

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): August 4, 2022

Arbutus Biopharma Corporation

(Exact name of registrant as specified in its charter)

British Columbia, Canada

(State or Other Jurisdiction of Incorporation)

001-34949

(Commission File Number)

98-0597776

(I.R.S. Employer Identification No.)

701 Veterans Circle

Warminster, Pennsylvania 18974

(Address of Principal Executive Offices) (Zip Code)

(267) 469-0914

(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Shares, without par value	ABUS	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On August 4, 2022, Arbutus Biopharma Corporation (the “Company”) issued a press release announcing its financial results for the second quarter ended June 30, 2022 and certain other information. A copy of the press release is furnished as Exhibit 99.1 hereto and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.**(d) Exhibits.**

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release dated August 4, 2022
104	Cover page interactive data file (formatted as inline XBRL).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Arbutus Biopharma Corporation

Date: August 4, 2022

By: /s/ David C. Hastings
David C. Hastings
Chief Financial Officer

Arbutus Reports Second Quarter 2022 Financial Results and Provides Corporate Update

Key milestones across our chronic hepatitis B virus (cHBV) and pan-coronavirus programs remain on track

Financially strong with a projected cash runway into the second quarter of 2024

Conference Call and Webcast Today at 8:45 AM ET

WARMINSTER, Pa., Aug. 04, 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 second quarter 2022 financial results and provides corporate updates.

“This quarter we presented data at the EASL ILC which highlighted the advancements we have made in developing our lead RNAi therapeutic AB-729, capsid inhibitor AB-836, and PD-L1 inhibitor AB-101 to potentially provide a functional cure for patients with chronic hepatitis B virus (cHBV). For AB-729 we presented exciting data showing achievement of virologic control in five cHBV patients after discontinuing treatment with AB-729 and nucleos(t)ide analog (NA)-therapy. We continue to follow these patients, as well as others that have elected to discontinue treatment, and look forward to providing additional follow-up data later this year,” said William Collier, Arbutus’ President and Chief Executive Officer. “In addition, we were impressed with the competitive and robust antiviral activity seen with AB-836 and we plan to initiate a Phase 1 study in healthy volunteers to better characterize the unexpected ALT increases seen in some patients. We also look forward to completing IND-enabling studies this year with AB-161, our RNAi destabilizer, and AB-101.”

Mr. Collier continued, “We are continuing to advance our development efforts with our nsp5 main protease (M^{Pro}) and nsp12 viral polymerase programs for SARS-CoV-2 and future coronavirus outbreaks. Finally, our financial position is strong with a projected cash runway into the second quarter of 2024.”

Pipeline Updates:

AB-729 (RNAi Therapeutic)

- Arbutus presented new on-treatment data as well as long-term off-treatment data for cHBV patients in the AB-729-001 clinical trial at the 2022 European Association for the Study of the Liver (EASL) International Liver Congress™ (ILC) on June 25th. Key findings included:
 - AB-729 provided robust and comparable HBsAg declines regardless of dose, dosing interval or baseline characteristics
 - 50% of patients (16 out of 32) maintained HBsAg levels below 100 IU/mL 24 weeks after their last dose of AB-729
 - There was no evidence of virologic or clinical relapse in 8-24 weeks of follow-up in the first five patients who discontinued both AB-729 and NA therapy
 - AB-729 continues to restore HBV-specific T-cells and decrease exhausted T-cells
 - AB-729 remains generally safe and well-tolerated after completing dosing in 41 patients
- Dosed first patient in the AB-729-202 Phase 2a clinical trial evaluating AB-729, in combination with VTP-300, Vaccitech plc’s (Vaccitech) therapeutic vaccine and nucleos(t)ide analogue therapy (NA), in cHBV patients.
- Enrollment is continuing in the Phase 2a clinical trial evaluating AB-729 in combination with ongoing NA therapy and short courses of Peg-IFN α -2a (AB-729-201) in cHBV patients. The Company is on-track to report initial data in the second half of 2022.
- Dosing is continuing in the Phase 2a clinical trial evaluating AB-729 in combination with vebicorvir (VBR), Assembly Biosciences, Inc.’s HBV core inhibitor (capsid inhibitor), and an NA in cHBV patients. Preliminary data are expected in the second half of 2022.

AB-836 (Oral Capsid Inhibitor)

- In June 2022 Arbutus presented data at EASL from its AB-836-001 Phase 1a/1b clinical trial in which the Company is evaluating the safety and tolerability of multiple doses of AB-836 in patients with cHBV infection. AB-836 dosed at 100mg or 200mg once daily for 28 days achieved mean declines in HBV DNA of 3.04 and 3.55 log₁₀ IU/mL, respectively. Two HBeAg+ patients in the 100mg dose cohort had transient Grade 3 ALT elevations that resolved with continued dosing and were not considered treatment emergent adverse events (TEAEs). Two patients in the 200mg cohort had Grade 3 and Grade 4 ALT elevations on the last day of dosing (Day 28) that returned to baseline during follow up which were reported as TEAEs. Based on these ALT findings, the Company plans to conduct an additional Phase 1 trial in healthy volunteers to determine whether or not these ALT elevations are beneficial or could be the result of liver toxicity. The Company will provide an update with respect to the status and timing of this clinical trial in the second half of 2022.

AB-101 (Oral PD-L1 Inhibitor)

- In June 2022 Arbutus presented data at EASL showing that once daily oral administration of AB-101 resulted in T-cell activation in a preclinical model. In addition, AB-101 activates and reinvigorates HBV-specific T-cells *in vitro*. The company is on-track to complete IND-enabling studies for AB-101 in the second half of 2022.

AB-161 (Oral RNA Destabilizer)

- Arbutus is conducting IND-enabling studies for AB-161, its oral RNA destabilizer. The Company intends to complete IND-enabling studies for AB-161 in the second half of 2022.

COVID-19 and Pan-Coronavirus Programs

- We see an opportunity to pursue a combination therapy consisting of compounds that inhibit the SARS-CoV-2 nsp5 main protease and nsp12 viral polymerase, to achieve better patient treatment outcomes and use in prophylactic settings.
- Arbutus plans to nominate a lead candidate that inhibits the SARS-CoV-2 nsp5 main protease (M^{Pro}) in the second half of 2022 and then advance that compound into IND-enabling studies.
- The Company is continuing lead optimization activities for an nsp12 viral polymerase candidate.

PD-L1 in Oncology

- Preclinical data was selected for publication at the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2022 showing that Arbutus' oral small-molecule PD-L1 inhibitors in development, which possess a novel mechanism of action, have the ability to mediate T-cell activation in primary human immune cells. The anti-tumor efficacy seen *in vivo* was comparable to anti-PD-L1 antibodies. The data was published in the Journal of Clinical Oncology.

Financial Results

Cash, Cash Equivalents and Investments

As of June 30, 2022, the Company had cash, cash equivalents and investments in marketable securities of \$200.6 million, as compared to \$191.0 million as of December 31, 2021.

During the six months ended June 30, 2022, the Company received a \$40.0 million (net of withholding taxes) upfront payment from Qilu Pharmaceutical Co., Ltd. ("Qilu") related to a technology transfer and license agreement for AB-729 in greater China, \$15.0 million of gross proceeds from Qilu's equity investment in the Company and \$0.3 million of net proceeds from the issuance of common shares under Arbutus's "at-the-market" offering program. These cash inflows were partially offset by \$43.7 million of cash used in operations. The Company expects a net cash burn between \$90 to \$95 million in 2022, not including the \$55 million of proceeds received from Qilu, and believes its cash runway will be sufficient to fund operations into the second quarter of 2024.

Revenue

Revenues were \$14.2 million for the three months ended June 30, 2022 compared to \$2.3 million for the same period in 2021. The increase of \$11.9 million was due primarily to \$11.0 million of revenue recognition from the Company's license agreement with Qilu based on employee labor hours expended by the Company during the three months ended June 30, 2022 to perform its manufacturing obligations under the license agreement.

Operating Expenses

Research and development expenses were \$22.9 million for the three months ended June 30, 2022, compared to \$15.8 million for the same period in 2021. The increase of \$7.1 million was due primarily to an increase in expenses related to the Company's multiple, ongoing AB-729 Phase 2a clinical trials, including its collaborations with Assembly and Vaccitech, and an increase in expenses for its early-stage development programs, including AB-101 and AB-161. General and administrative expenses were \$5.2 million for the three months ended June 30, 2022, compared to \$4.5 million for the same period in 2021. This increase was due primarily to increases in employee compensation and non-cash stock-based compensation expense.

Net Loss

For the three months ended June 30, 2022, the Company's net loss attributable to common shares was \$14.2 million, or a loss of \$0.10 per basic and diluted common share, as compared to a net loss attributable to common shares of \$22.7 million, or a loss of \$0.23 per basic and diluted common share, for the three months ended June 30, 2021. Net loss attributable to common shares for the three months ended June 30, 2021 included \$3.3 million of non-cash expense for the accrual coupon on the Company's convertible preferred shares, which converted into 22.8 million common shares in October 2021.

Outstanding Shares

As of June 30, 2022, the Company had approximately 148.8 million common shares issued and outstanding, as well as approximately 15.9 million stock options outstanding. Roivant Sciences Ltd. owned approximately 26% of the Company's outstanding common shares as of June 30, 2022.

COVID-19 Impact

The COVID-19 pandemic has resulted in and will likely continue to result in significant disruptions to businesses. Measures implemented around the world in attempts to slow the spread of COVID-19 have had, and will likely continue to have, a major impact on clinical development, at least in the near-term, including shortages and delays in the supply chain and prohibitions in certain countries on enrolling subjects and patients in new clinical trials. While the Company has been able to progress with its clinical and pre-clinical activities to date, it is not possible to predict if the COVID-19 pandemic will materially impact the Company's plans and timelines in the future.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue				
Collaborations and licenses	\$ 12,556	\$ 1,185	\$ 23,774	\$ 2,339
Non-cash royalty revenue	1,685	1,144	3,048	2,103
Total Revenue	14,241	2,329	26,822	4,442
Operating expenses				
Research and development	22,942	15,799	41,404	29,581
General and administrative	5,200	4,478	10,092	8,356
Change in fair value of contingent consideration	208	694	409	823
Total operating expenses	28,350	20,971	51,905	38,760
Loss from operations	(14,109)	(18,642)	(25,083)	(34,318)
Other income (loss)				
Interest income	396	31	555	70
Interest expense	(482)	(763)	(988)	(1,535)
Foreign exchange (losses) gains	3	(13)	3	15
Total other loss	(83)	(745)	(430)	(1,450)
Net loss before income tax expense	(14,192)	(19,387)	(25,513)	(35,768)
Income tax expense	-	-	(4,444)	-
Net loss	(14,192)	(19,387)	(29,957)	(35,768)
Dividend accretion of convertible preferred shares	-	(3,266)	-	(6,478)
Net loss attributable to common shares	\$ (14,192)	\$ (22,653)	\$ (29,957)	\$ (42,246)
Loss per share				
Basic and diluted	\$ (0.10)	\$ (0.23)	\$ (0.20)	\$ (0.44)
Weighted average number of common shares				
Basic and diluted	148,750,048	96,869,805	148,589,711	95,153,545

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	June 30, 2022	December 31, 2021
Cash, cash equivalents and marketable securities, current	\$ 150,199	\$ 155,317
Accounts receivable and other current assets	7,592	5,344
Total current assets	157,791	160,661
Property and equipment, net of accumulated depreciation	5,493	5,983
Investments in marketable securities, non-current	50,450	35,688
Right of use asset	1,922	2,092
Other non-current assets	180	61
Total assets	\$ 215,836	\$ 204,485
Accounts payable and accrued liabilities	\$ 12,474	\$ 10,838
Deferred revenue	16,973	-
Lease liability, current	377	383
Total current liabilities	29,824	11,221
Liability related to sale of future royalties	14,233	16,296
Deferred revenue, non-current	10,842	-
Contingent consideration	5,707	5,298

Lease liability, non-current	2,088	2,231
Total stockholders' equity	153,142	169,439
Total liabilities and stockholders' equity	\$ 215,836	\$ 204,485

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW
(in thousands)

	Six Months Ended June 30,	
	2022	2021
Net loss	\$ (29,957)	\$ (35,768)
Non-cash items	3,154	5,005
Change in deferred license revenue	27,815	-
Other changes in working capital	(686)	(1,127)
Net cash provided by (used in) operating activities	326	(31,890)
Net cash used in investing activities	(73,886)	(20,526)
Issuance of common shares pursuant to Share Purchase Agreement	10,973	-
Cash provided by other financing activities	625	31,163
Net cash provided by financing activities	11,598	31,163
Effect of foreign exchange rate changes on cash and cash equivalents	-	(44)
Decrease in cash and cash equivalents	(61,962)	(21,297)
Cash and cash equivalents, beginning of period	109,282	52,251
Cash and cash equivalents, end of period	47,320	30,954
Investments in marketable securities	153,329	90,331
Cash, cash equivalents and marketable securities, end of period	\$ 200,649	\$ 121,285

Conference Call and Webcast Today

Arbutus will hold a conference call and webcast today, Thursday, August 4, 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 (800) 715-9871 or (646) 307-1963 and reference conference ID: 5109143.

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 (800) 770-2030 or (609) 800-9909, and reference conference ID: 5109143

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.

About AB-101

Immune checkpoints such as PD-1/PD-L1 play an important role in the induction and maintenance of immune tolerance and in T-cell activation. We have identified a class of small molecule oral PD-L1 inhibitors that we believe will allow for controlled checkpoint blockade, enable oral dosing, and mitigate systemic safety issues typically seen with checkpoint antibody therapies. Our lead oral PD-L1 inhibitor candidate, AB-101, is currently in IND-enabling studies. We believe AB-101 has the potential to be used in combination with other approved and investigational agents for our mission to achieve a functional cure for HBV chronically infected patients. We are also exploring oncology applications for our internal PD-L1 portfolio.

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, an oral capsid inhibitor, an oral PD-L1 inhibitor, and an oral RNA destabilizer to potentially identify a combination regimen with the aim of providing 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. It is currently being evaluated in multiple phase 2 clinical trials. We also have an ongoing drug discovery and development program directed to identifying novel, orally active agents for treating coronavirus (including SARS-CoV-2). In addition, we are 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 with respect to the release of data from our clinical trials and the expected timing thereof; 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; and our expected financial condition, including the anticipated duration of cash runways and timing regarding needs for additional capital.

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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