

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

Form 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Fiscal Year Ended December 31, 2022

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Transition Period from to
Commission File Number: 001-34949

Arbutus Biopharma Corporation

(Exact Name of Registrant as Specified in Its Charter)

British Columbia, Canada
(State or Other Jurisdiction of
Incorporation or Organization)

98-0597776
(I.R.S. Employer
Identification No.)

701 Veterans Circle
Warminster
PA
18974

(Address of Principal Executive Offices)

267-469-0914

(Registrant's Telephone Number, Including Area Code)

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

Securities registered pursuant to Section 12(g) of the Act: None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer	Non-accelerated filer	Smaller reporting company	Emerging growth company
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b).

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

As of June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter, the approximate aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant was \$290,424,678 (based on the closing price of \$2.71 per share as reported on the Nasdaq Global Select Market as of that date).

As of February 28, 2023, the registrant had 162,570,989 common shares, without par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2023 Annual Meeting of Shareholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission no later than 120 days after the registrant's fiscal year ended December 31, 2022, are incorporated by reference into Part III of this Form 10-K.

ARBUTUS BIOPHARMA CORPORATION

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Cautionary Note Regarding Forward-looking Statements

This Annual Report on Form 10-K (this “Form 10-K”) contains “forward-looking statements” or “forward-looking information” within the meaning of applicable United States and Canadian securities laws (we collectively refer to these items as “forward-looking statements”). Forward-looking statements are generally identifiable by use of the words “believes,” “may,” “plans,” “will,” “anticipates,” “intends,” “budgets,” “could,” “estimates,” “expects,” “forecasts,” “projects” and similar expressions that are not based on historical fact or that are predictions of or indicate future events and trends, and the negative of such expressions. Forward-looking statements in this Form 10-K, including the documents incorporated by reference, include statements about, among other things:

- our strategy, future operations, pre-clinical research, pre-clinical studies, clinical trials, prospects and the plans of management;
- the potential for our product candidates to achieve their desired or anticipated outcomes;
- the expected cost, timing and results of our clinical development plans and clinical trials, including our clinical collaborations with third parties;
- the potential impact of the COVID-19 pandemic on our business and clinical trials;
- the discovery, development and commercialization of a curative combination regimen for chronic hepatitis B infection, a disease of the liver caused by the hepatitis B virus (“HBV”);
- the potential of our product candidates to improve upon the standard of care and contribute to a functional curative combination treatment regimen;
- obtaining necessary regulatory approvals;
- obtaining adequate financing through a combination of financing activities and operations;
- the potential for us to discover and/or develop new molecular entities for treating coronaviruses, including COVID-19;
- the expected returns and benefits from strategic alliances, licensing agreements, and research collaborations with third parties, and the timing thereof;
- our expectations regarding our technology licensed to third parties, and the timing thereof;
- our anticipated revenue and expense fluctuation and guidance;
- our expectations regarding the timing of announcing data from our ongoing clinical trials;
- our expectations regarding current patent disputes and litigation;
- our expectation of a net cash burn between \$95.0 million and \$100.0 million in 2023;
- our belief that we have sufficient cash resources to fund our operations into the fourth quarter of 2024; and
- the possibility that our clinical development plans could be further delayed or suspended as a result of the military action by Russia in Ukraine,

as well as other statements relating to our future operations, financial performance or financial condition, prospects or other future events. Forward-looking statements appear primarily in the sections of this Form 10-K entitled “Item 1-Business,” “Item 1A-Risk Factors,” “Item 7-Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Item 7A-Quantitative and Qualitative Disclosures About Market Risk,” and “Item 8-Financial Statements and Supplementary Data.”

Forward-looking statements are based upon current expectations and assumptions and are subject to a number of known and unknown risks, uncertainties and other factors that could cause actual results to differ materially and adversely from those expressed or implied by such statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this Form 10-K and in particular the risks and uncertainties discussed under “Item 1A-Risk Factors” of this Form 10-K. As a result, you should not place undue reliance on forward-looking statements.

Additionally, the forward-looking statements contained in this Form 10-K represent our views only as of the date of this Form 10-K (or any earlier date indicated in such statement). While we may update certain forward-looking statements from time to time, we specifically disclaim any obligation to do so, even if new information becomes available in the future. However, you are advised to consult any further disclosures we make on related subjects in the periodic and current reports that we file with the Securities and Exchange Commission.

The foregoing cautionary statements are intended to qualify all forward-looking statements wherever they may appear in this Form 10-K. For all forward-looking statements, we claim protection of the safe harbor for the forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

This Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

Risk Factors Summary

The following is a summary of the principal risks that could adversely affect our business, operations and financial results. For more information, see “Item 1A. Risk Factors” in this Annual Report on Form 10-K for the year ended December 31, 2022.

Risks Related to Our Business, Our Financial Results and Need for Additional Capital

- We are in the early stages of our development, and there is a limited amount of information about us upon which you can evaluate our product candidates.
- We will require substantial additional capital to fund our operations. Additional funds may be dilutive to shareholders or impose operational restrictions. Further, if additional capital is not available, we may need to delay, limit or eliminate our research, development and commercialization programs and modify our business strategy.
- We have incurred losses in nearly every year since our inception and we anticipate that we will not achieve profits for the foreseeable future. To date, we have had no product revenues.
- The COVID-19 pandemic could adversely impact our business, including our clinical development plans.

Risks Related to Development, Clinical Testing, Regulatory Approval, Marketing, and Coverage and Reimbursement of our Product Candidates

- Our product candidates are in early stages of development and must go through clinical trials, which are very expensive, time-consuming and difficult to design and implement. The timing and outcomes of clinical trials are uncertain.
- Pre-clinical studies and preliminary and interim data from clinical trials of our product candidates are not necessarily predictive of the results or success of ongoing or later clinical trials of our product candidates.
- Because we have limited resources, we may decide to pursue a particular product candidate and fail to advance product candidates that later demonstrate a greater chance of clinical and commercial success.
- Several of our current pre-clinical studies and clinical trials are being conducted outside the United States, and the FDA may not accept data from trials conducted in locations outside the United States.
- We cannot guarantee how long it will take regulatory agencies to review our applications for product candidates.
- If a particular product candidate causes undesirable side effects, then we may be unable to receive regulatory approval of or commercialize such product candidate.
- We may find it difficult to enroll patients in our clinical trials, which could hinder such clinical trials.
- Several of our and our collaboration partner’s current and planned clinical trials have been impacted and could be further delayed or suspended as a result of the military action by Russia in Ukraine.
- Even if our product candidates obtain regulatory approval, they will remain subject to ongoing regulatory requirements.
- We face significant competition from other biotechnology and pharmaceutical companies targeting HBV and coronaviruses, including COVID-19.
- We are largely dependent on the future commercial success of our HBV and coronavirus product candidates.
- We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.
- Coverage and adequate reimbursement may not be available for our product candidates, which could make it difficult for us to sell our products profitably.
- We are subject to United States and Canadian healthcare laws and regulations, which could expose us to adverse consequences such as criminal sanctions, civil penalties, contractual damages or reputational harm, among others.
- Failure to comply with the United States Foreign Corrupt Practices Act, and potentially other similar global laws could subject us to penalties and other adverse consequences.

Risks Related to Our Dependence on Third Parties

- We depend on our license agreement with Alnylam Pharmaceuticals, Inc. for the commercialization of ONPATPRO™ (Patisiran).

- We expect to depend in part on our licensing agreements for a significant portion of our revenues for the foreseeable future and to develop, conduct clinical trials with, obtain regulatory approvals for, and manufacture, market and sell some of our product candidates. If these licensing agreements are unsuccessful, or anticipated milestone or royalty payments are not received, our business could be materially adversely affected.
- We are dependent on our collaboration and licensing partners and, therefore, are subject to the efforts of these parties and our ability to successfully collaborate with them.
- We will depend on Qilu Pharmaceutical Co., Ltd. for the development and commercialization of AB-729 in China, Hong Kong, Macau and Taiwan.
- If conflicts arise between our collaboration or licensing partners and us, our collaboration or licensing partners may act in their best interest and not in our best interest, which could adversely affect our business.
- We rely on third parties to conduct our clinical trials, and if they fail to fulfill their obligations, our development plans may be adversely affected.
- We rely exclusively on third parties to formulate and manufacture our product candidates, which exposes us to risks that may delay or hinder development, regulatory approval and commercialization of our products.

Risks Related to Our Intellectual Property

- Other entities may assert patent rights that prevent us from developing or commercializing our products.
- Our patents and patent applications may be challenged and may be found to be invalid, which could adversely affect our business.
- We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights which could have a material adverse effect on our business and could cause the market value of our common shares to decline.
- Confidentiality agreements with employees and others, including collaborators, may not adequately prevent disclosure of trade secrets and other proprietary information.

Risks Related to the Ownership of our Common Shares

- The concentration of common share ownership will likely limit the ability of the other shareholders to influence corporate matters. Further, our articles and certain Canadian laws could delay or deter a change of control.
- We are incorporated in Canada, with our assets located both in Canada and the United States, with the result that it may be difficult for investors to enforce judgments obtained against us or some of our officers.
- If we are deemed to be a “passive foreign investment company,” investors who are subject to United States federal taxation would likely suffer materially adverse United States federal income tax consequences.

General Risk Factors

- If we are unable to attract and retain qualified key individuals, our ability to implement our business plan may be adversely affected.
- We could face liability from our controlled use of hazardous and radioactive materials.
- Our business, reputation, and operations could suffer in the event of information technology system failures.
- We may acquire other assets or businesses, or form strategic alliances or collaborations or make investments in other companies or technologies that could harm our business.

PART I

Item 1. Business

Overview

Arbutus Biopharma Corporation (“Arbutus”, the “Company”, “we”, “us”, and “our”) 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. To address HBV, we are developing an RNA interference (“RNAi”) therapeutic, 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 infection (“cHBV”) 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. AB-729 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 coronaviruses, including SARS-CoV-2, where we have nominated a compound and have begun IND-enabling pre-clinical studies. In addition, we are also exploring oncology applications for our internal PD-L1 portfolio.

Strategy

The core elements of our strategy include:

- **Developing a broad portfolio of compounds that target cHBV.** Our HBV product pipeline includes a subcutaneously-delivered RNAi therapeutic, an oral HBV RNA destabilizer compound and an oral PD-L1 inhibitor. We believe that a combination of compounds that can suppress HBV DNA replication and hepatitis B surface antigen (“HBsAg”) expression as well as reawaken patients’ HBV-specific immune response would address the most important elements to achieving a functional cure. We define a functional cure as unquantifiable plasma HBV DNA and HBsAg levels more than six months after discontinuation of all treatment, with or without quantifiable anti-HBsAg antibodies.

AB-729 is our proprietary subcutaneously-delivered RNAi therapeutic product candidate that suppresses all HBV antigens, including HBsAg expression, which is thought to be a key prerequisite to enable reawakening of a patient’s immune system to respond to HBV. AB-729 is currently in two Phase 2a proof-of-concept clinical trials in combination with other agents with potentially complementary mechanisms of action and we are also continuing to follow subjects from our Phase 1a/1b clinical trial (“AB-729-001”). Preliminary data from AB-729-001 has shown that treatment with AB-729 provided robust and comparable HBsAg declines regardless of dose, dosing interval or patient characteristics and was generally safe and well-tolerated after completing dosing in 41 subjects. Preliminary data also suggests that treatment with AB-729 increased HBV-specific immune responses and, in a small number of subjects who discontinued both AB-729 and nucleos(t)ide analogue (“NA”) therapy, a sustained reduction in HBsAg and HBV DNA persisted after stopping AB-729. The clinical data for AB-729 continues to support its development as a potential cornerstone agent for the treatment of cHBV infection.

AB-101 is our oral PD-L1 inhibitor that has the potential to reawaken patients’ HBV-specific immune response by inhibiting PD-L1. Preclinical data in an HBV mouse model was presented at the 2022 AASLD Liver Meeting showing that combination treatment with AB-101 and an HBV-targeting GalNAc-siRNA agent resulted in activation and increased frequency of HBV-specific T-cells and greater anti-HBsAg antibody production. This favorable preclinical profile supports further development of AB-101 as a therapeutic modality for cHBV treatment and we anticipate initiating a Phase 1 healthy subject clinical trial with AB-101 in the first half of 2023. We are also exploring potential oncology applications for our internal PD-L1 portfolio.

AB-161 is our next-generation oral HBV specific RNA destabilizer. We have conducted extensive non-clinical safety evaluations with AB-161 that gives us confidence in this molecule’s ability to circumvent the peripheral neuropathy findings seen in non-clinical safety studies with our first-generation oral RNA destabilizer, AB-452. We recently presented preclinical data at the Discovery on Target Conference showing that AB-161 reduced HBV RNA and

HBsAg in multiple preclinical models, with favorable liver centricity and lack of observed peripheral neuropathy. We anticipate initiating a Phase 1 healthy subject clinical trial with AB-161 in the first half of 2023.

- **Combining therapeutic product candidates with complementary mechanisms of action to find a functional cure for people with cHBV.** We believe that our proprietary product candidates AB-729, AB-101 and AB-161 may provide our first proprietary combination therapy for patients with cHBV. In-line with our strategy to position AB-729 as a potential cornerstone therapeutic in future HBV combination regimens, and to help guide future development of combination therapies of AB-729 with other compounds from our proprietary HBV portfolio, we are evaluating AB-729 in combination with other agents with potentially complementary mechanisms of action, including the following:
 - AB-729 in combination with ongoing standard-of-care NA therapy and short courses of Peg-IFN α -2a in subjects with cHBV in a Phase 2a proof-of-concept clinical trial (“AB-729-201”). Preliminary data from the lead-in phase of this clinical trial further validated AB-729’s potential to reduce HBsAg in cHBV patients.
 - AB-729 in combination with Vaccitech plc’s (“Vaccitech”) VTP-300, a proprietary T-cell stimulating antigen-specific immunotherapeutic, and NA therapy for the treatment of subjects with cHBV in a Phase 2a proof-of-concept clinical trial (“AB-729-202”). We recently amended the clinical trial to include an additional arm with an approved PD-1 monoclonal antibody inhibitor, nivolumab (Opdivo[®]).
- **Advancing small molecule antiviral product candidates to treat COVID-19 and future coronavirus outbreaks.** This program is focused on the discovery and development of new molecular entities for treating coronaviruses, including COVID-19, that address specific viral targets including the nsp5 viral protease (“M^{pro}”) and the nsp12 viral polymerase.
 - In the fourth quarter of 2022, we nominated AB-343 as our lead coronavirus drug candidate that inhibits the SARS-CoV-2 M^{pro}, a validated target for the treatment of COVID-19 and potential future coronavirus outbreaks. In our pre-clinical research conducted to date, AB-343 has shown pan-coronavirus antiviral activity, no reduction in potency against known SARS-CoV-2 variants, robust activity against SARS-CoV-2 M^{pro} resistant strains, and a favorable drug-drug interaction profile with no need for ritonavir boosting. We are advancing AB-343 into IND-enabling studies. We are also continuing lead optimization activities for an nsp12 viral polymerase, which could potentially be combined with AB-343 to achieve better patient treatment outcomes and for use in prophylactic settings.

Background on HBV

Hepatitis B is a potentially life-threatening liver infection caused by HBV. HBV can cause chronic infection which leads to a higher risk of death from cirrhosis and liver cancer. cHBV represents a significant unmet medical need. There are HBV vaccines approved by the FDA, which are indicated for the prevention of infection caused by HBV. However, the World Health Organization estimates that over 290 million people worldwide suffer from cHBV, while other estimates indicate that approximately 2.4 million people in the United States suffer from cHBV. Even with the availability of effective vaccines and current treatment options, approximately 820,000 people die every year from complications related to cHBV. We believe there is a compelling market opportunity for an HBV curative regimen. Currently, an estimated 30.4 million (10.5%) of a total of over 290 million people worldwide with cHBV are diagnosed and approximately 6.6 million (2.3%) are on treatment. We believe that the introduction of an HBV curative regimen with a finite duration would substantially increase diagnosis and treatment rates for people with cHBV.

Current treatments and their limitations

Today’s current treatment options for cHBV include pegylated interferon- α regimens (“Peg-IFN α ”) and NA therapies. Peg-IFN α , a synthetic version of a substance produced by the body to fight infection, is administered by injection and has numerous side effects including flu-like symptoms and depression. NA therapies are oral antiviral medications which, when taken chronically, reduce HBV virus replication and inflammation and significantly reduce HBV DNA in the blood. Oral NA

therapies have become the standard-of-care for HBV treatment, mainly due to their ability to drive viral load to undetectable levels in the serum of patients, their single pill once-a-day dosing and favorable safety profile. However, in most cases, once Peg-IFN α and NA therapies are stopped, virus replication resumes and liver inflammation and fibrosis may still progress. While these treatments reduce viral load, less than 5% of patients are functionally cured after a finite treatment duration. With such low cure rates, most patients with cHBV are required to take NA therapy daily for the rest of their lives.

Background on Coronaviruses

Coronaviruses are a large family of viruses that range from the common cold to more severe diseases such as severe acute respiratory syndrome (SARS), Middle East respiratory syndrome (MERS), and COVID-19. COVID-19 has caused approximately 7.2 million deaths globally according to an analysis by the Institute for Health Metrics and Evaluation (IHME). COVID-19 spreads when an infected person breathes out droplets and very small particles that contain the virus. As we strive to identify and develop new antiviral small molecules to treat COVID-19 and future coronavirus outbreaks, we have focused our research efforts on two essential targets critical for replication across all coronaviruses – nsp5 protease and nsp12 polymerase.

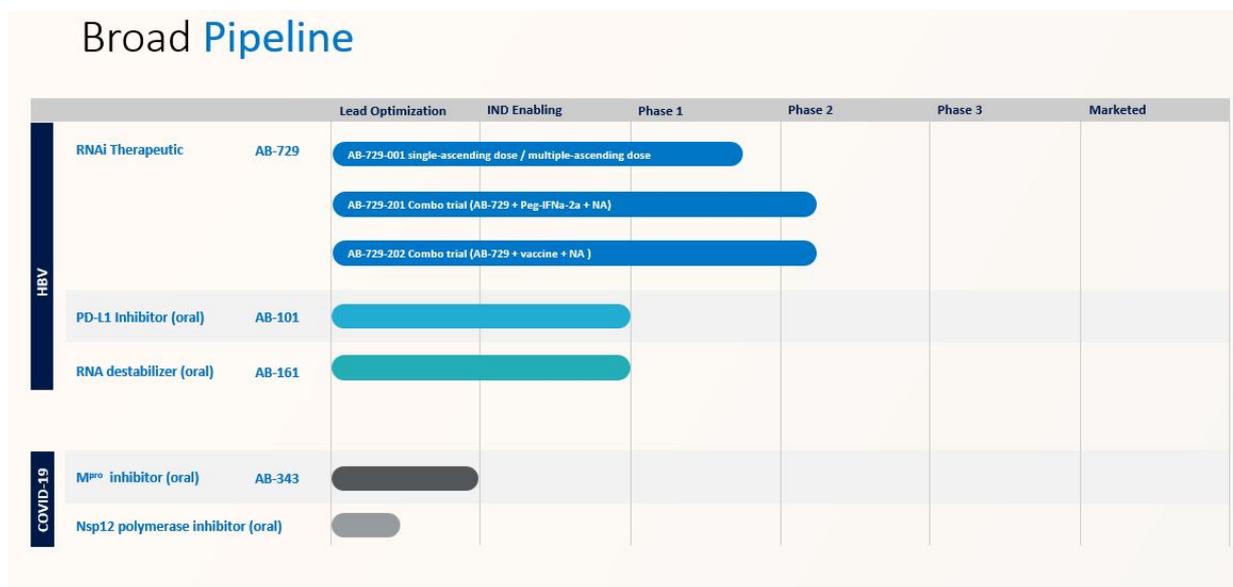
Current treatments and their limitations

Today’s current treatment options for COVID-19 include multiple vaccines, anti-viral drugs and antibodies to prevent or treat the disease. Despite the high efficacy of the COVID-19 vaccines, it is estimated that more than 25% of the world’s population remains unvaccinated against COVID-19. Today’s anti-viral treatments have certain limitations, including a short time frame to begin treatment, potential drug-drug interactions due to ritonavir boosting and frequently occurring side effects. Patients continue to be hospitalized and die from COVID-19. In addition to the availability of vaccines and other treatments, new effective and safe therapies are needed to successfully combat the COVID-19 pandemic and any future coronavirus outbreaks.

Our Product Candidates

Our product pipeline includes multiple product candidates that target various steps in the HBV viral lifecycle and pan-coronavirus compounds that target essential viral targets for replication.

Our product pipeline consists of the following programs:



We continue to explore expansion opportunities for our pipeline through internal discovery and development activities and through potential strategic alliances.

RNAi therapeutic (AB-729)

RNAi therapeutics represent a significant advancement in drug development. RNAi therapeutics utilize a natural pathway within cells to silence genes by eliminating the disease-causing proteins that they code for. We are developing RNAi therapeutics that are designed to reduce HBsAg expression and other HBV antigens in people with cHBV. Reducing HBsAg is widely believed to be a key prerequisite to enable a patient's immune system to reawaken and respond against the virus.

AB-729 is a subcutaneously-delivered RNAi single-trigger therapeutic targeted to hepatocytes using our proprietary covalently conjugated GalNAc delivery technology. AB-729 reduces all HBV antigens and inhibits viral replication.

Phase 1a/1b single- and multiple-dose clinical trial (AB-729-001)

In this three-part clinical trial, we investigated the safety, tolerability, pharmacokinetics, and pharmacodynamics of single- and multi-doses of AB-729 in healthy subjects and in cHBV patients with the goal of identifying the most appropriate doses and dosing intervals to take forward into Phase 2 clinical development.

The first two parts evaluated single ascending doses of AB-729 in healthy subjects and in patients with cHBV, respectively. Data showed that a 60mg or 90mg single dose of AB-729 results in robust HBsAg and HBV DNA declines in HBV DNA positive patients. Part 3 of the trial dosed HBV DNA negative/positive patients with 60mg or 90mg of AB-729 every 4, 8 or twelve weeks. Dosing of patients in Part 3 has been completed and we are continuing to follow these patients.

Data from Part 3 of the AB-729-001 clinical trial was presented at the 2022 European Association for the Study of the Liver (EASL) International Liver Congress™ (ILC) in June 2022 and showed that repeat dosing of 60mg and 90mg of AB-729 in 41 patients resulted in robust and comparable HBsAg declines in HBeAg positive/negative and HBV DNA positive/negative patients at week 48 (1.89 to 2.15 log₁₀ decline in HBsAg). Fifty percent of the patients (16 out of 32) maintained HBsAg levels below 100 IU/mL 24 weeks after their last dose of AB-729. Patients treated with AB-729 experienced an increase in HBV-specific T-cells activation and a decrease in exhausted T-cells. In this trial, AB-729 was generally safe and well-tolerated.

At the AASLD Liver Meeting in November 2022, we presented additional data from Part 3 of the AB-729-001 clinical trial, which included nine patients who had previously completed 48 weeks of treatment with AB-729, and 24 weeks later met protocol-defined criteria to also stop NA therapy. These nine patients had completed 12 to 44 weeks of follow-up after discontinuing their NA therapy. None had met the protocol-defined criteria to restart NA therapy and there was no evidence of clinical or biochemical relapse. HBsAg levels remained at 1.05 log₁₀ to 2.35 log₁₀ below pre-trial levels in all nine patients. Three patients experienced transient HBV DNA elevations that spontaneously resolved without intervention, which further supports AB-729's potential for immunological control. One patient restarted NA therapy at the investigator's request after the week 20 visit; no alanine transaminase ("ALT") elevation or safety signals were observed. There were no adverse events ("AEs") reported and no ALT flares were observed in the clinical trial. Recently, one of the eight remaining patients met the protocol-defined HBV DNA criteria to restart NA therapy without evidence of any ALT flare. We are continuing to follow the seven patients who remain off NA therapy and anticipate reporting additional off-treatment data in the first half of 2023.

The new clinical data for AB-729 continues to support its development as a potential cornerstone agent for the treatment of cHBV infection. The efficacy and safety data for AB-729, derived from up to one year of dosing, supported our view that 60 mg every 8 weeks was an appropriate dose to move forward in our Phase 2a clinical trials. To advance our efforts to position AB-729 as a potential cornerstone therapeutic in future HBV combination regimens, we are evaluating AB-729 in several Phase 2a proof-of-concept combination clinical trials with other agents with potentially complementary mechanisms of action, some via clinical collaborations with other companies as described below.

Phase 2a proof-of-concept clinical trial to evaluate AB-729 in combination with Peg-IFN α -2a (AB-729-201)

We have completed enrollment in a randomized, open label, multicenter Phase 2a proof-of-concept clinical trial investigating the safety and antiviral activity of AB-729 in combination with ongoing NA therapy and short courses of Peg-IFN α -2a in 43 stably NA-suppressed, HBeAg negative, non-cirrhotic patients with cHBV. After 24-weeks of dosing with AB-729 (60mg every 8 weeks), patients are randomized into one of four arms to receive ongoing NA therapy plus Peg-IFN α -2a for either 12 or 24 weeks, with or without additional doses of AB-729. After completion of the assigned Peg-IFN α -2a treatment period, all patients will remain on NA therapy for the initial 24-week follow-up period, and will then discontinue NA treatment, provided they meet protocol-defined stopping criteria. Patients who stop NA therapy will enter an intensive follow-up period for 48 weeks.

Preliminary data from the lead-in phase of the trial further validated AB-729's potential to reduce HBsAg. For the first 15 patients who reached week 16 of treatment and received two doses of AB-729 plus NA therapy, the mean HBsAg decline was 1.51 log₁₀, comparable to the decline observed at the same timepoint in the Phase 1b clinical trial AB-729-001 (1.56 log₁₀), while continuing to exhibit a generally safe and well-tolerated profile. We anticipate providing preliminary data from patients who have received doses of Peg-IFN α -2a in the first half of 2023.

Collaboration with Vaccitech (AB-729-202)

Through a clinical collaboration agreement with Vaccitech that we entered into in July 2021, we are enrolling patients in AB-729-202, a Phase 2a proof-of-concept clinical trial evaluating the safety, antiviral activity and immunogenicity of Vaccitech's VTP-300, a proprietary T-cell stimulating antigen-specific immunotherapeutic, administered after AB-729 in NA-suppressed patients with cHBV. The trial is designed to enroll 40 NA-suppressed, HBeAg negative or positive, non-cirrhotic cHBV patients. All patients will receive AB-729 (60mg every 8 weeks) plus NA therapy for 24 weeks. At week 24, treatment with AB-729 will stop. Patients will continue only their NA therapy and will be randomized to receive VTP-300 or placebo at Week 26, Week 30 and at Week 38 (if protocol-defined eligibility is met). At week 48, all patients will be evaluated for eligibility to discontinue NA therapy and will be followed for an additional 24-48 weeks. We anticipate providing preliminary data from patients who received AB-729, NA therapy and VTP-300 in the second half of 2023.

We recently amended the AB-729-202 protocol to include an additional arm with an approved PD-1 inhibitor, nivolumab (Opdivo®). Upon regulatory approval of the amendment, 20 patients will receive AB-729 (60mg every 8 weeks) plus NA therapy for 24 weeks, followed by administration of VTP-300 plus a low dose of nivolumab in conjunction with the booster dose(s) only while remaining on their NA therapy. At week 48, all patients will be evaluated for eligibility to discontinue NA therapy, and will be followed for an additional 24-48 weeks. We anticipate dosing the first patient in this arm in the first half of 2023, subject to regulatory approval.

This clinical trial is being managed by us, subject to oversight by a joint development committee comprised of representatives from both companies. We and Vaccitech retain full rights to our respective product candidates and will split all costs associated with the clinical trial. Pursuant to the agreement, the parties intend to undertake a larger Phase 2b clinical trial depending on the results of the initial Phase 2a clinical trial.

Collaboration with Assembly

Through a clinical collaboration agreement with Assembly that we entered into in August 2020, Assembly conducted a clinical trial evaluating AB-729 in combination with its first-generation HBV core inhibitor (capsid inhibitor) candidate VBR and standard-of-care NA therapy for the treatment of cHBV in HBeAg negative patients with cHBV. The randomized, multi-center, open-label Phase 2a proof-of-concept clinical trial was designed to evaluate the safety, pharmacokinetics, and antiviral activity of the triple combination of AB-729, VBR, and an NA (n=32) compared to the dual combinations of VBR with an NA (n=16) and AB-729 with an NA (n=17). Patients were dosed for 48 weeks with AB-729 (60mg subcutaneously every 8 weeks) and/or VBR (300mg orally once daily), with a 48-week follow-up period. At week 48, all patients were to be evaluated for eligibility to discontinue NA therapy. In July 2022, Assembly announced its plans to discontinue development of VBR. Despite this, in consultation with Assembly, we continued this Phase 2a proof-of-concept clinical trial in order to fully and accurately assess the results. Assembly completed enrollment in the clinical trial and preliminary data were presented at the 2022 AASLD Liver

Meeting, which indicated that adding VBR to AB-729 and NA therapy does not positively or negatively impact the reduction of HBsAg compared to AB-729 and NA therapy alone. Accordingly, we have mutually agreed to discontinue the clinical trial following completion of the final, on-treatment visit at week 48. All regimens were generally safe and well-tolerated in this trial. Both parties shared in the costs of the collaboration. Except to the extent necessary to carry out Assembly's responsibilities with respect to the collaboration trial, we have not provided any license grant to Assembly for use of AB-729.

Oral PD-L1 Inhibitor (AB-101)

PD-L1 inhibitors complement our pipeline of agents and could potentially be an important part of a combination therapy for the treatment of HBV by reawakening the immune system. Highly functional HBV-specific T cells within our immune system are believed to be required for long-term HBV viral resolution. However, HBV-specific T cells become functionally defective, and greatly reduced in their frequency during cHBV. One approach to boost HBV-specific T cells is to prevent PD-L1 proteins from binding to PD-1 and thus inhibiting the HBV-specific immune function of T cells. 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.

AB-101 is our oral PD-L1 inhibitor candidate that we believe will allow for controlled checkpoint blockade while minimizing the systemic safety issues typically seen with checkpoint antibody therapies. Preclinical data generated thus far indicates that AB-101 mediates activation and reinvigoration of HBV-specific T-cells from cHBV patients. In June 2022, we presented a poster at the 2022 EASL ILC highlighting data from a study that was designed to assess the preclinical activity of AB-101 and the compound's ability to reinvigorate patient HBV-specific T-cells. Studies were conducted using a transgenic MC38 tumor mouse model and peripheral blood mononuclear cells (PBMCs) from cHBV patients. The data presented showed that once daily oral administration of AB-101 resulted in profound tumor reduction that was associated with T-cell activation. In addition, AB-101 activates and reinvigorates HBV-specific T-cells in vitro. Additionally, preclinical data in an HBV mouse model was presented at the 2022 AASLD Liver Meeting showing that monotherapy with AB-101 reduced PD-L1 in liver immune cells, confirming liver target engagement of the compound. Combination treatment with AB-101 and an HBV-targeting GalNAc-siRNA agent resulted in activation and increased frequency of HBV-specific T-cells and greater anti-HBsAg antibody production. This favorable preclinical profile supports further development of AB-101 as a therapeutic modality for cHBV treatment. We believe AB-101, when used in combination with other approved and investigational agents, could potentially lead to a functional cure in HBV chronically infected patients. We anticipate initiating a Phase 1 healthy subject clinical trial with AB-101 in the first half of 2023 with data from the single-ascending dose portion of the clinical trial expected in the second half of 2023.

We are also exploring potential oncology applications for our internal PD-L1 portfolio. Preclinical data was selected for publication at the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2022 showing that our 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 is published in the Journal of Clinical Oncology.

Oral HBV RNA Destabilizer (AB-161)

HBV RNA destabilizers are small molecule orally available agents that cause the destabilization and ultimate degradation of HBV RNAs. Mechanistically, RNA destabilizers target the host proteins PAPD5/7, which are involved in regulating the stability of HBV RNA transcripts. In doing so, RNA destabilizers lead to the selective degradation of HBV RNAs, thus reducing HBsAg levels and inhibiting viral replication. To provide a proprietary all-oral treatment regimen for patients with cHBV, we believe inclusion of a small molecule RNA destabilizer is key. HBV RNA destabilizers have the potential to complement or replace subcutaneously delivered RNAi agents, such as AB-729.

AB-161 is our next-generation oral small molecule RNA destabilizer specifically designed to target the liver. We have conducted extensive non-clinical safety evaluations with AB-161 that provide confidence in this molecule's ability to circumvent the peripheral neuropathy findings seen in non-clinical safety studies with our first-generation oral RNA destabilizer, AB-452. We recently presented preclinical data at the 2022 Discovery on Target Conference showing that AB-161 reduced HBV RNA and HBsAg in multiple preclinical models, with favorable liver centricity and lack of observed peripheral neuropathy. We anticipate initiating a Phase 1 healthy subject clinical trial with AB-161 in the first half of 2023 with single-ascending dose data expected in the second half of 2023.

Coronavirus Program

While our core mission is to find a cure for HBV, the magnitude of the coronavirus pandemic is undeniable. Given our science team's proven expertise in the discovery of new antiviral therapies, in 2020 we initiated a drug discovery effort for treating coronaviruses, including COVID-19. To that end, we have assembled an internal team of expert scientists under the direction of our Chief Scientific Officer, Dr. Michael Sofia, to identify novel small molecule therapies 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 program. As we strive to identify and develop new antiviral small molecules to treat COVID-19 and future coronavirus outbreaks, we have focused our research efforts on two essential targets critical for replication across all coronaviruses – nsp5 protease and nsp12 polymerase. These targets are essential viral proteins that our science team has experience in targeting.

Oral M^{pro} Inhibitor (AB-343)

AB-343 is our lead coronavirus drug candidate that inhibits M^{pro}. In our pre-clinical research conducted to date, AB-343 has shown pan-coronavirus antiviral activity, no reduction in potency against known SARS-CoV-2 variants, robust activity against SARS-CoV-2 M^{pro} resistant strains, and a favorable drug-drug interaction profile with no need for ritonavir boosting. We anticipate completing IND-enabling studies and initiating a Phase 1 clinical trial with AB-343 in the second half of 2023. We also intend to nominate a nsp12 clinical candidate and initiate IND-enabling studies in the second half of 2023. An nsp12 viral polymerase could potentially be combined with AB-343 to achieve better patient treatment outcomes and for use in prophylactic settings.

Collaboration with X-Chem, Inc. and Proteros biostructures GmbH

In March 2021, we entered into a discovery research and license agreement, as amended, with X-Chem, Inc. (“X-Chem”) and Proteros biostructures GmbH (“Proteros”) to focus on the discovery of novel inhibitors targeting the SARS-CoV-2 nsp5 main protease (M^{pro}). The agreement is designed to accelerate the development of pan-coronavirus agents to treat COVID-19 and potential future coronavirus outbreaks. This collaboration brought together our expertise in the discovery and development of antiviral agents with X-Chem's industry leading DNA-encoded library (DEL) technology and Proteros' protein sciences, biophysics and structural biology capabilities and provides important synergies to potentially identify safe and effective therapies against coronaviruses, including SARS-CoV-2. The collaboration allows for the rapid screening of one of the largest small molecule libraries against M^{pro} (an essential protein required for the virus to replicate itself) and the use of state-of-the-art structure guided methods to rapidly optimize M^{pro} inhibitors to progress to clinical candidates. The agreement provides for payments by us to X-Chem and Proteros upon satisfaction of certain development, regulatory and commercial milestones, as well as royalties on sales. Through this collaboration, we identified and obtained a worldwide exclusive license to several molecules that inhibit M^{pro}, a validated target for the treatment of COVID-19 and potential future coronavirus outbreaks.

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 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.

Other Collaborations, Royalty Entitlements and Intellectual Property Litigation

Collaboration with Qilu Pharmaceutical Co., Ltd. (“Qilu”)

In December 2021, we entered into a technology transfer and license agreement (the “License Agreement”) with Qilu, pursuant to which we granted Qilu a sublicensable, royalty-bearing license, under certain intellectual property owned by us, which is non-exclusive as to development and manufacturing and exclusive with respect to commercialization of AB-729, including

pharmaceutical products that include AB-729, for the treatment or prevention of hepatitis B in China, Hong Kong, Macau and Taiwan (the “Territory”).

In partial consideration for the rights granted by us, Qilu paid us a one-time upfront cash payment of \$40 million on January 5, 2022 and agreed to pay us milestone payments totaling up to \$245 million, net of withholding taxes, upon the achievement of certain technology transfer, development, regulatory and commercialization milestones. Qilu also agreed to pay us double digit royalties into the low twenties percent based upon annual net sales of AB-729 in the Territory. The royalties are payable on a product-by-product and region-by-region basis, subject to certain limitations.

Qilu is responsible for all costs related to developing, obtaining regulatory approval for, and commercializing AB-729 for the treatment or prevention of hepatitis B in the Territory. Qilu is required to use commercially reasonable efforts to develop, seek regulatory approval for, and commercialize at least one AB-729 product candidate in the Territory. A joint development committee has been established between us and Qilu to coordinate and review the development, manufacturing and commercialization plans. Both parties also have entered into a supply agreement and related quality agreement pursuant to which we will manufacture or have manufactured and supply Qilu with all quantities of AB-729 necessary for Qilu to develop and commercialize in the Territory until we have completed manufacturing technology transfer to Qilu and Qilu has received all approvals required for it or its designated contract manufacturing organization to manufacture AB-729 in the Territory.

Concurrent with the execution of the License Agreement, we entered into a Share Purchase Agreement (the “Share Purchase Agreement”) with Anchor Life Limited, a company established pursuant to the applicable laws and regulations of Hong Kong and an affiliate of Qilu (the “Investor”), pursuant to which the Investor purchased 3,579,952 of our common shares, without par value (the “Common Shares”), at a purchase price of USD \$4.19 per share, which was a 15% premium on the thirty-day average closing price of the Common Shares as of the close of trading on December 10, 2021 (the “Share Transaction”). We received \$15.0 million of gross proceeds from the Share Transaction on January 6, 2022. The Common Shares sold to the Investor in the Share Transaction represented approximately 2.5% of the Common Shares outstanding immediately prior to the execution of the Share Purchase Agreement.

Alnylam Pharmaceuticals, Inc. (“Alnylam”) and Acuitas Therapeutics, Inc. (“Acuitas”)

We have two royalty entitlements to Alnylam’s global net sales of ONPATTRO.

In 2012, we entered into a license agreement with Alnylam that entitles Alnylam to develop and commercialize products with our lipid nanoparticle (“LNP”) delivery technology. Alnylam’s ONPATTRO, which represents the first approved application of our LNP technology, was approved by the United States FDA and the European Medicines Agency (“EMA”) during the third quarter of 2018 and was launched by Alnylam immediately upon approval in the United States. Under the terms of this license agreement, we are entitled to tiered royalty payments on global net sales of ONPATTRO ranging from 1.00% - 2.33% after offsets, with the highest tier applicable to annual net sales above \$500 million. This royalty interest was sold to the Ontario Municipal Employees Retirement System (“OMERS”), effective as of January 1, 2019, for \$20 million in gross proceeds before advisory fees. OMERS will retain this entitlement until it has received \$30 million in royalties, at which point 100% of this royalty entitlement on future global net sales of ONPATTRO will revert to us. OMERS has assumed the risk of collecting up to \$30 million of future royalty payments from Alnylam and we are not obligated to reimburse OMERS if they fail to collect any such future royalties. If this royalty entitlement reverts to us, it has the potential to provide an active royalty stream or to be otherwise monetized again in full or in part. From the inception of the royalty sale through December 31, 2022, an aggregate of \$18.9 million of royalties have been collected by OMERS.

We also have rights to a second royalty interest ranging from 0.75% to 1.125% on global net sales of ONPATTRO, with 0.75% applying to sales greater than \$500 million, originating from a settlement agreement and subsequent license agreement with Acuitas. This royalty entitlement from Acuitas has been retained by us and was not part of the royalty entitlement sale to OMERS.

Genevant Sciences, Ltd.

In April 2018, we entered into an agreement with Roivant Sciences Ltd. (“Roivant”), our largest shareholder, to launch Genevant Sciences Ltd. (“Genevant”), a company focused on a broad range of RNA-based therapeutics enabled by our LNP

and ligand conjugate delivery technologies. We licensed rights to our 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 (the “Genevant License”). We retained all rights to our LNP and conjugate delivery platforms for HBV.

Under the Genevant License, as amended, if a third party sublicensee of intellectual property licensed by Genevant from us commercializes a sublicensed product, we become entitled to receive a specified percentage of certain revenue that may be received by Genevant for such sublicense, including royalties, commercial milestones and other sales-related revenue, or, if less, tiered low single-digit royalties on net sales of the sublicensed product. The specified percentage is 20% in the case of a mere sublicense (i.e., naked sublicense) by Genevant without additional contribution and 14% in the case of a bona fide collaboration with Genevant.

Additionally, if Genevant receives proceeds from an action for infringement by any third parties of our intellectual property licensed to Genevant, we 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).

In July 2020, Roivant recapitalized Genevant through an equity investment and conversion of previously issued convertible debt securities held by Roivant. We participated in the recapitalization of Genevant with an equity investment of \$2.5 million. In connection with the recapitalization, the three parties entered into an Amended and Restated Shareholders Agreement that provides Roivant with substantial control of Genevant. We have a non-voting observer seat on Genevant’s Board of Directors. As of December 31, 2022, we owned approximately 16% of the common equity of Genevant and the carrying value of our investment in Genevant was zero. Our entitlement to receive future royalties or sublicensing revenue from Genevant was not impacted by the recapitalization.

Moderna Inter Partes Review Petitions

On February 21, 2018 and March 5, 2018, Moderna Therapeutics, Inc. (“Moderna”) filed petitions requesting the United States Patent and Trademark Office (“USPTO”) to institute an Inter Partes Review of Arbutus United States Patents 9,404,127 (the “’127 Patent”) and 9,364,435 (the “’435 Patent”). In its petitions, Moderna sought to invalidate all claims of each patent based on Moderna’s allegation that the claims are anticipated and/or obvious. We filed a response to Moderna’s petitions on June 14, 2018. On September 12, 2018, the Patent Trial and Appeal Board (the “PTAB”) rendered its decision to institute Inter Partes Review of both the ‘127 Patent and the ‘435 Patent.

The status of these patents, which collectively represent only a fraction of our extensive LNP patent portfolio, is as follows:

‘127 Patent

With respect to the ‘127 Patent, the PTAB held all claims as invalid on September 10, 2019, by reason of anticipatory prior art. However this decision was vacated and sent back (remanded) to the PTAB for a rehearing, pending the Supreme Court’s decision whether to grant certiorari in a different case, *United States v. Athrex, Inc.* (“US v. Athrex”), the holding of which could impact the findings in the ‘127 Patent matter. The Supreme Court granted certiorari in *US v. Athrex* on October 13, 2020 (i.e. agreed to review the decision appealed from a lower court). Until the Supreme Court rendered its opinion in *US v. Athrex*, the ‘127 Patent hearing remained in abeyance, with no decision reached as to the validity of its claims. The Supreme Court decided on the *US v. Athrex* case on June 21, 2021, following which the Federal Circuit reinstated the appeal sua sponte, requiring the parties to brief how the case should proceed in light of the Supreme Court’s opinion or for the Appellant to waive the challenge. We elected to waive the challenge and proceed with the appeal at the Federal Circuit. The opening brief was filed on October 25, 2021. Moderna’s responsive brief was filed on February 24, 2022 and our reply brief was filed on April 26, 2022. An oral hearing for this matter was held on November 4, 2022.

‘435 Patent

With respect to the ‘435 Patent, the PTAB rendered its decision on September 11, 2019, holding certain claims invalid and upholding other claims as valid. On November 13, 2019, we and Moderna both appealed the decision. Moderna filed its opening brief on May 4, 2020 and we provided our opening and responsive brief on July 27, 2020. Moderna subsequently filed its reply and responsive brief on October 5, 2020, and we filed our reply brief on November 9, 2020. An oral hearing on the

'435 Patent was held on October 7, 2021. On December 1, 2021, the Federal Circuit issued its opinion, leaving intact the PTAB's holding regarding the validity of certain claims in the '435 Patent and the invalidity of other claims in the '435 Patent. The decision in the '435 appeal was rendered final by mandate on January 25, 2022.

'069 Patent

On January 9, 2019, Moderna filed an additional petition requesting Inter Partes Review of Arbutus United States Patent 8,058,069 (the "'069 Patent"). The PTAB instituted Inter Partes Review of the '069 Patent and, on July 23, 2020, issued a decision upholding all claims as valid. On September 23, 2020, Moderna appealed the '069 Inter Partes Review decision to the Federal Circuit Court of Appeals. Moderna filed its opening brief in that appeal on February 23, 2021, we filed our responsive brief on May 11, 2021, and Moderna filed its reply brief on July 1, 2021. An oral hearing on the '069 Patent was held on October 7, 2021, in a joint hearing with the hearing regarding the '435 patent, before the U.S. Court of Appeals for the Federal Circuit. On December 1, 2021, the Federal Circuit also issued its ruling with respect to the '069 Patent, affirming the PTAB's finding that all claims were valid. The Federal Circuit's decision in the '069 appeal was rendered final by mandate on January 10, 2022.

Moderna and Merck European Oppositions

On April 5, 2018, Moderna and Merck, Sharp & Dohme Corporation ("Merck") filed Notices of Opposition to Arbutus' European patent EP 2279254 ("the '254 Patent") with the European Patent Office ("EPO"), requesting that the '254 Patent be revoked in its entirety for all contracting states. We filed a response to Moderna and Merck's oppositions on September 3, 2018. A hearing was conducted before the Opposition Division of the EPO on October 10, 2019. At the conclusion of the hearing, the EPO upheld an auxiliary request adopting the amendment, as put forth by us, of certain claims of the '254 Patent. In February 2020 Moderna and Merck filed Notices of Appeal challenging the EPO's grant of the auxiliary request. Merck filed its notice of appeal on February 24, 2020 and Moderna on February 27, 2020. Both Merck and Moderna perfected their appeals by filing Grounds of Appeal on April 30, 2020. We filed our responses to the appeals on September 18, 2020. On March 22, 2022, Moderna filed further written submissions to which Arbutus and Genevant responded in August 2022. The date for the oral proceedings has not been set.

While we are the patent holder, the '127 Patent, the '435 Patent, the '069 Patent and the '254 Patent have been licensed to Genevant and are included in the rights licensed by us to Genevant under the Genevant License.

Patent Infringement Litigation vs. Moderna

On February 28, 2022, we 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. The lawsuit does not seek an injunction or otherwise seek to impede the sale, manufacture or distribution of MRNA-1273. However, we seek fair compensation for Moderna's use of our patented technology that was developed with great effort and at great expense, without which Moderna's COVID-19 vaccine would not have been successful. On May 6, 2022, Moderna filed a partial motion to dismiss the claims "relating to Moderna's sale and provision of COVID-19 vaccine doses to the U.S. Government." On November 2, 2022, the Court issued an Order denying Moderna's motion. On November 30, 2022, Moderna filed its Answer to the Complaint and Counterclaims. Arbutus and Genevant filed their Answer to Moderna's Counterclaims on December 21, 2022. On February 14, 2023, the U.S. Dept. of Justice filed a Statement of Interest in the action. On February 16, 2023, the Court held an Initial Pretrial Conference after which it issued an Order, dated February 16, 2023, ordering that within 14 days of the issuance of the Order, the parties and the U.S. Government are to submit letters regarding the impact of the Governments' Statement of Interest on the scheduling of the matter.

Acuitas Declaratory Judgment Lawsuit

On March 18, 2022, Acuitas filed a lawsuit against us and Genevant in the Southern District of New York, asking the court to enter declaratory judgment that Arbutus patent Nos. 8,058,069, 8,492,359, 8,822,668, 9,006,417, 9,364,435, 9,404,127,

9,504,651, 9,518,272, and 11,141,378 do not infringe Pfizer and BioNTech's COVID-19 vaccine, COMIRNATY, which uses an mRNA lipid provided, under license, by Acuitas. Acuitas also seeks a declaration that each of the listed patents is invalid. On June 24, 2022, we and Genevant sought a pre-motion conference concerning our anticipated motion to dismiss all of Acuitas' claims due to lack of subject matter jurisdiction. The request for a pre-motion conference was granted, but the case was subsequently re-assigned to a new judge who entered an order directing: (i) Acuitas to inform the court whether it intended to file an amended complaint; (ii) that Acuitas must file any amended complaint by a certain date; and (iii) that if Acuitas did not file an amended complaint, we and Genevant must file our motion to dismiss by a certain date. Acuitas filed its amended complaint on September 6, 2022. On October 4, 2022, we and Genevant filed our motion to dismiss the Acuitas action for lack of subject matter jurisdiction based on the lack of a case or controversy. Acuitas filed its opposition to the motion to dismiss on November 1, 2022 and we and Genevant filed our reply brief on November 16, 2022. The motion is now fully briefed. No case schedule is yet in place.

Potential Additional Payments Related to the Acquisition of Enantigen Therapeutics, Inc.

In October 2014, Arbutus Inc., our wholly-owned subsidiary, acquired all of the outstanding shares of Enantigen Therapeutics, Inc. (“Enantigen”) pursuant to a stock purchase agreement. The amount paid to Enantigen’s selling shareholders could be up to an additional \$102.5 million in sales performance milestones in connection with the sale of the first commercialized product by us for the treatment of HBV, regardless of whether such product is based upon assets acquired under this agreement, and a low single-digit royalty on net sales of such first commercialized HBV product, up to a maximum royalty payment of \$1.0 million that, if paid, would be offset against our performance milestone payment obligations.

Patents and Proprietary Rights

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, novel discoveries, product development technologies and other know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing or in licensing United States and foreign patents and patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trademarks, trade secrets, know how, continuing technological innovation and potential in licensing opportunities to develop and maintain our proprietary position.

In addition to our proprietary expertise, we own a portfolio of patents and patent applications directed to HBV core/capsid protein assembly inhibitors, HBV surface antigens secretion inhibitors, coronavirus main protease inhibitors, coronavirus Nsp12 inhibitors, LNP inventions, LNP compositions for delivering nucleic acids such as mRNA and RNAi, the formulation and manufacture of LNP-based pharmaceuticals, chemical modification of RNAi molecules, and RNAi drugs and processes directed at particular disease indications. In the United States our patents might be challenged by inter partes review or opposition proceedings. In Europe, upon grant, a period of nine months is allowed for notification of opposition to such granted patents. If our patents are subjected to inter partes review or opposition proceedings, we would incur significant costs to defend them. Further, our failure to prevail in any such proceedings could limit the patent protection available to our therapeutic HBV programs, coronavirus programs or RNAi platform, including our product candidates.

We own more than 65 patent families related to our compounds, formulations, and technology, but we cannot be certain that issued patents will be enforceable or provide adequate protection or that pending patent applications will result in issued patents.

The following table shows the estimated expiration dates, based on filing dates of pending patent applications, in the United States and the European Union for the primary patents for our product candidates currently in clinical trials.

Product candidate	Estimated Patent Expiration in US	Estimated Patent Expiration in EU
AB-729	2038	2038

Human Capital

Employee Composition

As of December 31, 2022, we had 98 employees (96 full-time and 2 part-time), 76 of whom were engaged in research and development, including three medical doctors, 35 individuals with Doctors of Philosophy (PhDs) degrees, and another 10 individuals with Master of Science degrees. Our workforce is 49% female and 31% of our employees holding a position of vice president or higher are female. None of our employees are represented by a labor union or covered by a collective bargaining agreement, nor have we experienced any work stoppages. We believe that relations with our employees are good. We supplement our in-house expertise with outsourced capabilities when it would be cost prohibitive to build our own in-house capabilities. For example, we outsource a substantial portion of our clinical trial work to clinical research organizations and a majority of our drug manufacturing is out-sourced to contract manufacturers. Our in-house clinical development and manufacturing teams implement our development strategies and oversee the activities of our outside vendors.

Employee Oversight, Training and Development

We are invested in the professional development of our employees. In order to promote long-term retention and to maximize the potential of our employees, we provide individualized performance management programs. We also offer needs-based supplemental training to our employees. In order to monitor employee satisfaction and as well to identify ways in which employee satisfaction and engagement can be improved, we also survey our employees on a regular basis, reporting the results of the surveys to management and to our board of directors. In 2022, we experienced our lowest employee turnover in the previous seven years, while many other companies experienced their highest in the midst of an historically competitive job market. Given our financial resources and our track record, we were able to hire 17 new employees in 2022 to support our expanding pipeline of research programs and product candidates.

Compensation and Benefits

Drug development is a complex endeavor that requires deep expertise and attracting and retaining qualified employees for specialized biopharmaceutical positions. Our compensation programs are designed to attract and retain top talent. We offer every employee a total compensation package consisting of base salary, cash target bonus targeting the 50th to 75th percentile of market based on company size and industry, a comprehensive benefit package, including medical, dental and vision health care coverage, a 401(k) plan with an employer match, tax-advantaged savings accounts and equity compensation for every employee, which includes stock options and restricted stock units. We also provide eligible employees the opportunity to participate in our employee stock purchase plan and our employee rewards and recognition programs. In addition, we provide our employees with wellness programs and we offer mental health support to our employees and dependents.

Work-life Balance

We aim to ensure our employees maintain a work-life balance by offering 25 paid days of time-off, 12 days of paid holidays, and we shut down in the last week of December. We provide paid parental leave to both birth and adoptive parents. In addition, we allow our employees to have a flexible work schedule and, to the extent possible, depending on the nature of the work, remote and hybrid work arrangements. We believe our focus on total rewards and work-life balance contributed to our having been named one of Philadelphia Business Journal's Best Places to Work in 2022, a prestigious award that is based on employee survey results.

Environmental, Social and Governance

Environmental

We are a pre-commercial company of less than one hundred employees, engaged in research and development. Manufacturing activities to support these activities is almost entirely outsourced and biohazardous and chemical waste disposal is handled by

third party vendors. Although our environmental footprint is subsequently small, we regularly review and evaluate our energy use to identify ways in which we can maximize efficiencies and minimize waste.

Social

The culture at Arbutus reflects our commitment to our employees, to our community, and to making a meaningful contribution to world health. We are active in community outreach and participate in many local charities serving underserved communities in the Philadelphia area, including partnering with Life Sciences Cares Philadelphia.

Safety in the Workplace

We strive to provide a productive and safe working environment for our employees. To protect the health and safety of our employees, we have a Health and Safety Committee, officially certified by the PA Department of Labor and Industry - Bureau of Workers Compensation, which is committed to the principles of leadership, responsibility, prevention, and compliance. We follow all recognized Environmental Health and Safety standards and management systems. We have also established an Occupational Health and Safety policy and related standard operating procedures, all of which are used to train our employees in the proper procedures for the workplace. We also solicit employee and contractor recommendations to improve on the safety of our working conditions.

Diversity, Equity and Inclusion

Our commitment to diversity and inclusion is demonstrated by our placement of ultimate responsibility for diversity, equity and inclusion with our board of directors, informed by the recommendations of management and the board's Nominating and Governance Committee. Our Code of Business Conduct (the "Code of Conduct") prohibits discrimination and harassment of any kind, including discrimination or harassment based on age, race, ethnicity, religion, gender, sexual preference and disability. In addition to our anti-harassment and human rights policies, we also require mandatory annual training in unconscious bias and anti-harassment. Some of the diversity and inclusion initiatives at Arbutus include the formation of a Diversity and Inclusion Committee comprised of Arbutus employees and the broadening of the geographical reach of our recruitment efforts. We also celebrate Juneteenth as a corporate holiday.

Our Contribution to World Health

We are dedicated to meaningfully contributing to world health. We are pursuing the mission of finding a cure for Hepatitis B viral infections, an unmet medical need affecting over 290 million people worldwide, and we are working to develop a treatment for coronaviruses, including COVID-19.

Governance

As stated in our Code of Conduct, we are committed to complying with all applicable laws, rules and regulations not just in the United States and Canada, but in all the countries in which we operate. In addition to mandating training on our Code of Conduct on an annual basis, we also provide annual training on insider trading, anti-bribery and anti-corruption, among other topics. In addition, we require our suppliers' agreement to comply with anti-bribery and anti-fraud provisions, and to comply with all applicable laws. All vendors also receive our Code of Conduct at the time of their engagement with us. We comply with all applicable regulations in conducting clinical trials, including FDA ethical regulations, the Declaration of Helsinki and the International Conference on Harmonisation - good Clinical Practices (ICH-GCP).

Competition

We face a broad range of current and potential competitors, from established global pharmaceutical companies with significant resources, to research-stage companies. In addition, we face competition from academic and research institutions and government agencies for the discovery, development and commercialization of novel therapeutics to treat HBV and coronaviruses. Many of our competitors, either alone or with their collaborative partners, have significantly greater financial, product development, technical, manufacturing, sales, and marketing resources than we do. In addition, many of our direct competitors are large pharmaceutical companies with internal research and development departments that have significantly

greater experience in testing product candidates, obtaining FDA and other regulatory approvals of product candidates, and achieving widespread market acceptance for those products.

As a significant unmet medical need exists for HBV, there are several large and small pharmaceutical companies focused on delivering singular or combinations of therapeutics for the treatment of HBV. These companies include, but are not limited to, Johnson & Johnson, Roche, Vir Biotechnology, GlaxoSmithKline, Gilead Sciences, Assembly, Enanta Pharmaceuticals, Aligos Therapeutics and Vaccitech. These companies are developing products such as antisense oligonucleotides, capsid inhibitors, RNAi therapeutics, immune modulators and surface antigen inhibitors. These product candidates are in various stages of pre-clinical and clinical development. Further, in addition to current investigational therapeutics in development, it is likely that additional drugs will become available in the future for the treatment of HBV.

In addition, given the severity of the global coronavirus pandemic, several companies are developing or commercializing therapeutics for the treatment of coronaviruses. These companies include, but are not limited to, Pfizer, Merck, Gilead, Vir Biotechnology, Shionogi, PardesBio, Enanta Pharmaceuticals, Aligos Therapeutics and Cocrystal Pharma.

We anticipate that we will face competition as new products enter the marketplace. Our competitors' products may be safer, more effective, or more effectively marketed and sold than any product we may commercialize. Competitive singular or combination products may render one or more of our product candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our product candidates. It is also possible that the development of a cure or new treatment methods for HBV or coronaviruses could render one or more of our product candidates non-competitive, obsolete, or reduce the demand for our product candidates.

We believe that our ability to compete depends, in part, upon our ability to develop products, successfully complete the clinical trials and regulatory approval processes, and effectively market any approved products. Further, we need to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary product candidates or processes, and secure sufficient capital resources for the substantial time period between the discovery of lead compounds and their commercial sales, if any.

Manufacturing

We currently rely on third-party manufacturers to supply drug substance and drug products, including AB-729, AB-101, AB-161 and AB-343, for our ongoing and anticipated clinical trials and non-clinical studies. We currently have no plans to establish any large-scale internal manufacturing facilities for our product candidates.

Government Regulation

Regulation by governmental authorities in the United States and in other countries is a significant consideration in our product development, manufacturing and, if our product candidates are approved, marketing strategies. We expect that all our product candidates will require regulatory approval by the FDA and by similar regulatory authorities in foreign countries prior to commercialization and will be subjected to rigorous pre-clinical, clinical, and post-approval testing to demonstrate safety and effectiveness, as well as other significant regulatory requirements and restrictions in each jurisdiction in which we would seek to market our products. In the United States, we are subject to extensive regulation by the FDA and other federal, state, and local regulatory agencies. United States federal laws, such as the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), and regulations issued thereunder, govern the testing, development, manufacture, quality control, safety, effectiveness, approval, storage, labeling, record keeping, reporting, distribution, import, export, sale, and marketing of all biopharmaceutical products intended for therapeutic purposes. We believe that we and the third parties that work with us are in compliance in all material respects with currently applicable laws, rules and regulations; however, any failure to comply could have a material negative impact on our ability to successfully develop and commercialize our products, and therefore on our financial performance. In addition, the laws, rules and regulations that apply to our business are subject to change and it is difficult to foresee whether, how, or when such changes may affect our business.

Obtaining governmental approvals to market our product candidates and maintaining ongoing compliance with applicable federal, state, local and foreign statutes and regulations following any such approvals will require the expenditure of significant financial and human resources.

Development and Approval

The process to develop and obtain approval for biopharmaceutical products for commercialization in the United States and many other countries is lengthy, complex and expensive, and the outcome is far from certain. Although foreign requirements for conducting clinical trials and obtaining approval may differ in certain respects from those in the United States, there are many similarities and they often are equally rigorous, and the outcome cannot be predicted with confidence. A key component of any submission for approval in any jurisdiction is pre-clinical and clinical data demonstrating the product candidate's safety and effectiveness.

Pre-clinical Testing. Before testing any product candidate in humans in the United States, a company must develop pre-clinical data, generally including laboratory evaluation of the product candidate's chemistry and formulation, as well as toxicological and pharmacological studies in animal species to assess safety and quality. Certain types of animal studies must be conducted in compliance with the FDA's Good Laboratory Practice ("GLP") regulations and the Animal Welfare Act, which is enforced by the Department of Agriculture.

IND Application. A person or entity sponsoring clinical trials in the United States to evaluate a product candidate's safety and effectiveness must submit to the FDA, prior to commencing such trials, an investigational new drug ("IND") application, which contains, among other data and information, pre-clinical testing results and provides a basis for the FDA to conclude that there is an adequate basis for testing the drug in humans. If the FDA does not object to the IND application within 30 days of submission, the clinical testing proposed in the IND may begin. Even after the IND has gone into effect and clinical testing has begun, the FDA may put the clinical trials on "clinical hold," suspending (or in some cases, ending) them because of safety concerns or for other reasons.

Clinical Trials. Clinical trials involve administering a product candidate to human volunteers or patients under the supervision of a qualified clinical investigator. Clinical trials are subject to extensive regulation. In the United States, this includes compliance with the FDA's bioresearch monitoring regulations and current good clinical practices ("GCP") requirements, which establish standards for conducting, recording data from, and reporting the results of clinical trials, with the goals of assuring that the data and results are credible and accurate and that study participants' rights, safety and well-being are protected. Each clinical trial must be conducted under a protocol that details, among other things, the study objectives and parameters for monitoring safety and the efficacy criteria, if any, to be evaluated. The protocol is submitted to the FDA as part of the IND and reviewed by the agency. Additionally, each clinical trial must be reviewed, approved and conducted under the auspices of an Institutional Review Board ("IRB"). The sponsor of a clinical trial, the investigators and IRBs each must comply with requirements and restrictions that govern, among other things, obtaining informed consent from each study subject, complying with the protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting AEs. Foreign studies conducted under an IND must meet the same requirements applicable to studies conducted in the United States. However, if a foreign study is not conducted under an IND, the data may still be submitted to the FDA in support of a product application, if the study was conducted in accordance with GCP and the FDA is able to validate the data.

The sponsor of a clinical trial or the sponsor's designated responsible party may be required to register certain information about the trial and disclose certain results on government or independent registry websites, such as clinicaltrials.gov.

Clinical testing is typically performed in three phases, which may overlap or be subdivided in some cases.

In Phase 1 trials, the product candidate is administered to a small number of human subjects to assess its safety and to develop detailed profiles of its pharmacological and pharmacokinetic actions (i.e., absorption, distribution, metabolism and excretion), assess the early safety profile, determine side effects associated with increasing doses, and, if possible, gain early evidence of effectiveness. Although Phase 1 trials are typically conducted in healthy human subjects, in some instances (including, for example, with some cancer therapies) the trial subjects are patients with the targeted disease or condition.

In Phase 2 trials, the product candidate is administered to a relatively small sample of the intended patient population to develop initial data regarding efficacy in the targeted disease, determine the optimal dose range, and generate additional information regarding the product candidate's safety. Additional animal toxicology studies may precede this phase.

In Phase 3 trials, the product candidate is administered to a larger group of patients with the target disease or disorder, which may include patients with concomitant diseases and medications. Typically, Phase 3 trials are conducted at multiple study sites and may be conducted concurrently for the sake of time and efficiency. The purpose of Phase 3 clinical trials is to obtain additional information about safety and effectiveness necessary to evaluate the product candidate's overall risk-benefit profile and to provide a basis for product labeling. Phase 3 data often form the core basis on which the FDA evaluates a product candidate's safety and effectiveness when considering the product application.

The study sponsor, the FDA or an IRB may suspend or terminate a clinical trial at any time on various grounds, including a determination that study subjects are being exposed to an unacceptable health risk. Success in early-stage clinical trials does not assure success in later-stage clinical trials. Moreover, data from clinical trials are not always conclusive and may be subject to alternative interpretations that could delay, limit or prevent approval.

NDA Submission and Review. After completing the clinical studies, a sponsor seeking approval to market a product candidate in the United States submits to the FDA a New Drug Application ("NDA"). The NDA is a comprehensive application intended to demonstrate the product candidate's safety and effectiveness and includes, among other things, pre-clinical and clinical data, information about the product candidate's composition, the sponsor's plans for manufacturing and packaging and proposed labeling. When an NDA is submitted, the FDA makes an initial determination as to whether the application is sufficiently complete to be accepted for review. If the application is not, the FDA may refuse to accept the NDA for filing and request additional information. A refusal to file, which requires resubmission of the NDA with the requested additional information, delays review of the application.

FDA performance goals generally provide for action on an NDA within 10 months of the 60-day filing date, or within 12 months of the NDA submission. That deadline can be extended under certain circumstances, including by the FDA's requests for additional information. The targeted action date can also be shortened to 6 months of the 60-day filing date, or 8 months after NDA submission for product candidates that are granted priority review designation because they are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. The FDA has other programs to expedite development and review of product candidates that address serious or life-threatening conditions. For example, the Fast Track program is intended to facilitate the development and review of new drugs that demonstrate the potential to address unmet medical needs involving serious or life-threatening diseases or conditions. If a product candidate receives Fast Track designation, the FDA may review sections of the NDA on a rolling basis, rather than requiring the entire application to be submitted to begin the review. Product candidates with Fast Track designation also may be eligible for more frequent meetings and correspondence with the FDA about the product candidate's development. Another FDA program intended to expedite development is the Accelerated Approval pathway, which allows approval on the basis of a surrogate endpoint that is reasonably likely to predict clinical benefit or on an intermediate clinical endpoint. To qualify for review under the Accelerated Approval pathway, a product candidate must treat a serious condition, provide a meaningful advantage over available therapies, and demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on an intermediate clinical endpoint. On December 29, 2022, Congress enacted the Consolidated Appropriations Act of 2023, which included several changes to the Accelerated Approval pathway within the Food and Drug Omnibus Reform Act ("FDORA"). Under FDORA, the FDA must specify the conditions for any post-approval studies before granting an Accelerated Approval. FDORA gives the agency significant flexibility in setting forth such conditions, which may include enrollment targets, study protocol and milestones—including the target date of study completion. The FDA may also require, as appropriate, that certain post-approval studies be underway prior to Accelerated Approval or within a specified time from the date of approval. Accelerated Approval sponsors are required to report progress every six months on required post-approval trials. Breakthrough Therapy designation, which is available for product candidates under development for serious or life-threatening conditions and where preliminary clinical evidence shows that the product candidate may have substantial improvement on at least one clinically significant endpoint over available therapies, means that a product candidate will be eligible for all of the benefits of Fast Track designation, as well as more intensive guidance from the FDA on an efficient drug development program and a commitment from the agency to involve senior FDA managers in such guidance. Even if a product candidate qualifies for Fast Track designation or Breakthrough Therapy designation, the FDA may later decide that the product no longer meets the conditions for designation and may rescind the designation, and/or may determine that the product does not meet the standards for approval. As applicable, we anticipate seeking to utilize these programs to expedite the development and review of our product candidates, but we cannot ensure that our product candidates will qualify for such programs, or that we will be able to maintain such designations if we qualify for such programs.

The FDA reviews applications to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product's identity, strength, quality, and purity. For some NDAs, the FDA may convene an advisory committee to seek insights and recommendations on issues relevant to approval of the application. Although the FDA is not bound by the recommendation of an advisory committee, the agency considers such recommendations carefully when making decisions. Before approving a new drug product, the FDA also requires that the facilities at which the product will be manufactured or advanced through the supply chain be in compliance with current good manufacturing practices ("GMP") requirements and regulations governing, among other things, the manufacture, shipment, and storage of the product. The FDA also can conduct audits to determine if the clinical trials were conducted in compliance with GCP. After review of an NDA, the FDA may grant marketing approval, request additional information, or issue a complete response letter ("CRL") communicating the reasons for the agency's decision not to approve the application. The CRL may request additional information, including additional preclinical or clinical data, for the FDA to reconsider the application. An NDA may be resubmitted with the deficiencies addressed, but resubmission does not guarantee approval. Data from clinical trials are not always conclusive, and the FDA's interpretation of data may differ from the sponsor's. Obtaining approval can take years, requires substantial resources and depends on a number of factors, including the severity of the targeted disease or condition, the availability of alternative treatments, and the risks and benefits demonstrated in clinical trials. Additionally, as a condition of approval, the FDA may impose restrictions that could affect the commercial prospects of a product and increase our costs, such as a Risk Evaluation and Mitigation Strategy ("REMS"), and/or post-approval commitments to conduct additional clinical trials or non-clinical studies or to conduct surveillance programs to monitor the product's effects. Under the Pediatric Research Equity Act ("PREA"), certain applications for approval must also include an assessment, generally based on clinical study data, of the safety and effectiveness of the subject product in relevant pediatric populations, unless a waiver or deferral is granted.

Moreover, once a product is approved, information about its safety or effectiveness from broader clinical use may limit or prevent successful commercialization because of regulatory action, market forces or for other reasons. Post-approval modifications to a drug product, such as changes in indications, labeling or manufacturing processes or facilities, may require development and submission of additional information or data in a new or supplemental NDA, which would also require prior FDA approval.

Competition. The Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") establishes two abbreviated approval pathways for product candidates that are in some way follow-on versions of already approved branded NDA products: (i) generic versions of the approved reference listed drug ("RLD"), which may be approved under an abbreviated new drug application ("ANDA") by showing that the generic product is the "same as" the approved product in key respects; and (ii) a product that is similar but not identical to a listed drug, which may be approved under a 505(b)(2) NDA, in which the sponsor relies to some degree on information from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference, and submits its own product-specific data to support the differences between the product and the listed drug.

The sponsor of an ANDA or 505(b)(2) application seeking to rely on an approved product as the RLD or listed drug must make one of several certifications regarding each patent for the RLD that is listed in the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the *Orange Book*. A "Paragraph I" certification is the sponsor's statement that patent information has not been filed for the RLD. A "Paragraph II" certification is the sponsor's statement that the RLD's patents have expired. A "Paragraph III" certification is the sponsor's statement that it will wait for the patent to expire before obtaining approval for its product. A "Paragraph IV" certification is an assertion that the patent does not block approval of the later product, either because the patent is invalid or unenforceable or because the patent, even if valid, is not infringed by the new product. Once the FDA accepts for filing an ANDA or 505(b)(2) application containing a Paragraph IV certification, the applicant must within 20 days provide notice to the RLD or listed drug NDA holder and patent owner that the application has been submitted and provide the factual and legal basis for the applicant's assertion that the patent is invalid or not infringed. If the NDA holder or patent owner files suit against the ANDA or 505(b)(2) applicant for patent infringement within 45 days of receiving the Paragraph IV notice, the FDA is prohibited from approving the ANDA or 505(b)(2) application for a period of 30 months or the resolution of the underlying suit, whichever is earlier.

Exclusivity and Patent Protection. In the United States and elsewhere, certain regulatory exclusivities and patent rights can provide an approved drug product with protection from certain competitors' products for a period of time and within a certain scope. In the United States, those protections include regulatory exclusivity under the Hatch-Waxman Act, which provides periods of exclusivity for a branded drug product that would serve as an RLD for a generic drug applicant filing and an ANDA under section 505(j) of the FD&C Act or as a listed drug for an applicant filing an NDA under section 505(b)(2) of the FD&C Act. If such a product is a "new chemical entity" ("NCE") generally meaning that the active moiety has never before been approved in any drug, there is a period of five years from the product's approval during which the FDA may not accept for filing any ANDA or 505(b)(2) application for a drug with the same active moiety. An ANDA or 505(b)(2) application may be submitted after four years, however, if the sponsor of the application makes a Paragraph IV certification (as described above). Such a product that is not an NCE may qualify for a three-year period of exclusivity if its NDA contains new clinical data (other than bioavailability studies), derived from studies conducted by or for the sponsor, that were necessary for approval. In this instance, the three-year exclusivity period does not preclude filing or review of an ANDA or 505(b)(2) application; rather, the FDA is precluded from granting final approval to the ANDA or 505(b)(2) application until three years after approval of the RLD. This three-year exclusivity applies only to the conditions of approval that required submission of the clinical data.

The Hatch-Waxman Act also provides for the restoration of a portion of the patent term lost during product development and FDA review of an NDA if approval of the application is the first permitted commercial marketing of a drug containing the active ingredient. The patent term restoration period is generally one-half the time between the effective date of the IND or the date of patent grant (whichever is later) and the date of submission of the NDA, plus the time between the date of submission of the NDA and the date of FDA approval of the product. The maximum period of restoration is five years, and the patent cannot be extended to more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The USPTO, in consultation with the FDA, reviews and approves the application for patent term restoration.

Emergency Use Authorization ("EUA"). The Secretary of Health and Human Services may authorize unapproved medical products to be marketed in the context of an actual or potential emergency that has been designated by the U.S. government. The COVID-19 pandemic has been designated as such a national emergency. After an emergency has been announced, the Secretary of Health and Human Services may authorize the issuance of and the FDA Commissioner may issue EUAs for the use of specific products based on criteria established by the FDCA, including that the product at issue may be effective in diagnosing, treating, or preventing serious or life-threatening diseases when there are no adequate, approved, and available alternatives. Although the criteria of an EUA differ from the criteria for approval of an NDA, EUAs nevertheless require the development and submission of data to satisfy the relevant FDA standards, and a number of ongoing compliance obligations. The FDA expects EUA holders to work toward submission of full applications, such as an NDA, as soon as possible. An EUA is also subject to additional conditions and restrictions and is product-specific. An EUA terminates when the emergency determination underlying the EUA terminates. An EUA is not a long-term alternative to obtaining FDA approval, licensure, or clearance for a product. The FDA may revoke an EUA for a variety of reasons, including where it is determined that the underlying health emergency no longer exists or warrants such authorization, so it is not possible to predict how long an EUA may remain in place.

Post-Approval Regulation

Once approved, drug products are subject to continuing extensive regulation by the FDA, including ongoing monitoring for safety information, maintaining appropriate registrations and licenses, and hosting periodic inspections. If ongoing regulatory requirements are not met, or if safety problems occur after a product reaches market, the FDA may take actions to change the conditions under which the product is marketed, such as requiring labeling modifications, restricting distribution, or even withdrawing approval. In addition to FDA regulation, our business is also subject to extensive federal, state, local and foreign regulation.

Good Manufacturing Practices. Companies engaged in manufacturing drug products or their components must comply with applicable GMP requirements, which include requirements regarding organization and training of personnel, building and facilities, equipment, control of components and drug product containers, closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls and records and reports. The FDA inspects equipment, facilities and manufacturing processes before approval and conducts periodic re-inspections after approval. If, after receiving

approval, a company makes a material change in manufacturing equipment, location, or process (all of which are, to some degree, incorporated in the NDA), additional regulatory review and approval may be required. Failure to comply with applicable GMP requirements or the conditions of the product's approval may lead the FDA to take enforcement actions, such as issuing a warning letter, or to seek sanctions, including fines, civil penalties, injunctions, suspension of manufacturing operations, imposition of operating restrictions, withdrawal of FDA approval, seizure or recall of products, and criminal prosecution. Although we periodically monitor FDA compliance of the third parties on which we rely for manufacturing our product candidates, we cannot be certain that our present or future third-party manufacturers will consistently comply with GMP or other applicable FDA regulatory requirements.

Sales and Marketing. Once a product is approved, the advertising, promotion and marketing of the product will be subject to close regulation, including with regard to promotion to healthcare practitioners, direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities and promotional activities involving the internet. In addition to FDA restrictions on marketing of pharmaceutical products, state and federal fraud and abuse laws have been applied to restrict certain marketing practices in the pharmaceutical industry. Failure to comply with applicable requirements in this area may subject a company to adverse publicity, investigations and enforcement action by the FDA, the Department of Justice, the Office of the Inspector General of the Department of Health and Human Services, and/or state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products.

New Legislation. New legislation is passed periodically in Congress, or at the state level, that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. Further, the FDA revises its regulations and guidance in light of new legislation in ways that may affect our business or product candidates. It is impossible to predict whether other changes to legislation, regulation, or guidance will be enacted, or what the impact of such changes, if any, may be.

Other Requirements. Companies that manufacture or distribute drug products pursuant to approved NDAs must meet numerous other regulatory requirements, including adverse event reporting, submission of periodic reports, and record-keeping obligations.

Fraud and Abuse Laws. At such time as we market, sell and distribute any products for which we obtain marketing approval, it is possible that our business activities could be subject to scrutiny and enforcement under one or more federal or state health care fraud and abuse laws and regulations, which may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. These restrictions under applicable federal and state health care fraud and abuse laws and regulations that may affect our ability to operate include:

- The U.S. federal Anti-Kickback Law, which prohibits, among other things, knowingly or willingly offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or in kind, to induce or reward the purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any health care items or service for which payment may be made, in whole or in part, by federal healthcare programs such as Medicare and Medicaid. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and prescribers, purchasers and formulary managers on the other. Liability may be established under the U.S. federal Anti-Kickback Law without proving actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Law constitutes a false or fraudulent claim for purposes of the U.S. federal civil False Claims Act. Although there are a number of statutory exemptions and regulatory safe harbors to the U.S. federal Anti-Kickback Law protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exemption or safe harbor, or for which no exception or safe harbor is available, may be subject to scrutiny.
- The U.S. federal civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing or concealing an obligation to

pay money to the federal government. Actions under the False Claims Act may be brought by the United States Attorney General or as a qui tam action by a private individual (a whistleblower) in the name of the government and the individual, and the whistleblower may share in any monetary recovery. Many pharmaceutical and other healthcare companies have been investigated and have reached substantial financial settlements with the federal government under the civil False Claims Act for a variety of alleged improper marketing activities, including: providing free product to customers with the expectation that the customers would bill federal programs for the product; providing sham consulting fees, grants, free travel and other benefits to physicians to induce them to prescribe the company's products; and inflating prices reported to private price publication services, which are used to set drug payment rates under government healthcare programs. In addition, in recent years the government has pursued civil False Claims Act cases against a number of pharmaceutical companies for causing false claims to be submitted as a result of the marketing of their products for unapproved, and thus non-reimbursable, uses. Because of the threat of treble damages and mandatory penalties per false or fraudulent claim or statement, healthcare and pharmaceutical companies often resolve allegations without admissions of liability for significant and material amounts. Pharmaceutical and other healthcare companies also are subject to other federal false claim laws, including, among others, federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs.

- The fraud provisions of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which impose criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors, and prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry, in connection with the delivery of or payment for healthcare benefits, items or services.
- Analogous state and local laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs; and state and foreign laws that require drug manufacturers to report information related to clinical trials, or information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws and local ordinances that require identification or licensing of sales representatives.
- The U.S. federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, which requires manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare and Medicaid Services ("CMS") information related to direct or indirect payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members. As of 2022, applicable manufacturers are also required to report information regarding payments and transfers of value provided (starting in 2021) to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives.
- The federal Foreign Corrupt Practices Act of 1997 and other similar anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from providing money or anything of value to officials of foreign governments, foreign political parties or international organizations with the intent to obtain or retain business or seek a business advantage. Recently, there has been a substantial increase in anti-bribery law enforcement activity by United States regulators, with more frequent and aggressive investigations and enforcement proceedings by both the Department of Justice and the United States Securities and Exchange Commission (the "SEC"). Violations of United States or foreign laws or regulations could result in the imposition of substantial fines, interruptions of business, loss of supplier, vendor or other third-party relationships, termination of necessary licenses and permits and other legal or equitable sanctions. Other internal or government investigations or legal or regulatory proceedings, including lawsuits brought by private litigants, may also follow as a consequence.

Violations of any of the laws described above or any other governmental regulations are punishable by significant civil, criminal and administrative penalties, damages, fines and exclusion from government-funded healthcare programs, such as Medicare and Medicaid. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Privacy Laws. We are also subject to federal, state and foreign laws and regulations governing data privacy and security of health information, and the collection, use and disclosure, and protection of health-related and other personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues that may affect our business, including recently enacted laws in all jurisdictions where we operate. Numerous federal and state laws, including state security breach notification laws, state health information privacy laws, state genetic privacy laws, and federal and state consumer protection and privacy laws, (including, for example, Section 5 of the Federal Trade Commission Act (“FTC Act”), and the California Consumer Privacy Act (“CCPA”)) govern the collection, use and disclosure of personal information. These laws may differ from each other in significant ways, thus complicating compliance efforts. Federal regulators, state attorneys general, and plaintiffs’ attorneys have been and will likely continue to be active in this space. Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. The European Union’s General Data Protection Regulation (“GDPR”) and other data protection, privacy and similar national, state/provincial and local laws may restrict the access, use and disclosure of patient health information abroad. Compliance efforts will likely be an increasing and substantial cost in the future.

Failure to comply with such laws and regulations could result in government enforcement actions and create liability for us (including the imposition of significant penalties), private litigation and/or adverse publicity that could negatively affect our business. In addition, if we successfully commercialize our product candidates, we may obtain patient health information from healthcare providers who prescribe our products and research institutions we collaborate with, and they are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA other than potentially with respect to providing certain employee benefits, we could potentially be subject to criminal penalties if we, or our affiliates or our agents knowingly receive individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

The Federal Trade Commission (“FTC”) also sets expectations for failing to take appropriate steps to keep consumers’ personal information secure, or failing to provide a level of security commensurate to promises made to individual about the security of their personal information (such as in a privacy notice) may constitute unfair or deceptive acts or practices in violation of Section 5(a) of the FTC Act. The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. With respect to privacy, the FTC also sets expectations for failing to honor the privacy promises made to individuals about how the company handles consumers’ personal information; such failure may also constitute unfair or deceptive acts or practices in violation of the FTC Act. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions.

In California, the CCPA establishes certain requirements for data use and sharing transparency and provides California residents certain rights concerning the use, disclosure, and retention of their personal information. The CCPA and its implementing regulations have already been amended multiple times since their enactment. In November 2020, California voters approved the California Privacy Rights Act (“CPRA”) ballot initiative which introduced significant amendments to the CCPA and established and funded a dedicated California privacy regulator, the California Privacy Protection Agency (“CPPA”). The amendments introduced by the CPRA went into effect on January 1, 2023, and new implementing regulations are expected to be introduced by the CPPA. Failure to comply with the CCPA may result in, among other things, significant civil penalties and injunctive relief, or statutory or actual damages. In addition, California residents have the right to bring a private right of action in connection with certain types of incidents. These claims may result in significant liability and damages. Similarly, there are a number of legislative proposals in the United States, at both the federal and state level, that could impose new obligations or limitations in areas affecting our business. For example, other states, including Virginia, Colorado, Utah, and Connecticut have enacted privacy laws similar to the CCPA that impose new obligations or limitations in

areas affecting our business and we continue to assess the impact of these state legislations on our business as additional information and guidance becomes available. These laws and regulations are evolving and subject to interpretation, and may impose limitations on our activities or otherwise adversely affect our business.

Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. The European Union's GDPR, which imposes fines of up to EUR 20 million or 4% of the annual global revenue of a noncompliant company, whichever is greater, and other data protection, privacy and similar national, state/provincial and local laws may also restrict the access, use and disclosure of patient health information abroad. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers, or to alleviate problems caused by such breaches. Compliance with these laws is difficult, constantly evolving, time consuming, and requires a flexible privacy framework and substantial resources. Compliance efforts will likely be an increasing and substantial cost in the future. There are also a number of legislative proposals in the European Union, the United States, at both the federal and state level, as well as other jurisdictions that could impose new obligations or limitations in areas affecting our business. In addition, some countries are considering or have passed legislation implementing data protection requirements or requiring local storage and processing of data or similar requirements that could increase the cost and complexity of delivering our services and research activities. These laws and regulations, as well as any associated claims, inquiries, or investigations or any other government actions may lead to unfavorable outcomes including increased compliance costs, delays or impediments in the development of new products, negative publicity, increased operating costs, diversion of management time and attention, and remedies that harm our business, including fines or demands or orders that we modify or cease existing business practices.

With regard to transfer of personal data, the GDPR restricts the ability of companies to transfer personal data from the European Economic Area to the United States and other countries, which may adversely affect our ability to transfer personal data or otherwise may cause us to incur significant costs to come into compliance with applicable data transfer impact assessments and implementation of legal data transfer mechanisms. One mechanism previously relied upon by companies for such transfers was the EU-U.S. Privacy Shield Framework (the "Privacy Shield"). However, in July 2020, the European Court of Justice ruled the Privacy Shield to be an invalid data transfer mechanism and confirmed that the European Commission's Standard Contractual Clauses (the "Model Clauses") remain valid and in June 2021, the European Commission published updated versions of the Model Clauses, which must be incorporated into new and existing agreements within prescribed timeframes in order to continue to lawfully transfer personal data outside of the European Union. As a result, companies may no longer rely on the Privacy Shield as a basis on which to transfer personal data from the European Union to the United States. U.S.-based companies are permitted to rely on other authorized means and procedures to transfer personal data provided by the GDPR. The Model Clauses may also come under increased scrutiny as a result of the European Court of Justice's judgement in July 2020, though they remain the most common authorized procedure to transfer personal data out of the European Union. On December, 13 2022, the European Commission adopted a draft adequacy decision for the EU-U.S. Data Privacy Framework. The draft decision concludes that the United States ensures an adequate level of protection for personal data transferred from the European Union to the United States. The draft adequacy decision text will also have to be approved by a committee composed of representatives of the European Union Member States and the European Parliament can exercise its right of scrutiny. After this process, the European Commission is then expected to adopt the final adequacy decision, which will allow data to flow freely from the European Union to the United States. After one year from the notification date of the adequacy decision to the Member States and subsequently at least every four years, the European Commission will carry out a new evaluation and could conclude that an adequate level of protection is no longer ensured and decide to suspend, amend or repeal the adequacy decision, or limit its scope.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time

periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates even if our product candidates obtain marketing approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available in a timely manner from third-party payors, including government healthcare programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. Third-party payors may limit coverage to specific products on an approved list, or formulary, which may not include all of the FDA-approved products for a particular indication. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved.

A primary trend in the United States healthcare industry and elsewhere is cost containment. Government healthcare programs and other third-party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy, and have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available promptly or at all for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases. Limited coverage may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

Obtaining coverage and adequate reimbursement is a time-consuming and costly process. There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Limited coverage may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. Third-party payors also may seek additional clinical evidence, including expensive pharmacoeconomic studies, beyond the data required to obtain marketing approval, demonstrating clinical benefits and value in specific patient populations, before covering our products for those patients. If reimbursement is available only for limited indications, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

If we successfully commercialize any of our products, we may participate in the Medicaid Drug Rebate Program. Participation is required for federal funds to be available for our products under Medicaid and Medicare Part B. Under the Medicaid Drug Rebate Program, we would be required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and under Part B of the Medicare program. Rebates owed by manufacturers under the Medicaid Drug Rebate Program are currently capped at 100 percent of average manufacturer price, but, effective January 1, 2024, this cap will be lifted, which could adversely affect our rebate liability.

Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under

Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B “ceiling price” for the manufacturer’s covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients.

Medicare is a federal program that is administered by the federal government that covers individuals age 65 and over or that are disabled as well as those with certain health conditions. Medicare Part B generally covers drugs that must be administered by physicians or other health care practitioners; among others. Medicare Part B generally pays for such drugs under a payment methodology based on the average sales price of the drugs. Manufacturers are required to report average sales price information to CMS on a quarterly basis. The manufacturer-submitted information is used by CMS to calculate Medicare payment rates. Effective January 1, 2023, manufacturers will be obligated to pay refunds to Medicare for single source drugs or biologicals, or biosimilar biological products, reimbursed under Medicare Part B and packaged in single-dose containers or single-use packages, for units of discarded drug reimbursed by Medicare Part B in excess of 10 percent of total allowed charges under Medicare Part B for that drug. Manufacturers that fail to pay refunds could be subject to civil monetary penalties of 125 percent of the refund amount. Further, starting in January 2023, the Inflation Reduction Act of 2022 (“IRA”) establishes a Medicare Part B inflation rebate scheme, under which, generally speaking, manufacturers will owe rebates if the average sales price of a Part B drug increases faster than the pace of inflation. Failure to timely pay a Part B inflation rebate is subject to a civil monetary penalty.

Medicare Part D generally provides coverage to enrolled Medicare patients for self-administered drugs (*i.e.*, drugs that are not administered by a physician). Medicare Part D is administered by private prescription drug plans approved by the U.S. government and, subject to detailed program rules and government oversight, each drug plan establishes its own Medicare Part D formulary for prescription drug coverage and pricing, which the drug plan may modify from time to time. The prescription drug plans negotiate pricing with manufacturers and pharmacies, and may condition formulary placement on the availability of manufacturer discounts. In addition, under the coverage gap discount program, manufacturers are required to provide a 70% discount on brand name prescription drugs utilized by Medicare Part D beneficiaries when those beneficiaries are in the coverage gap phase of the Part D benefit design. Civil monetary penalties could be due if a manufacturer were to fail to offer discounts under the coverage gap discount program. The IRA sunsets the coverage gap discount program starting in 2025 and replaces it with a new manufacturer discount program. Failure to pay a discount under this new program will be subject to a civil monetary penalty. In addition, starting in October 2022, the IRA established a Medicare Part D inflation rebate scheme, under which, generally speaking, manufacturers will owe additional rebates if the average manufacturer price of a Part D drug increases faster than the pace of inflation. Failure to timely pay a Part D inflation rebate is subject to a civil monetary penalty.

The IRA also creates a drug price negotiation program under which the prices for Medicare units of certain high Medicare spend drugs and biologicals without generic or biosimilar competition will be capped by reference to, among other things, a specified non-federal average manufacturer price starting in 2026. Failure to comply with requirements under the drug price negotiation program is subject to an excise tax and/or a civil monetary penalty. This or any other legislative change could impact the market conditions for our product candidates.

In addition, in order to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by the Department of Veterans Affairs (the “VA”), Department of Defense (“DoD”), Public Health Service, and Coast Guard (the “Big Four agencies”) and certain federal grantees, a manufacturer also must participate in the VA Federal Supply Schedule (“FSS”) pricing program, established by Section 603 of the Veterans Health Care Act of 1992 (the “VHCA”). Under this program, the manufacturer is obligated to make its covered drugs (innovator multiple source drugs, single source drugs, and biologics) available for procurement on an FSS contract and charge a price to the Big Four agencies that is no higher than the Federal Ceiling Price (“FCP”), which is a price calculated pursuant to a statutory formula. The FCP is derived from a calculated price point called the “non-federal average manufacturer price” (“Non-FAMP”), which we will be required to calculate and report to the VA on a quarterly and annual basis. Moreover, pursuant to Defense Health Agency (“DHA”) regulations, manufacturers must provide rebates on utilization of their innovator and single source products that are dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies. The formula for determining the rebate is established in the regulations and is based on the difference between the annual non-federal average manufacturer price and the Federal Ceiling Price, each required to be calculated by us under the VHCA. The requirements under the Medicaid Drug Rebate Program, 340B program, FSS, and TRICARE programs could reduce the revenue we may generate from any products that are commercialized in the future and could adversely affect our business and operating results.

United States Healthcare Reform

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidate for which we obtain marketing approval. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs.

In recent years, Congress has considered reductions in Medicare reimbursement levels for drugs administered by physicians. The Centers for Medicare & Medicaid Services (CMS), the agency that administers the Medicare and Medicaid programs, has authority to revise reimbursement rates and to implement coverage restrictions. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products, which in turn would affect the price we can receive for those products. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payment from commercial payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

The Affordable Care Act, as amended (the "Affordable Care Act"), has substantially changed the way healthcare is financed by both governmental and private insurers, and has significantly impacted the pharmaceutical industry. The Affordable Care Act was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms.

Certain provisions of the Affordable Care Act have been subject to judicial challenges as well as efforts to modify them or to alter their interpretation and implementation. For example, the Tax Cuts and Jobs Act, enacted on December 22, 2017, eliminated the tax-based shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the individual mandate, effective January 1, 2019. Additional legislative changes, regulatory changes, and judicial challenges related to the Affordable Care Act remain possible. It is unclear how efforts to modify or invalidate the Affordable Care Act or its implementing regulations, or portions thereof, will affect our business. Any such changes could decrease the number of individuals with health coverage. It is possible that the Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures, including those that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to successfully commercialize our product candidates, if approved.

In addition, other legislative changes have been proposed since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction, which triggered the legislation's automatic reductions. In concert with subsequent legislation, this has resulted in aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2031. Sequestration is currently set at 2% and will increase to 2.25% for the first half of fiscal year 2030, to 3% for the second half of fiscal year 2030, and to 4% for the remainder of the sequestration period that lasts through the first six months of fiscal year 2031. As long as these cuts remain in effect, they could adversely impact payment for any of our products that are reimbursed under Medicare, once commercialized.

We expect that the Affordable Care Act, as well as other healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and new payment methodologies, and in additional downward pressure on coverage and payment and the price that we receive for any approved product, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a number of significant regulations in other jurisdictions regarding research, clinical trials, approval, manufacturing, distribution, marketing and promotion, safety reporting, privacy and pricing and reimbursement. These requirements and restrictions vary from country to country, but in many instances are similar to the United States requirements, and failure to comply with them could have similar negative effects as noncompliance in the United States.

Corporate Information

Tekmira Pharmaceuticals Corporation (“Tekmira”) was incorporated pursuant to the British Columbia Business Corporations Act (“BCBCA”) on October 6, 2005, and commenced active business on April 30, 2007, when Tekmira and its parent company, Inex Pharmaceuticals Corporation (“Inex”), were reorganized under a statutory plan of arrangement (the “Plan of Arrangement”) completed under the provisions of the BCBCA. Pursuant to the Plan of Arrangement, all of Inex’s business was transferred to Tekmira.

Protiva Biotherapeutics Inc. (“Protiva”) was acquired on May 30, 2008.

On March 4, 2015, we completed a business combination pursuant to which OnCore Biopharma, Inc. (“OnCore”) became our wholly-owned subsidiary of Tekmira.

On July 31, 2015, we changed our corporate name from Tekmira Pharmaceuticals Corporation to Arbutus Biopharma Corporation and OnCore changed its corporate name to Arbutus Biopharma, Inc.

On January 1, 2018, Protiva was amalgamated with Arbutus Biopharma Corporation.

We had one wholly-owned subsidiary as of December 31, 2022: Arbutus Biopharma, Inc.

Our principal executive office is located at 701 Veterans Circle, Warminster, Pennsylvania, USA, 18974, and our telephone number is (267) 469-0914.

Unless stated otherwise or the context otherwise requires, references herein to “Arbutus”, “we”, “us” and “our” refer to Arbutus Biopharma Corporation, and, unless the context requires otherwise, the subsidiaries through which we conduct business.

Investor Information

We are a reporting issuer in Canada under the securities laws of each of the Provinces of Canada. Our common shares trade on the Nasdaq Global Select Market under the symbol “ABUS”. We maintain a website at <http://www.arbutusbio.com>. The information on our website is not incorporated by reference into this Annual Report on Form 10-K and should not be considered to be a part of this Annual Report on Form 10-K. Our website address is included in this Annual Report on Form 10-K as an inactive technical reference only. Copies of this Annual Report on Form 10-K, and our other annual reports on Form 10-K, proxy statements, quarterly reports on Form 10-Q, current reports on Form 8-K and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge through our website under “Investors – Financial Information – SEC Filings” as soon as reasonably practicable after we electronically file these materials with, or otherwise furnish them to, the SEC. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov.

Item 1A. Risk Factors

Our business is subject to substantial risks and uncertainties. The occurrence of any of the following risks and uncertainties, either alone or taken together, could materially and adversely affect our business, financial condition, results of operations or prospects. In these circumstances, the market price of our common shares could decline and you may lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Risks and uncertainties of general applicability and additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially and adversely affect our business, financial condition, results of operations or prospects.

Risks Related to Our Business, Our Financial Results and Need for Additional Capital

We are in the early stages of our development, and there is a limited amount of information about us upon which you can evaluate our product candidates.

We have not begun to market or generate revenues from the commercialization of any of our product candidates. We have only a limited history upon which you can evaluate our business and prospects as our product candidates are still at an early stage of development and thus we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. For example, to execute our business plan, we will need to successfully:

- execute research and development activities using technologies involved in the development of our product candidates;
- build, maintain and protect a strong intellectual property portfolio;
- gain regulatory approval and market acceptance for the commercialization of any product candidates we develop;
- conduct sales and marketing activities if any of our product candidates are approved;
- develop and maintain successful strategic relationships; and
- manage our spending and cash requirements as our expenses are expected to continue to increase due to research and pre-clinical work, clinical trials, regulatory approvals, commercialization and maintaining our intellectual property portfolio.

If we are unsuccessful in accomplishing these objectives, we may not be able to develop our product candidates, raise capital, expand our business or continue our operations. The approach we are taking to discover and develop novel product candidates is unproven and may never lead to marketable products.

We are concentrating and intend to continue to concentrate our internal research and development efforts primarily on the discovery and development of product candidates targeting cHBV in order to ultimately develop a functional curative combination regimen, as well as on therapies to treat coronaviruses, including COVID-19. Our future success depends in part on the successful development of these product candidates. Our approach to the treatment of HBV is unproven, and we do not know whether we will be able to develop any products of commercial value.

There is no known functional cure for HBV. Any compounds that we develop may not effectively address HBV persistence. Even if we are able to develop compounds that address one or more of the key factors in the HBV life cycle (e.g., HBV replication, HBsAg expression and immune reactivation), targeting these key factors has not been proven to functionally cure HBV. If we cannot develop compounds to achieve our goal of functionally curing HBV internally, we may be unable to acquire additional product candidates on terms acceptable to us, or at all. Even if we are able to acquire or develop product candidates that address one of these mechanisms of action in pre-clinical studies, we may not succeed in demonstrating safety and efficacy of the product candidate in clinical trials. If we are unable to identify suitable compounds for pre-clinical and clinical development, we will not succeed in realizing our goal of a functional curative combination regimen for HBV.

We will require substantial additional capital to fund our operations. Additional funds may be dilutive to shareholders or impose operational restrictions. Further, if additional capital is not available, we may need to delay, limit or eliminate our research, development and commercialization programs and modify our business strategy.

Our principal sources of liquidity are cash, cash equivalents and investments in marketable securities, which were \$184.3 million as of December 31, 2022. We believe that our \$184.3 million of cash, cash equivalents and investments in marketable securities as of December 31, 2022 will be sufficient to fund our operations into the fourth quarter of 2024. However, changing circumstances may cause us to consume capital faster than we currently anticipate, and we may need to spend more money than

currently expected because of such circumstances. Within the next several years, substantial additional funds will be required to continue with the active development of our pipeline product candidates and technologies. In particular, our funding needs may vary depending on a number of factors including:

- revenues earned from our licensing partners, including Alnylam, Qilu, Acuitas and Gritstone Oncology, Inc. (“Gritstone”);
- the extent to which we continue the development of our product candidates or form licensing arrangements to advance our product candidates;
- our decisions to in-license or acquire additional products, additional product candidates or technology for development;
- our ability to attract and retain development or commercialization partners, and their effectiveness in carrying out the development and ultimate commercialization of one or more of our product candidates;
- whether batches of product candidates that we manufacture fail to meet specifications resulting in clinical trial delays and investigational and remanufacturing costs;
- the decisions, and the timing of decisions, made by health regulatory agencies regarding our technology and product candidates;
- competing products, product candidates and technological and market developments; and
- prosecuting and enforcing our patent claims and other intellectual property rights.

We will seek to obtain funding to maintain and advance our business from a variety of sources including equity financings, debt financings, licensing agreements, partnerships, government grants and contracts and other strategic transactions and funding opportunities. There can be no assurance that we will be able to complete any such transaction on acceptable terms or otherwise.

If we are able to raise additional capital through the issuance of equity securities, the percentage ownership of our current shareholders will be reduced. In addition, we may issue equity as part of the consideration to our licensors, to compensate consultants or to settle outstanding payables, all of which could cause our shareholders to experience additional dilution in net book value per share. Any such additional equity securities may have rights, preferences and privileges senior to those of the holders of our common shares.

Debt financing, if available, will result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences, which are not favorable to us or our existing shareholders. If we raise additional funds through corporate collaborations, partnerships or other strategic transactions, it may be necessary to relinquish valuable rights to our product candidates, our technologies or future revenue streams or to grant licenses or sell assets on terms that may not be favorable to us.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will need to curtail and reduce our operations and costs, and modify our business strategy which may require us to, among other things:

- significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or one or more of our research and development initiatives;
- seek collaborators for one or more of our product candidates or one or more of our research and development initiatives at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- sell or license on unfavorable terms our rights to one or more of our technologies, product candidates or research and development initiatives that we otherwise would seek to develop or commercialize ourselves; or
- cease operations.

We have incurred losses in nearly every year since our inception and we anticipate that we will not achieve profits for the foreseeable future. To date, we have had no product revenues.

With the exception of the years ended December 31, 2006 and December 31, 2012, we have incurred losses each fiscal year since inception through the year ended December 31, 2022 and have not received any revenues other than from research and development collaborations, royalties, license fees and milestone payments. From inception to December 31, 2022, we have an accumulated net deficit of approximately \$1.2 billion. Investment in drug development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. We continue to incur significant research, development and other expenses related to our ongoing operations, including development of our product candidates. We do not expect to achieve profits until such time as product sales, milestone payments and royalty payments, if any, generate sufficient revenues to fund our continuing operations. We cannot predict if we will ever achieve profitability and, if we do, we may not be able to remain consistently profitable or increase our profitability.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will continue to be significant if and as we:

- continue our research and pre-clinical and clinical development of our product candidates;
- initiate additional pre-clinical, clinical or other studies or trials for our product candidates;
- continue or expand our licensing arrangements with our licensing partners;
- change or add additional manufacturers or suppliers;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain regulatory approval;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel;
- create additional infrastructure to support our research, product development and planned future commercialization efforts; and
- experience any delays or encounter issues with any of the above.

The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

The COVID-19 pandemic could adversely impact our business, including our clinical development plans.

We continue to monitor the effects of COVID-19, which has caused significant disruptions around the world. We may continue to experience disruptions as a result of the COVID-19 pandemic that could severely impact our business, including:

- interruption of key manufacturing, research and clinical development activities due to limitations on work and travel imposed or recommended by federal or state governments, employers and others;
- delays or difficulties in clinical trial site operations, including difficulties in recruiting clinical site investigators and clinical site staff and difficulties in enrolling subjects or treating subjects in active trials;
- the diversion of healthcare resources away from the conduct of clinical trial matters to focus on COVID-19 pandemic concerns, including the administration of COVID-19 vaccines, which could negatively affect the attention of physicians serving as our clinical trial investigators, the hospitals serving as our clinical trial sites and the hospital staff supporting the conduct of our clinical trials;
- limitations on travel and quarantine requirements that interrupt key clinical trial activities, such as clinical trial site initiations, our ability and the ability of our clinical research organizations (“CROs”) to access and monitor clinical trial sites, and new clinical trial site policies resulting from the COVID-19 pandemic that determine essential and non-essential functions and staff, which may impact the ability of site staff to conduct assessments or result in delays to the conduct of the assessments as part of our clinical trial protocols, or impact the ability to enter assessment results into clinical trial databases in a timely manner, or limit the ability of a subject to participate in a clinical trial or delay access to product candidate dosing or assessments;

- interruption of key business activities due to illness and/or quarantine of key individuals and delays associated with recruiting, hiring and training new temporary or permanent replacements for such key individuals, both internally and at our third party service providers;
- delays in research and clinical trial sites receiving the supplies and materials needed to conduct preclinical studies and clinical trials, due to work stoppages, travel and shipping interruptions or restrictions or other reasons;
- potential clinical trial subjects may be unable or unwilling to participate further (or may have to limit participation) in our clinical trials due to risks related to the COVID-19 pandemic;
- difficulties in raising additional capital needed to pursue the development of our programs due to the slowing of our economy and near term and/or long term negative effects of the pandemic on the financial, banking and capital markets;
- changes in local regulations as part of a response to the COVID-19 outbreak that may require us to change the ways in which research, including clinical development, is conducted, which may result in unexpected costs; and
- delays in necessary interactions with regulators and other important agencies and contractors due to limitations in employee resources, travel restrictions or forced furlough of government employees.

If a subject participating in one of our clinical trials contracts COVID-19, this could negatively impact the data readouts from these trials; for example, the subject may be unable to participate further (or may have to limit participation) in our clinical trial, the subject may show a different clinical trial assessment than if the subject had not contracted the COVID-19, or the subject could experience an AE that could be attributed to our product candidate.

The global outbreak of COVID-19 continues to evolve, including with the emergence of new COVID-19 variants in 2022. The extent to which the COVID-19 pandemic may further impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the virus.

We do not generate revenues from product sales and may never be profitable.

Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic partners, to successfully complete the development of, and obtain the regulatory approvals necessary for, the manufacture and commercialization of our product candidates. We do not anticipate generating significant revenues from product sales for the foreseeable future, if ever. Our ability to generate future revenues from product sales depends heavily on our success in:

- completing research and pre-clinical and clinical development of our product candidates;
- seeking and obtaining regulatory approvals for product candidates for which we complete clinical trials;
- developing a sustainable, scalable, reproducible, and transferable manufacturing process for our product candidates;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate (in amount and quality) products and services to support clinical development and the market demand for our product candidates for which we obtain regulatory approval;
- launching and commercializing product candidates for which we obtain regulatory approval, either by collaborating with partners or, if launched independently, by establishing a sales force, marketing, sales operations and distribution infrastructure;
- obtaining market acceptance of our product candidates for which we obtain regulatory approval as viable treatment options;
- addressing any competing technological and market developments;
- implementing additional internal systems and infrastructure, as needed;
- identifying and validating new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory authorities outside the United States to perform clinical trials or

other studies in addition to those that we currently anticipate. Even if we are able to generate revenues from the sale of any approved product candidates, we may not become profitable and may need to obtain additional funding to continue operations.

Risks Related to Development, Clinical Testing, Regulatory Approval, Marketing, and Coverage and Reimbursement of our Product Candidates

Our product candidates are in early stages of development and must go through clinical trials, which are very expensive, time-consuming and difficult to design and implement. The outcomes of clinical trials are uncertain, and delays in the completion of or the termination of any clinical trial of our product candidates could harm our business, financial condition and prospects.

Our research and development programs are at an early stage of development. We must demonstrate our product candidates' safety and efficacy in humans through extensive clinical testing, which is expensive and time-consuming and requires specialized knowledge and expertise.

Clinical trials are also expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming, and the outcome is not certain. We estimate that clinical trials of our product candidates will take multiple years to complete. Failure can occur at any stage of a clinical trial, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed or precluded by a number of factors, including:

- delay or failure in reaching agreement with the FDA or other regulatory authority outside the United States on the design of a given trial, or in obtaining authorization to commence a trial;
- delay or failure in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- delay or failure in obtaining approval of an IRB or ethics committees before a clinical trial can be initiated at a given site;
- any shelter-in-place orders from local, state or federal governments or clinical trial site policies resulting from the COVID-19 pandemic that determine essential and non-essential functions and staff, which may impact the ability of the staff to conduct assessments or result in delays to the conduct of the assessments as part of our clinical trial protocols, or impact the ability to enter assessment results into clinical trial databases in a timely manner;
- withdrawal of clinical trial sites from our clinical trials, including as a result of changing standards of care or the ineligibility of a site to participate;
- delay or failure in recruiting and enrolling subjects in our clinical trials;
- delay or failure in having subjects complete a clinical trial or return for post-treatment follow up;
- clinical sites or investigators deviating from trial protocol, failing to conduct the trial in accordance with applicable regulatory requirements, or dropping out of a trial;
- inability to identify and maintain a sufficient number of trial sites;
- failure of CROs to meet their contractual obligations or deadlines;
- the need to modify a trial protocol;
- unforeseen safety issues;
- emergence of dosing issues;
- lack of effectiveness data during clinical trials;
- changes in the standard of care of the indication being studied;
- reliance on third-party suppliers for the clinical trial supply of product candidates and failure by our third-party suppliers to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- inability to monitor subjects adequately during or after treatment;
- limitations on our or our CROs' ability to access and verify clinical trial data captured at clinical trial sites through monitoring and source document verification;
- lack of sufficient funding to finance the clinical trials; and
- changes in governmental regulations or administrative action.

We, the FDA, other regulatory authorities outside the United States, or an IRB may suspend a clinical trial at any time for various reasons, including if it appears that the clinical trial is exposing participants to unacceptable health risks or if the FDA

or one or more other regulatory authorities outside the United States find deficiencies in our IND or similar application outside the United States or the conduct of the trial. If we experience delays in the completion of, or the termination of, any clinical trial of any of our product candidates, the commercial prospects of such product candidate will be harmed, and our ability to generate product revenues from such product candidate will be delayed or rendered impossible. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate revenues.

Even if our clinical trials are successfully completed as planned, the results may not support approval of our product candidates under the laws and regulations of the FDA or other regulatory authorities outside the United States. The clinical trial process may fail to demonstrate that our product candidates are both safe and effective for their intended uses. Pre-clinical and clinical data and analyses are often able to be interpreted in different ways. Even if we view our results favorably, if a regulatory authority has a different view, we may still fail to obtain regulatory approval of our product candidates.

Any of these occurrences may harm our business, financial condition, results of operations, cash flows and prospects significantly.

Pre-clinical studies and preliminary and interim data from clinical trials of our product candidates are not necessarily predictive of the results or success of ongoing or later clinical trials of our product candidates. If we cannot replicate the results from our pre-clinical studies and initial clinical trials of our product candidates in later clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates.

Pre-clinical studies and any positive preliminary and interim data from our clinical trials of our product candidates may not necessarily be predictive of the results of ongoing or later clinical trials. A number of companies in the pharmaceutical and biotechnology industries, including us and many other companies with greater resources and experience than we, have suffered significant setbacks in clinical trials, even after seeing promising results in prior pre-clinical studies and clinical trials. Even if we are able to complete our planned clinical trials of our product candidates according to our current development timeline, initial positive results from pre-clinical studies and clinical trials of our product candidates may not be replicated in subsequent clinical trials. The design of our later stage clinical trials could differ in significant ways (e.g., inclusion and exclusion criteria, endpoints, statistical analysis plan) from our earlier stage clinical trials, which could cause the outcomes of the later stage trials to differ from those of our earlier stage clinical trials. If we fail to produce positive results in our planned clinical trials of any of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be materially adversely affected.

Because we have limited resources, we may decide to pursue a particular product candidate and fail to advance product candidates that later demonstrate a greater chance of clinical and commercial success.

We are an early-stage company with limited resources and revenues. The product candidates we currently have under development will require significant development, pre-clinical and clinical testing and investment of significant funds before their commercialization. Because of this, we must make strategic decisions regarding resource allocations and which product candidates to pursue. There can be no assurance that we will be able to develop all potentially promising product candidates that we may identify. Based on preliminary results, we may choose to advance a particular product candidate that later fails to be successful, and simultaneously forgo or defer further investment in other product candidates that later are discovered to demonstrate greater promise in terms of clinical and commercial success. If we make resource allocation decisions that later are shown to be inaccurate, our business and prospects could be harmed.

Several of our current pre-clinical studies and clinical trials are being conducted outside the United States, and the FDA may not accept data from trials conducted in locations outside the United States.

Several of our current pre-clinical studies and clinical trials are being conducted outside the United States and we may conduct further pre-clinical studies and clinical trials outside the United States in the future. We are currently conducting clinical trials in Moldova, Thailand, Taiwan, South Korea, Hong Kong, the United Kingdom, Australia and New Zealand, among other countries. To the extent we do not conduct these clinical trials under an IND, the FDA may not accept data from such trials. Although the FDA may accept data from clinical trials conducted outside the United States that are not conducted under an IND, the FDA's acceptance of these data is subject to certain conditions. For example, the clinical trial must be well designed

and conducted and performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the United States population, and the data must be applicable to the United States population and United States medical practice in ways that the FDA deems clinically meaningful. In general, the patient population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its ability to verify the data and its determination that the trials complied with all applicable United States laws and regulations. We cannot assure you that the FDA will accept data from trials conducted outside of the United States that are not conducted under an IND. If the FDA does not accept the data from such clinical trials, we likely would need to conduct additional trials, which would be costly and time-consuming and could delay or permanently halt our development of our product candidates.

We cannot guarantee how long it will take regulatory agencies to review our applications for product candidates, and we may fail to obtain the necessary regulatory approvals to market our product candidates.

Before we can commercialize our product candidates in the United States, we must obtain approval from the FDA. We must similarly obtain approvals from comparable regulatory authorities to commercialize our product candidates in jurisdictions outside the United States.

To obtain marketing approval, United States laws require:

- controlled research and human clinical testing that comply with GLP and GCP, as applicable;
- establishment of the safety and efficacy of the product for each use sought;
- government review and approval of a submission containing, among other things, manufacturing, pre-clinical and clinical data; and
- compliance with GMP regulations.

The process of reviewing and approving a drug is time-consuming, unpredictable, and dependent on a variety of factors outside of our control. The FDA and corresponding regulatory authorities in jurisdictions outside the United States have a significant amount of discretion in deciding whether or not to approve a marketing application. Our product candidates could fail to receive regulatory approval from the FDA or comparable regulatory authorities outside the United States for several reasons, including:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that our product candidate is safe and effective for the proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- failure to demonstrate that the product candidate's benefits outweigh its risks;
- disagreement with our interpretation of pre-clinical or clinical data; and
- inadequacies in the manufacturing facilities or processes of third-party manufacturers.

The FDA or comparable regulatory authorities outside the United States may require us to conduct additional pre-clinical and clinical testing, which may delay or prevent approval of a product candidate and our commercialization plans, or cause us to abandon the development program. Further, any approval we receive may be for fewer or more limited indications than we request, may not include labeling claims necessary for successful commercialization of the product candidate, or may be contingent upon our conducting costly post-marketing studies. Any of these scenarios could materially harm the commercial prospects of a product candidate, and our operations will be adversely effected.

If a particular product candidate causes undesirable side effects, then we may be unable to receive regulatory approval of or commercialize such product candidate.

We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent commercialization of any of our product candidates, including the occurrence of undesirable side effects. Such side effects could lead to clinical trial challenges, such as difficulties in subject recruitment, retention, and adherence, potential product liability claims, and possible termination by health authorities. These types of clinical trial challenges could in turn, delay or prevent regulatory approval of our product candidate. Side effects may also lead regulatory authorities to require stronger product warnings on the product label, costly post-marketing studies, and/or a Risk Evaluation and Mitigation Strategy

("REMS"), among other possible requirements. If the product candidate has already been approved, such approval may be withdrawn. Any delay in, denial, or withdrawal of marketing approval for one of our product candidates will adversely affect our business, including our results of operations and financial position. Even if one or more of our product candidates receives marketing approval, undesirable side effects may limit such product's commercial viability. Patients may not wish to use our product, physicians may not prescribe our product, and our reputation may suffer. Any of these events may significantly harm our business and financial prospects.

We may find it difficult to enroll patients in our clinical trials, which could delay or prevent clinical trials of our product candidates.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends in part on the speed at which we can recruit patients to participate in testing our product candidates.

We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a clinical trial, or complete our clinical trials in a timely manner. Subject enrollment is affected by a variety of factors including, among others:

- severity of the disease under investigation;
- design of the trial protocol;
- prevalence of the disease/size of the patient population;
- eligibility criteria for the clinical trial in question;
- perceived risks and benefits of the product candidate under study;
- willingness or availability of patients to participate in the clinical trials;
- proximity and availability of clinical trial sites for prospective patients;
- ability to recruit clinical trial investigators with the appropriate competencies and experience;
- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- ability to obtain and maintain subject consents;
- patient referral practices of physicians;
- risk that patients enrolled in clinical trials will drop out of the trials before completion; and
- ability to monitor patients adequately during and after treatment.

If patients are unwilling to participate in our clinical trials, the timeline for recruiting patients, conducting clinical trials and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing or testing our product candidates or termination of the clinical trials altogether.

Several of our and our collaboration partner's current and planned clinical trials have been impacted and could be further delayed or suspended as a result of the military action by Russia in Ukraine.

In February 2022, Russia commenced a military invasion of Ukraine. A portion of our clinical trial evaluating AB-836 and a cohort of Antios Therapeutics, Inc.'s ("Antios") clinical trial evaluating a triple combination including AB-729 were being conducted in Ukraine at that time. We had also planned to conduct a portion of the following clinical trials in Ukraine: (i) our Phase 2a clinical trial evaluating AB-729 in combination with ongoing NA therapy and short courses of PEG-IFN α -2a in cHBV patients and (ii) our planned Phase 2a clinical trial to evaluate a triple combination of AB-729 with Vaccitech's VTP-300 and an NA therapy. As a result of such military invasion, we intend to utilize alternative clinical trial sites for our ongoing and planned clinical trials impacted by the military action in Ukraine.

Russia's invasion and the ensuing response by Ukraine has disrupted our and our collaboration partners' current clinical trials in such jurisdictions and could increase our costs and disrupt future planned clinical development activities. For example, enrollment was completed in a cohort of patients in Antios' ongoing Phase 2a proof-of-concept clinical trial evaluating a triple combination of AB-729, Antios' proprietary Active Site Polymerase Inhibitor Nucleotide (ASPIN), ATI-2173, and Viread (tenofovir disoproxil fumarate), a nucleos(t)ide reverse transcriptase inhibitor. However, the majority of patients in this cohort

were enrolled in Ukraine and, as a result, these patients have been lost to follow-up before completing the clinical trial. Antios terminated this clinical trial and we have terminated our clinical collaboration agreement with Antios.

Although the length and impact of Russia's military action is highly unpredictable, actions by Russia, or potentially other countries, against Ukraine and surrounding areas may adversely affect our ability to adequately conduct or complete certain clinical trials and maintain compliance with relevant protocols due to, among other reasons, the prioritization of hospital resources away from clinical trials, reallocation or evacuation of site staff and subjects, or as a result of government-imposed curfews, warfare, violence, or other governmental action or events that restrict movement. These developments may also result in our inability to access sites for monitoring or to obtain data from affected sites or patients going forward. We could also experience disruptions in our supply chain or limits to our ability to provide sufficient investigational materials in Ukraine and surrounding regions. Alternative sites to fully and timely compensate for our clinical trial activities in Ukraine may not be available and we may need to find other countries to conduct these clinical trials. If these clinical trials are further interrupted, our clinical development plans for these product candidates could be significantly delayed, which would increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

Even if our product candidates obtain regulatory approval, they will remain subject to ongoing regulatory requirements and oversight.

Approved drug products are subject to ongoing regulatory requirements and oversight, including requirements related to manufacturing, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting. In addition, we will be subject to continued compliance with GMP and GCP requirements for any clinical trials that we conduct post-approval. If we or any of the third parties on which we rely fail to meet those requirements, the FDA or comparable regulatory authorities outside the United States could initiate enforcement actions. Other potential consequences include the issuance of fines, warning letters, untitled letters or holds on clinical trials, product seizure or detention or refusal to permit the import or export of our product candidates, permanent injunctions and consent decrees, or the imposition of civil or criminal penalties, any of which could significantly impair our ability to successfully commercialize a given product. If the FDA or a comparable regulatory authority outside the United States becomes aware of new safety information, it can impose additional restrictions on how the product is marketed or may seek to withdraw marketing approval altogether.

Further, the U.S. and state governments have shown significant interest in establishing cost containment measures to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended (the "ACA"), became law in the United States. A primary goal of the ACA is to reduce the cost of health care, and it has substantially changed the way health care is financed by both government and private insurers. While we cannot predict with certainty what impact on federal and other reimbursement policies this legislation will have in general or on our business specifically, the ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of, and the price we may charge for, any products we develop that receives regulatory approval. Legislative changes to and regulatory changes under the ACA remain possible, but the nature and extent of such potential additional changes are uncertain at this time. We expect that the ACA, its implementation, efforts to modify or invalidate the ACA, or portions thereof, or its implementation, and other healthcare reform measures, including those that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to successfully commercialize our product candidates, if approved.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, cost containment measures in the United States has been an area of increasing emphasis, and we expect they will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be adopted in the future.

We face significant competition from other biotechnology and pharmaceutical companies targeting HBV and coronaviruses, including COVID-19.

As a significant unmet medical need exists for HBV, there are several large and small pharmaceutical companies focused on delivering therapeutics for treatment of HBV. These companies include, but are not limited to Roche, Vir Biotechnology, GlaxoSmithKline, Gilead Sciences, Assembly, Enanta Pharmaceuticals, Aligos Therapeutics and Vaccitech. Further, in addition to current investigational therapeutics in development, it is likely that additional drugs will become available in the future for the treatment of HBV.

In addition, given the severity of the global coronavirus pandemic, several companies are developing or commercializing therapeutics for the treatment of coronaviruses. These companies include, but are not limited to, Pfizer, Merck, Gilead, Vir Biotechnology, Shionogi, PardesBio, Enanta Pharmaceuticals, Aligos Therapeutics and Cocrystal Pharma.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the United States and other countries. Many of our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing.

We anticipate significant competition in the HBV and coronavirus markets, with several early and late phase product candidates announced. We will also face competition for other product candidates that we expect to develop in the future. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, product candidates that are more effective or less costly than any product candidate that we may develop.

If we successfully develop product candidates, and obtain approval for them, we will face competition based on many different factors, including the following:

- safety and effectiveness of our products;
- ease with which our products can be administered and the extent to which patients and physicians accept new routes of administration;
- timing and scope of regulatory approvals for these products;
- availability and cost of manufacturing, marketing and sales capabilities;
- price;
- reimbursement coverage; and
- patent position.

Our competitors may develop or commercialize products with significant advantages over any products we develop based on any of the factors listed above, or on other factors. Our competitors may therefore be more successful in commercializing their products than we are, which could adversely affect our competitive position and business. Competitive products may make any products we develop and commercialize obsolete or uncompetitive before we can recover the expenses of developing and commercializing such products. Such competitors could also recruit our employees, which could negatively impact our level of expertise and the ability to execute on our business plan.

We are largely dependent on the future commercial success of our HBV and coronavirus product candidates.

Our ability to generate revenues and become profitable will depend in large part on the future commercial success of our HBV and coronavirus product candidates, if they are approved for marketing. If any product that we commercialize in the future does not gain an adequate level of acceptance among physicians, patients and third parties, or our estimates of the number of people who have cHBV or are infected with coronaviruses are lower than expected, we may not generate significant product revenues or become profitable. Market acceptance by physicians, patients and third party payors of the products we may commercialize will depend on a number of factors, some of which are beyond our control, including:

- their efficacy, safety and other potential advantages in relation to alternative treatments;
- their relative convenience and ease of administration in relation to alternative treatments;

- the availability of adequate coverage or reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid;
- the prevalence and severity of adverse events;
- their cost of treatment in relation to alternative treatments, including generic products;
- the extent and strength of our third party manufacturer and supplier support;
- the extent and strength of marketing and distribution support;
- the limitations or warnings contained in a product's approved labeling; and
- distribution and use restrictions imposed by the FDA or other regulatory authorities outside the United States or that are part of a REMS or voluntary risk management plan.

For example, even if our products have been approved by the FDA, physicians and patients may not immediately be receptive to them and may be slow to adopt them. If our products do not achieve an adequate level of acceptance among physicians, patients and third party payors, we may not generate meaningful revenues and we may not become profitable.

We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.

The testing and marketing of medical products entail an inherent risk of product liability. Product liability claims may be brought against us by patients, healthcare providers or others using, administering or selling our products. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects, which is an example of just one possible product liability claim that may be brought against us. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with partners. Although we currently have product liability insurance coverage for our clinical trials for expenses or losses, our insurance coverage is limited to \$10 million per occurrence, and \$10 million in the aggregate, and may not reimburse us or may not be sufficient to reimburse us for any or all expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Further, even if our agreements with any current or future partners entitle us to indemnification against losses, such indemnification may not be available or adequate should any claims arise. A successful product liability claim or series of claims brought against us could cause our share price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Coverage and adequate reimbursement may not be available for our product candidates, which could make it difficult for us to sell our products profitably.

Market acceptance and sales of any products that we develop will depend in part on the extent to which reimbursement for these products and related treatments will be available from third party payors, including government health administration authorities and private health insurers. Third party payors decide which drugs they will pay for and establish reimbursement levels. Third party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for each of our products will be made on a plan by plan basis. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Additionally, a third party payor's decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Each plan determines whether or not it will provide coverage for a drug, what amount it will pay the manufacturer for the drug, and on what tier of its formulary the drug will be placed. The position of a drug on a formulary generally determines the copayment that a patient will need to make to obtain the drug and can strongly influence the adoption of a drug by patients and physicians. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

A primary trend in the United States healthcare industry and elsewhere is cost containment. Third party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize any product candidates that we develop.

Additionally, there have been a number of legislative and regulatory proposals to change the healthcare system in the United States and in some jurisdictions outside the United States that could affect our ability to sell any future products profitably. These legislative and regulatory changes may negatively impact the reimbursement for any future products, following approval.

We are subject to United States and Canadian healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, fines, disgorgement, exclusion from participation in government healthcare programs, curtailment or restricting of our operations and diminished profits and future earnings.

Healthcare providers, physicians and others will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with healthcare providers, patients and third party payors will expose us to broadly applicable United States and Canadian fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and collaborative partners through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations are described in further detail in the section entitled *Government Regulation – Post-Approval Regulation* and include the following:

- the U.S. federal Anti-Kickback Law prohibits persons from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending purchase, lease or order, any good or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the U.S. federal civil False Claims Act imposes civil penalties, sometimes pursued through whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented claims for payment of government funds that are false or fraudulent or making a false statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government;
- HIPAA imposes criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry, in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA and its implementing regulations also impose obligations on certain covered entity health care providers, health plans and health care clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA - other than with respect to providing certain employee benefits - we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly receive individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA;
- numerous federal and state laws and regulations that address privacy and data security, including state data breach notifications laws, state health information and/or genetic privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act, or FTC Act, and the CCPA), govern the collection, use, disclosure and protection of health-related and other personal information, many of which differ from each other in significant ways, thus complicating the compliance efforts. Compliance with these laws is difficult, constantly

evolving, and time-consuming, and companies that do not comply with these laws may face government enforcement actions, civil and/or criminal penalties, or private action, as well as adverse publicity that could negatively affect our operating results and business;

- activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. The European Union's GDPR and other data protection, privacy and similar national, state/provincial and local laws may restrict the access, use and disclosure of patient health information abroad. Compliance efforts will likely be an increasing and substantial cost in the future;
- the U.S. federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, which requires manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value to physicians and teaching hospitals (and certain other practitioners beginning as of 2022), as well as ownership and investment interests held in the company by physicians and their immediate family members;
- price reporting requirements under the Medicaid Drug Rebate Program and the 340B Program and with respect to average sales price reporting under the Medicare Part B program, and rebate or discount liability under the Medicaid Drug Rebate Program, the 340B Program, and Medicare Part D, with respect to which we could be subject to civil monetary penalties for a failure to comply with our reporting or rebate or discount obligations, or termination from the Medicaid Drug Rebate Program or 340B program, which, in turn, could jeopardize the availability of federal funds for our products under Medicaid and Medicare Part B;
- the IRA, which, among other things, requires the U.S. Secretary of Health and Human Services to negotiate, with respect to Medicare units and subject to a specified cap, the price of a set number of certain high Medicare spend drugs and biologics per year starting in 2026, penalizes manufacturers of certain Medicare Parts B and D drugs for price increases above inflation, and makes several changes to the Medicare Part D benefit, including a limit on annual out-of-pocket costs, and a change in manufacturer liability under the program which could negatively affect our business and financial condition; and
- analogous state laws and laws and regulations outside the United States, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws and laws outside the United States that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to certain healthcare providers; state laws and laws outside the United States that require drug manufacturers to report information related to clinical trials, or information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs; and state laws and local ordinances that require identification or licensing of sales representatives.

Efforts to ensure that our collaborations with third parties, and our business generally, will comply with applicable United States and Canadian healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, contractual damages, reputational harm, disgorgement, curtailment or restricting of our operations, any of which could substantially disrupt our operations and diminish our profits and future earnings. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations.

Failure to comply with the United States Foreign Corrupt Practices Act (“FCPA”), and potentially other global anti-corruption and anti-bribery laws such as the Canadian Corruption of Foreign Public Officials Act, could subject us to penalties and other adverse consequences.

We are subject to the FCPA, and potentially other applicable domestic or foreign anti-corruption or anti-bribery laws, which generally prohibit companies from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business and requires companies to maintain accurate books and records and internal controls, including at foreign-controlled subsidiaries.

Compliance with these anti-corruption laws and anti-bribery laws may be expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, these laws present particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and physicians and other hospital employees are considered to be foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to governmental officials and have led to FCPA enforcement actions.

We can make no assurance that our employees or other agents will not engage in prohibited conduct under our policies and procedures and anti-corruption laws and anti-bribery laws such as FCPA for which we might be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties and other consequences that may have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Dependence on Third Parties

We depend on our license agreement with Alnylam for the commercialization of ONPATTRO™ (Patisiran).

In 2012, we entered into a license agreement with Alnylam that entitles Alnylam to develop and commercialize products with our LNP technology. Alnylam received FDA approval in August 2018 and launched ONPATTRO immediately upon approval. We are entitled to low to mid-single-digit royalty payments escalating based on sales performance and received our first royalty payment in the fourth quarter of 2018. In July 2019, we sold this royalty entitlement to OMERS, the defined benefit pension plan for municipal employees based in the Province of Ontario, Canada, effective as of January 1, 2019, for \$20 million in gross proceeds before advisory fees. OMERS will retain this royalty entitlement until it has received \$30 million in royalties, at which point 100% of this royalty entitlement on future global net sales of ONPATTRO will revert to us. From the inception of the royalty sale through December 31, 2022, an aggregate of \$18.9 million of royalties have been collected by OMERS. The possibility and timing of any possible reversion of the royalty entitlement is affected by many factors including:

- Alnylam’s and its distributors’ and sublicensees’ ability to effectively market and sell ONPATTRO in each country where sold;
- the manner of sale, whether directly by Alnylam or by sublicensees or distributors, and the terms of sublicensing and distribution agreements;
- the amount and timing of sales of Alnylam in each country;
- regulatory approvals, appropriate labeling, and desirable pricing, insurance coverage and reimbursement;
- competition; and
- commencement of marketing in additional countries.

If Alnylam’s commercialization of ONPATTRO does not continue to be successful, the royalty entitlement may never revert back to us.

We expect to depend in part on our licensing agreements for a significant portion of our revenues for the foreseeable future and to develop, conduct clinical trials with, obtain regulatory approvals for, and manufacture, market and sell some of our product candidates. If these licensing agreements are unsuccessful, or anticipated milestone or royalty payments are not received, our business could be materially adversely affected.

We expect that we will depend in part on our licensing agreements with Alnylam, Qilu and Gritstone to provide revenue to partially fund our operations, especially in the near term. Furthermore, our strategy is to enter into various additional arrangements with corporate and academic collaborators, licensors, licensees and others for the research, development, clinical testing, manufacturing, marketing and commercialization of our product candidates or other products based upon our

technology. We may be unable to continue to establish such licensing agreements, and any licensing agreements we do establish may be unsuccessful, or we may not receive milestone payments or royalties as anticipated.

Should any licensing partner fail to develop or ultimately successfully commercialize any of the product candidates or technology to which it has obtained rights, our business may be adversely affected. In addition, once initiated, there can be no assurance that any of these licensing agreements will be continued or result in successfully commercialized products. Failure of a licensing partner to continue funding any particular program could delay or halt the development or commercialization of any products arising out of such program. In addition, there can be no assurance that the licensing partners will not pursue alternative technologies or develop alternative products either on their own or in collaboration with others, including our competitors.

We are dependent on our collaboration and licensing partners and, therefore, are subject to the efforts of these parties and our ability to successfully collaborate with them.

We have entered into a number of clinical collaboration agreements, including with Assembly and Vaccitech. We are responsible for managing the clinical trial under the collaboration agreement with Vaccitech, while Assembly is responsible for managing the clinical trials under the collaboration we have with them. The success of our collaborations depend on not only our efforts, but also on the efforts of our counterparties. Because we are not responsible for managing the clinical trials with Assembly, the success of those collaborations also depend on whether Assembly is successful in performance of its activities, to the extent it is responsible for performance of collaboration activities. Additionally, these counterparties could change their strategic focus or pursue alternative technologies, which could materially and adversely affect our business. Similarly, we are dependent on X-Chem and Proteros pursuant to our discovery and research agreement to work toward the development of pan-coronavirus agents to treat COVID-19 and potential future coronavirus outbreaks.

For example, through the clinical collaboration agreement with Assembly that we entered into in August 2020, Assembly conducted a clinical trial evaluating AB-729 in combination with its first-generation HBV core inhibitor (capsid inhibitor) candidate VBR and standard-of-care NA therapy for the treatment of cHBV in HBeAg negative patients with cHBV to evaluate the safety, pharmacokinetics, and antiviral activity of the triple combination of AB-729, VBR, and an NA (n=32). In July 2022, Assembly announced its plans to discontinue development of VBR. Despite this, in consultation with Assembly, we continued this Phase 2a proof-of-concept clinical trial in order to fully and accurately assess the results.

In addition, if we have a dispute or enter into litigation with any of these parties in the future, it could delay development programs, distract management from other business activities, and generate substantial expense.

We will depend on Qilu for the development and commercialization of AB-729 in China, Hong Kong, Macau and Taiwan.

In December 2021, we entered into the License Agreement with Qilu, pursuant to which we granted Qilu an exclusive (except as to certain retained rights), sublicensable, royalty-bearing license, under certain intellectual property owned by us, to develop, manufacture and commercialize AB-729 in the Territory. The timing and amount of any milestone and royalty payments we may receive under the License Agreement will depend, in part, on the efforts of Qilu. We will depend on Qilu to comply with all applicable laws relative to the development and commercialization of AB-729 in the Territory. Under the License Agreement, Qilu is required to use commercially reasonable efforts to develop, seek regulatory approval for, and commercialize at least one AB-729 product candidate in the Territory. Any failure by Qilu to use such commercially reasonable efforts could have a material adverse impact on financial results and operations. Additionally, if Qilu were to violate, or was alleged to have violated, any laws or regulations during the performance of its obligations to us, we could suffer financial and reputational harm or other negative outcomes. Any termination, breach or expiration of the License Agreement could also have a material adverse impact on our business by reducing or eliminating the potential for us to receive milestone and royalty payments. If that were to occur, we may be required to devote additional time, costs and attention to pursue the manufacture, development and commercialization of AB-729 in the Territory. In certain situations, Qilu has the ability to terminate the License Agreement and retain all rights to manufacture, develop and commercialize AB-729 in the Territory with no obligation to make any additional milestone or royalty payments to us.

If conflicts arise between our collaboration or licensing partners and us, our collaboration or licensing partners may act in their best interest and not in our best interest, which could adversely affect our business.

Conflicts may arise with our collaboration or licensing partners, including Alnylam, Qilu, Gritstone, Assembly and Vaccitech if they pursue alternative therapies for the diseases that we have targeted or develop alternative products either on their own or in collaboration with others. Competing products, either developed by our present collaboration or licensing partners or any future partners or to which our present partners or any future partners have rights, may result in development delays or the withdrawal of their support for one or more of our product candidates.

Additionally, conflicts may arise if there is a dispute about the progress of, or other activities related to, the clinical development of a product candidate, the achievement and payment of a milestone amount, the payment of royalties or the ownership of intellectual property that is developed during the course of the collaborative arrangement. Similarly, the parties to a licensing agreement may disagree as to which party owns newly developed products. If an agreement is terminated as a result of a dispute and before we have realized the benefits of the collaboration or licensing arrangement, our reputation could be harmed and we might not obtain revenues that we anticipated receiving.

We rely on third parties to conduct our clinical trials, and if they fail to fulfill their obligations, perform services in a satisfactory manner, and/or comply with applicable legal or regulatory requirements, our development plans may be adversely affected.

We rely on independent clinical investigators, CROs and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our clinical trials. We have contracted with, and we plan to continue to contract with, certain third parties to provide certain services, including site selection, enrollment, monitoring and data management. Although we depend heavily on these parties and have contractual agreements governing their activities, we do not control them and therefore, we cannot be assured that these third parties will adequately perform all of their contractual obligations to us. If our third-party service providers cannot adequately fulfill their obligations to us on a timely and satisfactory basis or if the quality or accuracy of our clinical trial data is compromised due to failure to adhere to our protocols or regulatory requirements, or if such third parties otherwise fail to meet deadlines or follow legal or regulatory requirements, our development plans may be delayed or terminated.

If any of our relationships with these third-parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms or at all. Switching or adding additional third-party service providers involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new third-party service provider begins work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines.

We rely exclusively on third parties to formulate and manufacture our product candidates, which exposes us to a number of risks that may delay development, regulatory approval and commercialization of our products or result in higher product costs.

We have limited experience in drug formulation or manufacturing and we lack the resources and expertise to formulate or manufacture our own product candidates internally. Therefore, we rely on, and expect to continue to rely on, third-party expertise to support us in this area. We have entered into contracts with third-party manufacturers to manufacture, supply, store and distribute supplies of our product candidates for our clinical trials. If any of our product candidates receive FDA approval, we expect to rely on third-party contractors to manufacture our products. We have no current plans to build internal manufacturing capacity for any product candidate, and we have no long-term supply arrangements.

Our reliance on third-party manufacturers exposes us to potential risks, such as the following:

- we may be unable to contract with third-party manufacturers on acceptable terms, or at all, because the number of potential manufacturers is limited. Potential manufacturers of any product candidate that is approved will be subject to FDA compliance inspections and any new manufacturer would have to be qualified to produce our products;
- our third-party manufacturers might be unable to formulate and manufacture our product candidates and products in the volume and of the quality required to meet our clinical and commercial needs, if any;

- our third-party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials through completion or to successfully produce, store and distribute our commercial products, if approved;
- drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and other government agencies to ensure compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards, but we may ultimately be responsible for any of their failures;
- if any third-party manufacturer makes improvements in the manufacturing process for our product candidates, we may not own, or may have to share, the intellectual property rights to such improvements; and
- a third-party manufacturer may gain knowledge from working with us that could be used to supply one of our competitors with a product that competes with ours.

Each of these risks could delay or have other adverse impacts on our clinical trials and the approval and commercialization of our product candidates, potentially resulting in higher costs, reduced revenues or both.

Risks Related to Our Intellectual Property

Other companies or organizations may assert patent rights that prevent us from developing or commercializing our products.

RNAi, capsid inhibitors and RNA destabilizer, as well as our other novel HBV assets, have generated many different patent applications from organizations and individuals seeking to obtain patents in the field. These applications claim many different methods, compositions and processes relating to the discovery, development and commercialization of these therapeutic products. It is likely that there could be litigation and other proceedings, such as inter partes review and opposition proceedings in various patent offices, relating to patent rights in RNAi, capsid inhibitors, RNA destabilizer and other small molecule compounds targeted at HBV. We are aware of patents and patent applications owned by third parties that may in the future be alleged by such third parties to cover the use of one or more of our products. We may need to acquire or obtain a license from such third parties to any such issued patents to market or sell any such products, which may not be available on commercially acceptable terms or at all. If such third parties obtain valid and enforceable patents and successfully prove infringement of an approved Arbutus product, and we are not able to acquire such issued patents or negotiate a license on acceptable terms, and if such approved Arbutus product is determined to infringe any such issued patents, then we may be forced to pay royalties, damages and costs, or we may be prevented from commercializing such approved Arbutus product altogether, which could have a material adverse impact on our business.

Our patents and patent applications may be challenged and may be found to be invalid, which could adversely affect our business.

Certain United States, Canadian and international patents and patent applications we own involve complex legal and factual questions for which important legal principles are largely unresolved. For example, no consistent policy has emerged for the breadth of biotechnology patent claims that are granted by the USPTO or enforced by the United States federal courts. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued. Also, we face at least the following intellectual property risks:

- some or all patent applications may not result in the issuance of a patent;
- patents issued to us may not provide us with any competitive advantages;
- patents could be challenged by third parties;
- competitors may find ways to design around our patents; and
- competitors could independently develop products which duplicate our products.

A number of industry competitors and institutions have developed technologies, filed patent applications or received patents on various technologies that may be related to or affect our business. Some of these technologies, applications or patents may conflict with our technologies or patent applications. Such conflict could limit the scope of the patents, if any, that we may be able to obtain or result in the denial of our patent applications. In addition, we could incur substantial costs in filing suits against others to have such patents declared invalid. As publication of discoveries in the scientific or patent literature often lags behind

actual discoveries, we cannot be certain we or any licensor was the first creator of inventions covered by pending patent applications or that we or such licensor was the first to file patent applications for such inventions. Any future proceedings could result in substantial costs, even if the eventual outcomes are favorable. There can be no assurance that our patents, if issued, will be held valid or enforceable by a court or that a competitor's technology or product would be found to infringe such patents.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights which could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

There has been significant litigation in the biotechnology industry over contractual obligations, patents and other proprietary rights, and we may become involved in various types of litigation that arise from time to time. Involvement in litigation could consume a substantial portion of our resources, regardless of the outcome of the litigation. Counterparties in litigation may be better able to sustain the costs of litigation because they have substantially greater resources. If claims against us are successful, in addition to any potential liability for damages, we could be required to obtain a license, grant cross-licenses, and pay substantial milestones or royalties in order to continue to develop, manufacture or market the affected products. Involvement and continuation of involvement in litigation may result in significant and unsustainable expense, and divert management's attention from ongoing business concerns and interfere with our normal operations. Litigation is also inherently uncertain with respect to the time and expenses associated therewith, and involves risks and uncertainties in the litigation process itself, such as discovery of new evidence or acceptance of unanticipated or novel legal theories, changes in interpretation of the law due to decisions in other cases, the inherent difficulty in predicting the decisions of judges and juries and the possibility of appeals. Ultimately we could be prevented from commercializing a product or be forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other intellectual property rights and the costs associated with litigation, which could have a material adverse effect on our business, financial condition, and operating results and could cause the market value of our common shares to decline.

Confidentiality agreements with employees and others, including collaborators, may not adequately prevent disclosure of trade secrets and other proprietary information.

Much of our know-how and technology may constitute trade secrets. There can be no assurance, however, that we will be able to meaningfully protect our trade secrets. In order to protect our proprietary technology and processes, we rely in part on confidentiality agreements with our collaborators, employees, vendors, consultants, outside scientific collaborators and sponsored researchers, and other advisors. These agreements offer only limited protection, and as such may not effectively prevent disclosure of confidential information and also may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover trade secrets and proprietary information, and in such cases we could not assert any trade secret rights against such party. Costly and time consuming litigation could continue to be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Risks Related to the Ownership of our Common Shares

The concentration of common share ownership will likely limit the ability of the other shareholders to influence corporate matters.

As of February 28, 2023, executive officers, directors, five percent or greater shareholders, and their respective affiliated entities beneficially owned, in the aggregate, approximately 26% of our outstanding common shares.

Entities associated with Roivant Sciences Ltd. ("Roivant") collectively held as a group approximately 25% of our outstanding common shares as of February 28, 2023.

As a result, Roivant can significantly influence the outcome of matters requiring shareholder approval, including the election of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common shares that you may feel are in your best interest. The interests of Roivant may not always coincide with your interests or the interests of other

shareholders and they may act in a manner that advances their best interests and not necessarily those of other shareholders, including seeking a premium value for their common shares. These actions might affect the prevailing market price for our common shares. In addition, Roivant and certain of our other principal shareholders that have held their shares for several years may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other shareholders. Such concentration of ownership control may also:

- delay, defer or prevent a change in control;
- entrench our management and/or the board of directors; or
- impede a merger, consolidation, takeover or other business combination involving us that other shareholders may desire.

We are incorporated in Canada, with our assets located both in Canada and the United States, with the result that it may be difficult for investors to enforce judgments obtained against us or some of our officers.

We are incorporated under the laws of the Province of British Columbia and some of our assets are located outside the United States. While we have appointed National Registered Agents, Inc. as our agent for service of process to effect service of process within the United States upon us, it may not be possible for you to enforce against us or our insiders in the United States, judgments obtained in United States courts based upon the civil liability provisions of the United States federal securities laws or other laws of the United States. In addition, there is doubt as to whether original action could be brought in Canada against us or our directors or officers based solely upon United States federal or state securities laws and as to the enforceability in Canadian courts of judgments of United States courts obtained in actions based upon the civil liability provisions of United States federal or state securities laws.

Conversely, all of our directors and officers reside outside Canada, and the majority of our physical assets are also located outside Canada. While we have appointed Farris LLP as our agent for service of process in Canada, it may not be possible for you to enforce in Canada against our assets or those directors and officers residing outside Canada, judgments obtained in Canadian courts based upon the civil liability provisions of the Canadian securities laws or other laws of Canada.

If we are deemed to be a “passive foreign investment company” for the current or any future taxable year, investors who are subject to United States federal taxation would likely suffer materially adverse United States federal income tax consequences.

We generally will be a “passive foreign investment company” under the meaning of Section 1297 of the Code (a “PFIC”) if (a) 75% or more of our gross income is “passive income” (generally, dividends, interest, rents, royalties, and gains from the disposition of assets producing passive income) in any taxable year, or (b) if at least 50% or more of the quarterly average value of our assets produce, or are held for the production of, passive income in any taxable year. We have determined that we have not been a PFIC for the three taxable years ended December 31, 2022, however recent changes to Treasury regulations under the Code have made this determination more challenging for us, and we cannot provide any assurances that we will not become a PFIC in the future. If we are a PFIC for any taxable year during which a United States person holds our common shares, it would likely result in materially adverse United States federal income tax consequences for such United States person, including, but not limited to, any gain from the sale of our common shares would be taxed as ordinary income, as opposed to capital gain, and such gain and certain distributions on our common shares would be subject to an interest charge, except in certain circumstances. It may be possible for United States persons to fully or partially mitigate such tax consequences by making a “qualifying electing fund election,” as defined in the Code (a “QEF Election”), but although we have provided this information in the past, there is no requirement that we do so.

Our articles and certain Canadian laws could delay or deter a change of control.

Our preferred shares are available for issuance from time to time at the discretion of our board of directors, without shareholder approval. Our articles allow our board, without shareholder approval, to determine the special rights to be attached to our preferred shares, and such rights may be superior to those of our common shares.

In addition, limitations on the ability to acquire and hold our common shares may be imposed by the Competition Act in Canada. This legislation permits the Commissioner of Competition of Canada to review any acquisition of a significant interest in us. This legislation grants the Commissioner jurisdiction to challenge such an acquisition before the Canadian Competition

Tribunal if the Commissioner believes that it would, or would be likely to, result in a substantial lessening or prevention of competition in any market in Canada. The Investment Canada Act subjects an acquisition of control of a Canadian-company by a non-Canadian to government review if the value of our assets, as calculated pursuant to the legislation, exceeds a threshold amount. A reviewable acquisition may not proceed unless the relevant minister is satisfied that the investment is likely to result in a net benefit to Canada. Any of the foregoing could prevent or delay a change of control and may deprive or limit strategic opportunities for our shareholders to sell their shares.

General Risk Factors

If we are unable to attract and retain qualified key management, scientific staff, consultants and advisors, our ability to implement our business plan may be adversely affected.

We depend upon our senior executive officers as well as key scientific, management and other personnel. The competition for qualified personnel in the biotechnology field is intense. We rely heavily on our ability to attract and retain qualified managerial, scientific and technical staff. The loss of the service of any of the members of our senior management, including William H. Collier, our President and Chief Executive Officer, and Michael J. Sofia, our Chief Scientific Officer, may adversely affect our ability to develop our technology, add to our pipeline, advance our product candidates and manage our operations. We do not carry key person life insurance on any of our employees.

We rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by other entities and may have commitments under consulting or advisory contracts with those entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified personnel, our ability to develop and commercialize our product candidates will be limited.

We could face liability from our controlled use of hazardous and radioactive materials in our research and development processes.

We use certain radioactive materials, biological materials and chemicals, including organic solvents, acids and gases stored under pressure, in our research and development activities. Our use of radioactive materials is regulated by the United States Nuclear Regulatory Commission and Pennsylvania Department of Environmental Protection for the possession, transfer, import, export, use, storage, handling and disposal of radioactive materials. Our use of biological materials and chemicals, including the use, manufacture, storage, handling and disposal of such materials and certain waste products is regulated by a number of federal, state and local laws and regulations. Although we believe that our safety procedures for handling such materials comply with the standards prescribed by such laws and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result or penalized with fines, and any such liability could exceed our resources. We are not specifically insured with respect to this liability.

Our business, reputation, and operations could suffer in the event of information technology system failures, such as a cybersecurity breach.

We are increasingly dependent on sophisticated software applications and computing infrastructure to conduct critical operations. We depend on both our own systems, networks, and technology as well as the systems, networks and technology of our contractors, consultants, vendors and other business partners. Disruption, degradation, or manipulation of systems, networks or technology through intentional or accidental means could materially adversely impact key business processes. Despite the implementation of security measures, our systems, networks and technology and those of our contractors and consultants are vulnerable to damage from computer viruses (including ransomware), cybersecurity breaches and other forms of unauthorized access, as well as natural disasters, terrorism, war, telecommunication and electrical failures, cyberattacks, phishing or other fraudulent schemes, persons inside our organization, or persons with access to systems inside our organization or those with whom we do business. The risk of a cyberattack or other cybersecurity incidents has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Although to date the cybersecurity incidents we have experienced have not resulted in any material losses, such events impacting either our own systems, networks and technology, or those of our contractors, consultants, vendors, or other business partners could threaten the confidentiality, integrity and availability of regulated personal information, confidential information or intellectual property. This could result in the modification of critical data, the loss of Company funds and/or the failure or interruption of critical operations. For example, the loss of pre-clinical trial data or data from completed or ongoing clinical trials for our product candidates could result in delays in our regulatory filings and development efforts and significantly increase our costs. There can be no assurance that our efforts to protect data and systems will prevent service interruption or the loss of critical or sensitive information from our or third party providers' databases or systems. Additionally, while we have implemented security measures that we believe are appropriate and continue to enhance cybersecurity protections, a regulator could deem our

security measures not to be appropriate given the lack of prescriptive measures in certain data protection laws. To the extent that any disruption or cybersecurity incident results or appears to result in such interruption or loss, we could incur material financial, legal, business or reputational harm, including regulatory fines, penalties or intervention, or claims by third parties that we have breached privacy- or confidentiality-related obligations. Furthermore, the development of our product candidates could be delayed, and our insurance may not provide any or adequate coverage of any such losses.

We may acquire other assets or businesses, or form strategic alliances or collaborations or make investments in other companies or technologies that could harm our financial condition, results of operations or cash flows, dilute our shareholders' ownership, incur debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of assets or businesses, or strategic alliances or collaborations, to expand our existing technologies and operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any such transaction, any of which could have a detrimental effect on our financial condition, results of operations or cash flows. We may not be able to find suitable acquisition candidates, and if we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business and we may incur debt or assume unknown or contingent liabilities in connection therewith. Integration of an acquired company or assets may also disrupt ongoing operations, require the hiring of additional personnel and the implementation of additional internal systems and infrastructure, especially the acquisition of commercial assets, and require management resources that would otherwise focus on developing our existing business. We may not be able to find suitable collaboration partners or identify other investment opportunities, and we may experience losses related to any such investments.

To finance any acquisitions or collaborations, we may choose to issue debt or equity securities as consideration. Any such issuance of shares would dilute the ownership of our shareholders. If the price of our common shares is low or volatile, we may not be able to acquire other assets or businesses or fund a transaction using our equity securities as consideration. Alternatively, it may be necessary for us to raise additional capital for acquisitions through public or private financings. Additional capital may not be available on terms that are favorable to us, or at all.

Item 1B. Unresolved Staff Comments

There are currently no unresolved staff comments.

Item 2. Properties

Since November 1, 2016, we have had a lease agreement for our headquarters at 701 Veterans Circle, Warminster, Pennsylvania. The building has approximately 35,000 square feet of laboratory facilities and office space. The lease expires on April 30, 2027. We also have the option of extending the lease for two further five-year terms.

From January 2019 through June 2021, we leased approximately 8,500 square feet of office space at 626 Jacksonville Rd, Warminster, Pennsylvania. In mid-2021, we amended the contract to relet a portion of the leased space and, as the initial three-year lease term was set to expire on December 31, 2021, we extended the lease through December 31, 2022. On August 31, 2022, we terminated the lease early in full.

We believe that the total space available to us under our current leases will meet our needs for the foreseeable future and that additional space would be available to us on commercially reasonable terms if required.

Item 3. Legal Proceedings

Patent Infringement Litigation vs. Moderna

On February 28, 2022, we and Genevant filed a lawsuit in the U.S. District Court for the District of Delaware against Moderna, Inc. and a Moderna affiliate (collectively, “Moderna”) 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. The lawsuit does not seek an injunction or otherwise seek to impede the sale, manufacture or distribution of mRNA-1273. However, the Company seeks fair compensation for Moderna’s use of its patented technology that was developed with great effort and at great expense, without which Moderna’s COVID-19 vaccine would not have been successful. On May 6, 2022, Moderna filed a partial motion to dismiss the claims “relating to Moderna’s sale and provision of COVID-19 vaccine doses to the U.S. Government.” On November 2, 2022, the Court issued an Order denying Moderna’s motion. On November 30, 2022, Moderna filed its Answer to the Complaint and Counterclaims. Arbutus and Genevant filed their Answer to Moderna’s Counterclaims on December 21, 2022. On February 14, 2023, the U.S. Dept. of Justice filed a Statement of Interest in the action. On February 16, 2023, the Court held an Initial Pretrial Conference after which it issued an Order, dated February 16, 2023, ordering that within 14 days of the issuance of the Order, the parties and the U.S. Government are to submit letters regarding the impact of the Governments’ Statement of Interest on the scheduling of the matter.

Acuitas Declaratory Judgment Lawsuit

On March 18, 2022, Acuitas Therapeutics Inc. (“Acuitas”) filed a lawsuit against us and Genevant in the U.S. District Court for the Southern District of New York, asking the court to enter declaratory judgment that Arbutus patent Nos. 8,058,069, 8,492,359, 8,822,668, 9,006,417, 9,364,435, 9,404,127, 9,504,651, 9,518,272, and 11,141,378 do not infringe Pfizer and BioNTech’s COVID-19 vaccine, COMIRNATY, which uses an mRNA lipid provided, under license, by Acuitas. Acuitas also seeks a declaration that each of the listed patents is invalid. On June 24, 2022, we and Genevant sought a pre-motion conference concerning our anticipated motion to dismiss all of Acuitas’ claims due to lack of subject matter jurisdiction. The request for a pre-motion conference was granted, but the case was subsequently re-assigned to a new judge who entered an order directing: (i) Acuitas to inform the court whether it intended to file an amended complaint; (ii) that Acuitas must file any amended complaint by a certain date; and (iii) that if Acuitas did not file an amended complaint, we and Genevant must file our motion to dismiss by a certain date. Acuitas filed its amended complaint on September 6, 2022. On October 4, 2022, we and Genevant filed our motion to dismiss the Acuitas action for lack of subject matter jurisdiction based on the lack of a case or controversy. Acuitas filed its opposition to the motion to dismiss on November 1, 2022, and we and Genevant filed our reply brief on November 16, 2022. The motion is now fully briefed. No case schedule is yet in place.

Certain early work on lipid nanoparticle delivery systems and related inventions was undertaken at the University of British Columbia (“UBC”), as well as by us that was subsequently assigned to UBC. These inventions are licensed to us by UBC under a license agreement, initially entered into in 1998 and as amended in 2001, 2006 and 2007. We granted sublicenses under the UBC license to certain third parties, including Alnylam. In November 2014, UBC filed a demand for arbitration against us which alleged entitlement to unpaid royalties. In August 2019, the arbitrator issued his decision for the second phase of the arbitration, awarding UBC \$5.9 million, which included interest of approximately \$2.6 million. We paid the \$5.9 million award to UBC in September 2019 and paid an additional \$0.2 million award for costs and attorneys’ fees in March 2021, and this matter is now fully resolved.

On December 18, 2020, UBC delivered to us a notice of arbitration alleging that under its cross license with us, it is due royalties of \$2.0 million plus interest arising from our sale to OMERS of part of our royalty interest on future global net sales of ONPATRO, currently being sold by Alnylam. Oral hearings for this matter were held in April 2022 and, on July 11, 2022, the arbitrator issued his decision fully dismissing UBC’s claim for royalties. As a result, no payments are owed to UBC. In September 2022, the arbitrator awarded the Company \$0.5 million for reimbursement of costs and attorneys’ fees, which the Company received from UBC in October 2022. This matter is now fully resolved.

We are also involved with various legal matters arising in the ordinary course of business. We make provisions for liabilities when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Such provisions are reviewed at least quarterly and adjusted to reflect the impact of any settlement negotiations, judicial and administrative rulings, advice of legal counsel, and other information and events pertaining to a particular case. Litigation is inherently unpredictable. Although the ultimate resolution of these various matters cannot be determined at this time, we do not believe that such matters, individually or in the aggregate, will have a material adverse effect on our consolidated results of operations, cash flows, or financial condition.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common shares trade on the Nasdaq Global Select Market under the symbol “ABUS” following our name change to Arbutus Biopharma Corporation on July 31, 2015. As of February 28, 2023, there were 103 registered holders of common shares and 162,570,989 common shares issued and outstanding.

Securities Authorized for Issuance under Equity Compensation Plans

Information regarding securities authorized for issuance under equity compensation plans is incorporated by reference into the information in Part III, Item 12 of this Form 10-K.

Recent Sales of Unregistered Securities

Other than as previously disclosed on our Current Reports on Form 8-K or Quarterly Reports on Form 10-Q, we did not issue any unregistered equity securities during the twelve months ended December 31, 2022.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not repurchase any of our equity securities during the year ended December 31, 2022.

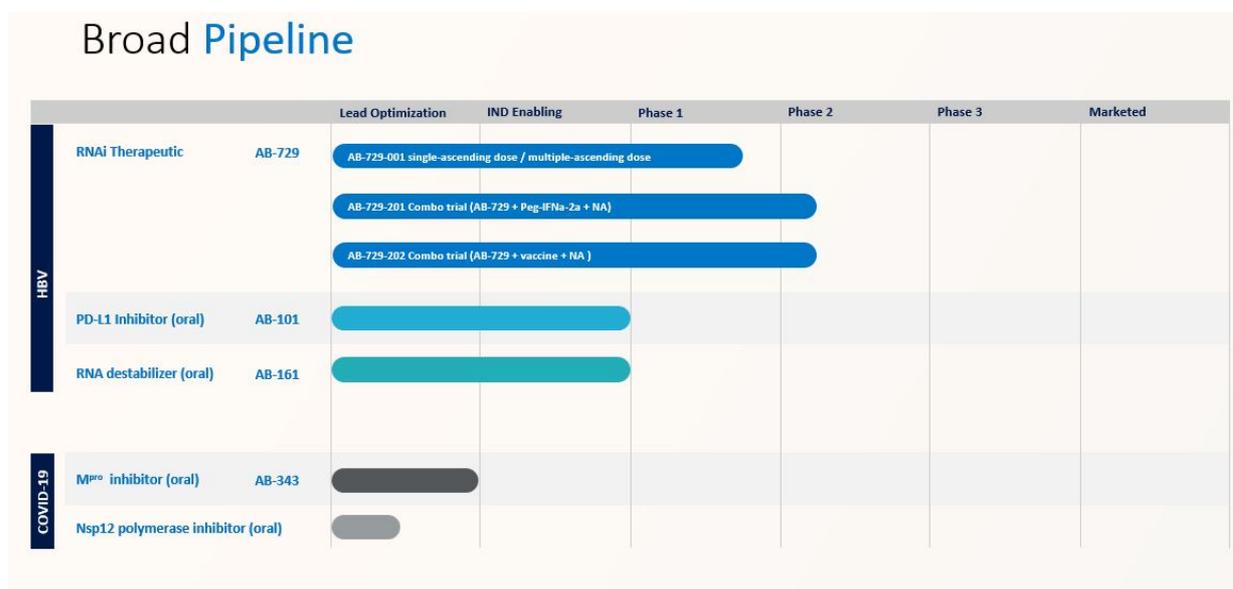
Item 6. Reserved

Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations

Overview

Arbutus Biopharma Corporation (“Arbutus”, the “Company”, “we”, “us”, and “our”) 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. To address HBV, we are developing an RNA interference (“RNAi”) therapeutic, 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 infection (“cHBV”) 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. AB-729 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 coronaviruses, including SARS-CoV-2, where we have nominated a compound and have begun IND-enabling pre-clinical studies. In addition, we are also exploring oncology applications for our internal PD-L1 portfolio.

Our product pipeline consists of the following programs:



AB-729, our proprietary subcutaneously-delivered RNAi therapeutic product candidate that suppresses HBsAg expression, which is thought to be a key prerequisite to enable reawakening of a patient’s immune system to respond to HBV, is currently in two Phase 2a proof-of-concept clinical trials in combination with other agents with potentially complementary mechanisms of action and we are continuing to follow patients from our Phase 1a/1b clinical trial (“AB-729-001”). Preliminary data from AB-729-001 has shown that treatment with AB-729 resulted in meaningful declines in HBsAg while being well tolerated with no serious adverse events (SAEs) noted after both single and repeat dosing. Preliminary data also suggests that long-term suppression of HBsAg with AB-729 results in increased HBV-specific immune response. The clinical data for AB-729 continues to support its development as a potential cornerstone agent for the treatment of cHBV infection.

AB-101 is our oral PD-L1 inhibitor that has the potential to reawaken patients’ HBV-specific immune response by inhibiting PD-L1. Preclinical data in an HBV mouse model was presented at the 2022 AASLD Liver Meeting showing that combination treatment with AB-101 and an HBV-targeting GalNAc-siRNA agent resulted in activation and increased frequency of HBV-specific T-cells and greater anti-HBsAg antibody production. This favorable preclinical profile supports further development of AB-101 as a therapeutic modality for cHBV treatment. We are also exploring potential oncology applications for our internal PD-L1 portfolio.

AB-161 is our next-generation oral HBV specific RNA destabilizer. We have conducted extensive non-clinical safety evaluations with AB-161 that gives us confidence in this molecule's ability to circumvent the peripheral neuropathy findings seen in non-clinical safety studies with our first-generation oral RNA destabilizer, AB-452. We recently presented preclinical data at the Discovery on Target Conference showing that AB-161 reduced HBV RNA and HBsAg in multiple preclinical models, with favorable liver centricity and lack of observed peripheral neuropathy.

AB-343 is our lead candidate that inhibits the SARS-CoV-2 nsp5 M^{pro}. We also intend to nominate a nsp12 clinical candidate and initiate IND-enabling studies in the second half of 2023. An nsp12 viral polymerase could potentially be combined with AB-343 to achieve better patient treatment outcomes and for use in prophylactic settings.

COVID-19 Impact

We continue to monitor the effects of COVID-19, which has caused significant disruptions around the world. 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 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.

Collaborations and Royalty Entitlements

Qilu Pharmaceutical Co., Ltd. ("Qilu")

In December 2021, we entered into a technology transfer and license agreement (the "License Agreement") with Qilu, pursuant to which we granted Qilu a sublicensable, royalty-bearing license, under certain intellectual property owned by us, which is non-exclusive as to development and manufacturing and exclusive with respect to commercialization of AB-729, including pharmaceutical products that include AB-729, for the treatment or prevention of hepatitis B in China, Hong Kong, Macau and Taiwan (the "Territory").

In partial consideration for the rights granted by us, Qilu paid us a one-time upfront cash payment of \$40 million on January 5, 2022 and agreed to pay us milestone payments totaling up to \$245 million, net of withholding taxes, upon the achievement of certain technology transfer, development, regulatory and commercialization milestones. Qilu also agreed to pay us double digit royalties into the low twenties percent based upon annual net sales of AB-729 in the Territory. The royalties are payable on a product-by-product and region-by-region basis, subject to certain limitations.

Qilu is responsible for all costs related to developing, obtaining regulatory approval for, and commercializing AB-729 for the treatment or prevention of hepatitis B in the Territory. Qilu is required to use commercially reasonable efforts to develop, seek regulatory approval for, and commercialize at least one AB-729 product candidate in the Territory. A joint development committee has been established between us and Qilu to coordinate and review the development, manufacturing and commercialization plans. Both parties also have entered into a supply agreement and related quality agreement pursuant to which we will manufacture or have manufactured and supply Qilu with all quantities of AB-729 necessary for Qilu to develop and commercialize in the Territory until we have completed manufacturing technology transfer to Qilu and Qilu has received all approvals required for it or its designated contract manufacturing organization to manufacture AB-729 in the Territory.

Concurrent with the execution of the License Agreement, we entered into a Share Purchase Agreement (the "Share Purchase Agreement") with Anchor Life Limited, a company established pursuant to the applicable laws and regulations of Hong Kong and an affiliate of Qilu (the "Investor"), pursuant to which the Investor purchased 3,579,952 of our common shares, without par value (the "Common Shares"), at a purchase price of USD \$4.19 per share, which was a 15% premium on the thirty-day average closing price of the Common Shares as of the close of trading on December 10, 2021 (the "Share Transaction"). We received \$15.0 million of gross proceeds from the Share Transaction on January 6, 2022. The Common Shares sold to the Investor in the Share Transaction represented approximately 2.5% of the Common Shares outstanding immediately prior to the execution of the Share Purchase Agreement.

Alnylam Pharmaceuticals, Inc. and Acuitas Therapeutics, Inc

We have a royalty entitlement on ONPATTRO® (Patisiran) (“ONPATTRO”), a drug developed by Alnylam Pharmaceuticals, Inc. (“Alnylam”) under a license agreement with us that incorporates our lipid nanoparticle delivery (“LNP”) technology. In July 2019, we received \$20 million in gross proceeds before advisory fees from the sale of this royalty interest to Ontario Municipal Employees Retirement System (“OMERS”), effective as of January 1, 2019. The royalty interest will revert back to us after OMERS receives \$30 million in royalty payments from Alnylam. We also have rights to a second, lower royalty interest on global net sales of ONPATTRO originating from a settlement agreement and subsequent license agreement with Acuitas Therapeutics, Inc. (“Acuitas”). The royalty entitlement from Acuitas has been retained by us and was not part of the royalty entitlement sale to OMERS.

Genevant Sciences, Ltd.

As of December 31, 2022, we owned approximately 16% of the common equity of Genevant Sciences Ltd. (“Genevant”), a company we launched with Roivant Sciences, Ltd. and to which we licensed rights to our lipid nanoparticle (“LNP”) and ligand conjugate delivery platforms for RNA-based applications outside of HBV, except to the extent certain rights had already been licensed to other third parties (the “Genevant License”). We retained all rights to our LNP and conjugate delivery platforms for HBV. Under the Genevant License, as amended, if a third party sublicensee of intellectual property licensed by Genevant from us commercializes a sublicensed product, we become entitled to receive a specified percentage of certain revenue that may be received by Genevant for such sublicense, including royalties, commercial milestones and other sales-related revenue, or, if less, tiered low single-digit royalties on net sales of the sublicensed product. The specified percentage is 20% in the case of a mere sublicense (i.e., naked sublicense) by Genevant without additional contribution and 14% in the case of a bona fide collaboration with Genevant.

Additionally, if Genevant receives proceeds from an action for infringement by any third parties of our intellectual property licensed to Genevant, we 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).

Refer to “Item 1. Business.” and Note 9 of the Consolidated Financial Statements for a discussion of our clinical collaborations and other royalty entitlements.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The accounting for our contingent consideration and our License Agreement with Qilu are significant accounting policies that we believe are critical in fully understanding and evaluating our financial results. These accounting policies require us to make certain estimates and assumptions. We believe that the estimates and assumptions upon which we rely are reasonable, based upon information available to us at the time that these estimates and assumptions are made. Actual results may differ from our estimates. Our critical accounting estimates affect the calculation of our net income or loss.

Contingent Consideration

In connection with the acquisition of Enantigen Therapeutics, Inc. (“Enantigen”) in October 2014, we have obligations to make potential future payments of up to \$102.5 million upon the achievement of certain commercial milestones. The sales milestones are tied to the first commercial sales by us of a product indicated for the treatment of CHBV. These potential contingent payments are recorded as a liability and remeasured to fair value as of each reporting date. In assessing the fair value of the liability, significant judgments are required to be made by management to estimate the probability of program success, the timing and extent of future product sales, appropriate discount rates, and other estimates and assumptions that could materially affect the determination of fair value.

In order to estimate the probability of program success, we evaluate the status and progress of our clinical trials with our lead product candidate, AB-729, in comparison to actual historical success rates for other clinical trials. We update our assumptions related to probability of success as AB-729 advances through clinical trials. For the timing and extent of future product sales, we also consider the status and progress of AB-729, future revenue forecasts and other macroeconomic indicators that forecast market conditions. The discount rate at which we calculate the present value of our potential future liability is based on consideration of market-comparative data, market-based discount rates, and company-specific risk premiums.

As assumptions related to the probability of program success and timing and amount of potential future product sales are highly uncertain due to the unpredictable nature of product development, we assessed the sensitivity of the fair value measurement to changes in assumptions, and determined that changes within a reasonable range would not result in a materially different assessment of fair value.

Revenue from collaborations and licenses

We generate revenue primarily through collaboration agreements and license agreements. Such agreements may require us to deliver various rights and/or services, including intellectual property rights or licenses and research, development and manufacturing services. Under such agreements, we are generally eligible to receive non-refundable upfront payments, funding for research, development and manufacturing services, milestone payments, and royalties.

Our collaboration agreements fall under the scope of ASC Topic 808, *Collaborative Arrangements*, (“ASC 808”) when both parties are active participants in the arrangement and are exposed to significant risks and rewards. For certain arrangements under the scope of ASC 808, we analogize to ASC 606 for some aspects, including for the delivery of a good or service (i.e., a unit of account).

ASC 606, *Revenue From Contracts with Customers* (“ASC 606”) requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers under a five-step model: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as a performance obligation is satisfied.

In contracts where we have more than one performance obligation to provide its customer with goods or services, each performance obligation is evaluated to determine whether it is distinct based on whether (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available and (ii) the good or service is separately identifiable from other promises in the contract. The consideration under the contract is then allocated between the distinct performance obligations based on their respective relative stand-alone selling prices. The estimated stand-alone selling price of each deliverable reflects our best estimate of what the selling price would be if the deliverable was regularly sold on a

stand-alone basis and is determined by reference to market rates for the good or service when sold to others or by using an adjusted market assessment approach if the selling price on a stand-alone basis is not available.

The consideration allocated to each distinct performance obligation is recognized as revenue when control is transferred to the customer for the related goods or services. Consideration associated with at-risk substantive performance milestones, including sales-based milestones, is recognized as revenue when it is probable that a significant reversal of the cumulative revenue recognized will not occur. Sales-based royalties received in connection with licenses of intellectual property are subject to a specific exception in the revenue standards, whereby the consideration is not included in the transaction price and recognized in revenue until the customer's subsequent sales or usages occur.

Prior to recognizing revenue, we make estimates of the transaction price, including variable consideration that is subject to a constraint. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur and when the uncertainty associated with the variable consideration is subsequently resolved. These estimates are re-assessed each reporting period as required.

For performance obligations satisfied over time, we estimate the efforts needed to complete the performance obligation and recognize revenue by measuring the progress towards complete satisfaction of the performance obligation using an input measure.

Management may be required to exercise considerable judgment in estimating revenue to be recognized. Judgment is required in identifying performance obligations, estimating the transaction price, estimating the stand-alone selling price of identified performance obligations, and estimating the progress towards satisfaction of performance obligations.

RESULTS OF OPERATIONS

The following summarizes our results of operations for the year ended December 31, 2022 compared to the year ended December 31, 2021:

	Year Ended December 31,	
	2022	2021
	(in thousands)	
Revenue	\$ 39,019	\$ 10,988
Operating expenses	104,475	84,510
Loss from operations	(65,456)	(73,522)
Other income (loss)	444	(2,725)
Loss before income taxes	(65,012)	(76,247)
Income tax expense	(4,444)	—
Net loss	(69,456)	(76,247)
Dividend accretion of convertible preferred shares	—	(12,139)
Net loss attributable to common shares	\$ (69,456)	\$ (88,386)

For the fiscal year ended December 31, 2022, our net loss attributable to common shares was \$69.5 million, or a loss of \$0.46 per basic and diluted common share, as compared to a net loss of \$88.4 million, or a loss of \$0.83 per basic and diluted common share, for the year ended December 31, 2021.

Revenue

Revenue for the years ended December 31, 2022 and 2021 is summarized in the following table:

	Year ended December 31,			
	2022		2021	
	(in thousands, except percentages)			
Revenue from collaborations and licenses				
Royalties from sales of Onpattro	\$ 5,316	14 %	\$ 4,675	43 %
Qilu Pharmaceutical Co., Ltd.	26,015	67 %	—	— %
Other milestone and royalty payments	35	— %	205	2 %
Non-cash royalty revenue				
Royalties from sales of Onpattro	7,653	20 %	6,108	56 %
Total revenue	\$ 39,019	101 %	\$ 10,988	100 %

Revenue consists mainly of royalties received from other companies for sales of products that utilize our licensed technologies.

Total revenue increased \$28.0 million for the year ended December 31, 2022 compared to 2021, due primarily to \$26.0 million in license revenue recognized related to our progress towards the satisfaction of our performance obligations with respect to our technology transfer and licensing agreement with Qilu, which closed in January 2022, as well as a \$2.2 million increase in license royalty revenue from Alnylam and Acuitas due to the growth of Alnylam's sales of ONPATTRO.

The royalty interest for ONPATTRO from Alnylam was sold to OMERS, effective as of January 1, 2019, for \$20 million in gross proceeds before advisory fees. OMERS will retain this entitlement until it has received \$30 million in royalties, at which point 100% of such royalty interest on future global net sales of ONPATTRO will revert back to us. OMERS has assumed the risk of collecting up to \$30 million of future royalty payments from Alnylam and we are not obligated to reimburse OMERS if they fail to collect any such future royalties. During the term of this agreement, we recognize non-cash royalty revenue related to the sales of ONPATTRO. From the inception of the royalty sale through December 31, 2022, we have recorded an aggregate

of \$18.9 million of non-cash royalty revenue for royalties earned by OMERS. The royalty interest for ONPATTRO from Acuitas was not part of the royalty sale to OMERS and we have retained the rights to receive those royalties. Revenue contracts are described in more detail in “Item 1. Business.”

Operating expenses

Operating expenses for the years ended December 31, 2022 and 2021 are summarized in the following table:

	Year ended December 31,			
	2022		2021	
	(in thousands, except percentages)			
Research and development	\$ 84,408	81 %	\$ 65,502	78 %
General and administrative	17,834	17 %	17,136	20 %
Change in fair value of contingent consideration	2,233	2 %	1,872	2 %
Total operating expenses	\$ 104,475	100 %	\$ 84,510	100 %

Research and development

Research and development expenses consist primarily of personnel expenses, fees paid to clinical research organizations and contract manufacturers, consumables and materials, consulting, and other third party expenses to support our clinical and pre-clinical activities, as well as a portion of stock-based compensation and general overhead costs.

Research and development expenses increased \$18.9 million in 2022 compared to 2021 due primarily to an increase in expenses for our ongoing AB-729 Phase 2a clinical trials, an increase in expenses for our early-stage development programs, including AB-101 and AB-161, and an increase in compensation costs due to hiring several new employees for our research and development team in early 2022, partially offset by a decrease in expenses for our AB-836 Phase 1a/1b clinical trial, which we discontinued during the fourth quarter of 2022.

A significant portion of our research and development expenses are not tracked by project, as they benefit multiple projects or our overall technology platform.

General and administrative

General and administrative expenses increased \$0.7 million in 2022 compared to 2021, due primarily to increases in employee compensation costs and non-cash stock-based compensation expense.

Change in fair value of contingent consideration

In October 2014, Arbutus Inc., our wholly-owned subsidiary, acquired all of the outstanding shares of Enantigen pursuant to a stock purchase agreement. The amount paid to Enantigen’s selling shareholders could be up to an additional \$102.5 million in sales performance milestones in connection with the sale of the first commercialized product by us for the treatment of HBV, regardless of whether such product is based upon assets acquired under this agreement, and a low single-digit royalty on net sales of such first commercialized HBV product, up to a maximum royalty payment of \$1.0 million.

In general, increases in the fair value of the contingent consideration are related to the progress of our programs as they get closer to triggering these contingent payments. In 2022 and 2021, the fair value of our contingent consideration liability increased \$2.2 million and \$1.9 million, respectively, related to fair value adjustments for the passage of time and the progression of our programs through clinical trials and our assessment of the probability of commercialization.

Other income (losses)

Other income (losses) for the years ended December 31, 2022 and 2021 are summarized in the following table:

	Year ended December 31,					
	2022		2021			
	(in thousands, except percentages)					
Interest income	\$	2,192	494 %	\$	127	(5)%
Interest expense		(1,726)	(389)%		(2,857)	105 %
Foreign exchange (loss) gain		(22)	(5)%		5	— %
Total other income (loss)	\$	444	100 %	\$	(2,725)	100 %

Interest income

Interest income increased \$2.1 million in 2022 compared to 2021 due primarily to a general increase in market interest rates related to our investments in marketable securities.

Interest expense

Interest expense decreased \$1.1 million in 2022 compared to 2021 due primarily to a decrease in the non-cash amortization of discount and issuance costs related to the sale of a portion of our ONPATTRO royalty interest to OMERS in July 2019.

Dividend accretion of convertible preferred shares

Dividend accretion of convertible preferred shares decreased to zero in 2022 compared to \$12.1 million in 2021. The dividend accretion on the convertible preferred shares previously held by Roivant was equal to 8.75% per annum, compounded annually. All convertible preferred shares mandatorily converted into 22,833,922 common shares on October 18, 2021.

Income tax expense

Income tax expense for the years ended December 31, 2022 and 2021 are summarized in the following table:

	Year ended December 31,					
	2022		2021			
	(in thousands, except percentages)					
Income tax expense	\$	4,444	100 %	\$	—	— %

We recognized income tax expense of \$4.4 million during 2022 for withholding taxes paid to the Chinese taxing authority by Qilu on our behalf in connection with the upfront license fee Qilu paid us.

LIQUIDITY AND CAPITAL RESOURCES

Since our incorporation, we have financed our operations through the sales of equity, debt, revenues from research and development collaborations and licenses with corporate partners, a royalty monetization, interest income on funds available for investment, and government contracts, grants and tax credits.

As of December 31, 2022, we had cash and cash equivalents of \$30.8 million and investments in marketable securities of \$153.5 million, totaling \$184.3 million. We had no outstanding debt as of December 31, 2022.

Sources of Liquidity

Sale Agreement

We have an Open Market Sale AgreementSM with Jefferies dated December 20, 2018, as amended by Amendment No. 1, dated December 20, 2019, Amendment No. 2, dated August 7, 2020 and Amendment No. 3, dated March 4, 2021 (as amended, the “Sale Agreement”), under which we may offer and sell common shares, from time to time.

On December 23, 2019, we filed a shelf registration statement on Form S-3 with the SEC (File No. 333-235674) and accompanying base prospectus, declared effective by the SEC on January 10, 2020 (the “January 2020 Registration Statement”), for the offer and sale of up to \$150 million of our securities.

On August 28, 2020, we filed a shelf registration statement on Form S-3 with the SEC (File No. 333-248467) and accompanying base prospectus, declared effective by the SEC on October 22, 2020 (the “October 2020 Registration Statement”), for the offer and sale of up to \$200 million of our securities. On March 4, 2021, we filed a prospectus supplement with the SEC in connection with the offering of up to an additional \$75.0 million of our common shares pursuant to the Sale Agreement under the October 2020 Registration Statement, which we fully utilized during 2021. On October 8, 2021, we filed a prospectus supplement with the SEC for the offer and sale of up to an additional \$75.0 million of our common shares pursuant to the Sale Agreement under the October 2020 Registration Statement.

On November 4, 2021, we filed a shelf registration statement on Form S-3 with the SEC (File No. 333-248467) and accompanying base prospectus, declared effective by the SEC on November 18, 2021 (the “November 2021 Registration Statement”), for the offer and sale of up to \$250 million of our securities.

On March 3, 2022, we filed a prospectus supplement with the SEC (the “March 2022 Prospectus Supplement”) for the offer and sale of up to an additional \$100.0 million of our common shares pursuant to the Sale Agreement under: (i) the January 2020 Registration Statement; (ii) the October 2020 Registration Statement; and (iii) the November 2021 Registration Statement.

During the years ended December 31, 2022 and 2021, we issued 8,645,426 and 31,571,036 common shares, respectively, under the Sale Agreement resulting in net proceeds of approximately \$20.3 million and \$134.7 million, respectively. As of December 31, 2022, we had an aggregate of \$131.1 million remaining available under the October 2021 Prospectus Supplement and the March 2022 Prospectus Supplement.

Royalty Entitlements

Additionally, we have a royalty entitlement on ONPATPRO, a drug developed by Alnylam that incorporates our LNP technology and was approved by the FDA and the EMA during the third quarter of 2018 and was launched by Alnylam immediately upon approval in the United States. In July 2019, we sold a portion of this royalty interest to OMERS, effective as

of January 1, 2019, for \$20 million in gross proceeds before advisory fees. OMERS will retain this entitlement until it has received \$30 million in royalties, at which point 100% of such royalty interest on future global net sales of ONPATTRO will revert to us. OMERS has assumed the risk of collecting up to \$30 million of future royalty payments from Alnylam and Arbutus is not obligated to reimburse OMERS if they fail to collect any such future royalties. From the inception of the royalty sale through December 31, 2022, we have recorded an aggregate of \$18.9 million of non-cash royalty revenue for royalties earned by OMERS. If this royalty entitlement reverts to us, it has the potential to provide an active royalty stream or to be otherwise monetized again in full or in part. In addition to the royalty from the Alnylam LNP license agreement, we are also receiving a second, lower royalty interest on global net sales of ONPATTRO originating from a settlement agreement and subsequent license agreement with Acuitas. The royalty from Acuitas has been retained by us and was not part of the royalty sale to OMERS.

In December 2021, we entered into a technology transfer and exclusive licensing agreement with Qilu pursuant to which we granted Qilu an exclusive (with certain exceptions), sublicensable, royalty-bearing license, under certain intellectual property owned by us, to develop, manufacture and commercialize AB-729 for the treatment or prevention of cHBV in the Territory. In partial consideration for the rights granted by us, Qilu paid us a one-time upfront cash payment of \$40 million and made an equity investment of \$15.0 million, both received in January 2022, and agreed to pay us milestone payments totaling up to \$245 million, net of withholding taxes, upon the achievement of certain technology transfer, development, regulatory and commercialization milestones. Qilu also agreed to pay us double digit royalties into the low twenties percent based upon annual net sales of AB-729 in the Territory.

Cash requirements

We believe that our \$184.3 million of cash, cash equivalents and investments in marketable securities as of December 31, 2022 will be sufficient to fund our operations into the fourth quarter of 2024 based on our expectation of a net cash burn between \$95.0 million and \$100.0 million in 2023. In the future, substantial additional funds will be required to continue with the active development of our pipeline products and technologies. In particular, our funding needs may vary depending on a number of factors including:

- the effects of the COVID-19 pandemic on our business, the medical community and the global economy;
- revenue earned from our legacy collaborative partnerships and licensing agreements, including potential royalty payments from Alnylam's ONPATTRO;
- revenue earned from ongoing collaborative partnerships, including milestone and royalty payments;
- the potential requirement to make milestone payments related to our legacy agreements;
- the extent to which we continue the development of our product candidates, add new product candidates to our pipeline, or form collaborative relationships or licensing arrangements to advance our product candidates;
- delays in the development of our product candidates due to pre-clinical and clinical findings;
- our decisions to in-license or acquire additional products, product candidates or technology for development;
- our ability to attract and retain development or commercialization partners, and their effectiveness in carrying out the development and ultimate commercialization of one or more of our product candidates;
- whether batches of product candidates that we manufacture fail to meet specifications resulting in clinical trial delays and investigational and remanufacturing costs;
- the decisions, and the timing of decisions, made by health regulatory agencies regarding our technology and product candidates;
- competing products, product candidates and technological and market developments; and
- costs associated with prosecuting and enforcing our patent claims and other intellectual property rights, including litigation and arbitration arising in the course of our business activities.

We intend to seek funding to maintain and advance our business from a variety of sources including public or private equity or debt financing, potential monetization transactions, collaborative or licensing arrangements with pharmaceutical companies and government grants and contracts. There can be no assurance that funding will be available at all or on acceptable terms to permit further development of our research and development programs. Further, the COVID-19 pandemic has also led to severe disruption and volatility in the global capital markets, which could increase our cost of capital and adversely affect our ability to access the capital markets in the future.

If adequate funding is not available, we may be required to delay, reduce or eliminate one or more of our research or development programs or reduce expenses associated with our non-core activities. We may need to obtain funds through arrangements with collaborators or others that may require us to relinquish most or all of our rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise seek if we were better funded. Insufficient financing may also mean failing to prosecute our patents or relinquishing rights to some of our technologies that we would otherwise develop or commercialize.

Cash Flows

The following table summarizes our cash flow activities for the periods indicated:

	Year ended December 31,	
	2022	2021
	(in thousands)	
Net loss	\$ (69,456)	\$ (76,247)
Non-cash items	4,857	7,790
Change in deferred license revenue	22,455	—
Net change in operating items	6,788	925
Net cash used in operating activities	\$ (35,356)	\$ (67,532)
Net cash used in investing activities	(74,942)	(12,678)
Issuance of common shares pursuant to Share Purchase Agreement	10,973	—
Issuance of common shares pursuant to exercise of ESPP	395	461
Net cash provided by other financing activities	20,446	136,775
Net cash provided by financing activities	31,814	137,236
Effect of foreign exchange rate changes on cash and cash equivalents	(22)	5
(Decrease) increase in cash and cash equivalents	\$ (78,506)	\$ 57,031
Cash and cash equivalents, beginning of period	109,282	52,251
Cash and cash equivalents, end of period	\$ 30,776	\$ 109,282

Net cash used in operating activities in 2022 decreased \$32.2 million compared to 2021 due primarily to a January 2022 upfront cash payment of \$40.0 million from Qilu in connection with the License Agreement and a \$4.0 million premium paid by Qilu as part of their \$15.0 million equity investment. These cash inflows were offset by \$79.4 million of cash used in operations.

Net cash used in investing activities in 2022 increased by \$62.3 million compared to 2021 due primarily to the timing of acquisitions and maturities of investments in marketable securities.

Net cash provided by financing activities in 2022 decreased \$105.4 million compared to 2021. Cash provided by financing activities in 2022 consisted primarily of \$20.3 million of proceeds from sales of common shares under the Sale Agreement and \$11.0 million for the fair value of shares purchased by Qilu as part of their \$15.0 million equity investment, of which the remaining \$4.0 million was a premium paid by Qilu on the equity investment and was allocated to deferred revenue. Cash

provided by financing activities in 2021 consisted primarily of \$134.7 million of proceeds from sales of common shares under the Sale Agreement.

RECENT ACCOUNTING PRONOUNCEMENTS

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board or other standard setting bodies that we adopt as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

Please refer to note 2 to our consolidated financial statements included in Part II, Item 8, “Financial Statements and Supplementary Data,” of this Annual Report on Form 10-K for a description of recent accounting pronouncements applicable to our business.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

Item 8. Financial Statements and Supplementary Data

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Arbutus Biopharma Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Arbutus Biopharma Corporation (the Company) as of December 31, 2022 and 2021, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters do not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Valuation of contingent consideration liability

Description of the Matter

As discussed in Note 10 to the consolidated financial statements, the Company's contingent consideration liability, which consists of sales-based milestones and royalties, resulting from the acquisition of Enantigen in 2014, is remeasured to its estimated fair value each reporting period. As of December 31, 2022, the contingent consideration liability was \$7.5 million.

Auditing the valuation of the contingent consideration liability was complex and highly judgmental due to the significant estimation required in determining the fair value. In particular, the fair value estimate was sensitive to significant assumptions such as the probability of successfully commercializing a treatment for the hepatitis B virus, the timing and amount of future revenues related to commercial sales, and the discount rate. These assumptions are affected by expectations about future industry, regulatory, market or economic conditions and are forward-looking and inherently uncertain.

How We Addressed the Matter in Our Audit

To test the estimated fair value of the contingent consideration liability, we performed audit procedures that included, among others, assessing the terms of the arrangement, evaluating the methodology used, and testing the significant assumptions discussed above used by the Company in its analysis. We also compared the significant assumptions to current industry, market and economic trends to corroborate the Company's estimates and performed sensitivity analyses of significant assumptions to evaluate the changes in the contingent consideration liability that would result from changes in the significant assumptions. We also involved our valuation specialists to assist us in testing the discount rate.

Collaboration and License Agreement with Qilu

Description of the Matter

As discussed in Note 11 to the consolidated financial statements, in December 2021, the Company entered into a technology transfer and license agreement with Qilu Pharmaceuticals Co., Ltd. (Qilu). Under the agreement, the Company granted Qilu an exclusive right to develop and commercialize AB-729 for the treatment and prevention of hepatitis B in the People's Republic of China, Hong Kong, Macau, and Taiwan. The Company agreed to provide clinical supply of the licensed product to Qilu until the Company has completed the manufacturing technology transfer to Qilu. The Company received a \$40.0 million up-front payment, net of withholding taxes, during 2022 in connection with this arrangement and is also eligible to receive additional development and regulatory milestone payments, sales-based milestones and royalties as well as additional payments for clinical supply under the arrangement. The Company identified two commitments under the arrangement: (i) rights to develop, use, sell, have sold, offer for sale and import any product comprised of Licensed Product (the "Qilu License") and (ii) drug supply obligations and manufacturing technology transfer (the "Manufacturing Obligations"). The Company determined that these two commitments are not distinct performance obligations for purposes of recognizing revenue as the manufacturing process is highly specialized and Qilu would not be able to benefit from the Qilu License without the Company's involvement in the manufacturing activities until the transfer of the manufacturing know-how is complete. As such, the Company combined these commitments into one performance obligation to which the transaction price is allocated and recognized over time using an inputs method based on labor hours expended by the Company on its Manufacturing Obligations.

Auditing the Company's revenue recognition for the Qilu collaboration and license agreement was challenging, as significant judgment was required to apply the authoritative accounting guidance to the arrangement. The Company exercised significant judgment in determining the revenue recognition for this arrangement, including as it relates to the identification of performance obligations, as well as estimating the total number of labor hours that will be expended to complete the Manufacturing Obligations.

How We Addressed the Matter in Our Audit

Our audit procedures to test the Company's determination of revenue recognition for the Qilu collaboration and license agreement included, among others, reading the contractual agreement, testing management's identification of significant terms for completeness, including identification of performance obligations, and evaluating the appropriateness of management's application of authoritative guidance and existing accounting policies. We also discussed the judgments inherent in the Company's determination of revenue recognition, including the identification of the performance obligations and estimating the total number of expected hours required to complete the Manufacturing Obligations, with research and development personnel responsible for overseeing the satisfaction of the Company's Manufacturing Obligations. We also tested a sample of actual hours expended during 2022 on the Manufacturing Obligations and performed a lookback analysis, comparing the total actual hours expended throughout the year to the total number of future expected hours as of December 31, 2022, based on the progress to date and the nature of the future activities to be performed.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2019.

Philadelphia, Pennsylvania

March 2, 2023

ARBUTUS BIOPHARMA CORPORATION

Consolidated Balance Sheets

(Expressed in thousands of US Dollars, except share and per share amounts)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 30,776	\$ 109,282
Investments in marketable securities, current	116,137	46,035
Accounts receivable	1,352	899
Prepaid expenses and other current assets	2,874	4,445
Total current assets	151,139	160,661
Property and equipment, net of accumulated depreciation	5,070	5,983
Investments in marketable securities, non-current	37,363	35,688
Right of use asset	1,744	2,092
Other non-current assets	103	61
Total assets	\$ 195,419	\$ 204,485
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 16,029	\$ 10,838
Deferred license revenue, current	16,456	—
Lease liability, current	372	383
Total current liabilities	32,857	11,221
Liability related to sale of future royalties	10,365	16,296
Deferred license revenue, non-current	5,999	—
Contingent consideration	7,531	5,298
Lease liability, non-current	1,815	2,231
Total liabilities	58,567	35,046
Stockholders' equity		
Common shares		
Authorized: unlimited number without par value		
Issued and outstanding: 157,455,363 (December 31, 2021: 144,987,736)	1,318,737	1,286,636
Additional paid-in capital	72,406	65,485
Deficit	(1,203,803)	(1,134,347)
Accumulated other comprehensive loss	(50,488)	(48,335)
Total stockholders' equity	136,852	169,439
Total liabilities and stockholders' equity	\$ 195,419	\$ 204,485

See accompanying notes to the consolidated financial statements.

ARBUTUS BIOPHARMA CORPORATION

Consolidated Statements of Operations and Comprehensive Loss

(Expressed in thousands of US Dollars, except share and per share amounts)

	Year ended December 31,	
	2022	2021
Revenue		
Collaborations and licenses	\$ 31,366	\$ 4,880
Non-cash royalty revenue	7,653	6,108
Total revenue	<u>39,019</u>	<u>10,988</u>
Operating expenses		
Research and development	84,408	65,502
General and administrative	17,834	17,136
Change in fair value of contingent consideration	2,233	1,872
Total operating expenses	<u>104,475</u>	<u>84,510</u>
Loss from operations	(65,456)	(73,522)
Other income (loss)		
Interest income	2,192	127
Interest expense	(1,726)	(2,857)
Foreign exchange (loss) gain	(22)	5
Total other income (loss)	<u>444</u>	<u>(2,725)</u>
Loss before income taxes	(65,012)	(76,247)
Income tax expense	(4,444)	—
Net loss	<u>\$ (69,456)</u>	<u>\$ (76,247)</u>
Items applicable to preferred shares		
Dividend accretion of convertible preferred shares	—	(12,139)
Net loss attributable to common shares	<u>\$ (69,456)</u>	<u>\$ (88,386)</u>
Loss per share		
Basic and diluted	\$ (0.46)	\$ (0.83)
Weighted average number of common shares		
Basic and diluted	150,939,337	106,242,452
Comprehensive loss		
Unrealized loss on available-for-sale securities	\$ (2,153)	\$ (164)
Comprehensive loss	<u>\$ (71,609)</u>	<u>\$ (76,411)</u>

See accompanying notes to the consolidated financial statements.

ARBUTUS BIOPHARMA CORPORATION

Consolidated Statement of Stockholders' Equity

(Expressed in thousands of US Dollars, except share and per share amounts)

	Convertible Preferred Shares		Common Shares		Additional paid-in capital	Deficit	Accumulated other comprehensive loss	Total stockholders' equity
	Number of shares	Share capital	Number of shares	Share capital				
Balance at December 31, 2020	1,164,000	\$ 149,408	89,678,722	\$ 985,939	\$ 60,751	\$ (1,045,961)	\$ (48,171)	\$ 101,966
Accretion of accumulated dividends on Preferred Shares	—	12,139	—	—	—	(12,139)	—	—
Conversion of Preferred Shares into Common Shares	(1,164,000)	(161,547)	22,833,922	161,547	—	—	—	—
Stock-based compensation	—	—	—	—	6,385	—	—	6,385
Certain fair value adjustments to liability stock option awards	—	—	—	—	263	—	—	263
Issuance of common shares pursuant to the Open Market Sales Agreement	—	—	31,571,036	134,665	—	—	—	134,665
Issuance of common shares pursuant to exercise of ESPP	—	—	196,335	817	(356)	—	—	461
Issuance of common shares pursuant to exercise of stock options	—	—	707,721	3,668	(1,558)	—	—	2,110
Unrealized loss on available-for-sale securities	—	—	—	—	—	—	(164)	(164)
Net loss	—	—	—	—	—	(76,247)	—	(76,247)
Balance at December 31, 2021	<u>—</u>	<u>\$ —</u>	<u>144,987,736</u>	<u>\$ 1,286,636</u>	<u>\$ 65,485</u>	<u>\$ (1,134,347)</u>	<u>\$ (48,335)</u>	<u>\$ 169,439</u>
Stock-based compensation	—	—	—	—	7,182	—	—	7,182
Certain fair value adjustments to liability stock option awards	—	—	—	—	26	—	—	26
Issuance of common shares pursuant to the Open Market Sales Agreement	—	—	8,645,426	20,324	—	—	—	20,324
Issuance of common shares pursuant to exercise of ESPP	—	—	171,224	588	(193)	—	—	395
Issuance of common shares pursuant to Share Purchase Agreement	—	—	3,579,952	10,973	—	—	—	10,973
Issuance of common shares pursuant to exercise of stock options	—	—	71,025	216	(94)	—	—	122
Unrealized loss on available-for-sale securities	—	—	—	—	—	—	(2,153)	(2,153)
Net loss	—	—	—	—	—	(69,456)	—	(69,456)
Balance at December 31, 2022	<u>—</u>	<u>\$ —</u>	<u>157,455,363</u>	<u>\$ 1,318,737</u>	<u>\$ 72,406</u>	<u>\$ (1,203,803)</u>	<u>\$ (50,488)</u>	<u>\$ 136,852</u>

See accompanying notes to the consolidated financial statements.

ARBUTUS BIOPHARMA CORPORATION

Consolidated Statements of Cash Flows

(Expressed in thousands of US Dollars, except share and per share amounts)

	Year ended December 31,	
	2022	2021
OPERATING ACTIVITIES		
Net loss	\$ (69,456)	\$ (76,247)
Non-cash items:		
Depreciation	1,427	1,753
Stock-based compensation expense	7,182	6,424
Change in fair value of contingent consideration	2,233	1,872
Non-cash royalty revenue	(7,653)	(6,108)
Non-cash interest expense	1,722	2,850
Net accretion and amortization of investments in marketable securities	(54)	999
Net change in operating items:		
Accounts receivable	(453)	413
Prepaid expenses and other assets	2,430	(1,025)
Accounts payable and accrued liabilities	5,216	1,911
Deferred license revenue	22,455	—
Other liabilities	(405)	(374)
Net cash used in operating activities	(35,356)	(67,532)
INVESTING ACTIVITIES		
Purchase of investments in marketable securities	(130,430)	(82,219)
Disposition of investments in marketable securities	56,000	70,350
Acquisition of property and equipment	(512)	(809)
Net cash used in investing activities	(74,942)	(12,678)
FINANCING ACTIVITIES		
Issuance of common shares pursuant to Share Purchase Agreement	10,973	—
Issuance of common shares pursuant to the ATM	20,324	134,665
Issuance of common shares pursuant to exercise of stock options	122	2,110
Issuance of common shares pursuant to exercise of ESPP	395	461
Net cash provided by financing activities	31,814	137,236
Effect of foreign exchange rate changes on cash and cash equivalents	(22)	5
(Decrease) increase in cash and cash equivalents	\$ (78,506)	\$ 57,031
Cash and cash equivalents, beginning of period	\$ 109,282	\$ 52,251
Cash and cash equivalents, end of period	\$ 30,776	\$ 109,282
Supplemental cash flow information		
Preferred shares dividends accrued	\$ —	\$ (12,139)

See accompanying notes to the consolidated financial statements.

ARBUTUS BIOPHARMA CORPORATION

Notes to Consolidated Financial Statements

(Tabular amounts in thousands of US Dollars, except share and per share amounts)

1. Organization

Description of the Business

Arbutus Biopharma Corporation (“Arbutus” or the “Company”) is a clinical-stage biopharmaceutical company leveraging its extensive virology expertise to develop novel therapeutics that target specific viral diseases. The Company’s current focus areas include Hepatitis B virus (“HBV”), SARS-CoV-2 and other coronaviruses. To address HBV, the Company is developing an RNA interference (“RNAi”) therapeutic, 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 infection (“cHBV”) by suppressing viral replication, reducing surface antigen and reawakening the immune system. The Company believes its lead compound, AB-729, is the only RNAi therapeutic with evidence of immune re-awakening. AB-729 is currently being evaluated in multiple phase 2 clinical trials. The Company also has an ongoing drug discovery and development program directed to identifying novel, orally active agents for treating coronaviruses, including SARS-CoV-2, where the Company has nominated a compound and has begun IND-enabling pre-clinical studies. In addition, the Company is also exploring oncology applications for its internal PD-L1 portfolio.

Liquidity

At December 31, 2022, the Company had an aggregate of \$184.3 million in cash, cash equivalents and investments in marketable securities. The Company had no outstanding debt as of December 31, 2022. The Company believes it has sufficient cash resources to fund its operations for at least the next 12 months.

The success of the Company is dependent on obtaining the necessary regulatory approvals to bring its products to market and achieve profitable operations. The Company’s research and development activities and the commercialization of its products are dependent on its ability to successfully complete these activities and to obtain adequate financing through a combination of financing activities and operations. It is not possible to predict either the outcome of the Company’s existing or future research and development programs or the Company’s ability to continue to fund these programs in the future.

COVID-19 Impact

The Company continues to monitor the effects of COVID-19, which has caused significant disruptions around the world. 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 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.

2. Significant accounting policies

Basis of presentation and principles of consolidation

These consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) and include the accounts of Arbutus Biopharma Corporation and its one wholly-owned subsidiary, Arbutus Biopharma, Inc. All intercompany balances and transactions have been eliminated. Certain prior year amounts have been reclassified to conform to the current year presentation. In February 2021, Arbutus Biopharma US Holdings, Inc., which was another wholly-owned subsidiary, merged into Arbutus Biopharma, Inc. with Arbutus Biopharma, Inc. continuing its legal existence and Arbutus Biopharma US Holdings, Inc. ceasing to exist.

Use of estimates

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions about future events that affect the reported amounts of assets, liabilities, revenue, expenses and contingent liabilities as of the end or during the reporting period. Actual results could significantly differ from those estimates. Significant estimates in the accompanying consolidated financial statements impact contingent consideration, income tax recoveries, stock-based compensation, clinical trial accruals and the sale of future royalties liability.

Cash and cash equivalents

Cash and cash equivalents are all highly liquid instruments with an original maturity of three months or less when purchased. Cash equivalents are recorded at cost plus accrued interest. The carrying value of these cash equivalents approximates their fair value.

Investments in marketable securities

The Company's short-term investments consist of marketable securities that have original maturities exceeding three months and remaining maturities of less than one year. The Company classifies investments with remaining maturities of one year or longer as non-current. These investments are accounted for as available-for-sale securities and are reported at fair value, with unrealized gains and losses reported in other comprehensive loss until their disposition. Realized gains and losses from the sale of marketable securities, if any, are calculated using the specific-identification method, and are recorded as a component of other income or loss. The Company reviews its available-for-sale securities at each period end to determine if they remain available-for-sale based on the Company's current intent and ability to sell the security if it is required to do so. Declines in value judged to be other-than-temporary are included in interest expense in the Company's statements of operations and comprehensive loss. As of December 31, 2022, the recorded value of the Company's investments in marketable securities was deemed to be recoverable in all respects.

All investments are governed by the Company's Investment Policy approved by the Company's board of directors.

Foreign currency translation and functional currency conversion

The Company's functional currency is the United States dollar. Monetary assets and liabilities denominated in foreign currencies are translated into United States dollars using exchange rates in effect at the balance sheet date. Opening balances related to non-monetary assets and liabilities are based on prior period translated amounts, and non-monetary assets and non-monetary liabilities are translated at the approximate exchange rate prevailing at the date of the transaction. Revenue and expense transactions are translated at the approximate exchange rate in effect at the time of the transaction. Foreign exchange gains and losses are included in the statement of operations and comprehensive loss as foreign exchange gains or losses.

Investment in Genevant

Arbutus accounts for its interest in Genevant as equity securities without readily determinable fair values. Accordingly, an estimate of the fair value of the securities is based on the original cost less previously recognized equity method losses, less impairments, plus or minus changes resulting from observable price changes in orderly transactions for identical or similar Genevant securities. As of December 31, 2022, Arbutus owned approximately 16% of the common equity of Genevant and the carrying value of Arbutus' investment in Genevant was zero.

See note 5 for more information.

Property and equipment

Property and equipment is recorded at cost less impairment losses and accumulated depreciation. The Company records depreciation using the straight-line method over the estimated useful lives of the capital assets as follows:

	<u>Useful Life (Years)</u>
Laboratory equipment	5
Computer and office equipment	2 to 5
Furniture and fixtures	5

Leasehold improvements are depreciated over their estimated useful lives but in no case longer than the lease term, except where lease renewal is reasonably assured.

Property and equipment is reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. If such a review should indicate that the carrying amount of long-lived assets is not recoverable, then such assets are written down to their fair values.

Revenue from collaborations and licenses

The Company generates revenue primarily through collaboration agreements and license agreements. Such agreements may require the Company to deliver various rights and/or services, including intellectual property rights or licenses and research, development and manufacturing services. Under such agreements, the Company is generally eligible to receive non-refundable upfront payments, funding for research, development and manufacturing services, milestone payments, and royalties.

The Company's collaboration agreements fall under the scope of ASC Topic 808, *Collaborative Arrangements*, ("ASC 808") when both parties are active participants in the arrangement and are exposed to significant risks and rewards. For certain arrangements under the scope of ASC 808, the Company analogizes to ASC 606 for some aspects, including for the delivery of a good or service (i.e., a unit of account).

ASC 606, *Revenue From Contracts with Customers* ("ASC 606") requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers under a five-step model: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as a performance obligation is satisfied.

In contracts where the Company has more than one performance obligation to provide its customer with goods or services, each performance obligation is evaluated to determine whether it is distinct based on whether: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available; and (ii) the good or service is separately identifiable from other promises in the contract. The consideration under the contract is then allocated between the distinct performance obligations based on their respective relative stand-alone selling prices. The estimated stand-alone selling price of each deliverable reflects the Company's best estimate of what the selling price would be if the deliverable was regularly sold on a stand-alone basis and is determined by reference to market rates for the good or service when sold to others or by using an adjusted market assessment approach if the selling price on a stand-alone basis is not available.

The consideration allocated to each distinct performance obligation is recognized as revenue when control is transferred to the customer for the related goods or services. Consideration associated with at-risk substantive performance milestones, including sales-based milestones, is recognized as revenue when it is probable that a significant reversal of the cumulative revenue recognized will not occur. Sales-based royalties received in connection with licenses of intellectual property are subject to a specific exception in the revenue standards, whereby the consideration is not included in the transaction price and recognized in revenue until the customer's subsequent sales or usages occur.

Leases

The Company accounts for its lease under ASC 842, *Leases*, which generally requires the recognition of operating and financing lease liabilities with corresponding right-of-use assets on the balance sheet. See note 6 for more information.

Research and development costs

Research and development costs include compensation and benefits for research and development employees, an allocation of overhead expenses and costs associated with materials and supplies used in clinical trials and research and development, outside contracted services including clinical and pre-clinical study costs, legal, regulatory compliance and fees paid to consultants or outside parties for research and development activities performed on the Company's behalf. Such costs are charged to expense in the period in which they are incurred.

Research and development costs that are paid in advance of performance or receipt are recorded as prepaid expense and are amortized over the period that the services are performed.

Net loss attributable to common shareholders per share

Net loss attributable to common shareholders per share is calculated based on the weighted average number of common shares outstanding. Diluted net loss attributable to common shareholders per share does not differ from basic net loss attributable to common shareholders per share for the years ended December 31, 2022 and 2021, since the effect of including potential common shares would be anti-dilutive. For the year ended December 31, 2022, potential common shares of 15.5 million pertaining to outstanding stock options were excluded from the calculation of net loss attributable to common shareholders per share. A total of approximately 11.4 million outstanding stock options were excluded from the calculation for the year ended December 31, 2021.

On October 18, 2021, the Company's outstanding Series A participating convertible preferred shares ("Preferred Shares") were converted into 22,833,922 common shares. Prior to that date, the Company followed the two-class method when computing net loss attributable to common shareholders per share as the Preferred Shares, as further described in note 12, met the definition of participating securities. The Company's Preferred Shares entitled the holders to participate in dividends but did not require the holders to participate in losses of the Company. Accordingly, net losses attributable to holders of the Company's common shares were not allocated to holders of the Preferred Shares.

See note 12 and note 13 for more information about the Company's common shares.

Deferred income taxes

Income taxes are accounted for using the asset and liability method of accounting. Deferred income taxes are recognized for the future income tax consequences attributable to differences between the carrying values of assets and liabilities and their respective income tax bases and for loss carry-forwards. Deferred income tax assets and liabilities are measured using enacted income tax rates expected to apply to taxable income in the periods in which temporary differences are expected to be recovered or settled. The effect on deferred income tax assets and liabilities of a change in tax laws or rates is included in earnings in the period that includes the enactment date. When realization of deferred income tax assets does not meet the more-likely-than-not criterion for recognition, a valuation allowance is provided.

Stock-based compensation

The Company measures and recognizes compensation expense for all share-based compensation arrangements based on estimated fair values. The Company uses the Black-Scholes option valuation model to estimate the fair value of stock options at the date of grant. The Black-Scholes option valuation model requires the input of subjective assumptions to calculate the value of stock options. For those assumptions, the Company uses historical data and other information to estimate the expected price volatility and risk free interest rate for all awards. The expected life of stock options granted are estimated to be five years for employees and six years for directors and executives, based on the Company's historical experience. Assumptions on the dividend yield are based on the fact that the Company has never paid cash dividends and has no present intention to pay cash dividends. Expense is recognized over the vesting period for all awards and commences at the grant date for time-based awards and upon the Company's determination that the achievement of such performance conditions is probable for performance-based awards. Forfeitures are recognized as they occur.

For the Company's Employee Stock Purchase Plan, the fair value of the right to acquire stock at a discounted price under the plan is calculated using the Black-Scholes valuation model. Expense is recognized over the period the employee contributes to the plan through payroll deductions.

The Company accounts for liability-classified stock option awards ("liability options") under ASC 718 - *Compensation - Stock Compensation* ("ASC 718"), under which awards of options that provide for an exercise price that is not denominated in: (a) the currency of a market in which a substantial portion of the Company's equity securities trades, (b) the currency in which the employee's pay is denominated, or (c) the Company's functional currency, are required to be classified as liabilities. As of January 1, 2016, the Company changed its functional currency to US dollars, which resulted in certain stock option awards with exercise prices denominated in Canadian dollars having an exercise price that is not denominated in the Company's functional currency. As such, the historic equity classification of these stock option awards changed to liability classification effective January 1, 2016. The change in classification resulted in reclassification of these awards from additional paid-in capital to a liability.

Liability options are re-measured to their fair values at each reporting date with changes in the fair value recognized in share-based compensation expense or additional paid-in capital until settlement or cancellation. Under ASC 718, when an award is reclassified from equity to liability, if at the reclassification date the original vesting conditions are expected to be satisfied, then the minimum amount of compensation cost to be recognized is based on the grant date fair value of the original award. Fair value changes below this minimum amount are recorded in additional paid-in capital.

Preferred Shares

The Company accounted for its Preferred Shares under ASC 480 - *Distinguishing Liabilities from Equity* ("ASC 480"), which provides guidance for equity instruments with conversion features. The Company classified the Preferred Shares in its consolidated balance sheet wholly as equity, with no bifurcation of conversion feature from the host contract, given that the Preferred Shares could not be cash-settled and the redemption features, which included a fixed conversion ratio with predetermined timing and proceeds, were within the Company's control. The Company accrued for the 8.75% per annum compounding accrual at each reporting period-end date as an increase to share capital, and an increase to deficit. The Company's Preferred Shares were converted into 22,833,922 common shares on October 18, 2021.

Segment information

As of December 31, 2022, the Company viewed its operations and managed its business as one operating segment consistent with how its chief operating decision-maker, the Chief Executive Officer, makes decisions regarding resource allocation and assessing performance. Substantially all of the Company's premises, property and equipment are located in the United States.

Comprehensive loss

Comprehensive loss is comprised of net loss and adjustments for the change in unrealized gains and losses on investments in available-for-sale marketable securities. The Company includes comprehensive loss and its components in the consolidated statements of operations and comprehensive loss, net of tax effects if any.

Concentrations of Credit Risk

Financial instruments which potentially subject the Company to credit risk consist primarily of cash, cash equivalents and marketable securities. The Company holds these investments in highly rated financial institutions, and, by policy, limits the amounts of credit exposure to any one financial institution. These amounts at times may exceed federally insured limits. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant credit risk on these funds. The Company has no off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

Recent accounting pronouncements

In June 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-13, Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments (ASC 326). The guidance is effective for the Company beginning January 1, 2023 and it changes how entities account for credit losses on financial assets and other instruments that are not measured at fair value through net income, including available-for-sale debt securities. The Company does not anticipate that the new guidance will have a material impact on its results of operations or financial position.

3. Fair value measurements

The Company measures certain financial instruments and other items at fair value.

To determine the fair value, the Company uses the fair value hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs market participants would use to value an asset or liability and are developed based on market data obtained from independent sources. Unobservable inputs are inputs based on assumptions about the factors market participants would use to value an asset or liability. The three levels of inputs that may be used to measure fair value are as follows:

- Level 1 inputs are quoted market prices for identical instruments available in active markets. The Company’s cash and cash equivalents are measured using Level 1 inputs.
- Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability either directly or indirectly. If the asset or liability has a contractual term, the input must be observable for substantially the full term. An example includes quoted market prices for similar assets or liabilities in active markets. The Company’s investments in marketable securities are measured using Level 2 inputs.
- Level 3 inputs are unobservable inputs for the asset or liability and will reflect management’s assumptions about market assumptions that would be used to price the asset or liability. The Company’s liability-classified options and contingent consideration are measured using Level 3 inputs.

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. Changes in the observability of valuation inputs may result in a reclassification of levels for certain securities within the fair value hierarchy.

The carrying values of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate their fair values due to the immediate or short-term maturity of these financial instruments.

To determine the fair value of the contingent consideration (note 10), the Company uses a probability weighted assessment of the likelihood the milestones would be met and the estimated timing of such payments, and then the potential contingent payments were discounted to their present value using a probability adjusted discount rate that reflects the early stage nature of the development program, time to complete the program development, and overall biotech indices. The Company determined that the fair value of the contingent consideration was \$7.5 million as of December 31, 2022 and the increase of \$2.2 million has been recorded within operating expenses in the statement of operations and comprehensive loss for the year ended December 31, 2022. The assumptions used in the discounted cash flow model are level 3 inputs as defined above. The

Company assessed the sensitivity of the fair value measurement to changes in these unobservable inputs, and determined that changes within a reasonable range would not result in a materially different assessment of fair value.

The following tables present information about the Company's assets and liabilities that are measured at fair value on a recurring basis, and indicates the fair value hierarchy of the valuation techniques used to determine such fair value:

As of December 31, 2022	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets				
Cash and cash equivalents	\$ 30,776	\$ —	\$ —	\$ 30,776
Investments in marketable securities, current	—	116,137	—	116,137
Investments in marketable securities, non-current	—	37,363	—	37,363
Total	\$ 30,776	\$ 153,500	\$ —	\$ 184,276
Liabilities				
Liability-classified options	\$ —	\$ —	\$ 1	\$ 1
Contingent consideration	—	—	7,531	7,531
Total	\$ —	\$ —	\$ 7,532	\$ 7,532

As of December 31, 2021	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets				
Cash and cash equivalents	\$ 109,282	\$ —	\$ —	\$ 109,282
Investments in marketable securities, current	—	46,035	—	46,035
Investments in marketable securities, non-current	—	35,688	—	35,688
Total	\$ 109,282	\$ 81,723	\$ —	\$ 191,005
Liabilities				
Liability-classified options	\$ —	\$ —	\$ 26	\$ 26
Contingent consideration	—	—	5,298	5,298
Total	\$ —	\$ —	\$ 5,324	\$ 5,324

The following table presents the changes in fair value of the Company's liability-classified stock option awards:

	Liability at beginning of the period	Fair value of liability-classified options exercised in the period	Decrease in fair value of liability	Liability at end of the period
	(in thousands)			
Year ended December 31, 2022	\$ 26	\$ —	\$ (25)	\$ 1
Year ended December 31, 2021	\$ 250	\$ (96)	\$ (128)	\$ 26

The following table presents the changes in fair value of the Company's contingent consideration:

	Liability at beginning of the period	Increase in fair value of liability	Liability at end of the period
	(in thousands)		
Year ended December 31, 2022	\$ 5,298	\$ 2,233	\$ 7,531
Year ended December 31, 2021	\$ 3,426	\$ 1,872	\$ 5,298

4. Investments in marketable securities

Investments in marketable securities and cash equivalents consisted of the following:

<u>As of December 31, 2022</u>	<u>Amortized Cost</u>	<u>Gross Unrealized Gain⁽¹⁾</u>	<u>Gross Unrealized Loss⁽¹⁾</u>	<u>Fair Value</u>
	(in thousands)			
Cash equivalents				
Money market fund	\$ 23,218	\$ —	\$ —	\$ 23,218
Total	\$ 23,218	\$ —	\$ —	\$ 23,218
Investments in marketable short-term securities				
US government agency bonds	\$ 26,686	\$ —	\$ (424)	\$ 26,262
US corporate bonds	27,144	—	(303)	26,841
US treasury bills	8,483	—	(16)	8,467
US government bonds	55,361	—	(794)	54,567
Total	\$ 117,674	\$ —	\$ (1,537)	\$ 116,137
Investments in marketable long-term securities				
US government agency bonds	\$ 3,724	\$ —	\$ (130)	\$ 3,594
US corporate bonds	25,433	—	(336)	25,097
US government bonds	8,972	—	(300)	8,672
Total	\$ 38,129	\$ —	\$ (766)	\$ 37,363

⁽¹⁾ Gross unrealized gain (loss) is pre-tax and is reported in accumulated other comprehensive loss.

<u>As of December 31, 2021</u>	<u>Amortized Cost</u>	<u>Gross Unrealized Gain⁽¹⁾</u>	<u>Gross Unrealized Loss⁽¹⁾</u>	<u>Fair Value</u>
	(in thousands)			
Cash equivalents				
Money market fund	\$ 93,211	\$ —	\$ —	\$ 93,211
Total	\$ 93,211	\$ —	\$ —	\$ 93,211
Investments in marketable short-term securities				
US government agency bonds	\$ 8,131	\$ —	\$ (11)	\$ 8,120
US government bonds	37,968	—	(53)	37,915
Total	\$ 46,099	\$ —	\$ (64)	\$ 46,035
Investments in marketable long-term securities				
US government agency bonds	\$ 13,068	\$ —	\$ (29)	\$ 13,039
US treasury bills	22,707	—	(58)	22,649
Total	\$ 35,775	\$ —	\$ (87)	\$ 35,688

⁽¹⁾ Gross unrealized gain (loss) is pre-tax and is reported in accumulated other comprehensive loss.

The contractual maturity of the \$116.1 million of short-term marketable securities held by the Company as of December 31, 2022 is less than one year. As of December 31, 2022, the Company held \$37.4 million of long-term marketable securities with contractual maturities of more than one year, but less than five years. As of December 31, 2021, the Company's \$46.0 million of short-term marketable securities had contractual maturities of less than one year, while the Company's \$35.7 million of long-term marketable securities had maturities of more than one year, but less than five years.

The Company had realized gains on investments of less than \$0.1 million and zero for the years ended December 31, 2022 and 2021, respectively.

5. Investment in Genevant

In April 2018, the Company 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 the Company’s LNP and ligand conjugate delivery technologies. The Company 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 (the “Genevant License”). The Company retained all rights to its LNP and conjugate delivery platforms for HBV.

Under the Genevant License, as amended, if a third party sublicensee of intellectual property licensed by Genevant from the Company commercializes a sublicensed product, the Company becomes entitled to receive a specified percentage of certain revenue that may be received by Genevant for such sublicense, including royalties, commercial milestones and other sales-related revenue, or, if less, tiered low single-digit royalties on net sales of the sublicensed product. The specified percentage is 20% in the case of a mere sublicense (i.e., naked sublicense) by Genevant without additional contribution and 14% in the case of a bona fide collaboration with Genevant.

Additionally, if Genevant receives proceeds from an action for infringement by any third parties of the Company’s intellectual property licensed to Genevant, the Company 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).

The Company accounts for its interest in Genevant as equity securities without readily determinable fair values. Accordingly, an estimate of the fair value of the securities is based on the original cost less previously recognized equity method losses, less impairments, plus or minus changes resulting from observable price changes in orderly transactions for identical or a similar Genevant securities. As of December 31, 2022, the carrying value of the Company’s investment in Genevant was zero and the Company owned approximately 16% of the common equity of Genevant.

6. Leases

The Company had one operating lease for its office and laboratory space as of December 31, 2022. The Company’s corporate headquarters is located at 701 Veterans Circle, Warminster, Pennsylvania. The lease expires on April 30, 2027, and the Company has the option of extending the lease for two further five-year terms. The Company also previously leased office space located at 626 Jacksonville Road, Warminster, Pennsylvania under a lease that terminated on August 31, 2022.

The Company accounts for its leases under ASC 842, *Leases*. Leases with an initial term of 12 months or less are not recorded on the balance sheet. The Company determines if an arrangement is a lease at inception. Right-of-use assets represent the Company’s right to use an underlying asset for the lease term and lease liabilities represent the Company’s obligation to make lease payments arising from the lease. Operating lease right-of-use assets and lease liabilities are recognized based on the present value of lease payments over the lease term. The leases do not provide an implicit rate so in determining the present value of lease payments, the Company utilized its incremental borrowing rate for the applicable lease, which was 9.0% for the 701 Veterans Circle lease and 7.6% for the 626 Jacksonville Road lease. The Company recognizes lease expense on a straight-line basis over the remaining lease term.

During each of the years ended December 31, 2022 and 2021, the Company incurred total operating lease expenses of \$0.7 million, which included lease expenses associated with fixed lease payments of \$0.6 million, and variable payments associated with common area maintenance and similar expenses of \$0.1 million.

Weighted average remaining lease term and discount rate were as follows:

	As of December 31, 2022
Weighted-average remaining lease term (years)	4.3
Weighted average discount rate	9.0%

The Company did not include options to extend its lease terms as part of its ROU asset and lease liabilities.

Supplemental cash flow information related to the Company's operating leases was as follows:

	2022	(in thousands)		2021
Cash paid for amounts included in the measurement of lease liabilities	\$	641	\$	650

Future minimum lease payments under operating leases that have remaining terms as of December 31, 2022 are as follows:

	As of December 31, 2022	
	(in thousands)	
2023	\$	598
2024		616
2025		635
2026		654
2027		134
Thereafter		—
Total lease payments	\$	2,637
Less: interest		(450)
Present value of lease payments	\$	2,187

7. Property and equipment

The Company's property and equipment balances as of the years ended December 31, 2022 and 2021 are as follows:

	Cost	Accumulated depreciation	Net book value
	(in thousands)		
December 31, 2022			
Lab equipment	\$ 6,890	\$ (5,679)	\$ 1,211
Leasehold improvements	8,590	(4,749)	3,841
Computer hardware and software	391	(373)	18
	<u>\$ 15,871</u>	<u>\$ (10,801)</u>	<u>\$ 5,070</u>
December 31, 2021			
Lab equipment	\$ 6,408	\$ (5,178)	\$ 1,230
Leasehold improvements	8,563	(3,883)	4,680
Computer hardware and software	386	(313)	73
	<u>\$ 15,357</u>	<u>\$ (9,374)</u>	<u>\$ 5,983</u>

Depreciation expense for the years ended December 31, 2022 and 2021 was \$1.4 million and \$1.8 million, respectively.

8. Accounts payable and accrued liabilities

Accounts payable and accrued liabilities are comprised of the following:

	December 31, 2022	December 31, 2021
	(in thousands)	
Trade accounts payable	\$ 3,520	\$ 3,174
Payroll accruals	3,730	4,279
Research and development accruals	8,261	2,371
Professional fee accruals	512	983
Other accrued liabilities	6	31
Total	\$ 16,029	\$ 10,838

9. Sale of future royalties

On July 2, 2019, the Company entered into a Purchase and Sale Agreement (the “Agreement”) with the Ontario Municipal Employees Retirement System (“OMERS”), pursuant to which the Company sold to OMERS part of its royalty interest on future global net sales of ONPATTRO, an RNA interference therapeutic currently being sold by Alnylam.

ONPATTRO utilizes Arbutus’s LNP technology, which was licensed to Alnylam pursuant to the Cross-License Agreement, dated November 12, 2012, by and between the Company and Alnylam (the “LNP License Agreement”). Under the terms of the LNP License Agreement, the Company is entitled to tiered royalty payments on global net sales of ONPATTRO ranging from 1.00% to 2.33% after offsets, with the highest tier applicable to annual net sales above \$500 million. This royalty interest was sold to OMERS, effective as of January 1, 2019, for \$20 million in gross proceeds before advisory fees. OMERS will retain this entitlement until it has received \$30 million in royalties, at which point 100% of such royalty interest on future global net sales of ONPATTRO will revert to the Company. OMERS has assumed the risk of collecting up to \$30 million of future royalty payments from Alnylam and Arbutus is not obligated to reimburse OMERS if they fail to collect any such future royalties. From the inception of the royalty sale through December 31, 2022, an aggregate of \$18.9 million of royalties have been collected by OMERS.

The \$30 million in royalties to be paid to OMERS is accounted for as a liability, with the difference between the liability and the gross proceeds received accounted for as a discount. The discount, as well as \$1.5 million of transaction costs, will be amortized as interest expense based on the projected balance of the liability as of the beginning of each period. Management estimated an effective annual interest rate of approximately 8%. Over the course of the Agreement, the actual interest rate will be affected by the amount and timing of royalty revenue recognized and changes in the timing of forecasted royalty revenue. On a quarterly basis, the Company will reassess the expected timing of the royalty revenue, recalculate the amortization and effective interest rate and adjust the accounting prospectively as needed.

The Company recognizes non-cash royalty revenue related to the sales of ONPATTRO during the term of the Agreement. As royalties are remitted to OMERS from Alnylam, the balance of the recognized liability is effectively repaid over the life of the Agreement. There are a number of factors that could materially affect the amount and timing of royalty payments from Alnylam, none of which are within the Company’s control.

During the year ended December 31, 2022, the Company recognized non-cash royalty revenue of \$7.7 million and \$1.7 million of related non-cash interest expense. During the year ended December 31, 2021, the Company recognized non-cash royalty revenue of \$6.1 million and related non-cash interest expense of \$2.9 million.

The table below shows the activity related to the net liability for the years ended December 31, 2022 and December 31, 2021:

	Twelve Months Ended December 31,	
	2022	2021
	(in thousands)	
Net liability related to sale of future royalties - beginning balance	\$ 16,296	\$ 19,554
Non-cash royalty revenue	(7,653)	(6,108)
Non-cash interest expense	1,722	2,850
Net liability related to sale of future royalties - ending balance	\$ 10,365	\$ 16,296

In addition to the royalty from the LNP License Agreement, the Company is also receiving a second royalty interest ranging from 0.75% to 1.125% on global net sales of ONPATTRO, with 0.75% applying to sales greater than \$500 million, originating from a settlement agreement and subsequent license agreement with Acuitas Therapeutics, Inc. (“Acuitas”). The royalty from Acuitas has been retained by the Company and was not part of the royalty sale to OMERS.

10. Contingencies and commitments

Arbitration with the University of British Columbia

Certain early work on lipid nanoparticle delivery systems and related inventions was undertaken at the University of British Columbia (“UBC”), as well as by the Company that was subsequently assigned to UBC. These inventions are licensed to the Company by UBC under a license agreement, initially entered into in 1998 and as amended in 2001, 2006 and 2007. The Company has granted sublicenses under the UBC license to certain third parties, including Alnylam.

In November 2014, UBC filed a demand for arbitration against the Company which alleged entitlement to unpaid royalties. In August 2019, the arbitrator issued its decision for the second phase of the arbitration, awarding UBC \$5.9 million, which included interest of approximately \$2.6 million. The Company paid the \$5.9 million award to UBC in September 2019 and paid an additional \$0.2 million for costs and attorneys’ fees in March 2021, and this matter is now fully resolved.

On December 18, 2020, UBC delivered to the Company a notice of arbitration alleging that under the cross license between UBC and Arbutus, it was due royalties of \$2.0 million plus interest arising from the Company’s sale to OMERS of part of its royalty interest on future global net sales of ONPATTRO, currently being sold by Alnylam. Oral hearings for this matter were held in April 2022 and, on July 11, 2022, the arbitrator issued his decision fully dismissing UBC’s claim for royalties. As a result, no payments are owed to UBC. In September 2022, the arbitrator awarded the Company \$0.5 million for reimbursement of costs and attorneys’ fees, which the Company received from UBC in October 2022. This matter is now fully resolved.

Stock Purchase Agreement with Enantigen

In October 2014, Arbutus Inc., the Company’s wholly-owned subsidiary, acquired all of the outstanding shares of Enantigen Therapeutics, Inc. (“Enantigen”) pursuant to a stock purchase agreement. The amount paid to Enantigen’s selling shareholders could be up to an additional \$102.5 million in sales performance milestones in connection with the sale of the first commercialized product by Arbutus for the treatment of HBV, regardless of whether such product is based upon assets acquired under this agreement, and a low single-digit royalty on net sales of such first commercialized HBV product, up to a maximum royalty payment of \$1.0 million that, if paid, would be offset against Arbutus’ milestone payment obligations. Certain other development milestones related to the acquisition were tied to programs which are no longer under development by Arbutus, and therefore the contingency related to those development milestones is zero.

The contingent consideration is a financial liability and is measured at its fair value at each reporting period, with any changes in fair value from the previous reporting period recorded in the statement of operations and comprehensive loss (note 3).

The fair value of the contingent consideration was \$7.5 million as of December 31, 2022.

11. Collaborations and royalty entitlements

Collaborations

Qilu Pharmaceuticals Co, Ltd.

In December 2021, the Company entered into a technology transfer and exclusive licensing agreement (the “License Agreement”) with Qilu, pursuant to which the Company granted Qilu an exclusive (except as to certain retained rights), sublicensable, royalty-bearing license, under certain intellectual property owned by the Company, to develop, manufacture and commercialize AB-729, including pharmaceutical products that include AB-729, for the treatment or prevention of hepatitis B in China, Hong Kong, Macau and Taiwan (the “Territory”).

In partial consideration for the rights granted by the Company, Qilu paid the Company a one-time upfront cash payment of \$40.0 million on January 5, 2022 and agreed to pay the Company milestone payments totaling up to \$245 million, net of withholding taxes, upon the achievement of certain technology transfer, development, regulatory and commercialization milestones (the “Milestone Payments”). Qilu paid \$4.4 million of withholding taxes to the Chinese taxing authority on the Company’s behalf, related to the upfront cash payment. In addition, Qilu also agreed to pay the Company double digit royalties into the low twenties percent based upon annual net sales of AB-729 in the Territory. The royalties are payable on a product-by-product and region-by-region basis, subject to certain limitations.

Qilu is responsible for all costs related to developing, obtaining regulatory approval for, and commercializing AB-729 for the treatment or prevention of hepatitis B in the Territory. Qilu is required to use commercially reasonable efforts to develop, seek regulatory approval for, and commercialize at least one AB-729 product candidate in the Territory. A joint development committee has been established between the Company and Qilu to coordinate and review the development, manufacturing and commercialization plans. Both parties also have entered into a supply agreement and related quality agreement pursuant to which the Company will manufacture or have manufactured and supply Qilu with all quantities of AB-729 necessary for Qilu to develop and commercialize in the Territory until the Company has completed manufacturing technology transfer to Qilu and Qilu has received all approvals required for it or its designated contract manufacturing organization to manufacture AB-729 in the Territory.

Concurrent with the execution of the license agreement, the Company entered into a Share Purchase Agreement (the “Share Purchase Agreement”) with Anchor Life Limited, a company established pursuant to the applicable laws and regulations of Hong Kong and an affiliate of Qilu (the “Investor”), pursuant to which the Investor purchased 3,579,952 of the Company’s common shares, without par value (the “Common Shares”), at a purchase price of USD \$4.19 per share, which was a 15% premium on the thirty-day average closing price of the Common Shares as of the close of trading on December 10, 2021 (the “Share Transaction”). The Company received \$15.0 million of gross proceeds from the Share Transaction on January 6, 2022. The Common Shares sold to the Investor in the Share Transaction represented approximately 2.5% of the Common Shares outstanding immediately prior to the execution of the Share Purchase Agreement.

The License Agreement falls under the scope of ASC 808 as both parties are active participants in the arrangement and are exposed to significant risks and rewards. While this arrangement is in the scope of ASC 808, the Company analogizes to ASC 606 for some aspects of this arrangement, including for the delivery of a good or service (i.e., a unit of account). In accordance with the guidance, the Company identified the following commitments under the arrangement: (i) rights to develop, use, sell, have sold, offer for sale and import any product comprised of Licensed Product (the “Qilu License”); and (ii) drug supply obligations and manufacturing technology transfer (the “Manufacturing Obligations”). The Company determined that these two commitments are not distinct performance obligations for purposes of recognizing revenue as the manufacturing process is highly specialized and Qilu would not be able to benefit from the Qilu License without the Company’s involvement in the manufacturing activities until the transfer of the manufacturing know-how is complete. As such, the Company will combine these commitments into one performance obligation to which the transaction price will be allocated to and will recognize this transaction price associated with the bundled performance obligation over time using an inputs method based on labor hours expended by the Company on its Manufacturing Obligations.

The Company determined the initial transaction price of the combined performance obligation to be \$49.3 million, which includes the \$40.0 million upfront fee, \$4.4 million of withholding taxes paid by Qilu on behalf of the Company, the premium

paid for the Share Transaction of \$4.1 million, and \$0.8 million associated with certain manufacturing costs expected to be reimbursed by Qilu. The Company determined the Milestone Payments to be variable consideration subject to constraint at inception. At the end of each subsequent reporting period, the Company will reevaluate the probability of achievement of the future development, regulatory, and sales milestones subject to constraint and, if necessary, will adjust its estimate of the overall transaction price. Any such adjustments will be recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

The following table outlines the transaction price and the changes to the related asset and liability balances during the twelve months ended December 31, 2022:

	Twelve Months Ended December 31, 2022		
	Transaction Price	Cumulative Collaboration Revenue Recognized	Deferred License Revenue
	(in thousands)		
Combined performance obligation	\$ 49,270	\$ 26,015	\$ 23,255
Less contract asset			(800)
Total deferred license revenue			22,455
Less current portion of deferred license revenue			16,456
Non-current deferred license revenue			\$ 5,999

The Company recognized \$26.0 million of revenue based on labor hours expended by the Company on its Manufacturing Obligations during the twelve months ended December 31, 2022.

As of December 31, 2022, the balance of the deferred license revenue was \$23.3 million, which, in accordance with ASC 210-20, was partially offset by the contract asset associated with the manufacturing cost reimbursement of \$0.8 million, resulting in a net deferred license revenue liability of \$22.5 million. The \$4.4 million of withholding taxes paid by Qilu on behalf of the Company was recorded as income tax expense during the twelve months ended December 31, 2022.

The Company incurred \$0.6 million of incremental costs in obtaining the Qilu License, which the Company capitalized in other current assets and other assets and amortizes as a component of general and administrative expense commensurate with the recognition of the combined performance obligation. The Company recognized \$0.3 million of related amortization expense for the twelve months ended December 31, 2022.

The Company reevaluates the transaction price and the total estimated labor hours expected to be incurred to satisfy the performance obligations and adjusts the deferred revenue at the end of each reporting period. Such changes will result in a change to the amount of collaboration revenue recognized and deferred revenue.

Assembly Biosciences, Inc.

In August 2020, the Company entered into a clinical collaboration agreement with Assembly Biosciences, Inc. (“Assembly”) to evaluate AB-729 in combination with Assembly’s first-generation HBV core inhibitor (capsid inhibitor) candidate vebicorvir (“VBR”) and standard-of-care NA therapy for the treatment of patients with HBV infection. Assembly has completed enrollment in the clinical trial. In July 2022, Assembly announced its plan to discontinue development of VBR. Despite this, in consultation with Assembly, the Company continued dosing patients in this Phase 2a proof-of-concept clinical trial in order to fully and accurately assess the results. Preliminary data from 65 patients indicated that adding VBR to AB-729 and NA therapy does not positively or negatively impact the reduction of HBsAg compared to AB-729 and NA therapy alone. Accordingly, the Company and Assembly mutually agreed to discontinue the clinical trial following completion of the final, on-treatment visit at week 48. The Company and Assembly shared in the costs of the collaboration. The Company incurred \$2.8 million and \$2.6 million of costs related to the collaboration during the years ended December 31, 2022 and 2021, respectively, and reflected those costs in research and development in the statements of operations and comprehensive loss. Except to the extent necessary

to carry out Assembly's responsibilities with respect to the collaboration trial, the Company has not provided any license grant to Assembly for use of the Company's AB-729 compound.

Vaccitech plc

In July 2021, the Company entered into a clinical collaboration agreement with Vaccitech plc ("Vaccitech") to evaluate AB-729 followed by Vaccitech's VTP-300, a proprietary T-cell stimulating antigen-specific immunotherapeutic, in NrtI-suppressed patients with cHBV.

The Company is responsible for managing this Phase 2a proof-of-concept clinical trial, subject to oversight by a joint development committee comprised of representatives from the Company and Vaccitech. The Company and Vaccitech retain full rights to their respective product candidates and will split all costs associated with the clinical trial. The Company incurred \$0.8 million and \$0.5 million of costs related to the collaboration, net of Vaccitech's 50% share, during the years ended December 31, 2022 and 2021, respectively, and reflected those net costs in research and development in the statements of operations and comprehensive loss.

X-Chem, Inc. and Proteros biostructures GmbH

In March 2021, the Company entered into a discovery research and license agreement, as amended, with X-Chem, Inc. ("X-Chem") and Proteros biostructures GmbH ("Proteros") to focus on the discovery of novel inhibitors targeting the SARS-CoV-2 nsp5 main protease (M^{pro}). The agreement is designed to accelerate the development of pan-coronavirus agents to treat COVID-19 and potential future coronavirus outbreaks. This collaboration brought together the Company's expertise in the discovery and development of antiviral agents with X-Chem's industry leading DNA-encoded library (DEL) technology and Proteros' protein sciences, biophysics and structural biology capabilities and provides important synergies to potentially identify safe and effective therapies against coronaviruses including SARS-CoV-2. The collaboration allows for the rapid screening of one of the largest small molecule libraries against M^{pro} (an essential protein required for the virus to replicate itself) and the use of state-of-the-art structure guided methods to rapidly optimize M^{pro} inhibitors to progress to clinical candidates. Through this collaboration, the Company has identified and obtained a worldwide exclusive license to several molecules that inhibit M^{pro}, a validated target for the treatment of COVID-19 and potential future coronavirus outbreaks. In the fourth quarter of 2022, the Company nominated AB-343 as its lead candidate that inhibits M^{pro} and the Company is also continuing lead optimization activities for an nsp12 viral polymerase candidate.

The agreement provides for payments by the Company to X-Chem and Proteros upon satisfaction of certain development, regulatory and commercial milestones, as well as royalties on sales. The agreement with X-Chem and Proteros was amended effective March 31, 2022 primarily to extend the term of the collaboration and update the funding and fee structure. The Company incurred \$1.3 million and \$1.9 million of costs related to the collaboration during the years ended December 31, 2022 and 2021, respectively, and reflected those costs in research and development in the statements of operations and comprehensive loss.

Royalty Entitlements

Alnylam Pharmaceuticals, Inc. and Acuitas Therapeutics, Inc.

The Company has two royalty entitlements to Alnylam's global net sales of ONPATTRO.

In 2012, the Company entered into a license agreement with Alnylam Pharmaceuticals, Inc. (“Alnylam”) that entitles Alnylam to develop and commercialize products with the Company’s LNP technology. Alnylam’s ONPATTRO, which represents the first approved application of the Company’s LNP technology, was launched by Alnylam in 2018. Under the terms of this license agreement, the Company is entitled to tiered royalty payments on global net sales of ONPATTRO ranging from 1.00% - 2.33% after offsets, with the highest tier applicable to annual net sales above \$500 million. This royalty interest was sold to OMERS, effective as of January 1, 2019, for \$20 million in gross proceeds before advisory fees. OMERS will retain this entitlement until it has received \$30 million in royalties, at which point 100% of this royalty entitlement on future global net sales of ONPATTRO will revert back to the Company. OMERS has assumed the risk of collecting up to \$30.0 million of future royalty payments from Alnylam and the Company is not obligated to reimburse OMERS if they fail to collect any such future royalties. If this royalty entitlement reverts to the Company, it has the potential to provide an active royalty stream or to be otherwise monetized again in full or in part. From the inception of the royalty sale through December 31, 2022, an aggregate of \$18.9 million of royalties have been earned by OMERS. See note 9 for further details.

The Company also has rights to a second royalty interest ranging from 0.75% to 1.125% on global net sales of ONPATTRO, with 0.75% applying to sales greater than \$500 million, originating from a settlement agreement and subsequent license agreement with Acuitas Therapeutics, Inc. (“Acuitas”). This royalty entitlement from Acuitas has been retained by the Company and was not part of the royalty entitlement sale to OMERS.

Gritstone Oncology, Inc.

On October 16, 2017, the Company entered into a license agreement with Gritstone that granted them worldwide access to its portfolio of proprietary and clinically validated LNP technology and associated intellectual property to deliver Gritstone’s self-replicating, non-mRNA, RNA-based neoantigen immunotherapy products. Gritstone paid the Company an upfront payment, and will make payments for achievement of development, regulatory, and commercial milestones and royalties. As a result of the Company’s agreement with Genevant (see note 5 for details), from April 11, 2018 going forward, Genevant is entitled to 50% of the revenues earned by the Company from Gritstone. The Company is the agent in this arrangement and records revenue on a net basis. Milestone payments that are not within the control of the Company or the licensee, such as those that require regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company did not receive any payments from Gritstone during the years ended December 31, 2022 or 2021.

Revenues from the Company’s royalty entitlements are summarized in the following table:

	Year ended December 31,	
	2022	2021
	(in thousands)	
Revenue from collaborations and licenses		
Royalties from sales of Onpattro	\$ 5,316	\$ 4,675
Qilu Pharmaceutical Co., Ltd.	26,015	—
Other milestone and royalty payments	35	205
Non-cash royalty revenue		
Royalties from sales of Onpattro	7,653	6,108
Total revenue	\$ 39,019	\$ 10,988

12. Shareholders’ equity

Authorized share capital

The Company’s authorized share capital consists of an unlimited number of common shares and preferred shares, without par value, and 1,164,000 Series A participating convertible preferred shares, without par value.

Open Market Sale Agreement

The Company has an Open Market Sale Agreement with Jefferies LLC (“Jefferies”) dated December 20, 2018, as amended by Amendment No. 1, dated December 20, 2019, Amendment No. 2, dated August 7, 2020 and Amendment No. 3, dated March 4, 2021 (as amended, the “Sale Agreement”), under which the Company may issue and sell common shares, from time to time.

On December 23, 2019, the Company filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission (the “SEC”) (File No. 333-235674) and accompanying base prospectus, which was declared effective by the SEC on January 10, 2020 (the “January 2020 Registration Statement”), for the offer and sale of up to \$150.0 million of the Company’s securities. The January 2020 Registration Statement also contained a prospectus supplement in connection with the offering of up to \$50.0 million of the Company’s common shares pursuant to the Sale Agreement. This prospectus supplement was fully utilized during 2020. On August 7, 2020, the Company filed a prospectus supplement with the SEC (the “August 2020 Prospectus Supplement”) in connection with the offering of up to an additional \$75.0 million of its common shares pursuant to the Sale Agreement under the January 2020 Registration Statement. The August 2020 Prospectus Supplement was fully utilized during 2020.

On August 28, 2020, the Company filed a shelf registration statement on Form S-3 with the SEC (File No. 333-248467) and accompanying base prospectus, which was declared effective by the SEC on October 22, 2020 (the “October 2020 Registration Statement”), for the offer and sale of up to \$200.0 million of the Company’s securities. On March 4, 2021, the Company filed a prospectus supplement with the SEC (the “March 2021 Prospectus Supplement”) in connection with the offering of up to an additional \$75.0 million of its common shares pursuant to the Sale Agreement under October 2020 Registration Statement. The March 2021 Prospectus Supplement was fully utilized during 2021. On October 8, 2021, the Company filed a prospectus supplement with the SEC (the “October 2021 Prospectus Supplement”) in connection with the offering of up to an additional \$75.0 million of its common shares pursuant to the Sale Agreement under the October 2020 Registration Statement.

On November 4, 2021, the Company filed a shelf registration statement on Form S-3 with the SEC (File No. 333-260782) and accompanying base prospectus, declared effective by the SEC on November 18, 2021 (the “November 2021 Registration Statement”), for the offer and sale of up to \$250.0 million of the Company’s securities.

On March 3, 2022, the Company filed a prospectus supplement with the SEC (the “March 2022 Prospectus Supplement”) in connection with the offering of up to an additional \$100.0 million of its common shares pursuant to the Sale Agreement under: (i) the January 2020 Registration Statement; (ii) the October 2020 Registration Statement; and (iii) the November 2021 Registration Statement.

During the years ended December 31, 2022 and 2021, the Company issued 8,645,426 and 31,571,036 common shares, respectively, under the Sale Agreement, resulting in net proceeds of approximately \$20.3 million and \$134.7 million, respectively.

As of December 31, 2022, there was approximately \$131.1 million remaining available in aggregate under the October 2021 Prospectus Supplement and the March 2022 Prospectus Supplement.

Series A Preferred Shares

In October 2017, the Company entered into a subscription agreement with Roivant for the sale of Preferred Shares to Roivant for gross proceeds of \$116.4 million. The Preferred Shares were non-voting and were convertible into common shares at a conversion price of \$7.13 per share (which represented a 15% premium to the closing price of \$6.20 per share). The purchase price for the Preferred Shares plus an amount equal to 8.75% per annum, compounded annually, was subject to mandatory conversion into common shares on October 18, 2021, at which time the Preferred Shares were converted into 22,833,922 common shares and both the lockup and standstill periods that Roivant had previously agreed to expired. As of December 31, 2022, Roivant owned approximately 25% of the Company’s outstanding common shares.

The Company recorded the Preferred Shares wholly as equity with no bifurcation of conversion feature from the host contract, given that the Preferred Shares could not be cash settled and the redemption features were within the Company’s control, which included a fixed conversion ratio with predetermined timing and proceeds. The Company accrued for the 8.75% per annum

compounding coupon at each reporting period end date as an increase to share capital, and an increase to deficit (see statement of stockholder's equity).

13. Stock-based compensation

Awards outstanding and available for issuance

During the year ended December 31, 2022, the Company had stock options outstanding under the following plans (collectively, the "Plans"): the 2016 Omnibus Share and Incentive Plan (the "2016 Plan"), the 2011 Omnibus Share Compensation Plan (the "2011 Plan"); the 2019 inducement grant; and the OnCore Option Plan.

As of December 31, 2022, the aggregate number of shares authorized for awards under all Plans was 28,290,202. As of December 31, 2022, the Company had 15,450,598 options outstanding and 8,842,931 awards available for issuance under the Plans.

The Company issues new common shares of stock to settle options exercised.

The 2011 Plan expired in June 2021. Under the 2016 Plan, the Company's board of directors may grant options, and other types of awards, to employees, directors and consultants of the Company. The exercise price of the options is determined by the Company's board of directors but will be at least equal to the closing market price of the common shares on the date of grant and the term may not exceed 10 years. Options granted generally vest over four years for employees and for directors' initial grants, and immediately for directors' annual grants.

In June 2019, the Company provided an inducement grant of 1,112,000 options to its newly hired Chief Executive Officer. These options were awarded in a separate plan as non-qualified awards and are governed by the substantially the same terms as the 2016 Plan.

Hereafter, information on options governed by the 2016 Plan, the 2011 Plan and the 2019 inducement grant (the "Arbutus Plans") is presented on a consolidated basis as the terms of the plans are similar. Information on the OnCore Option Plan is presented separately.

Stock options under the Arbutus Plans

Equity-classified stock options under the Arbutus Plans

The following table summarizes activity related to the Company's equity-classified stock options, including its performance options, for the year ended December 31, 2022:

	Stock Options Outstanding		Vested Stock Options	Non-Vested Stock Options	
	Number	Weighted-Average Exercise Price	Number	Number	Weighted-Average Grant-Date Fair Value
Balance as of December 31, 2021	11,309,974	\$ 4.14	6,544,348	4,765,626	\$ 2.71
Options granted	4,808,295	\$ 2.77	—	4,808,295	\$ 2.09
Options exercised	(71,025)	\$ 1.70	(71,025)	—	\$ —
Options forfeited, canceled or expired	(697,246)	\$ 3.31	(100,399)	(596,847)	\$ 2.44
Options vested	—	\$ —	3,258,855	(3,258,855)	\$ 2.42
Balance as of December 31, 2022	15,349,998	\$ 3.76	9,631,779	5,718,219	\$ 2.39

The intrinsic value of options exercised under the Arbutus Plans during 2022 and 2021 are \$0.1 million and \$0.2 million, respectively.

The following table summarizes additional information related to the Company's equity-classified stock options, including its performance options, as of December 31, 2022:

	As of December 31, 2022	
<u>Options outstanding and expected to vest</u>		
Number of stock options outstanding		15,349,998
Weighted-average exercise price	\$	3.76
Intrinsic value (in \$000s)	\$	380
Weighted-average term remaining		7.3 years
<u>Vested stock options</u>		
Number of vested stock options		9,631,779
Weighted-average exercise price	\$	4.07
Intrinsic value (in \$000s)	\$	327
Weighted-average term remaining		6.6 years

The assumptions used in the Black-Scholes option-pricing for grants made during the years ended December 31, 2022 and 2021 are as follows:

	December 31, 2022	December 31, 2021
Expected average option term	5.5 years	5.6 years
Expected volatility	97.0 %	93.4 %
Expected dividends	— %	— %
Risk-free interest rate	1.77 %	0.67 %

The Company considers all available information when estimating the fair value of its stock option grants.

Stock options under the other plans

As of December 31, 2022, the Company also has 20,000 liability option awards outstanding with a weighted average exercise price of \$12.10 and 80,600 stock option awards outstanding under the OnCore Option Plan with a weighted average exercise price of \$0.56.

Employee Stock Purchase Plan

In May 2020, the Company's stockholders approved the 2020 Employee Stock Purchase Plan (the "ESPP") which became effective on May 28, 2020. A total of 1,500,000 common shares were reserved for issuance under the ESPP. Company employees contribute funds via payroll deductions, which are used to buy Company common shares at a discount of up to 15% based on the lower of the price at the start of the offering period and at the end of the relevant purchase period within such offering period. The initial offering period under the ESPP was September 1, 2020 through August 31, 2021 with purchase dates set on February 26, 2021 and August 31, 2021, with subsequent offering periods beginning on September 1 and ending on August 31. The Company issued 171,224 and 196,335 shares under its ESPP for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, there were 1,132,441 shares remaining for issuance under the ESPP. For the years ended December 31, 2022 and 2021, the Company recognized \$0.2 million and \$0.3 million, respectively, of stock-based compensation expense related to the ESPP. The fair value of the right to acquire stock at a discounted price under the ESPP is calculated using the Black-Scholes valuation model and recorded as stock-based compensation. Expense is recognized over the period the employee contributes to the plan through payroll deductions.

Stock-based compensation expense

Total stock-based compensation expense was comprised of: (1) vesting of options awarded to employees under the Arbutus and OnCore Plans calculated in accordance with the fair value method as described above; (2) fair value adjustments for the Company's liability-classified stock options; and (3) amortization of compensation cost related to the ESPP.

The Company recognizes forfeitures as they occur, and the effects of forfeitures are reflected in stock-based compensation expense.

Stock-based compensation has been recorded in the consolidated statement of operations and comprehensive loss as follows:

	Year Ended December 31,	
	2022	2021
	(in thousands)	
Research and development	\$ 2,912	\$ 2,777
General and administrative	4,270	3,647
Total	\$ 7,182	\$ 6,424

At December 31, 2022, there remained \$13.2 million of unrecognized compensation expense related to unvested equity employee stock options to be recognized as expense over a weighted-average period of approximately 2.4 years.

For each of the years ended December 31, 2022 and 2021, the Company had zero performance based stock compensation expense.

14. Income taxes

The Company is subject to taxation and files income tax returns in Canadian federal and provincial, United States federal and several state jurisdictions. In December 2022, the United States Internal Revenue service completed its examination of the Company's federal tax return for 2018. In May 2022, The Canada Revenue Agency completed its examination of the Company's Canadian tax returns for 2018 and 2019, with no adjustments proposed.

Income tax expense varies from the amounts that would be computed by applying the combined Canadian federal and provincial income tax rate of 27% (2021 - 27%) to the loss before income taxes as shown in the following tables:

	Year ended December 31,	
	2022	2021
	(in thousands)	
Computed taxes (benefits) at Canadian federal and provincial tax rates	\$ (17,554)	\$ (23,864)
Withholding taxes	4,444	—
Other	761	(1,041)
Permanent and other differences	869	4,292
Foreign tax credit applied	(4,444)	—
Federal and Provincial ITCs applied	(324)	(611)
Change in valuation allowance	14,563	15,928
Difference due to income taxed at foreign rates	5,625	4,840
Stock-based compensation	504	456
Income tax expense	\$ 4,444	\$ —

As of December 31, 2022, the Company had investment tax credits available to reduce Canadian federal income taxes of \$7.2 million, versus \$7.4 million as of December 31, 2021, which expire between 2030 and 2037, and provincial income taxes of \$2.0 million, versus \$2.1 million as of December 31, 2021, which expire between 2024 and 2027. The investment tax credits are accounted for under a flow-through method. In addition, the Company had research and development credits of \$3.7 million as of December 31, 2022, and \$3.8 million as of December 31, 2021, which expire between 2031 and 2038 and which can be used to reduce future taxable income in the United States.

As of December 31, 2022, the Company had scientific research and experimental development expenditures of \$62.2 million available for indefinite carry-forward, versus \$62.8 million as of December 31, 2021. The Company also had net operating losses of \$148.1 million as of December 31, 2022 and \$177.7 million as of December 31, 2021, which are due to expire between 2028 and 2038 and which can be used to offset future taxable income in Canada.

As of December 31, 2022 and December 31, 2021, the Company had \$11.7 million of net operating losses due to expire in 2035 which can be used to offset future taxable income in the United States. Future use of a portion of the United States loss carryforwards are subject to limitations under Internal Revenue Code Section 382. United States net operating loss carryforwards arising in 2019 and future periods have an indefinite carryforward period. As of December 31, 2022 and December 31, 2021, the Company had \$203.9 million and \$197.8 million, respectively, of total regular net operating losses which can be used to offset future taxable income in the United States.

As a result of ownership changes occurring on October 1, 2014 and March 4, 2015, the Company's ability to use these losses may be limited. Losses incurred to date may be further limited if a subsequent change in control occurs.

The Company generated \$28.7 million and \$93.7 million in pre-tax domestic and foreign losses, respectively, for the year ended December 31, 2022. The Company generated \$7.7 million and \$80.7 million in pre-tax domestic and foreign losses, respectively, for the year ended December 31, 2021.

As required by the 2017 Tax Cuts and Jobs Act and effective in 2022, the deferred tax asset as of December 31, 2022 included \$16.5 million related to the mandatory capitalization and amortization of research and development expenses.

Significant components of the Company's deferred tax assets and liabilities are shown below:

	As of December 31,	
	2022	2021
	(in thousands)	
Deferred tax assets (liabilities):		
Non-capital losses carryforwards	\$ 83,564	\$ 90,255
Canadian research and development deductions	16,791	16,968
Book amortization in excess of tax	(461)	(634)
Revenue recognized for tax purposes in excess of revenue recognized for accounting purposes	2,799	4,400
Tax value in excess of accounting value in lease inducements	93	549
Deferred revenue	6,063	—
Canadian Federal investment tax credits	5,278	5,301
Canadian Provincial investment tax credits	1,953	2,119
Equity accounted for investment	3,375	3,375
U.S. Federal research and development credits	3,633	3,741
Deductible stock options	3,681	3,309
U.S. research and experimental expenditures capitalization	16,471	—
Accrued interest payable	1,507	—
Amortization	387	—
Other	153	1,341
Total deferred tax assets	\$ 145,287	\$ 130,724
Valuation allowance	(145,287)	(130,724)
Net deferred tax assets (liabilities)	\$ —	\$ —

15. Related party transactions

Pursuant to a financing and related subscription agreement, the Company issued Roivant the Preferred Shares in October 2017. On October 18, 2021, the Preferred Shares were converted into 22,833,922 common shares. As of December 31, 2022, Roivant owned approximately 25% of the Company's outstanding common shares. See note 12 for further details.

As of December 31, 2022, the carrying value of the Company's investment in Genevant was zero and the Company owned approximately 16% of the common equity of Genevant. See note 5 for further details.

During each of the years ended December 31, 2022 and 2021, Genevant purchased certain administrative and transitional services from the Company totaling less than \$0.1 million. These services were billed at agreed hourly rates and reflective of market rates for such services and these costs were netted in research and development in the income statement.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Our management, including our principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), as of the end of the period covered by this Annual Report on Form 10-K. Based upon that evaluation, our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer), concluded that, as of December 31, 2022, our disclosure controls and procedures were effective to provide reasonable assurance that (a) the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and (b) such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Management’s Annual Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our principal executive officer and our principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in the Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO 2013”).

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America. Our internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Based on our evaluation under the framework in COSO 2013, our management concluded that our internal control over financial reporting was effective as of December 31, 2022.

Changes in Internal Control over Financial Reporting

There have not been changes in our internal control over financial reporting during the quarter ended December 31, 2022 that have materially affected or are reasonably likely to materially affect the Company’s internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item is incorporated herein by reference to our Proxy Statement for the 2023 Annual General Meeting of the Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2022.

We have adopted a code of business conduct for directors, officers and employees (the “Code of Conduct”), which is available on our website at <http://investor.arbutusbio.com/corporate-governance-0> and also at www.sedar.com. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding any amendment to, or waiver from, a provision of this Code of Conduct by posting such information on the website address and location specified above.

Item 11. Executive Compensation

The information required by this item is incorporated herein by reference to our Proxy Statement for the 2023 Annual General Meeting of the Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2022.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item is incorporated herein by reference to our Proxy Statement for the 2023 Annual General Meeting of the Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2022.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item is incorporated herein by reference to our Proxy Statement for the 2023 Annual General Meeting of the Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2022.

Item 14. Principal Accounting Fees and Services

The information required by this item is incorporated herein by reference to our Proxy Statement for the 2023 Annual General Meeting of the Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2022.

PART IV

Item 15. Exhibits and Financial Statement Schedules

Exhibit	Description
2.1*	<u>Agreement and Plan of Merger and Reorganization, dated January 11, 2015, by and among Tekmira Pharmaceuticals Corporation, TKM Acquisition Corporation and OnCore Biopharma, Inc. (incorporated herein by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K/A, filed with the SEC on January 26, 2015).</u>
3.1*	<u>Notice of Articles and Articles of the Company, as amended (incorporated herein by reference to Exhibit 3.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 16, 2018).</u>
3.2*	<u>Amendment to Articles of the Company (incorporated herein by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, filed with the SEC on November 7, 2018).</u>
4.1**	<u>Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.</u>
10.1†*	<u>Amended and Restated License Agreement, between Inex Pharmaceuticals Corporation and Hana Biosciences, Inc., dated April 30, 2007 (incorporated herein by reference to Exhibit 4.2 to the Registrant's Amendment No. 1 to Form 20-F for the year ended December 31, 2010, filed with the SEC on January 31, 2012).</u>
10.2†*	<u>Amendment No. 1 to the Amended and Restated Agreement, between the Company (formerly Inex Pharmaceuticals Corporation) and Hana Biosciences, Inc., effective as of May 27, 2009 (incorporated herein by reference to Exhibit 4.1 to the Registrant's Annual Report on Form 20-F for the year ended December 31, 2010, filed with the SEC on June 3, 2011).</u>
10.3†*	<u>Amendment No. 2 to the Amended and Restated Agreement, between the Company (formerly Inex Pharmaceuticals Corporation) and Hana Biosciences, Inc., effective as of September 20, 2010 (incorporated herein by reference to Exhibit 4.21 to the Registrant's Annual Report on Form 20-F for the year ended December 31, 2010, filed with the SEC on June 3, 2011).</u>
10.4*#	<u>Form of Arbutus Biopharma Corporation Indemnity Agreement (incorporated herein by reference to Exhibit 10.4 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 3, 2022).</u>
10.5†*	<u>License Agreement between the University of British Columbia and Inex Pharmaceuticals Corporation executed on July 30, 2001 (incorporated herein by reference to Exhibit 4.17 to the Registrant's Annual Report on Form 20-F for the year ended December 31, 2010, filed with the SEC on June 3, 2011).</u>
10.6†*	<u>Amendment Agreement between the University of British Columbia and Inex Pharmaceuticals Corporation dated July 11, 2006 (incorporated herein by reference to Exhibit 4.18 to the Registrant's Annual Report on Form 20-F for the year ended December 31, 2010, filed with the SEC on June 3, 2011).</u>
10.7†*	<u>Second Amendment Agreement between the University of British Columbia and Inex Pharmaceuticals Corporation dated January 8, 2007 (incorporated herein by reference to Exhibit 4.19 to the Registrant's Annual Report on Form 20-F for the year ended December 31, 2010, filed with the SEC on June 3, 2011).</u>
10.8†*	<u>Consent Agreement of the University of British Columbia to Inex/Alnylam Sublicense Agreement dated January 8, 2007 (incorporated herein by reference to Exhibit 4.20 to the Registrant's Annual Report on Form 20-F for the year ended December 31, 2010, filed with the SEC on June 3, 2011).</u>
10.9*#	<u>Tekmira 2011 Omnibus Share Compensation Plan approved by shareholders on June 22, 2011 (incorporated herein by reference to Exhibit 4.25 to the Registrant's Annual Report on Form 20-F for the year ended December 31, 2011, filed with the SEC on March 27, 2012).</u>
10.10†*	<u>Settlement Agreement and General Release, by and among Tekmira Pharmaceuticals Corporation, Protiva Biotherapeutics Inc., Alnylam Pharmaceuticals, Inc., and AICana Technologies, Inc., dated November 12, 2012 (incorporated herein by reference to Exhibit 4.26 to the Registrant's Annual Report on Form 20-F for the year ended December 31, 2012, filed with the SEC on March 27, 2013).</u>

- 10.11†* [Cross-License Agreement by and among Alnylam Pharmaceuticals, Inc., Tekmira Pharmaceuticals Corporation and Protiva Biotherapeutics Inc., dated November 12, 2012 \(incorporated herein by reference to Exhibit 4.27 to the Registrant's Annual Report on Form 20-F for the year ended December 31, 2012, filed with the SEC on March 27, 2013\).](#)
- 10.12* [Form of Standstill Agreement \(incorporated herein by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K/A, filed with the SEC on January 26, 2015\).](#)
- 10.13** [Executive Employment Agreement, dated effective as of February 25, 2016, between Arbutus Biopharma, Inc. and Elizabeth Howard \(incorporated herein by reference to Exhibit 10.78 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC on March 9, 2016\).](#)
- 10.14** [Amending Agreement, dated as of November 2, 2015, among Arbutus Biopharma Corporation, Roivant Sciences Ltd., Patrick T. Higgins, Michael J. McElhaugh, Michael J. Sofia and Bryce A. Roberts \(incorporated herein by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed with the SEC on November 5, 2015\).](#)
- 10.15†* [Stock Purchase Agreement by and among OnCore Biopharma, Inc. and each of the stockholders of Enantigen Therapeutics, Inc., dated as of October 1, 2014 \(incorporated herein by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed with the SEC on May 6, 2015\).](#)
- 10.16** [Executive Employment Agreement, dated effective as of July 11, 2015, between OnCore Biopharma, Inc. and Michael J. Sofia \(incorporated herein by reference to Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed with the SEC on August 7, 2015\).](#)
- 10.17** [Amended 2011 Omnibus Share Compensation Plan \(incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, filed with the SEC on August 4, 2016\).](#)
- 10.18†* [Lease Agreement between the Company and ARE-PA Region No. 7, LLC dated August 9, 2016 \(incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, filed with the SEC on November 3, 2016\).](#)
- 10.19†* [First Amendment to Lease Agreement between Arbutus Biopharma, Inc. and ARE-PA Region No. 7, LLC dated October 7, 2016 \(incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, filed with the SEC on November 3, 2016\).](#)
- 10.20* [Acknowledgment of Commencement Date in connection with Lease Agreement between the Company and ARE-PA Region No. 7, LLC dated August 9, 2016 and as amended on October, 7, 2016 \(incorporated herein by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, filed with the SEC on November 3, 2016\).](#)
- 10.21* [Master Contribution And Share Subscription Agreement, by and between the Company, Genevant Sciences Ltd. and Roivant Sciences LTD. \(incorporated herein by reference Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, filed with the SEC on May 4, 2018\).](#)
- 10.22* [Open Market Sale AgreementSM, dated December 20, 2018, by and between the Company and Jefferies LLC \(incorporated herein by reference to Exhibit 1.1 of the Current Report on Form 8-K, filed with the SEC on December 20, 2018\).](#)
- 10.23* [Amendment No. 1 to the Open Market Sale AgreementSM, dated December 20, 2019, by and between the Company and Jefferies LLC \(incorporated herein by reference to Exhibit 1.3 to the Registrant's Registration Statement on Form S-3, filed with the SEC on December 20, 2019\).](#)
- 10.24* [Amendment No. 2 to the Open Market Sale AgreementSM, dated August 7, 2020, by and between the Company and Jefferies LLC \(incorporated herein by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 7, 2020\).](#)
- 10.25* [Amendment No. 3 to the Open Market Sale AgreementSM, dated March 4, 2021, by and between Arbutus Biopharma Corporation and Jefferies LLC \(incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on March 4, 2021\).](#)
- 10.26** [Executive Employment Agreement, dated June 11, 2018, by and between the Company and David Hastings \(incorporated herein by reference to Exhibit 10.52 of the Registrant's Annual Report on Form 10-K for the year end December 31, 2018, filed with the SEC on March 7, 2019\).](#)

- 10.27*# [Employment Agreement, dated June 13, 2019, by and between the Company and William H. Collier \(incorporated herein by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, filed with the SEC on June 18, 2019\).](#)
- 10.28*# [Executive Employment Agreement, dated July 10, 2015, by and between the Company and Michael McElhaugh, as amended by the First Amendment to Executive Employment Agreement, dated April 20, 2016, and the Second Amendment to Executive Employment Agreement dated December 11, 2018 \(incorporated herein by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, filed with the SEC on August 5, 2019\).](#)
- 10.29* [Purchase and Sale Agreement, dated July 2, 2019, by and between the Company and OCM IP Healthcare Portfolio LP \(incorporated herein by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, filed with the SEC on August 5, 2019\).](#)
- 10.30*# [Arbutus Biopharma Corporation 2020 Employee Stock Purchase Plan \(incorporated herein by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on June 1, 2020\).](#)
- 10.31*# [Form of Arbutus Biopharma Corporation Option Agreement \(incorporated herein by reference to Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, filed with the SEC on August 5, 2019\).](#)
- 10.32*# [Option Agreement, dated June 24, by and between the Company and William H. Collier \(incorporated herein by reference to Exhibit 10.9 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, filed with the SEC on August 5, 2019\).](#)
- 10.33†* [Cross License Agreement, dated April 11, 2018, by and between the Company and Genevant Sciences Ltd. \(incorporated herein by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, filed with the SEC on August 7, 2020\).](#)
- 10.34†* [First Amendment to Cross License Agreement, dated June 27, 2018, by and among the Company, Genevant Sciences Ltd and Genevant Sciences GmbH. \(incorporated herein by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, filed with the SEC on August 7, 2020\).](#)
- 10.35†* [Second Amendment to Cross License Agreement, dated June 27, 2018, by and among the Company, Genevant Sciences Ltd. and Genevant Sciences GmbH. \(incorporated herein by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, filed with the SEC on August 7, 2020\).](#)
- 10.36†* [License Agreement, dated December 9, 2021, by and between the Company and Genevant Sciences GmbH \(incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 10, 2021\).](#)
- 10.37†* [Technology Transfer and Exclusive License Agreement, dated December 13, 2021, by and between the Company and Qilu Pharmaceutical Co., Ltd. \(incorporated herein by reference to Exhibit 10.41 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 3, 2022\).](#)
- 10.38* [Arbutus Biopharma Corporation 2016 Omnibus Share and Incentive Plan, as supplemented and amended \(incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 31, 2022\).](#)
- 10.39*# [Third Amendment to Executive Employment Agreement, dated November 1, 2022, by and between the Company and Michael McElhaugh \(incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on October 24, 2022\).](#)
- 10.41** [Form of Arbutus Biopharma Corporation Restricted Stock Unit Agreement.](#)
- 21.1** [List of Subsidiaries.](#)
- 23.1** [Consent of Ernst and Young LLP, an Independent Registered Public Accounting Firm.](#)
- 31.1** [Certification of Chief Executive Officer pursuant to Rule 13a-14 or 15d-14 of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.](#)

31.2**	Certification of Chief Financial Officer pursuant to Rule 13a-14 or 15d-14 of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document
104**	Cover Page Interactive Data File (formatted as Inline XBRL and Contained in Exhibit 101).

* Previously filed

** Filed or furnished herewith, as applicable

† Certain confidential portions of the agreement were omitted by means of marking such portions with brackets (due to the registrant customarily and actually treating such information as private or confidential and such omitted information not being material) pursuant to Item 601 of Regulation S-K promulgated by the SEC. Arbutus agrees to supplementally furnish a copy of any confidential portions to the SEC upon request.

Management Contract or Compensatory Arrangement.

Financial Statements

See Index to Consolidated Financial Statements under Item 8 of Part II.

Financial Statement Schedules

None.

Item 16. Form 10-K Summary

None.

**DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934**

As of the date of the Annual Report on Form 10-K of which this exhibit forms a part, the only class of securities of Arbutus Biopharma Corporation (“we,” “us” and “our”) registered under Section 12 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), is our common shares, without par value.

CAPITAL STOCK

The following description of our capital stock summarizes provisions of our Notice of Articles and Articles, as amended, or our Articles, the Investment Canada Act (Canada), the Competition Act (Canada) and the Business Corporations Act (British Columbia). The following description does not purport to be complete and is subject to, and qualified in its entirety by, our Articles, which are incorporated by reference as exhibits to the Annual Report on Form 10-K of which this exhibit is a part, and to the applicable provisions of the Investment Canada Act, the Competition Act and the Business Corporations Act.

Authorized and Outstanding Shares

Our authorized share capital consists of (i) an unlimited number of common shares, without par value, (ii) an unlimited number of preferred shares, without par value, and (iii) 1,164,000 Series A Participating Convertible Preferred Shares. As of February 28, 2023 there were (a) 162,570,989 common shares outstanding and (b) 0 Series A Participating Convertible Preferred Shares outstanding. None of our common shares or preferred shares are held by us or on behalf of us.

Voting Rights

The holders of our common shares are entitled to receive notice of any meeting of our shareholders and to attend and vote thereat, except those meetings at which only the holders of shares of another class or of a particular series are entitled to vote. Each common share entitles its holder to one vote. There are no cumulative voting rights.

Dividends

Subject to the rights of the holders of preferred shares, the holders of common shares are entitled to receive on a pro rata basis such dividends as our Board of Directors may declare out of funds legally available for payment of dividends.

Liquidation Rights

In the event of the dissolution, liquidation, winding-up or other distribution of our assets, those holders are entitled to receive on a pro rata basis all of our assets remaining after payment of all of our liabilities, subject to the rights of holders of preferred shares.

Other Rights and Preferences.

The terms of our common shares do not include any preemptive, conversion or subscription rights, nor any redemption or sinking fund provisions. The common shares are not subject to future calls or assessments by us.

Limitations to Control due to Certain Provisions of Canadian and British Columbian Law and our Articles

Unless such offer constitutes an exempt transaction, an offer made by a person, or an offeror, to acquire outstanding shares of a Canadian entity that, when aggregated with the offeror’s holdings (and those of persons or companies acting jointly with the offeror), would constitute 20% or more of the outstanding shares, would be subject to the take-over provisions of Canadian securities laws. The foregoing is a limited and general summary of certain aspects of applicable securities law in the provinces and territories of Canada, all in effect as of the date hereof.

In addition to the take-over bid requirements noted above, the acquisition of shares may trigger the application of additional statutory regimes including amongst others, the Investment Canada Act (Canada) and the Competition Act (Canada).

As well, under the Business Corporations Act (British Columbia), unless otherwise stated in our Articles, certain corporate actions require the approval of a special majority of shareholders, meaning holders of shares representing 66 2/3% of those votes cast in respect of a shareholder vote addressing such matter. Those items requiring the approval of a special majority generally relate to fundamental changes with respect to our business, and include amongst others, resolutions: (i) removing a

director prior to the expiry of his or her term; (ii) altering our Articles, (iii) approving an amalgamation; (iv) approving a plan of arrangement; and (v) providing for a sale of all or substantially all of our assets.

The Nasdaq Global Select Market

Our common shares are listed on the Nasdaq Global Select Market under the symbol “ABUS.”

Transfer Agent and Registrar

The transfer agent and registrar for our common shares is TSX Trust Company.

**ARBUTUS BIOPHARMA CORPORATION
2016 OMNIBUS SHARE AND INCENTIVE PLAN**

RESTRICTED STOCK UNIT AGREEMENT

COVER SHEET

Arbutus Biopharma Corporation, a corporation incorporated under the laws of British Columbia, Canada (the “**Company**”), hereby grants Restricted Stock Units (the “**RSUs**”) representing the right to receive common shares, without par value, of the Company (the “**Shares**”), to the individual named below as Participant, subject to the vesting and other conditions set forth below. The terms and conditions of the RSUs are set forth in this cover sheet, in the attachment (collectively, the “**Agreement**”) and in the Company’s 2016 Omnibus Share and Incentive Plan (as it may be amended from time to time, the “**Plan**”).

Grant Date: _____

Name of Participant: _____

Number of Shares Covered by RSUs: _____

Vesting Schedule:

The RSUs vest in three equal annual installments beginning one year from the grant date, subject to the Reporting Person's continuous service as of each vesting date.

By signing this cover sheet, you agree to all of the terms and conditions described in this Agreement and in the Plan, a copy of which is also attached. You acknowledge that you have carefully reviewed the Plan, and you agree that the Plan will control in the event any provision of this Agreement should appear to be inconsistent. Certain capitalized terms used in this Agreement are defined in the Plan, and have the respective meanings set forth in the Plan.

Grantee: _____

(Signature)

Company: _____

(Signature)

Title: Chief Financial Officer

Attachment

This document is not a stock certificate or a negotiable instrument.

**ARBUTUS BIOPHARMA CORPORATION
2016 OMNIBUS SHARE AND INCENTIVE PLAN**

RESTRICTED STOCK UNIT AGREEMENT

Restricted Stock Units

This Agreement evidences an award of RSUs in the number set forth on the cover sheet. Each RSU represents the right to receive one Share, subject to the vesting and other conditions set forth in this Agreement and in the Plan.

Vesting

The RSUs shall vest in accordance with the vesting schedule set forth on the cover sheet of this Agreement; provided, however, that for purposes of vesting, fractional numbers of Shares shall be rounded to the nearest whole number, and the number of RSUs that shall vest on the final vesting date shall be rounded up or down as necessary such that the total number of RSUs that vest pursuant to the vesting schedule shall be equal to the number of RSUs covered by this grant as set forth on the cover sheet of this Agreement.

Unless the termination of your service as an Eligible Person (“**Service**”) triggers accelerated vesting or other treatment of the RSUs pursuant to the terms of this Agreement or the Plan, you shall immediately and automatically forfeit the unvested RSUs to the Company in the event your Service terminates for any reason. No RSUs shall vest after your termination of Service.

Change in Control

In the event of a Change in Control, the RSUs will be treated in the manner provided in Section 7(b) of the Plan.

Leaves of Absence

This section of the Agreement applies solely to Participants who are employees of the Company or any of its subsidiaries. For purposes of the RSUs, your Service does not terminate when you go on a *bona fide* employee leave of absence that was approved by the Company in writing, if the terms of the leave provide for continued service crediting, or when continued service crediting is required by applicable law. However, in all other cases, your Service will be treated as terminating ninety (90) days after you went on employee leave, unless your right to return to active work is guaranteed by law or by a contract. Your Service terminates in any event when the approved leave ends, unless you immediately return to active employee work.

The Company determines, in its sole discretion, which leaves count for this purpose, and when your Service terminates for all purposes under the Plan.

Issuance

The issuance of the Shares underlying any RSUs that become vested hereunder shall be made within thirty (30) days after the applicable vesting date. Any such issuance shall be evidenced in such a manner as the Company, in its discretion, will deem appropriate, including, without limitation, book-entry, direct registration or issuance of one or more Share certificates.

Withholding Taxes

In order to comply with all applicable federal, state, local or foreign tax laws or regulations, the Company may take such actions as it deems appropriate to ensure that all applicable federal, state, local or foreign payroll, withholding, income or other taxes that may be due relating to the RSUs and the issuance of Shares with respect to the RSUs, which are your sole and absolute responsibility, are withheld or collected from you. If you are an employee of the Company or any of its subsidiaries as of the Grant Date, then you hereby agree as a condition of this Agreement that you will enter into a side letter agreement with the Company prior to or as soon as practicable following the Grant Date (or at such other time as directed by the Company), in a form that is acceptable to the Company, pursuant to which you will make an election to satisfy all tax withholding obligations that arise hereunder pursuant to the “sell to cover” tax withholding method.

Transfer of RSUs

The RSUs are not transferable by you other than to a designated beneficiary upon your death or by will or the laws of descent and distribution. No assignment or transfer of the RSUs, or the rights represented thereby, whether voluntary or involuntary, by operation of law or otherwise (except to a designated beneficiary upon death by will or the laws of descent or distribution) will vest in the assignee or transferee any interest or right herein whatsoever, but immediately upon such assignment or transfer the RSUs will terminate and become of no further effect.

Retention Rights

This section of the Agreement applies solely to Participants who are employees of the Company or any of its subsidiaries. Neither the RSUs nor this Agreement gives you the right to be retained or employed by the Company (or any subsidiary of the Company) in any capacity. Unless otherwise specified in any written employment or other agreement between the Company and you, the Company reserves the right to terminate your Service at any time and for any reason.

Shareholder Rights

You, or your estate or heirs, have no rights as a shareholder of the Company until the Shares have been issued to you upon vesting of the RSUs and either a certificate evidencing your Shares has been issued or an appropriate entry has been made on the Company’s books. No adjustments are made for dividends or other rights if the applicable record date occurs before your share certificate is issued (or an appropriate book entry has been made).

Clawback

The RSUs are subject to mandatory repayment by you to the Company to the extent you are or in the future become subject to (i) any “clawback” or recoupment policy that is adopted by the Company or a subsidiary of the Company to comply with the requirements of any applicable laws, or (ii) any applicable laws which impose mandatory recoupment, under circumstances set forth in such applicable laws.

Adjustments

The number of Shares subject to issuance upon vesting of the RSUs is subject to adjustment in accordance with Section 4(c) of the Plan. The RSUs shall be subject to the terms of any applicable agreement of merger, liquidation or reorganization in the event the Company is subject to such corporate activity.

Applicable Law

This Agreement will be interpreted and enforced under the laws of the Province of British Columbia and the laws of Canada applicable therein, other than any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

The Plan

The text of the Plan is incorporated into this Agreement by reference.

This Agreement and the Plan constitute the entire understanding between you and the Company regarding the RSUs. Any prior agreements, commitments or negotiations concerning this grant are superseded; except that any written employment, consulting, confidentiality, non-solicitation, non-competition, and/or severance agreement between you and the Company or any subsidiary of the Company shall supersede this Agreement with respect to its subject matter.

Data Privacy

In order to administer the Plan, the Company may process personal data about you. Such data includes, but is not limited to the information provided in this Agreement and any changes thereto, other appropriate personal and financial data about you such as home address and business addresses and other contact information, payroll information and any other information that might be deemed appropriate by the Company to facilitate the administration of the Plan.

By accepting this grant of RSUs, you give explicit consent to the Company to process any such personal data. You also give explicit consent to the Company to transfer any such personal data outside the country in which you work or are employed, including, with respect to non-U.S. resident grantees, to the United States, to transferees who shall include the Company and other persons who are designated by the Company to administer the Plan.

Consent to Electronic Delivery

By accepting this grant of RSUs, you consent to receive documents related to the RSUs by electronic delivery (including e-mail or reference to a website or other URL) and, if requested, agree to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company, and your consent shall remain in effect throughout your term of Service and thereafter until you withdraw such consent in writing to the Company.

Code Section 409A

The RSUs are intended to be exempt from, Code Section 409A except to the extent subject thereto, in which case the RSUs are intended to comply with Code 409A, and, accordingly, to the maximum extent permitted, this Agreement will be interpreted and administered to be in compliance with Code Section 409A. Notwithstanding anything to the contrary in the Plan or this Agreement, neither the Company, any subsidiaries of the Company, the Board, nor the Committee will have any obligation to take any action to prevent the assessment of any excise tax or penalty on you under Code Section 409A, and neither the Company, any subsidiaries of the Company, the Board, nor the Committee will have any liability to you for such tax or penalty.

For purposes of this Agreement, a termination of Service only occurs upon an event that constitutes a “separation from service” (within the meaning of Code Section 409A and the regulations thereunder). Notwithstanding anything in this Agreement to the contrary, if at the time of your separation from service, (i) you are a “specified employee” (within the meaning of Code Section 409A and the regulations thereunder, and using the identification methodology selected by the Company from time to time), and (ii) the Company makes a good faith determination that an amount payable to you on account of such separation from service constitutes deferred compensation (within the meaning of Code Section 409A) the payment of which is required to be delayed pursuant to the six (6)-month delay rule set forth in Code Section 409A in order to avoid taxes or penalties under Section 409A (the “**Delay Period**”), then the Company will not pay such amount on the otherwise scheduled payment date but will instead pay it in a lump sum on the first payroll date after such Delay Period (or upon your death, if earlier), without interest thereupon.

Successors and Assigns

This Agreement shall inure to the successors and assigns of the parties; provided, however, that neither this Agreement nor any rights hereunder may be assigned by you, except to the extent expressly permitted herein.

Severability

If any provision of this Agreement is held invalid or unenforceable by any court of competent jurisdiction, the other provisions of this Agreement will remain in full force and effect. Any provision of this Agreement held invalid or unenforceable only in part or degree will remain in full force and effect to the extent not held invalid or unenforceable.

Arbutus Biopharma Corporation

List of Subsidiaries

Name	Jurisdiction
Arbutus Biopharma Inc.	Delaware, United States of America

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

1. Registration Statement (Form S-8 No. 333-266527) pertaining to the Arbutus Biopharma Corporation 2016 Omnibus Share and Incentive Plan,
2. Registration Statement (Form S-3 No. 333-260782) pertaining to the offering, issuance and sale of up to (a) \$250,000,000 of common shares, preferred shares, warrants, debt securities and units of Arbutus Biopharma Corporation and (b) 38,847,462 common shares offered by the selling shareholder named therein,
3. Registration Statement (Form S-3 No. 333-248467) pertaining to the offering, issuance and sale of up to \$200,000,000 of common shares, preferred shares, warrants, debt securities and units of Arbutus Biopharma Corporation,
4. Registration Statement (Form S-8 No. 333-258494) pertaining to the Arbutus Biopharma Corporation 2016 Omnibus Share and Incentive Plan,
5. Registration Statement (Form S-8 No. 333-239407) pertaining to the Arbutus Biopharma Corporation 2016 Omnibus Share and Incentive Plan and the Arbutus Biopharma Corporation 2020 Employee Stock Purchase Plan,
6. Registration Statement (Form S-8 No. 333-233192) pertaining to the Inducement Stock Option Award of Arbutus Biopharma Corporation,
7. Registration Statement (Form S-8 No. 333-228919) pertaining to the Arbutus Biopharma Corporation 2011 Omnibus Share Compensation Plan,
8. Registration Statement (Form S-8 No. 333-212115) pertaining to the Arbutus Biopharma Corporation 2016 Omnibus Share and Incentive Plan,
9. Registration Statement (Form S-8 No. 333-202762) pertaining to the OnCore Biopharma, Inc. 2014 Equity Incentive Plan, and
10. Registration Statement (Form S-8 No. 333-186185) pertaining to the Tekmira 2011 Omnibus Share Compensation Plan, the Tekmira Share Option Plan and the Protiva 2000 Incentive Stock Option Plan,

of our report dated March 2, 2023, with respect to the consolidated financial statements of Arbutus Biopharma Corporation included in this Annual Report (Form 10-K) of Arbutus Biopharma Corporation for the year ended December 31, 2022.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
March 2, 2023

CERTIFICATION PURSUANT TO RULE 13a-14 AND 15d-14 OF THE SECURITIES
EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE
SARBANES-OXLEY ACT OF 2002

I, William Collier, President and Chief Executive Officer of Arbutus Biopharma Corporation, certify that:

1. I have reviewed this Annual Report on Form 10-K of Arbutus Biopharma Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2023

/s/ William Collier

Name: William Collier
Title: President and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION PURSUANT TO RULE 13a-14 AND 15d-14 OF THE SECURITIES
EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE
SARBANES-OXLEY ACT OF 2002

I, David C. Hastings, Chief Financial Officer of Arbutus Biopharma Corporation, certify that:

1. I have reviewed this Annual Report on Form 10-K of Arbutus Biopharma Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2023

/s/ David C. Hastings

Name: David C. Hastings
Title: Chief Financial Officer
(Principal Financial Officer)

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Arbutus Biopharma Corporation (the “Company”) on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I William Collier, President and Chief Executive Officer of the Company, certify that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of the operations of the Company.

Date: March 2, 2023

/s/ William Collier

Name: William Collier
Title: President and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Arbutus Biopharma Corporation (the “Company”) on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I David C. Hastings, Chief Financial Officer of the Company, certify that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of the operations of the Company.

Date: March 2, 2023

/s/ David C. Hastings

Name: David C. Hastings
Title: Chief Financial Officer
(Principal Financial Officer)