Arbutus Reports Fourth Quarter and Year End 2021 Financial Results and Provides Corporate Update

March 3, 2022

Anticipate reporting data from four clinical trials in chronically infected HBV patients in 2022

Expected to complete IND-enabling studies for two oral compounds (PD-L1 inhibitor AB-101 and RNA destabilizer AB-161) to treat HBV in the second half of 2022

Anticipate advancing an oral compound that inhibits the SARS-CoV-2 nsp5 main protease into IND enabling studies in the second half of 2022

Arbutus and Genevant Sciences filed patent infringement lawsuit against Moderna

Conference Call and Webcast Today at 8:45 AM ET

WARMINSTER,Pa., March 03, 2022 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS), a clinical-stage biopharmaceutical company leveraging its extensive virology expertise to develop novel therapeutics that target specific viral diseases, today reports its fourth quarter and year end 2021 financial results and provides pipeline updates.

“2021 was a transformative year for Arbutus as we greatly expanded our development efforts in Hepatitis B and coronavirus infections, including SARS-CoV-2,” said William Collier, Arbutus’ President and Chief Executive Officer. “We formed strategic and clinical partnerships that allowed us to explore several combination therapies with AB-729, our RNAi therapeutic, as a potential cornerstone agent in a functional cure for Hepatitis B, expand the reach of AB-729 to greater China and broaden our pipeline to include programs targeting coronaviruses. In addition, we have expanded our preclinical programs in HBV with our oral PD-L1 inhibitor, AB-101, and our oral RNA destabilizer, AB-161, both of which are expected to complete IND-enabling studies this year. Multiple key clinical trial data read-outs expected later this year for AB-729 and AB-836 will inform our go-forward clinical and regulatory strategy for HBV Phase 2b development.”

Pipeline Update

AB-729 (RNAi Therapeutic)

- Arbutus is currently dosing patients in the last cohort of its Phase 1a/1b clinical trial to evaluate the safety and tolerability of AB-729 in patients with chronic Hepatitis B (cHBV) infection (AB-729-001 Trial). Data observed to-date show that AB-729 continues to reduce HBsAg across all doses and dosing intervals with a favorable safety and tolerability profile. Additionally, long term dosing of AB-729 has increased HBV-specific immune responses in some patients.
- The Company intends to present updated and new on-treatment data on multiple cohorts of patients included in the AB-729-001 Trial, as well as long-term follow-up data for patients in the AB-729-001 Trial who completed treatment and have discontinued AB-729 and standard-of-care nucleos(t)ide analogues (NA) therapy at a medical conference this year.
- In-line with the Company’s strategy to combine multiple therapies that target different points of the viral replication cycle to develop a curative treatment regimen for cHBV, Arbutus is currently enrolling patients in its Phase 2a randomized, open-label, proof-of-concept clinical trial designed to evaluate the safety and tolerability of AB-729 in combination with ongoing NA therapy and short courses of PEG-IFNα-2a in 40 patients with cHBV infection. The Company is expecting initial data from this clinical trial in the second half of 2022.
- Also, in line with the Company’s strategy, Arbutus has entered into separate clinical collaboration agreements with Assembly Biosciences, Inc. (Assembly), Vaccitech plc (Vaccitech) and Antios Therapeutics, Inc. (Antios) to evaluate AB-729 as the cornerstone agent in combination with Assembly’s capsid inhibitor, Vaccitech’s T-cell stimulating therapeutic vaccine, and Antios’ Active Site Polymerase Inhibitor Nucleotide (ASPIN), respectively, in patients with cHBV infection.
    - Enrollment is on-going in the Phase 2a proof-of-concept triple combination clinical trial evaluating AB-729, vebicorvir (VBR), Assembly’s lead HBV core inhibitor (capsid inhibitor), and an NA. Assembly is conducting this clinical trial and expecting initial data in the second half of 2022.
    - Arbutus is on-track to initiate a triple combination Phase 2a clinical trial in the first half of 2022 to evaluate AB-729, combined with VTP-300, Vaccitech’s therapeutic vaccine and an NA.
    - Enrollment is complete in a cohort of patients in Antios’ Phase 2a clinical trial evaluating AB-729, ATI-2173, Antios’ ASPIN, and Viread (tenofovir disoproxil fumarate). With the majority of patients in this cohort enrolled in Ukraine, which is currently in a state of war, they may be lost to follow-up before completing the trial. Therefore, Arbutus and Antios may report limited data on a reduced number of patients from this clinical trial.

AB-836 (Oral Capsid Inhibitor)

- AB-836 is Arbutus' novel, next generation oral capsid inhibitor with improved intrinsic potency, activity against resistant variants and an enhanced ability to starve replenishment of cccDNA, which is responsible for HBV persistence.
- Arbutus is enrolling patients in part 3 of its on-going Phase 1a/1b clinical trial evaluating the safety and tolerability of multiple doses of AB-836 in patients with cHBV infection. The Company is on-track to report additional data from patients with cHBV infection in the first half of 2022.

AB-101 (Oral PD-L1 Inhibitor)

- AB-101 is Arbutus' oral PD-L1 inhibitor that is designed to reawaken the immune system, which the Company believes may be a key component in developing a functional cure for HBV.
- Arbutus has commenced IND-enabling studies for AB-101 and intends to complete those studies in the second half of 2022.

AB-161 (Oral RNA destabilizer)

- AB-161 is Arbutus' next-generation oral HBV specific RNA destabilizer, which is being developed to create an all-oral treatment regimen to functionally cure HBV.
- Arbutus has conducted extensive non-clinical safety evaluations with AB-161 that provide confidence in the molecule's ability to circumvent the peripheral neuropathy findings seen in non-clinical safety studies with the Company's first-generation oral RNA destabilizer, AB-452.
- Arbutus has commenced IND-enabling studies for AB-161 and intends to complete those studies in the second half of 2022.

COVID-19 and Pan-Coronavirus Programs

- Leveraging its extensive antiviral drug discovery experience, Arbutus is focused on the discovery and development of new pan-coronavirus molecular entities to treat COVID-19 and future coronavirus outbreaks by targeting essential viral proteins including the nsp12 viral polymerase and the nsp5 viral protease.
- Arbutus intends to nominate a candidate that inhibits the SARS-CoV-2 nsp5 main protease (M^{pro}) in the first half of 2022 and advance that candidate into IND-enabling studies. In addition, the Company intends to continue lead optimization activities for an Nsp12 viral polymerase candidate.

Corporate Update

- In April 2018, Arbutus entered into an agreement with Roivant Sciences Ltd. (Roivant), its largest shareholder, to launch Genevant Sciences Ltd. (Genevant), a company focused on a broad range of RNA-based therapeutics enabled by Arbutus' LNP and ligand conjugate delivery technologies. Arbutus licensed rights to its LNP and ligand conjugate delivery platforms to Genevant for RNA-based applications outside of HBV, except to the extent certain rights had already been licensed to other third parties. Arbutus retained all rights to its LNP and conjugate delivery platforms for HBV and owns approximately 16% of the common equity of Genevant.

- In February 2022, Arbutus and Genevant filed a lawsuit in the U.S. District Court for the District of Delaware against Moderna, Inc. and a Moderna affiliate seeking damages for infringement of U.S. Patent Nos. 8,058,069, 8,492,359, 8,822,668, 9,364,435, 9,504,651, and 11,141,378 in the manufacture and sale of MRNA-1273, Moderna's vaccine for COVID-19. The patents relate to nucleic acid-lipid particles and lipid vesicles, as well as compositions and methods for their use. Arbutus, and Genevant, do not seek an injunction or otherwise seek to impede the sale, manufacture or distribution of MRNA-1273. However, the parties seek fair compensation for Moderna's use of their patented technology that was developed with great effort and at a great expense, without which Moderna's COVID-19 vaccine would not have been successful.

- Under the license agreement with Genevant, as amended, if Genevant receives proceeds from an action for infringement by any third parties of Arbutus' intellectual property licensed to Genevant, Arbutus would be entitled to receive, after deduction of litigation costs, 20% of the proceeds received by Genevant or, if less, tiered low single-digit royalties on net sales of the infringing product (inclusive of the proceeds from litigation or settlement, which would be treated as net sales).

Financial Results

Cash, Cash Equivalents and Investments

As of December 31, 2021, the Company had cash and cash equivalents of $109.3 million and investments in marketable securities of $81.7 million, totaling $191.0 million, as compared to $123.3 million as of December 31, 2020. The ending cash, cash equivalents and marketable securities as of December 31, 2021 do not include a $40 million upfront payment and a $15 million equity investment from Qilu Pharmaceutical as part of an exclusive licensing agreement and strategic partnership to develop and commercialize AB-729 in China, received in January 2022.

During the year ended December 31, 2021, Arbutus used $67.5 million in operating activities, which was offset by $134.7 million of net proceeds from the issuance of common shares under Arbutus's "at-the-market" offering program. Arbutus expects a net cash burn between $90 to $95 million in 2022 and believes its cash runway, including $55 million of gross proceeds received from Qilu Pharmaceutical in January 2022, will be sufficient to fund the Company's operations into the second quarter of 2024.

Net Loss

For the year ended December 31, 2021, the Company's net loss attributable to common shares was $88.4 million, or a loss of $0.83 per basic and diluted common share, as compared to a net loss of $75.9 million, or a loss of $1.00 per basic and diluted common share, for the year ended December 31, 2020. Net loss attributable to common shares for the year ended December 31, 2021 and 2020 included $12.1 million of non-cash expense in both periods for the accrual of coupon on the Company's convertible preferred shares, which converted into 22.8 million common shares in October 2021.

Operating Expenses

Research and development expenses were $65.5 million for the year ended December 31, 2021 compared to $49.3 million for the same period in 2020. The increase of $16.2 million in research and development expenses for the year ended December 31, 2021 versus the same period in 2020 was due primarily to an increase in expenses related to the Company's multiple, ongoing AB-729 clinical trials, including its collaboration with Assembly, an increase in expenses for its ongoing AB-836 Phase 1a/1b clinical trial, and an increase in expenses for its early stage development programs, including its coronavirus programs.

Outstanding Shares

As of December 31, 2021, the Company had approximately 145.0 million common shares issued and outstanding, as well as approximately 11.4 million stock options outstanding. Following the conversion of preferred shares in October 2021, Roivant owned approximately 27% of the Company's outstanding common shares as of December 31, 2021.

COVID-19 Impact

The COVID-19 virus, first identified in December 2019, 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 and patients 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 materially impact our plans and timelines in the future.

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

	Year ended December 31,	
	2021	**2020**
Revenue		
Revenue from collaborations and licenses	$ 4,880	$ 3,519
Non-cash royalty revenue	6,108	3,395
Total revenue	10,988	6,914
Operating expenses		
Research and development	65,502	49,338
General and administrative	17,136	14,845
Change in fair value of contingent consideration	1,872	473
Site consolidation	—	64
Total operating expenses	84,510	64,720
Loss from operations	(73,522)	(57,806)
Other income (loss)		
Interest income	127	741
Interest expense	(2,857)	(4,011)
Net equity investment loss	—	(2,545)
Foreign exchange gains (losses)	5	(124)
Total other loss	(2,725)	(5,939)
Net loss	$ (76,247)	$ (63,745)
Dividend accretion of convertible preferred shares	(12,139)	(12,123)
Net loss attributable to common shares	$ (88,386)	$ (75,868)
Net loss per common share		

Basic and diluted	$ (0.83)	$ (1.00)
Weighted average number of common shares		
Basic and diluted	106,242,452	75,835,378

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	December 31, 2021	December 31, 2020
Cash, cash equivalents and marketable securities, current	$ 155,317	$ 123,268
Accounts receivable and other current assets	5,344	4,436
Total current assets	160,661	127,704
Property and equipment, net of accumulated depreciation	5,983	6,927
Investments in marketable securities, non-current	35,688	—
Right of use asset	2,092	2,405
Other non-current assets	61	44
Total assets	$ 204,485	$ 137,080
Accounts payable and accrued liabilities	$ 10,838	$ 9,151
Lease liability, current	383	390
Total current liabilities	11,221	9,541
Liability related to sale of future royalties	16,296	19,554
Contingent consideration	5,298	3,426
Lease liability, non-current	2,231	2,593
Total stockholders' equity	169,439	101,966
Total liabilities and stockholders' equity	$ 204,485	$ 137,080

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW
(in thousands)

	Twelve Months Ended December 31,	
	2021	2020
Net loss	$ (76,247)	$ (63,745)
Other non-cash items	7,785	11,873
Changes in working capital	930	431
Net cash used in operating activities	(67,532)	(51,441)
Net cash used in investing activities	(12,678)	(14,909)
Net cash provided by financing activities	137,236	86,297
Effect of foreign exchange rate changes on cash and cash equivalents	5	56
Increase in cash and cash equivalents	57,031	20,452
Cash and cash equivalents, beginning of period	52,251	31,799
Cash and cash equivalents, end of period	109,282	52,251
Investments in marketable securities	81,723	71,017
Cash, cash equivalents and marketable securities, end of period	$ 191,005	$ 123,268

Conference Call and Webcast Today

Arbutus will hold a conference call and webcast today, Thursday, March 3, 2022, 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: 3977368.

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: 3977368.

About AB-729

AB-729 is an RNA interference (RNAi) therapeutic specifically designed to reduce all HBV viral proteins and antigens, including hepatitis B surface antigen, which is thought to be a key prerequisite to enable reawakening of a patient's immune system to respond to the virus. AB-729 targets hepatocytes using Arbutus' novel covalently conjugated N-acetylgalactosamine (GalNAc) delivery technology that enables subcutaneous delivery. Clinical data generated thus far has shown single- and multi-doses of AB-729 to be generally safe and well-tolerated while providing meaningful reductions in hepatitis B surface antigen and hepatitis B DNA. AB-729 is currently in multiple Phase 2a clinical trials.

About AB-836

AB-836 is a next generation oral hepatitis B virus (HBV) capsid inhibitor that interacts with HBV core protein, which in turn is required for viral replication. The current standard-of-care therapy for HBV is primarily nucleos(t)ide analogues that inhibit the viral polymerase and significantly reduce, but do not eliminate viral replication. AB-836 in combination with nucleos(t)ide analogues is designed to completely eliminate viral replication in infected cells by preventing the assembly of functional viral capsids. In addition, AB-836 has been shown to inhibit the replenishment of covalently

closed circular DNA (cccDNA), the viral genetic reservoir which the virus needs to replicate itself. Preliminary data from an on-going Phase 1a/1b clinical trial has shown that AB-836 is generally safe and well-tolerated and provides robust antiviral activity.

About HBV

Hepatitis B is a potentially life-threatening liver infection caused by the hepatitis B virus (HBV). HBV can cause chronic infection which leads to a higher risk of death from cirrhosis and liver cancer. Chronic HBV infection represents a significant unmet medical need. The World Health Organization estimates that over 290 million people worldwide suffer from chronic HBV infection, while other estimates indicate that approximately 2.4 million people in the United States suffer from chronic HBV infection. Approximately 820,000 people die every year from complications related to chronic HBV infection despite the availability of effective vaccines and current treatment options.

About Arbutus

Arbutus Biopharma Corporation (Nasdaq: ABUS) is a clinical-stage biopharmaceutical company leveraging its extensive virology expertise to develop novel therapeutics that target specific viral diseases. Our current focus areas include Hepatitis B virus (HBV), SARS-CoV-2, and other coronaviruses. In HBV, we are developing a RNAi therapeutic, oral capsid inhibitor, oral PD-L1 inhibitor, and oral RNA destabilizer that we intend to combine to provide a functional cure for patients with chronic HBV by suppressing viral replication, reducing surface antigen and reawakening the immune system. We believe our lead compound, AB-729, is the only RNAi therapeutic with evidence of immune re-awakening, and is currently being evaluated in multiple phase 2 clinical trials. We have an ongoing drug discovery and development program directed to identifying novel, orally active agents for treating coronavirus (including SARS-CoV-2). We are also exploring oncology applications for our internal PD-L1 portfolio. 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 future development plans for our product candidates; the expected cost, timing and results of our clinical development plans and clinical trials with respect to our product candidates; our expectations and goals for our collaborations with third parties and any potential benefits related thereto; the potential for our product candidates to achieve success in clinical trials; our expected financial condition, including the anticipated duration of cash runways and timing regarding needs for additional capital; the patent infringement lawsuit against Moderna; and our expectations regarding the impact of the COVID-19 pandemic on our business and clinical trials.

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 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 and patent litigation matters.

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 product candidate; Arbutus may elect to change its 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; uncertainties associated with litigation generally and patent litigation specifically; Arbutus and its collaborators may never realize the expected benefits of the collaborations; market shifts may require a change in strategic focus; and the ongoing COVID-19 pandemic could significantly disrupt Arbutus' 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.

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