-cash items	2,448	6,589
Changes in working capital	(4,040)	82
Net cash used in operating activities	(15,453)	(16,580)
Net cash provided by / (used in) investing activities	(2,401)	61,033
Net cash provided by financing activities	12,481	2,536
Effect of foreign exchange rate changes on cash and cash equivalents	(10)	38
Increase / (decrease) in cash and cash equivalents	$ (5,383)	$ 47,027
Cash and cash equivalents, beginning of period	31,799	36,942
Cash and cash equivalents, end of period	$ 26,416	$ 83,969
Investments in marketable securities	61,690	26,621
Cash, cash equivalents and investments, end of period	$ 88,106	$ 110,590

Conference Call and Webcast Today

Arbutus will hold a conference call and webcast today, Monday, May 11, 2020 at 8:00 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 or directly at Live Webcast. Alternatively, you can dial (866) 393-1607 or (914) 495-8556 and reference conference ID 2993486.

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 2993486.

About Arbutus

Arbutus Biopharma Corporation is a publicly traded (Nasdaq: ABUS) biopharmaceutical company dedicated to discovering, developing and commercializing a cure for people with chronic hepatitis B virus (HBV) infection. The Company is advancing multiple drug product candidates that may be combined into a potentially curative regimen for chronic HBV infection. 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 expectations regarding the timing and clinical development of our product candidates, including our expectations that certain data from the 60 mg single-dose cohort will be available in the second quarter of 2020, that results from the multi-dose 60 mg and single-dose 90 mg cohorts will be available in the second half of 2020 and that IND-enabling studies for AB-836 will be complete by the end of 2020; our planned 2020 objectives and cash burn guidance; the potential safety and efficacy of our product candidates, including the potential for AB-836 to have increase potency and an enhanced resistance profile compared to AB-506; our expectations regarding our new internal and external research efforts to combat COVID-19; the expected sufficiency of our ending first quarter cash, cash equivalents and investments to fund operations into mid-2021; and our expectations regarding the effect of the COVID-19 pandemic on our business.

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 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 the ongoing COVID-19 pandemic.

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; and the ongoing COVID-19 pandemic could significantly disrupt our clinical development programs.

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