

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, 2020

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.

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, 2020, 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 \$129,686,974 (based on the closing price of \$1.82 per share as reported on the Nasdaq Global Select Market as of that date).

As of March 3, 2021, the registrant had 95,583,915 common shares, without par value, outstanding. In addition, the registrant had outstanding 1,164,000 convertible preferred shares, which will be mandatorily converted into approximately 23 million common shares on October 18, 2021. Assuming the convertible preferred shares were converted as of March 3, 2021, the registrant would have had approximately 118 million common shares outstanding at March 3, 2021.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2021 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, 2020, 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 impact of the COVID-19 pandemic on our business;
- 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”);
- our beliefs and development path and strategy to achieve a curative combination regimen for HBV;
- obtaining necessary regulatory approvals;
- obtaining adequate financing through a combination of financing activities and operations;
- using the results from our HBV studies to adaptively design additional clinical trials to test the efficacy of the combination therapy and the duration of the result in patients;
- the expected timing of and amount for payments related to the Enantigen Therapeutics, Inc.’s transaction and its programs;
- the potential of our product candidates to improve upon the standard of care and contribute to a functional curative combination treatment regimen;
- the potential benefits of the reversion of the Ontario Municipal Employees Retirement System (“OMERS”) royalty monetization transaction for our ONPATTRO® (Patisiran) (“ONPATTRO”) royalty interest;
- developing a suite of products that intervene at different points in the viral life cycle, with the potential to reactivate the host immune system;
- using pre-clinical results to adaptively design clinical trials for additional cohorts of patients, testing the combination and the duration of therapy;
- selecting combination therapy regimens and treatment durations to conduct Phase 3 clinical trials intended to ultimately support regulatory filings for marketing approval;
- the potential of substantially increasing diagnosis and treatment rates for people with chronic HBV through the introduction of an HBV curative regimen with a finite duration;
- expanding our HBV product candidate pipeline through internal development, acquisitions and in-licenses;
- our expectation for additional data from ongoing cohorts of the Phase 1a/1b trial of AB-729 to be available late in the first half of 2021 (other than initial data from the 90 mg every 12 week cohort, which is expected in the second half of 2021);
- our expectation that AB-729 could be combined with our lead capsid inhibitor candidate, AB-836, and approved NAs, in our first combination therapy for HBV patients;
- our intention to initiate multiple Phase 2 clinical trials with AB-729, some with one or more investigational agents, in both the first half and second half of 2021;
- our expectations regarding the anticipated trial design, timing, number of patients and dosing of our Phase 2 clinical trial of Assembly Biosciences, Inc.’s investigational HBV core inhibitor candidate, also known as a capsid inhibitor, vebicorvir, in combination with our proprietary GalNAc delivered RNAi therapeutic candidate, AB-729, and standard-of-care nucleos(t)ide reverse transcriptase inhibitor (NrtI) therapy for the treatment of patients with chronic HBV infection;
- the potential for an oral HBsAg-reducing agent and potential all-oral combination therapy;
- our expectation for AB-836 to progress into a Phase 1a/1b clinical trial in the first half of 2021 and for us to obtain initial data therefrom in the second half of 2021;
- the potential for AB-836 to have increased potency and an enhanced resistance profile, compared to our previous capsid inhibitor candidate, AB-506;
- the potential for AB-836 to be once-daily dosing;

- the potential for AB-79 to have a dosing schedule as infrequently as every 8 to 12 weeks;
- our expectation to pursue development of a next generation oral HBV RNA-destabilizer;
- the potential for us to discover and/or develop new molecular entities for treating coronaviruses, including COVID-19;
- payments from the Gritstone Oncology, Inc. licensing agreement;
- the potential for royalty payments from the agreement related to Genevant Sciences Ltd.;
- the expected return from strategic alliances, licensing agreements, and research collaborations;
- statements with respect to revenue and expense fluctuation and guidance;
- having sufficient cash resources to fund our operations through the third quarter of 2022 based on our expectation of a net cash burn between \$70 million and \$75 million in 2021; and
- obtaining funding to maintain and advance our business from a variety of sources including public or private equity or debt financing, collaborative arrangements with pharmaceutical companies, other non-dilutive commercial arrangements and government grants and contracts.

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, 2020.

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 additional capital to fund our operations, and such capital may be dilutive to shareholders or impose operational restrictions. If such capital is not available, we may need to delay, limit or eliminate our research, development and commercialization programs and modify our overall 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, and we may never be profitable.
- The COVID-19 coronavirus 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 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.
- Pre-clinical studies and data during our clinical trials are not necessarily predictive of the results or success of ongoing or later clinical trials. If we cannot replicate the results from our pre-clinical studies and initial clinical trials, we may be unable to successfully develop and commercialize 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, and we may fail to obtain the necessary regulatory approvals to market our 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 subjects in our clinical trials, which could delay or prevent our clinical trials.
- Any approved product candidates may be negatively impacted by future development or regulatory difficulties.
- We face significant competition from other biotechnology and pharmaceutical companies targeting HBV.
- We are largely dependent on the future commercial success of our HBV product candidates.
- We may incur substantial liabilities and may be required to limit commercialization of our products.
- 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 U.S. and Canadian healthcare laws and regulations. This could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from participation in government healthcare programs, curtailment or restricting of our operations and diminished profits and future earnings.
- Failure to comply with the United States Foreign Corrupt Practices Act, and potentially other global anti-corruption and anti-bribery laws such as the Canadian Corruption of Foreign Public Officials Act, could subject us to adverse consequences.

Risks Related to Our Dependence on Third Parties

- We expect to depend 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 license agreement with Alnylam Pharmaceuticals, Inc. for the commercialization of ONPATTRO™ (Patisiran). In addition, we are dependent on Assembly Biosciences, Inc. (“Assembly”) pursuant to our clinical collaboration agreement, and as such we are subject to the efforts of Assembly and our ability to successfully collaborate with Assembly.
- 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.
- If the third parties we rely on to conduct our clinical trials fail to meet their obligations, perform services satisfactorily, and/or comply with legal requirements, our development plans may be adversely affected.
- 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.

Risks Related to Our Intellectual Property

- Other companies 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.
- 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.
- 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 with insiders, as well as director nomination rights held by the largest shareholder, will likely limit the ability of the other shareholders to influence corporate matters.
- 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 a “passive foreign investment company” for the current or any future taxable year, investors subject to U.S. federal taxation would likely suffer materially adverse U.S. federal income tax consequences.
- Our articles and certain Canadian laws could delay or deter a change of control.

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 could face liability from our use of hazardous and radioactive materials in our research and development processes.
- 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 financial condition, results of operations or cash flows, dilute our shareholders' ownership, incur debt or cause us to incur significant expense.

PART I

Item 1. Business

Overview

Arbutus Biopharma Corporation (“Arbutus”, the “Company”, “we”, “us”, and “our”) is a clinical-stage, biopharmaceutical company focused primarily on developing a cure for people with chronic hepatitis B virus (“HBV”) infection. We are advancing multiple product candidates with distinct mechanisms of action and we believe the combination of two or more of these product candidates has the potential to provide a new curative regimen for chronic HBV infection. We have also initiated a drug discovery and development effort for treating coronaviruses, including COVID-19.

Strategy

The core elements of our strategy include:

- **Developing a broad portfolio of proprietary therapeutic product candidates that target multiple elements of the HBV viral lifecycle.** Our HBV product pipeline includes RNA interference (“RNAi”) therapeutics, oral capsid inhibitors, oral HBV RNA destabilizer compounds and oral compounds that inhibit PD-L1 with the intention of reawakening patients’ HBV-specific immune response. We believe that suppressing HBV DNA replication and hepatitis B surface antigen (“HBsAg”) expression as well as reawakening patients’ HBV-specific immune response are the most important elements to achieving a functional cure. We define a functional cure as unquantifiable plasma HBV DNA and HBsAg levels greater than six months after end of therapy with or without quantifiable anti-HBsAg antibodies.

Our two lead product candidates are AB-729, our proprietary subcutaneously-delivered RNAi 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, and AB-836, our proprietary next-generation oral capsid inhibitor that suppresses HBV DNA replication.

AB-729 is currently in an ongoing Phase 1a/1b clinical trial. We have announced positive preliminary results from several single and multi-dose cohorts of subjects with chronic HBV infection, which have demonstrated that treatment with AB-729 resulted in meaningful declines in HBsAg while being well tolerated with no serious adverse events noted after both single and repeat dosing. We expect to provide additional data from ongoing cohorts of this Phase 1a/1b clinical trial in the first half of 2021, except for initial data from the 90 mg every 12-week cohort which is expected in the second half of 2021.

We expect AB-836 to progress into a Phase 1a/1b clinical trial in the first half of 2021 with initial data anticipated in the second half of 2021. AB-836 is from a novel chemical series differentiated from competitor compounds and has the potential to provide increased efficacy and an enhanced resistance profile.

Additionally, we are in lead optimization with oral compounds that inhibit PD-L1 with the intention of reawakening patients’ HBV-specific immune response and next-generation oral HBV RNA destabilizer compounds that are designed to destabilize and ultimately degrade HBV RNAs resulting in the reduction of HBsAg.

- **Creating combinations of therapeutic product candidates with complementary mechanisms of action designed to provide a functional cure for people with chronic HBV infection.** We believe that our proprietary product candidates AB-729 and AB-836, along with existing approved therapies, may be combined into our first combination therapy for people with chronic HBV infection. Additionally, through our collaboration with Assembly Biosciences, Inc. (“Assembly”), screening has initiated for a Phase 2 proof-of-concept clinical trial with AB-729, our RNAi product candidate, in combination with Assembly’s lead HBV core inhibitor (capsid inhibitor) product candidate, vebicorvir (“VBR”), and nucleos(t)ide analog (“NA”) therapy for the treatment of people with chronic HBV infection. We also intend to initiate two Phase 2 clinical trials with AB-729, both with one or more approved or investigational agents, in the second half of 2021.

- **Advancement of an internal research program focused on identifying new small molecule antiviral medicines 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 nsp12 viral polymerase and the nsp5 viral protease.

Background

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. Chronic HBV infection 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 250 million people worldwide suffer from chronic HBV infection, while other estimates indicate that approximately 2 million people in the United States suffer from chronic HBV infection. Even with the availability of effective vaccines and current treatment options, approximately 900,000 people die every year from complications related to chronic HBV infection. We believe there is a compelling market opportunity for an HBV curative regimen. Currently, an estimated 27 million (10.5%) of a total of over 250 million people worldwide with chronic HBV infection are diagnosed and approximately 4.5 million (1.8%) 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 chronic HBV.

Current treatments and their limitations

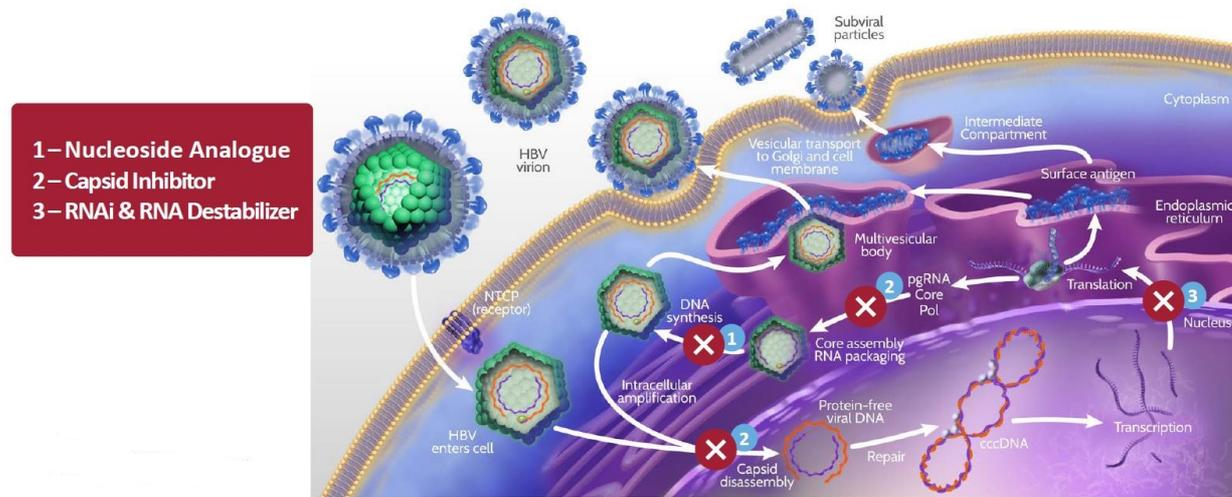
Today's current treatment options for chronic HBV infection include pegylated interferon- α regimens ("Peg-IFN α ") and nucleos(t)ide analogues ("NAs"). Peg-IFN α , a synthetic version of a substance produced by the body to fight infection, is administered by injection and has numerous side effects including flu-like symptoms and depression. NAs are oral antiviral medications which, when taken chronically, reduce HBV virus replication and inflammation and significantly reduce HBV DNA in the blood. Oral NAs 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, easy 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 chronic HBV infection are required to take NA therapy daily for the rest of their lives.

HBV Lifecycle and Key Points for Intervention

The viral lifecycle of HBV is shown below. Given the biology of HBV, we believe combination therapies are the key to more effective HBV treatment and a potential functional cure. Our product pipeline includes multiple product candidates that target various steps in the viral lifecycle. We believe each of these mechanisms, when administered for a finite duration in combination with existing approved therapies, have the potential to improve upon the standard of care and potentially lead to a functional cure.

HBV Lifecycle Illustrates Key Points for Intervention

A combination of agents with complementary MOA is needed to cure HBV



- 1 – Nucleoside Analogue
- 2 – Capsid Inhibitor
- 3 – RNAi & RNA Destabilizer

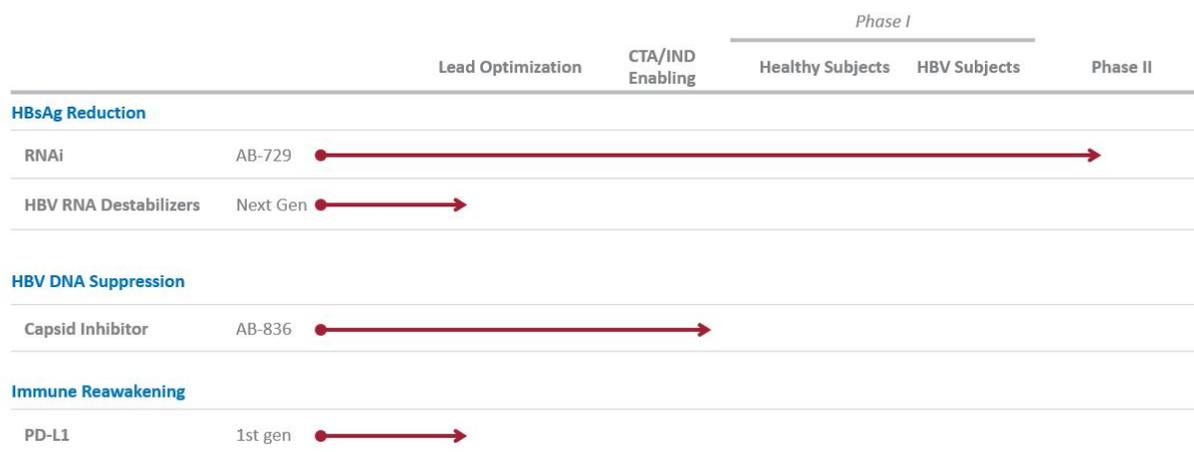
1. NAs: NAs work by inhibiting HBV DNA polymerase activity and suppressing HBV replication. However, NAs functionally cure only a small percentage of patients and typically require chronic dosing to maintain their benefits, which can be challenging for patients.
2. Capsid inhibitor (AB-836): this orally-delivered product candidate has the potential to inhibit HBV replication by preventing the assembly of functional viral capsids. HBV core protein assembles into a capsid structure, which is required for viral replication. The current standard-of-care therapy for HBV, primarily NAs that work by inhibiting the viral polymerase, significantly reduce virus replication, but not completely. Capsid inhibitors inhibit replication by destabilizing core particle assembly or disassembly. Capsid inhibitors also have been shown to inhibit the uncoating step of the viral life cycle thus reducing the formation of new covalently closed circular DNA ("cccDNA"), the viral reservoir which resides in the cell nucleus and which is believed to play a role in viral persistence.
3. RNAi (AB-729): this subcutaneously-delivered RNAi therapeutic product candidate targeted to hepatocytes uses our novel covalently conjugated N-acetylgalactosamine ("GalNAc") delivery technology. AB-729 inhibits viral replication and reduces all HBV antigens, including HBsAg. Reducing HBsAg is thought to be a key prerequisite to enable reawakening of a patient's immune system to respond to the virus.

HBV RNA destabilizers: these small molecule orally active agents cause the destabilization and ultimate degradation of HBV RNAs. These agents result in the reduction of HBsAg and other viral proteins in both whole cell systems and animal models. They have the potential to selectively impact HBV versus other RNA or DNA viruses and demonstrate pangenotypic characteristics. HBV RNA destabilizers have demonstrated additive effects in combination with other mechanism of action anti-HBV agents. HBV RNA destabilizers have the potential to complement or replace subcutaneously delivered RNAi agents with an oral therapy in combination with a capsid inhibitor and an approved NA.

Our Product Pipeline

Our HBV product pipeline consists of the following programs:

Arbutus HBV Pipeline



In addition to our HBV product pipeline, we have an internal research program focused on identifying new small molecule antiviral medicines to treat COVID-19 and future coronavirus outbreaks.

We continue to explore expansion of our HBV pipeline through internal discovery and development and potential strategic alliances.

Our Product Candidates

GalNAc RNAi (AB-729)

RNAi therapeutics represent a recent 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 chronically infected with HBV. 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 therapeutic targeted to hepatocytes using our proprietary covalently conjugated GalNAc delivery technology. AB-729 reduces all HBV antigens and inhibits viral replication. In July 2019, we initiated a single- and multi-dose Phase 1a/1b clinical trial for AB-729, designed to investigate the safety, tolerability, pharmacokinetics, and pharmacodynamics of AB-729 in healthy volunteers and in chronic HBV subjects and determine the most appropriate doses and dosing intervals to take forward into Phase 2 clinical development.

The ongoing first-in-human clinical trial of AB-729 consists of three parts:

- In Part 1, three cohorts of healthy volunteers were randomized 4:2 to receive single doses (60 mg, 180 mg or 360 mg) of AB-729 or placebo.
- In Part 2, non-cirrhotic, hepatitis B e-antigen ("HBeAg") positive or negative chronic HBV subjects (n=6) currently taking NA therapy with HBV DNA below the limit of quantitation received single doses (60 mg to 180 mg) of AB-729. An additional cohort in Part 2 included 90 mg single-dose of AB-729 in HBV DNA positive chronic HBV subjects (n=6).

- In Part 3, chronic HBV subjects, HBV DNA negative first and HBV DNA positive later, receive multiple doses of AB-729 for up to six months. Upon completion of six months of dosing, so far, all subjects in the 60 mg dose every 4 weeks and 60 mg dose every 8 weeks cohorts have elected the option to re-consent and receive an additional six months of dosing for a total of 48 weeks.

Part 1 of the trial, which dosed healthy volunteers, was completed and supported advancing doses ranging from 60 mg to 180 mg into Part 2. We expect Part 2, which dosed subjects with chronic HBV infection with single doses of AB-729, to complete its 48 weeks of follow-up period in the first half of 2021. Additionally, several cohorts in Part 3 have received multiple doses of AB-729. Results to date demonstrate that treatment of AB-729 has been safe and well tolerated. Efficacy results to date suggest that:

- Single doses of 60 mg, 90 mg and 180 mg resulted in comparable mean HBsAg declines at week 12 followed by a sustained plateau phase (-0.99 log₁₀ IU/mL vs -1.23 log₁₀ IU/mL, vs -1.10 log₁₀ IU/mL, respectively)
- Repeat dosing using the 60 mg dose every 4 weeks resulted in a continuous and robust mean HBsAg decline at week 16 (-1.44 log₁₀ IU/mL, N=7) and continued through week 24 (-1.84 log₁₀ IU/mL, N=7)
- Repeat dosing using the 60 mg dose every 8 weeks resulted in comparable mean HBsAg declines relative to the 60 mg dose every 4 weeks at week 16 (-1.39 log₁₀ IU/mL vs -1.44 log₁₀ IU/mL, p<0.7, respectively)
- In HBV DNA positive HBV subjects, a single 90 mg dose resulted in robust mean declines in HBsAg (-1.02 log₁₀ IU/mL) and HBV DNA (-1.53 log₁₀ IU/mL) at week 12, as well as decreases in HBV RNA and core-related antigen
 - Similar mean HBsAg reductions were observed in HBV DNA positive and negative chronic HBV subjects
 - These findings support complete target engagement by AB-729

We expect to provide additional data from ongoing cohorts of the Phase 1a/1b clinical trial in the first half of 2021, including additional data from the 60 mg multi-dose cohort (4 week and 8 week dosing intervals), initial data from the 90 mg multi-dose cohort (8 week dosing interval), and initial data from the 90 mg multi-dose cohort (8 week dosing interval) in HBV DNA positive subjects. We expect initial data from the 90 mg every 12-week dosing interval cohort to be available in the second half of 2021. Additionally, we intend to advance AB-729 into two Phase 2 combination clinical trials with one or more approved or investigational agents in the second half of 2021 with dosing of AB-729 as infrequently as every 8 or 12 weeks.

Collaboration with Assembly

In August 2020, we entered into a clinical collaboration agreement with Assembly to evaluate AB-729 in combination with Assembly's lead HBV core inhibitor (capsid inhibitor) candidate vebicorvir ("VBR") and standard-of-care NA therapy for the treatment of subjects with chronic HBV infection. Under the terms of the agreement, this trial will be a randomized, multi-center, open-label Phase 2 proof-of-concept clinical trial that will evaluate the safety, pharmacokinetics, and antiviral activity of the triple combination of AB-729, VBR, and an NA compared to the double combinations of VBR with an NA and AB-729 with an NA. We expect to enroll approximately 60 virologically-suppressed subjects with HBeAg negative chronic HBV infection in the first cohort of this trial. Patients will be dosed for 48 weeks with AB-729 60 mg subcutaneously every 8 weeks and VBR 300 mg orally once daily, with a 48-week follow-up period. We and Assembly recently initiated screening for this clinical trial. We and Assembly will share in the costs of the collaboration. Under the terms of the collaboration, we and Assembly may also add additional cohorts in the future to evaluate other patient populations and/or combinations. 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 our AB-729 compound.

Oral Capsid Inhibitors (AB-836)

HBV core protein assembles into a capsid structure, which is required for viral replication. The current commercially available therapies (NAs or Peg-IFN) significantly reduce HBV DNA levels in the serum, but HBV replication continues in the liver, thereby enabling HBV infection to persist. More effective therapies for patients require new agents which will further block viral replication. We are developing capsid inhibitors (also known as core protein inhibitors) as oral therapeutics which, in combination with NAs, could further reduce HBV replication. By inhibiting assembly of functional viral capsids, the ability of HBV to replicate is impaired. Capsid inhibitor molecules also inhibit the uncoating step of the viral life cycle and thus reduce the formation of cccDNA, the viral reservoir which resides in the cell nucleus, and which is believed to play a role in viral persistence.

Our oral capsid inhibitor discovery effort generated promising next-generation compounds, which led to the nomination of AB-836 in January 2020. AB-836 is a novel chemical series differentiated from competitor compounds with the potential for increased efficacy and an enhanced resistance profile. AB-836 leverages a novel binding site within the core protein dimer-dimer interface, has shown to be active against NA resistant variants and has the potential to address certain known capsid resistant variants. AB-836 is anticipated to be combinable with other mechanisms of action and is also anticipated to be dosed once daily. We completed CTA/IND-enabling studies for AB-836 in the fourth quarter of 2020 and anticipate initiating a Phase 1a/1b clinical trial for AB-836 in the first half of 2021 with initial data expected in the second half of 2021.

Oral PD-L1 Inhibitors

PD-L1 inhibitors complement our pipeline of agents and could potentially be an important part of a combination therapy for the treatment of HBV. 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 chronic HBV infection. One approach to boost HBV-specific T cells is to prevent PD-L1 proteins from attaching to and inhibiting the HBV-specific T cells. We are in lead optimization with oral compounds which are potentially capable of reawakening patients' HBV-specific immune response by inhibiting PD-L1.

Oral HBV RNA Destabilizers

HBV RNA destabilizers are small molecule orally available agents that cause the destabilization and ultimate degradation of HBV RNAs. These agents result in the reduction of HBsAg and other viral proteins in both whole cell systems and animal models. They have the potential to selectively impact HBV versus other RNA or DNA viruses and demonstrate pangenotypic characteristics. HBV RNA destabilizers have demonstrated additive effects in combination with other anti-HBV mechanisms of action. HBV RNA destabilizers have the potential to complement or replace subcutaneously delivered RNAi agents, such as AB-729, with an oral therapy in combination with a capsid inhibitor and an approved NA. We continue to advance next-generation oral HBV RNA-destabilizers through lead optimization.

COVID-19 Research Efforts

While our core mission is to find a cure for HBV, the magnitude of the coronavirus pandemic is undeniable. Given our proven expertise in the discovery of new antiviral therapies, we initiated a drug discovery effort for treating coronaviruses, including COVID-19, in 2020. 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 new program. We are also a member of the COVID R&D consortium to address the SARS-CoV-2 pandemic and any future coronavirus outbreaks. At this time, our COVID-19 research program is focused on the discovery and development of new molecular entities that address specific viral targets including the nsp12 viral polymerase and the nsp5 viral protease. These targets are essential viral proteins which we have experience in targeting. We are actively screening multiple new oral molecular entities.

COVID-19 Impact

In December 2019, an outbreak of a novel strain of coronavirus (COVID-19) was identified in Wuhan, China. This virus continues to spread globally, has been declared a pandemic by the World Health Organization and has spread to nearly every country in the world. The impact of this pandemic has been, and will likely continue to be, extensive in many aspects of society. The pandemic has resulted in and will likely continue to result in significant disruptions to businesses. A number of countries and other jurisdictions around the world have implemented extreme measures to try and slow the spread of the virus. These measures include the closing of businesses and requiring people to stay in their homes, the latter of which raises uncertainty regarding the ability to travel to hospitals in order to participate in clinical trials. Additional measures that have had, and will likely continue to have, a major impact on clinical development, at least in the near-term, include shortages and delays in the supply chain, and prohibitions in certain countries on enrolling subjects in new clinical trials. Future disruptions related to the COVID-19 pandemic could negatively impact our plans and timelines in 2021 and beyond, including enrolling and monitoring subjects in our clinical trials.

Collaborations and Royalty Entitlements

Collaboration with Assembly

In August 2020, we entered into a clinical collaboration agreement with Assembly to evaluate AB-729 in a Phase 2 proof-of-concept clinical trial in combination with Assembly's lead HBV core inhibitor (capsid inhibitor) candidate VBR and standard-of-care NA therapy for the treatment of patients with chronic HBV infection. We and Assembly have initiated screening and will share in the costs of the collaboration.

Alnylam Pharmaceuticals, Inc. and Acuitas Therapeutics, Inc.

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 Food and Drug Administration ("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, 2020, an aggregate of \$5.1 million of royalties have been collected by OMERS.

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"). 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 the discovery, development, and commercialization of a broad range of RNA-based therapeutics enabled by our LNP and ligand conjugate delivery technologies. We licensed exclusive 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, we are entitled to receive tiered low single-digit

royalties on future sales of Genevant products covered by the licensed patents. If Genevant sub-licenses the intellectual property licensed by us to Genevant, we are entitled to receive under the Genevant License, upon the commercialization of a product developed by such sub-licensee, the lesser of (i) twenty percent of the revenue received by Genevant for such sublicensing and (ii) tiered low single-digit royalties on product sales by the sublicensee.

On July 23, 2020, the United States Patent and Trademark Office before the Patent Trial and Appeal Board (“PTAB”) announced its decision in Moderna Therapeutics, Inc.’s (“Moderna”) challenge of the validity of U.S. Patent 8,058,069 (“the ‘069 Patent”). In this decision, the PTAB determined no challenged claims were unpatentable. On September 23, 2020, Moderna appealed the ‘069 Patent decision to the Federal Circuit Court of Appeals. Moderna filed its opening brief in that appeal on February 23, 2021, and our responsive brief is due on May 4, 2021. While we are the patent holder, this patent has been licensed to Genevant. The ‘069 Patent was included in the exclusive rights licensed by us to Genevant under the Genevant License.

On July 31, 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, 2020, 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 under the Genevant License was not impacted by the recapitalization.

Gritstone Oncology, Inc.

In October 2017, we entered into a license agreement with Gritstone Oncology, Inc. (“Gritstone”) that granted Gritstone a worldwide license to our 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 us an upfront payment, and is obligated to make payments to us for achievement of development, regulatory, and commercial milestones, as well as royalties (which Genevant has a right to 50% of such royalty payments under the Genevant License).

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, 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 parte 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 parte 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 or RNAi platform, including our product candidates.

We have a portfolio of approximately 55 patent families, in the United States and abroad, that are directed to our therapeutic HBV product candidates, HBV technology and various aspect of LNPs and LNP formulations. The portfolio includes approximately 150 issued patents throughout the world and an extensive portfolio of pending patent applications. The earliest any of the material patents with respect to our current product candidates will expire is 2037.

Human Capital

We are committed to an inclusive culture that values equality, opportunity, and respect. We seek to secure and develop top talent with a diversity of thought, experiences and backgrounds. Drug development is a complex endeavor that requires deep expertise and attracting and retaining qualified employees for specialized biopharmaceutical positions is very competitive. 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 geography and company size, a comprehensive benefit package and equity compensation for every employee. Bonus opportunity and equity compensation generally increase as a percentage of total compensation based on level of responsibility. Actual bonus payout is based on performance. We also provide eligible employees the opportunity to participate in our employee stock purchase plan and wellness programs to allow our employees to maintain a work/life balance while striving to achieve company objectives.

We are invested in the development of our employees, including performance management and mentorship programs. In 2020, we experienced our lowest turnover in the previous five years. Given our financial resources and our track record, we continue to be successful in filling vacated positions and in supporting our expanding pipeline of research programs and product candidates. 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 to contract manufacturers. Our in-house clinical development and manufacturing teams implement our HBV development strategies and oversee the activities of our outside vendors.

At December 31, 2020, Arbutus had 78 employees (76 full-time and 2 part-time), 57 of whom were engaged in research and development, including three medical doctors, 30 individuals with Doctors of Philosophy (PhDs) degrees, and eight scientists with Master of Science degrees. Substantially all of our employees work out of our corporate headquarters in Warminster, PA. 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.

During the COVID-19 pandemic, fewer than half of our employees have continued to work at our facilities, where we have adopted health screening, implemented social distancing and personal protective equipment requirements, enhanced cleaning and sanitation procedures, and modified workspaces to reduce the potential for disease transmission. Our employees who do not require access to our facility to perform their work have been working from home during the pandemic. The change in protocols and working arrangements have not had a significant impact on productivity.

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. 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, Dicerna Pharmaceuticals, Replicor, Enanta Pharmaceuticals and Aligos Therapeutics. These companies are developing products such as capsid

inhibitors, RNAi agents, immune modulators, surface antigen inhibitors, and gene editing agents. 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.

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 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 and AB-836, 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 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 adverse events. 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. 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 U.S. Patent and Trademark Office (“USPTO”), in consultation with the FDA, reviews and approves the application for patent term restoration.

Post-Approval Regulation

Once approved, drug products are subject to continuing extensive regulation by the FDA. 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 cGMP 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.

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 could affect our ability to operate our business. These restrictions under applicable federal and state health care fraud and abuse laws and regulations that may affect our ability to operate include:

- The 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 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 federal Anti-Kickback Law constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exemptions and regulatory safe harbors to the 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 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.
- 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 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. Beginning in 2022, applicable manufacturers also will be 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 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.

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 the Health Insurance Portability and Accountability Act of 1996 (“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 obtain, use or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

In California, the CCPA took effect on January 1, 2020. 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 data. The CCPA and its implementing regulations have already been amended multiple times since their enactment. 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. These laws and regulations are evolving and subject to interpretation, and may impose limitations on our activities or otherwise adversely affect our business. Similarly, there are 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.

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 government 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 Part B of the Medicare program.

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.

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 by the Health Care and Education Reconciliation Act of 2010 (collectively, 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 repeal or replace 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. Currently, the Supreme Court is considering whether the Affordable Care Act’s individual mandate, post-repeal of its associated tax penalty, is unconstitutional, and, if so, whether the remaining provisions of the Affordable Care Act are inseverable from the mandate. A ruling is expected by mid-2021 and could produce any of a number of results, including invalidation of the Affordable Care Act in its entirety if there is a finding of inseverability. It is unclear how the ultimate decision in this case, or other efforts to repeal, replace or otherwise modify, or invalidate, the Affordable Care Act or its implementing regulations, or portions thereof, will impact our business. Additional legislative changes, regulatory changes, and

judicial challenges related to the Affordable Care Act remain possible. 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 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 2030 (with the exception of a temporary suspension from May 1, 2020 through March 31, 2021) unless Congress takes additional action. 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 and safety reporting. 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 the same 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.

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.

We had two wholly-owned subsidiaries as of December 31, 2020: Arbutus Biopharma, Inc. and Arbutus Biopharma US Holdings, Inc. In February 2021, Arbutus Biopharma US Holdings, Inc. merged with Arbutus Biopharma, Inc. with Arbutus Biopharma, Inc. as the surviving entity.

Protiva Biotherapeutics Inc. ("Protiva") was acquired on May 30, 2008. On January 1, 2018, Protiva was amalgamated with Arbutus Biopharma Corporation.

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 chronic HBV 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 marketable securities, which were \$123.3 million as of December 31, 2020. From January 1, 2021 through March 4, 2021, we received an additional \$24.3 million of net proceeds from the issuance of common shares under the ATM program. We believe that our cash resources will be sufficient to fund our operations through the third quarter of 2022. 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 and 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, 2020 and have not received any revenues other than from research and development collaborations, royalties, license fees and milestone payments. From inception to December 31, 2020, we have an accumulated net deficit of approximately \$1.0 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 coronavirus could adversely impact our business, including our clinical development plans.

In December 2019, a novel strain of coronavirus, SARS-CoV-2 (the “COVID-19 coronavirus”), was reported to have surfaced in Wuhan, China. Since then, the COVID-19 coronavirus has spread to multiple countries, including the United States, and has caused significant disruptions around the world. We may continue to experience disruptions as a result of the COVID-19 coronavirus 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 coronavirus pandemic concerns, including the administration of COVID-19 coronavirus 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 CROs to access and monitor clinical trial sites, and new clinical trial site policies resulting from the COVID-19 coronavirus 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 coronavirus 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 coronavirus 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 coronavirus, 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 coronavirus, or the subject could experience an adverse event that could be attributed to our product candidate.

The global outbreak of the COVID-19 coronavirus continues to rapidly evolve. The extent to which the COVID-19 coronavirus 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 clinical research organizations ("CROs") and clinical trial sites;
- delay or failure in obtaining approval of an institutional review board ("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 coronavirus 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, such as our decisions to no longer pursue the development of AB-452 and AB-506. 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, South Korea, Hong Kong, Australia and New Zealand. 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 subjects in our clinical trials, which could delay or prevent clinical trials of our product candidates.

Identifying and qualifying subjects 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 subjects to participate in testing our product candidates.

We may not be able to identify, recruit and enroll a sufficient number of subjects, 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 subjects to participate in the clinical trials (including due to the COVID-19 coronavirus pandemic);
- proximity and availability of clinical trial sites for prospective subjects;
- 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 subjects enrolled in clinical trials will drop out of the trials before completion; and
- ability to monitor subjects adequately during and after treatment.

If patients are unwilling to participate in our clinical trials, the timeline for recruiting subjects, 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.

Even if our product candidates obtain regulatory approval, they may be negatively impacted by future development or regulatory difficulties.

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 action. 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.

We face significant competition from other biotechnology and pharmaceutical companies targeting HBV.

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, Johnson & Johnson, Roche, Vir Biotechnology, GlaxoSmithKline, Gilead Sciences, Assembly Biosciences, Dicerna Pharmaceuticals, Replicor, Enanta

Pharmaceuticals and Aligos Therapeutics. Further, it is likely that additional drugs will become available in the future for the treatment of HBV.

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 market with several early 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 product candidates.

Our ability to generate revenues and become profitable will depend in large part on the future commercial success of our HBV 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 chronic HBV are lower than we 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 include the following:

- the 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 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 embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, or knowingly and willfully making false statements relating to healthcare matters;
- 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 obtain, use, or disclose 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;
- the 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 in 2022), as well as ownership and investment interests held in the company by physicians and their immediate family members; 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.

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, effect 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. 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 is not successful in commercializing ONPATTRO, the royalty entitlement may never revert back to Arbutus.

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 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 Assembly pursuant to our clinical collaboration agreement and, therefore, are subject to the efforts of Assembly and our ability to successfully collaborate with Assembly.

In August 2020, we entered into a clinical collaboration agreement with Assembly to evaluate AB-729 in combination with Assembly’s lead HBV core inhibitor (capsid inhibitor) candidate VBR and standard-of-care NA therapy for the treatment of subjects with chronic HBV infection. Under the terms of the agreement, this trial will be a randomized, multi-center, open-label Phase 2 clinical trial that will evaluate the safety, pharmacokinetics, and antiviral activity of the triple combination of AB-729, VBR, and an NA compared to the double combinations of VBR with an NA and AB-729 with an NA. This trial has initiated screening and is anticipated to enroll approximately 60 virologically-suppressed patients with HBeAg negative chronic HBV infection. Patients will be dosed for 48 weeks with AB-729 60 mg subcutaneously every 8 weeks and VBR 300 mg orally once daily, with a 48-week follow-up period. Assembly will be responsible for managing the clinical trial. Under the terms of the collaboration, we and Assembly may also add additional cohorts in the future to evaluate other patient populations and/or combinations. The success of our collaboration with Assembly depends upon the efforts of Assembly, to the extent it is responsible for performance of collaboration activities. Assembly may not be successful in performance of such activities. Assembly may change its strategic focus or pursue alternative technologies. In addition, if we have a dispute or enter into litigation with Assembly in the future, it could delay development programs, distract management from other business activities, and generate substantial expense. 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 our AB-729 compound.

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, Gritstone and Assembly, 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.

RNA interference, capsid inhibitors and RNA destabilizer, as well as our other novel HBV assets, are relatively new scientific fields that 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. Because the field is so new, very few of these patent applications have been fully processed by government patent offices around the world, and there is a great deal of uncertainty about which patents will be issued, when, to whom, and with what claims. It is likely that there could be litigation and other proceedings, such as inter parte 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 United States Patent and Trademark Office 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 with insiders, as well as director nomination rights held by the largest shareholder, will likely limit the ability of the other shareholders to influence corporate matters.

As of March 1, 2021, 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 23% of our outstanding common shares as of March 1, 2021. In addition, in October 2017, we issued 500,000 Series A participating convertible preferred shares ("Preferred Shares") to Roivant for gross proceeds of \$50.0 million. We issued a second tranche of 664,000 Preferred Shares to Roivant in January 2018 for gross proceeds of \$66.4 million. The Preferred Shares are non-voting and are convertible into common shares at a conversion price of \$7.13 per share (which represents a 15% premium to the closing price of \$6.20 per share on October 16, 2017). The Preferred Shares are currently not convertible into common shares. The purchase price for the Preferred Shares plus an amount equal to 8.75% per annum, compounded annually, will be subject to mandatory conversion into approximately 23 million common shares on October 18, 2021 (subject to limited exceptions in the event of certain fundamental corporate transactions relating to our capital structure or assets, which would permit earlier conversion at

Roivant's option). Assuming the Preferred Shares were converted as of March 1, 2021, Roivant would have held approximately 39 million common shares, or, 32%, of our outstanding common shares. Roivant has agreed to a four year lock-up period and standstill period whereby, pursuant to the standstill, Roivant will not acquire greater than 49.99% of our common shares or securities convertible into common shares. Both the lockup and standstill periods expire on October 18, 2021. Following the expiration of the standstill period, Roivant will no longer be contractually prohibited from acquiring control of our company.

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.

In addition, for so long as Roivant has beneficial ownership or exercises control or direction over not less than: (i) 30% of the issued and outstanding common shares (including common shares issuable upon the conversion of the Preferred Shares), Roivant has the right to nominate three individuals for election to our board of directors, one of whom must be "independent" within the meaning of applicable law and the rules and regulations of The Nasdaq Stock Market LLC, not including the rules related to the independence of audit committee members; (ii) 20% of the issued and outstanding common shares (including common shares issuable upon the conversion of the Preferred Shares), Roivant has the right to nominate two individuals for election to our board of directors; and (iii) 10% of the issued and outstanding common shares (including common shares issuable upon the conversion of the Preferred Shares), Roivant has the right to nominate one individual for election to our board of directors. For so long as Roivant has the right to nominate one or more directors to our board of directors, the total number of directors will not, without the prior written consent of Roivant, be permitted to exceed eight directors, the majority of whom must be "independent." While the directors appointed by Roivant are obligated to act in accordance with their fiduciary duty to the Company, they may have equity or other interests in Roivant and, accordingly, their personal interests may be aligned with Roivant's interests, which may not always coincide with our corporate interests or the interests of our other shareholders. The directors are required to disclose any potential material conflicts of interest. The current Roivant nominated directors are Frank Torti, M.D., our Chairman of the Board, Eric Venker, M.D., Pharm.D. and Keith Manchester, M.D.

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, 2020, 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, Michael J. Sofia, our Chief Scientific Officer, and Gaston Picchio, our Chief Development 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. Disruption, degradation, or manipulation of these applications and systems through intentional or accidental means could materially adversely impact key business processes. Despite the implementation of security measures, including controls over unauthorized access, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, cybersecurity breaches and other forms of unauthorized access, as well as natural disasters, terrorism, war, telecommunication and electrical failures, cyberattacks or cyber-intrusions over the Internet, loss of funds or information from phishing or other fraudulent schemes, attachments to emails, persons inside our organization, or persons with access to systems inside our organization or those with whom we do business. The risk of a security breach or disruption, particularly through cyberattacks or cyber-intrusions, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Such events could result in exposure of confidential information, 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. To the extent that any disruption or security breach results in such interruption or loss, we could incur material financial, legal, business or reputational harm, 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.

Since January 1, 2019, we have leased approximately 8,500 square feet of office space at 626 Jacksonville Rd, Warminster, Pennsylvania. The lease has a three year term and we have an option to extend the lease term to April 30, 2027.

Previously, we leased 51,000 square feet of laboratory facilities and office space located at 100-8900 Glenlyon Parkway, Burnaby, British Columbia, Canada. In early 2018, we implemented a site consolidation and organizational restructuring to align our HBV business in Warminster, Pennsylvania. We ceased use of our Burnaby facility for R&D activities as of June 30, 2018 and we allowed the lease to expire according to its terms on July 31, 2019.

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

We are 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.

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 us 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 his decision, 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 recorded a charge of \$6.3 million, consisting of \$5.9 million for the award (including interest) and \$0.4 million for an estimate of a potential award for costs and attorneys’ fees. An award for costs and attorneys’ fees is still to be determined.

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. We do not believe that any royalties are due to UBC and we intend to vigorously contest UBC’s allegation.

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 March 3, 2021, there were 102 registered holders of common shares and 95,583,915 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

We did not issue any unregistered equity securities during the year ended December 31, 2020.

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, 2020.

Item 6. Selected Financial Data

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

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

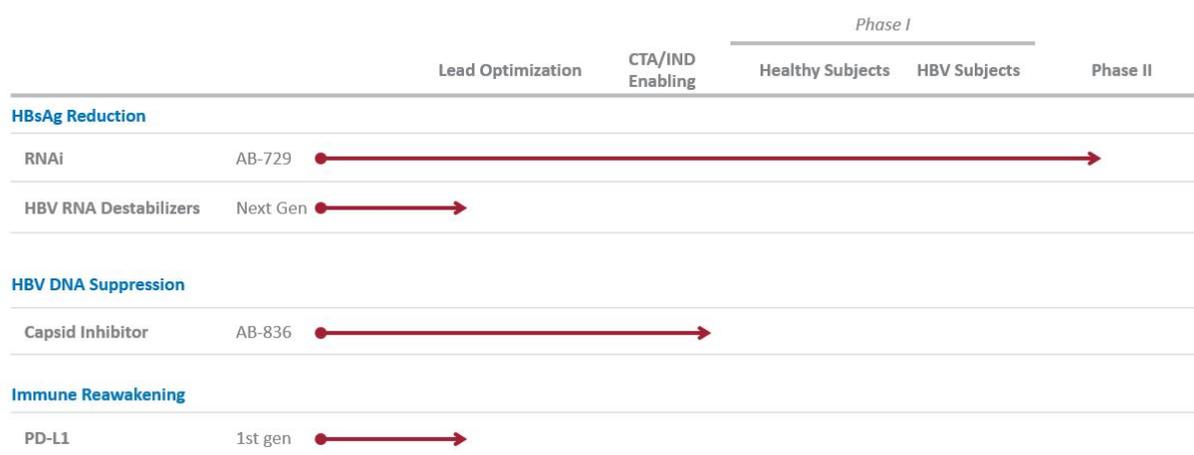
Overview

We are a clinical-stage, biopharmaceutical company focused primarily on developing a cure for people with chronic hepatitis B virus (“HBV”) infection. We are advancing multiple product candidates with distinct mechanisms of action that we believe have the potential to provide a new curative regimen for chronic HBV infection. We have also initiated a drug discovery and development effort for treating coronaviruses, including COVID-19.

Given the biology of HBV, we believe combination therapies are the key to more effective HBV treatment and a potential functional cure. Our product pipeline includes multiple product candidates that target various steps in the viral lifecycle. We believe each of these mechanisms, when administered for a finite duration in combination with existing approved therapies, have the potential to improve upon the standard of care and potentially lead to a functional cure.

Our HBV product pipeline consists of the following programs:

Arbutus HBV Pipeline



Our two lead product candidates are AB-729, our proprietary subcutaneously-delivered RNAi product candidate that suppresses HBsAg expression, and AB-836, our proprietary next-generation oral capsid inhibitor that suppresses HBV DNA replication. AB-729 is currently in an ongoing Phase 1a/1b clinical trial and we expect AB-836 to progress into a Phase 1a/1b clinical trial in the first half of 2021. In parallel, we are in lead optimization with oral compounds for our PD-L1 program and next-generation HBV RNA destabilizer program. At this time, our coronavirus research program is focused on the discovery and development of new molecular entities that address specific viral targets including the nsp12 viral polymerase and the nsp5 viral protease.

COVID-19 Impact

In December 2019, an outbreak of a novel strain of coronavirus (COVID-19) was identified in Wuhan, China. This virus continues to spread globally, has been declared a pandemic by the World Health Organization and has spread to nearly every country in the world. The impact of this pandemic has been, and will likely continue to be, extensive in many aspects of society. The pandemic has resulted in and will likely continue to result in significant disruptions to businesses. A number of countries and other jurisdictions around the world have implemented extreme measures to try and slow the spread of the virus. These measures include the closing of businesses and requiring people to stay in their homes, the latter of which raises uncertainty regarding the ability to travel to hospitals in order to participate in clinical trials. Additional measures that have had, and will

likely continue to have, a major impact on clinical development, at least in the near-term, include shortages and delays in the supply chain, and prohibitions in certain countries on enrolling subjects in new clinical trials. Future disruptions related to the COVID-19 pandemic could negatively impact our plans and timelines in 2021 and beyond, including enrolling and monitoring subjects in our clinical trials.

Collaborations and Royalty Entitlements

In August 2020, we entered into a clinical collaboration agreement with Assembly Biosciences, Inc. (“Assembly”) to evaluate AB-729 in combination with Assembly’s lead HBV core inhibitor (capsid inhibitor) candidate vebicorvir (“VBR”) and standard-of-care NA therapy for the treatment of patients with chronic HBV infection. We and Assembly will share in the costs of the collaboration.

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.

As of December 31, 2020, 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 exclusive 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”). Under the Genevant License, we are entitled to receive tiered low single-digit royalties on future sales of Genevant products covered by the licensed patents. If Genevant sub-licenses the intellectual property licensed by us to Genevant, we are entitled to receive under the Genevant License, upon the commercialization of a product developed by such sub-licensee, the lesser of (i) twenty percent of the revenue received by Genevant for such sublicensing and (ii) tiered low single-digit royalties on product sales by the sublicensee.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Contingent Consideration

The significant accounting policy that we believe to be most critical in fully understanding and evaluating our financial results relates to our contingent consideration. This accounting policy requires 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.

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 HBV. 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. These judgments include the use of, but are not limited to: future forecasts and other macroeconomic indicators that forecast market conditions, the timing and amount of estimated future revenues, market-based discount rates and other market-comparative data. 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, management risk adjusts the estimated cash flows to reflect these uncertainties.

RESULTS OF OPERATIONS

The following summarizes our results of operations for the year ended December 31, 2020 compared to the year ended December 31, 2019:

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Total revenue	\$ 6,914	\$ 6,011
Impairment of intangible assets	—	43,836
Impairment of goodwill	—	22,471
Total other operating expenses	64,720	83,605
Loss from operations	(57,806)	(143,901)
Other income (loss)	(5,939)	(22,478)
Loss before income taxes	(63,745)	(166,379)
Income tax benefit	—	12,656
Net loss	(63,745)	(153,723)
Dividend accretion of convertible preferred shares	(12,123)	(11,149)
Net loss attributable to common shares	\$ (75,868)	\$ (164,872)

For the fiscal year ended December 31, 2020, our net loss attributable to common shares was \$75.9 million, or a loss of \$1.00 per basic and diluted common share, as compared to a net loss of \$164.9 million, or a loss of \$2.89 per basic and diluted common share, for the year ended December 31, 2019.

Revenue

Revenue for the years ended December 31, 2020 and 2019 is summarized in the following table:

	Year ended December 31,			
	2020	2019		
	(in thousands, except percentages)			
Revenue from collaborations and licenses				
Acuitas Therapeutics, Inc.	\$ 3,259	47 %	\$ 1,931	32 %
Gritstone Oncology, Inc.	—	— %	1,819	30 %
Acrotech Biopharma, LLC	269	4 %	605	10 %
Non-cash royalty revenue				
Alnylam Pharmaceuticals, Inc.	3,386	49 %	1,656	28 %
Total revenue	\$ 6,914	100 %	\$ 6,011	100 %

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

Total revenue increased \$0.9 million for the year ended December 31, 2020 compared to 2019, primarily due to a \$3.1 million increase in license royalty revenue from Alnylam and Acuitas due to the growth of Alnylam's sales of ONPATRO. This increase was partially offset by a \$1.8 million decrease in revenue from Gritstone Oncology, Inc. primarily due to a \$1.5 million milestone payment received in 2019.

The royalty interest for ONPATRO 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 ONPATRO 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, 2020, the Company has recorded an aggregate of \$5.1 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, 2020 and 2019 are summarized in the following table:

	Year ended December 31,			
	2020		2019	
	(in thousands, except percentages)			
Research and development	\$ 47,481	73 %	\$ 57,601	38 %
General and administrative	14,724	23 %	17,727	12 %
Depreciation	1,978	3 %	2,028	1 %
Change in fair value of contingent consideration	473	1 %	(173)	— %
Site consolidation	64	— %	156	— %
Impairment of intangible assets	—	— %	43,836	29 %
Impairment of goodwill	—	— %	22,471	15 %
Arbitration	—	— %	6,266	4 %
Total operating expenses	\$ 64,720	100 %	\$ 149,912	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 decreased \$10.1 million in 2020 compared to 2019 due primarily to the October 2019 decision to discontinue development of AB-506, our prior generation capsid inhibitor product candidate and higher expenses for AB-729 during 2019 for preclinical studies and drug product supply in preparation for our Phase 1a/1b clinical trial which commenced in the second quarter of 2019. These decreases were partially offset by an increase in expenses associated with development of our lead capsid inhibitor product candidate (AB-836), including preclinical studies and drug product supply in preparation for our Phase 1a/1b clinical trial, which is expected to initiate in the first half of 2021.

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 decreased \$3.0 million in 2020 compared to 2019, due primarily to severance related to the departure of our former President and Chief Executive Officer in June 2019. In accordance with the terms of his legacy employment agreement, our former President and Chief Executive Officer received \$2.3 million of cash severance and we recognized \$1.1 million of non-cash stock-based compensation expense for the accelerated vesting of his stock options in 2019. In addition, legal fees decreased \$1.1 million in 2020 compared to 2019 due primarily to the settlement of an arbitration case with the University of British Columbia (“UBC”) in September 2019. These decreases in general and administrative expenses in 2020 compared to 2019 were partially offset by increases in employee compensation and insurance premiums.

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 2020, the fair value of our contingent consideration liability increased \$0.5 million related to the passage of time. In 2019, the fair value of our contingent consideration liability decreased by \$0.2 million after we re-evaluated the timing of the future sales milestones following the discontinuation of the AB-506 program.

Site consolidation charges

In February 2018, we announced a site consolidation and organizational restructuring to better align our HBV business in Warminster, PA, including closing our Burnaby, Canada facility. Most of the employee-related site consolidation expenses were expensed ratably over the period that employees provided services, which was substantially completed in 2018. Total site consolidation expenses were \$5.0 million, which was fully recognized as of December 31, 2020.

Impairment of intangible assets and goodwill

In 2019, we recorded a \$43.8 million non-cash impairment expense to reduce the carrying value of its in-process research and development (“IPR&D”) intangible assets to zero. We also recognized a corresponding income tax benefit of \$12.7 million in 2019 related to the decrease in our deferred tax liability related to the IPR&D intangible assets. The impairment was due to a decision to delay indefinitely the further development of our cccDNA program while we focus on our other development programs.

Also during 2019, we recorded a \$22.5 million non-cash impairment to reduce the carrying amount of our goodwill asset to zero. Due to a sustained decrease in our share price in the months leading-up to the assessment, our market capitalization was reduced below the book value of our net assets and we concluded that the fair value of our single reporting unit was below its carrying amount by an amount in excess of the carrying amount of the goodwill asset.

We did not record any impairments during 2020.

Arbitration

In the third quarter of 2019, the arbitrator in the arbitration proceedings between UBC and us issued his decision, awarding UBC approximately \$5.9 million, which included interest of approximately \$2.6 million. An award for costs and attorneys’ fees is still to be determined. We recorded expense of \$6.3 million in 2019, consisting of \$5.9 million for the award (including interest) and \$0.4 million for an estimate of a potential award for costs and attorney’s fees.

This arbitration concerned certain early work on lipid nanoparticle delivery systems and related inventions undertaken by us and assigned to UBC. These inventions were subsequently licensed back to us by UBC under a license agreement, initially entered into in 1998 and subsequently amended in 2001, 2006 and 2007. We have granted sublicenses under the UBC license to Alnylam as well as other third parties.

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 ONPATTRO, currently being sold by Alnylam.

Other income (losses)

Other income (losses) for the years ended December 31, 2020 and 2019 are summarized in the following table:

	Year ended December 31,			
	2020		2019	
	(in thousands, except percentages)			
Interest income	\$ 741	(12)%	\$ 2,111	(9)%
Interest expense	(4,011)	68 %	(2,108)	9 %
Equity investment loss	(2,545)	43 %	(22,522)	100 %
Foreign exchange gain (loss)	(124)	2 %	41	— %
Total other loss	\$ (5,939)	101 %	\$ (22,478)	100 %

Interest income

Interest income decreased \$1.4 million in 2020 compared to 2019 due primarily to a general decline in market interest rates.

Interest expense

Interest expense increased \$1.9 million in 2020 compared to 2019 due primarily to 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.

Equity investment loss

In July 2020, we participated in the recapitalization of Genevant, led by Roivant, with an equity investment of \$2.5 million. We determined that this \$2.5 million additional investment in Genevant was funding prior losses and recorded the amount as an equity investment loss in 2020. Due to our loss of significant influence with respect to Genevant as a result of the recapitalization, we discontinued the use of equity method accounting for our interest in Genevant in 2020. Following the recapitalization, we account for our 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 future observable price changes in orderly transactions for identical or similar Genevant securities. As of December 31, 2020, the carrying value of our investment in Genevant was zero and we owned approximately 16% of the common equity of Genevant.

The equity investment losses for 2019 reflected our proportionate share of Genevant's net results under the equity method of accounting on a one-quarter lag basis of \$14.9 million and a \$7.6 million impairment charge to reduce the carrying value of our investment in Genevant to zero. The impairment was due to uncertainty surrounding the recovery of the remaining carrying value of our investment in Genevant.

Foreign exchange gains (losses)

In connection with our site consolidation to Warminster, PA, our Canadian dollar-denominated expenses and cash balances have decreased significantly now that a majority of our business transactions are based in the United States. We continue to incur expenses and hold some cash balances in Canadian dollars, and as such, we will remain subject to risks associated with foreign currency fluctuations. During the year ended December 31, 2020, we recorded foreign exchange losses of \$0.1 million. During the year ended December 31, 2019, we recorded foreign exchange gains of less than \$0.1 million.

Income tax benefit

For the year ended December 31, 2019, we recorded an income tax benefit of \$12.7 million related to the decrease of our deferred tax liability associated with impairments of our IPR&D intangible assets.

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, 2020, we had cash and cash equivalents of \$52.3 million and investments in marketable securities of \$71.0 million, totaling \$123.3 million. We had no outstanding debt as of December 31, 2020.

Sources of Liquidity

In December 2018, we entered into an Open Market Sale Agreement (“Sale Agreement”) with Jefferies LLC (“Jefferies”), under which we could issue and sell our common shares, from time to time, for an aggregate sales price of up to \$50.0 million. In December 2019, we entered into an amendment to the Sale Agreement with Jefferies (the “2019 Amendment”) in connection with the filing of a shelf registration statement on Form S-3 (File No. 333-235674), filed with the SEC on December 23, 2019 (the “Shelf Registration Statement”). The 2019 Amendment revised the original Sale Agreement to reflect that we may sell our common shares, from time to time, for an aggregate sales price of up to \$50.0 million, under the Shelf Registration Statement. During July 2020, we fully utilized the remaining availability under the Sale Agreement, as amended by the 2019 Amendment. In August 2020, we entered into a new amendment to the Sale Agreement (the “2020 Amendment”) with Jefferies. Pursuant to the 2020 Amendment, we can issue and sell common shares, from time to time, for an aggregate sales price of up to an additional \$75.0 million under the Sale Agreement. During 2020, we issued 24,728,368 common shares under the Sale Agreement, as amended, resulting in net proceeds of approximately \$86.3 million. From January 1, 2021 through March 3, 2021, we received an additional \$24.3 million of net proceeds from the issuance of our common shares under the Sale Agreement, as amended, and as of March 3, 2021 there was approximately \$16.4 million available under the Sale Agreement, as amended.

In August 2020, we filed a new \$200 million shelf registration statement on Form S-3 (File No. 333-248467), which was declared effective by the SEC on October 22, 2020 (the “New Shelf Registration Statement”). As of March 4, 2021, we have not sold any securities under the New Shelf Registration Statement.

Additionally, we have a royalty entitlement on ONPATTRO, 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. 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.

Cash requirements

At December 31, 2020 we held an aggregate of \$123.3 million in cash, cash equivalents and investments in marketable securities. From January 1, 2021 through March 3, 2021, we received an additional \$24.3 million of net proceeds from the issuance of common shares under the ATM program. We believe that our cash resources will be sufficient to fund our operations through the third quarter of 2022 based on our expectation of a net cash burn between \$70 million and \$75 million in 2021. 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 extent to which we continue the development of our product candidates, add new product candidates to our pipeline, or form collaborative relationships 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, in particular for our HBV therapeutics programs;
- our ability to attract and retain corporate partners, and their effectiveness in carrying out the development and ultimate commercialization of our product candidates;
- whether batches of drugs that we manufacture fail to meet specifications resulting in delays and investigational and remanufacturing costs;
- the decisions, and the timing of decisions, made by health regulatory agencies regarding our technology and products;
- competing technological and market developments; and
- costs associated with prosecuting and enforcing and defending 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 continued spread of COVID-19 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,	
	2020	2019
	(in thousands)	
Net loss	\$ (63,745)	\$ (153,723)
Non-cash items	11,873	84,942
Net change in operating items	431	(2,225)
Net cash used in operating activities	\$ (51,441)	\$ (71,006)
Net cash provided by (used in) investing activities	(14,909)	28,338
Net cash provided by financing activities	86,746	37,457
Effect of foreign exchange rate changes on cash and cash equivalents	56	68
Increase (decrease) in cash and cash equivalents	\$ 20,452	\$ (5,143)
Cash and cash equivalents, beginning of period	31,799	36,942
Cash and cash equivalents, end of period	\$ 52,251	\$ 31,799

Net cash used in operating activities in 2020 decreased \$19.6 million compared to 2019 due primarily to (i) a decrease in research and development payments of approximately \$10.1 million, which was due primarily to the October 2019 decision to

discontinue development of AB-506, our prior generation capsid inhibitor product candidate, and (ii) higher spend on AB-729 during 2019 for preclinical studies and drug product supply in preparation for our Phase 1a/1b clinical trial which commenced in the second quarter of 2019. The decrease in cash used in operating activities in 2020 compared to 2019 was also due to the payment of a \$5.9 million arbitration award to UBC in 2019 and a \$2.3 million cash severance payment to our former President and Chief Executive Officer in 2019.

Net cash from investing activities in 2020 decreased by \$43.2 million compared to 2019 due primarily to the timing of maturities and acquisitions of investments in marketable securities.

Net cash from financing activities in 2020 increased \$49.3 million compared to 2019. Cash provided by financing activities in 2020 consisted primarily of \$86.3 million of proceeds from sales of common shares under the Sale Agreement, as amended. Cash provided by financing activities in 2019 consisted primarily of \$18.5 million of net proceeds from the sale a portion of our future royalties from sales of ONPATTRO and \$18.6 million of proceeds from sales of common shares under the Sale Agreement, as amended.

OFF-BALANCE SHEET ARRANGEMENTS

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors.

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, 2020 and 2019, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, 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 Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does 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 matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Valuation of contingent consideration liability

Description of the Matter

As discussed in Note 11 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, 2020, the contingent consideration liability was \$3.4 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.

/s/ Ernst & Young LLP

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

Philadelphia, Pennsylvania

March 4, 2021

ARBUTUS BIOPHARMA CORPORATION

Consolidated Balance Sheets

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

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 52,251	\$ 31,799
Investments in marketable securities, current	71,017	59,035
Accounts receivable	1,312	1,204
Prepaid expenses and other current assets	3,124	1,790
Total current assets	127,704	93,828
Property and equipment, net of accumulated depreciation	6,927	8,676
Right of use asset	2,405	2,738
Other non-current assets	44	293
Total assets	\$ 137,080	\$ 105,535
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 8,901	\$ 7,235
Liability-classified options	250	253
Lease liability, current	390	340
Total current liabilities	9,541	7,828
Liability related to sale of future royalties	19,554	18,992
Contingent consideration	3,426	2,953
Lease liability, non-current	2,593	3,018
Total liabilities	35,114	32,791
Stockholders' equity		
Preferred shares		
Authorized: unlimited number without par value		
Issued and outstanding: 1,164,000	149,408	137,285
Common shares		
Authorized: unlimited number without par value		
Issued and outstanding: 89,678,722 (December 31, 2019: 64,780,314)	985,939	898,535
Additional paid-in capital	60,751	55,246
Deficit	(1,045,961)	(970,093)
Accumulated other comprehensive loss	(48,171)	(48,229)
Total stockholders' equity	101,966	72,744
Total liabilities and stockholders' equity	\$ 137,080	\$ 105,535

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,	
	2020	2019
Revenue		
Collaborations and licenses	\$ 3,519	\$ 4,355
Non-cash royalty revenue	3,395	1,656
Total revenue	<u>6,914</u>	<u>6,011</u>
Operating expenses		
Research and development	47,481	57,601
General and administrative	14,724	17,727
Depreciation	1,978	2,028
Change in fair value of contingent consideration	473	(173)
Site consolidation	64	156
Impairment of intangible assets	—	43,836
Impairment of goodwill	—	22,471
Arbitration	—	6,266
Total operating expenses	<u>64,720</u>	<u>149,912</u>
Loss from operations	(57,806)	(143,901)
Other income (loss)		
Interest income	741	2,111
Interest expense	(4,011)	(2,108)
Equity investment loss	(2,545)	(22,522)
Foreign exchange gain (loss)	(124)	41
Total other loss	<u>(5,939)</u>	<u>(22,478)</u>
Loss before income taxes	(63,745)	(166,379)
Income tax benefit	—	12,656
Net loss	<u>\$ (63,745)</u>	<u>\$ (153,723)</u>
Items applicable to preferred shares		
Dividend accretion of convertible preferred shares	(12,123)	(11,149)
Net loss attributable to common shares	<u>\$ (75,868)</u>	<u>\$ (164,872)</u>
Loss per share		
Basic and diluted	\$ (1.00)	\$ (2.89)
Weighted average number of common shares		
Basic and diluted	75,835,378	57,093,454
Comprehensive income (loss)		
Unrealized gain on available-for-sale securities	\$ 14	\$ —
Currency translation adjustments	44	(59)
Comprehensive loss	<u>\$ (63,687)</u>	<u>\$ (153,782)</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, 2018	1,164,000	\$ 126,136	55,518,800	\$ 879,405	\$ 48,084	\$ (805,221)	\$ (48,170)	\$ 200,234
Accretion of accumulated dividends on Preferred Shares	—	11,149	—	—	—	(11,149)	—	—
Stock-based compensation	—	—	—	—	7,204	—	—	7,204
Certain fair value adjustments to liability stock option awards	—	—	—	—	180	—	—	180
Issuance of common shares pursuant to the Open Market Sales Agreement	—	—	9,138,232	18,601	—	—	—	18,601
Issuance of common shares pursuant to exercise of options	—	—	123,282	529	(222)	—	—	307
Currency translation adjustment	—	—	—	—	—	—	(59)	(59)
Net loss	—	—	—	—	—	(153,723)	—	(153,723)
Balance at December 31, 2019	1,164,000	\$ 137,285	64,780,314	\$ 898,535	\$ 55,246	\$ (970,093)	\$ (48,229)	\$ 72,744
Accretion of accumulated dividends on Preferred Shares	—	12,123	—	—	—	(12,123)	—	—
Stock-based compensation	—	—	—	—	6,145	—	—	6,145
Certain fair value adjustments to liability stock option awards	—	—	—	—	18	—	—	18
Issuance of common shares pursuant to the Open Market Sales Agreement	—	—	24,728,368	86,297	—	—	—	86,297
Issuance of common shares pursuant to exercise of options	—	—	170,040	1,107	(658)	—	—	449
Unrealized gain on available-for-sale securities	—	—	—	—	—	—	14	14
Currency translation adjustment	—	—	—	—	—	—	44	44
Net loss	—	—	—	—	—	(63,745)	—	(63,745)
Balance at December 31, 2020	1,164,000	\$ 149,408	89,678,722	\$ 985,939	\$ 60,751	\$ (1,045,961)	\$ (48,171)	\$ 101,966

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,	
	2020	2019
OPERATING ACTIVITIES		
Net loss	\$ (63,745)	\$ (153,723)
Non-cash items:		
Deferred income tax benefit	—	(12,661)
Depreciation	1,978	2,028
Loss on sale of property and equipment	—	20
Stock-based compensation expense	6,161	6,799
Unrealized foreign exchange gains	(56)	(68)
Change in fair value of contingent consideration	473	(173)
Impairment of intangible assets	—	43,836
Impairment of goodwill	—	22,471
Net equity investment loss	2,545	22,522
Non-cash royalty revenue	(3,395)	(1,656)
Non-cash interest expense	3,957	2,099
Net accretion and amortization of investments in marketable securities	210	(275)
Net change in operating items:		
Accounts receivable	(108)	227
Prepaid expenses and other assets	(752)	1,606
Accounts payable and accrued liabilities	1,666	(3,314)
Lease liabilities	(375)	(744)
Net cash used in operating activities	(51,441)	(71,006)
INVESTING ACTIVITIES		
Purchase of investments in marketable securities	(85,578)	(58,759)
Disposition of investments in marketable securities	73,398	87,675
Investment in Genevant	(2,500)	—
Proceeds from sale of property and equipment	—	11
Acquisition of property and equipment	(229)	(589)
Net cash provided by (used in) investing activities	(14,909)	28,338
FINANCING ACTIVITIES		
Proceeds from sale of future royalties, net	—	18,549
Issuance of common shares pursuant to exercise of options	449	307
Issuance of common shares pursuant to the Open Market Sales Agreement	86,297	18,601
Net cash provided by financing activities	86,746	37,457
Effect of foreign exchange rate changes on cash and cash equivalents	56	68
Increase (decrease) in cash and cash equivalents	\$ 20,452	\$ (5,143)
Cash and cash equivalents, beginning of period	\$ 31,799	\$ 36,942
Cash and cash equivalents, end of period	\$ 52,251	\$ 31,799
Supplemental cash flow information		
Preferred shares dividends accrued	\$ (12,123)	\$ (11,149)

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 (the “Company” or “Arbutus”) is a clinical-stage, biopharmaceutical company primarily focused on developing a cure for people with chronic hepatitis B virus (“HBV”) infection. The Company is advancing multiple product candidates with distinct mechanisms of action that it believes have the potential to provide a new curative regimen for chronic HBV infection. The Company has also initiated a drug discovery and development effort for treating coronaviruses, including COVID-19.

The Company’s two lead product candidates are AB-729, the Company’s proprietary subcutaneously-delivered RNA interference (“RNAi”) product candidate that suppresses HBsAg expression, and AB-836, the Company’s proprietary next-generation oral capsid inhibitor that suppresses HBV DNA replication. AB-729 is currently in an ongoing Phase 1a/1b clinical trial and the Company expects AB-836 to progress into a Phase 1a/1b clinical trial in the first half of 2021.

Liquidity

At December 31, 2020, the Company had an aggregate of \$123.3 million in cash, cash equivalents and investments in marketable securities. From January 1, 2021 through March 3, 2021, the Company received an additional \$24.3 million of net proceeds from the issuance of common shares under the ATM program. The Company believes that its cash resources will be sufficient to fund its operations through the third quarter of 2022.

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 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

In December 2019, an outbreak of a novel strain of coronavirus (COVID-19) was identified in Wuhan, China. This virus continues to spread globally, has been declared a pandemic by the World Health Organization and has spread to nearly every country in the world. The impact of this pandemic has been, and will likely continue to be, extensive in many aspects of society. The pandemic has resulted in and will likely continue to result in significant disruptions to businesses. A number of countries and other jurisdictions around the world have implemented extreme measures to try and slow the spread of the virus. These measures include the closing of businesses and requiring people to stay in their homes, the latter of which raises uncertainty regarding the ability to travel to hospitals in order to participate in clinical trials. Additional measures that have had, and will likely continue to have, a major impact on clinical development, at least in the near-term, include shortages and delays in the supply chain, and prohibitions in certain countries on enrolling subjects in new clinical trials. Future disruptions related to the COVID-19 pandemic could negatively impact the Company’s plans and timelines in 2021 and beyond, including enrolling and monitoring subjects in its clinical trials.

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 two wholly-owned subsidiaries, Arbutus Biopharma, Inc. and Arbutus Biopharma U.S. Holdings, 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 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 income or expense in the Company’s statements of operations and comprehensive loss. As of December 31, 2020, 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.

Investment in Genevant

As the result of a recapitalization of Genevant Sciences Ltd. (“Genevant”) in July 2020, Arbutus’ ownership interest in Genevant decreased to approximately 16%. Due to Arbutus’ loss of significant influence with respect to Genevant as a result of the recapitalization, Arbutus discontinued the use of the equity method of accounting for its interest in Genevant. Ownership interests that do not confer the ability to exercise significant influence are accounted for at fair value, except when the investment does not have a readily-determinable fair value. In that case, the investment is carried at cost, less any impairment. The carrying value is subsequently adjusted to fair value based on any observable price changes. Following the recapitalization, 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 a similar Genevant securities. As of December 31, 2020, the carrying value of Arbutus’ investment in Genevant was zero and Arbutus owned approximately 16% of the common equity of Genevant.

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 recognition

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.

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 and development services. Under such agreements, the Company is generally eligible to receive non-refundable upfront payments, funding for research and development services, milestone payments, and royalties.

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

As of January 1, 2019, the Company adopted FASB's Accounting Standards Update 2016-02, *Leases* (ASC 842), which generally requires the recognition of operating and financing lease liabilities with corresponding right-of-use assets on the balance sheet. The Company adopted the new standard using the modified retrospective basis applied at the effective date of the new standard and elected to utilize a package of practical expedients. 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

The Company follows the two-class method when computing net loss attributable to common shareholders per share as the Company has issued Series A participating convertible preferred shares ("Preferred Shares"), as further described in note 13, that meet the definition of participating securities. The Company's Preferred Shares entitle the holders to participate in dividends but do not require the holders to participate in losses of the Company. Accordingly, if the Company reports a net loss attributable to holders of the Company's common shares, net losses are not allocated to holders of the Preferred Shares.

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, 2020 and 2019, since the effect of the Company's stock options and convertible preferred stock is anti-dilutive. For the year ended December 31, 2020, potential common shares of 10.7 million pertaining to stock options outstanding and approximately 21.1 million pertaining to if-converted preferred shares for a total of approximately 31.8 million shares were excluded from the calculation of net loss attributable to common shareholders, per share because their inclusion would be anti-dilutive. A total of approximately 28.4 million potential common shares and if-converted preferred shares were excluded from the calculation for the year ended December 31, 2019.

The following table sets out the computation of basic and diluted net loss attributable to common shareholders per share:

	For the year ended December 31,	
	2020	2019
	(in thousands, except share and per share amounts)	
Numerator:		
Allocation of distributable earnings	\$ —	\$ —
Allocation of undistributable loss	(75,868)	(164,872)
Allocation of net loss attributed to common shareholders	\$ (75,868)	\$ (164,872)
Denominator:		
Weighted average number of common shares - basic and diluted	75,835,378	57,093,454
Basic and diluted net loss attributable to common shareholders per share	\$ (1.00)	\$ (2.89)

See note 13 and note 14 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

We measure and recognize compensation expense for all share-based compensation arrangements based on estimated fair values. We use 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, we use 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 seven years for directors and executives, based on our 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 accounts for Preferred Shares under ASC 480 – *Distinguishing Liabilities from Equity* (“ASC 480”), which provides guidance for equity instruments with conversion features. The Company classifies 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 cannot be cash-settled and the redemption features, which include a fixed conversion ratio with predetermined timing and proceeds, are within the Company’s control. The Company accrues 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.

Segment information

The Company operates in a single reporting segment. Substantially all of the Company’s revenues to date were earned from customers or collaborators based in the United States. 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, the impact of foreign currency translation adjustments and adjustments for the change in unrealized gains and losses on investments in available-for-sale marketable securities. The Company displays 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 is currently evaluating the impact of the new standard on its consolidated financial statements.

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.
- 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.
- 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.

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 11), 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 the fair value of the contingent consideration was \$3.4 million as of December 31, 2020 and the increase of \$0.5 million has been recorded within operating expenses in the statement of operations and comprehensive loss for the year ended December 31, 2020. 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:

<u>As of December 31, 2020</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
	<u>(in thousands)</u>			
Assets				
Cash and cash equivalents	\$ 52,251	\$ —	\$ —	\$ 52,251
Investments in marketable securities	71,017	—	—	71,017
Total	\$ 123,268	\$ —	\$ —	\$ 123,268
Liabilities				
Liability-classified options	\$ —	\$ —	\$ 250	\$ 250
Contingent consideration	—	—	3,426	3,426
Total	\$ —	\$ —	\$ 3,676	\$ 3,676

As of December 31, 2019	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets				
Cash and cash equivalents	\$ 31,799	\$ —	\$ —	\$ 31,799
Investments in marketable securities	59,035	—	—	59,035
Total	\$ 90,834	\$ —	\$ —	\$ 90,834
Liabilities				
Liability-classified options	\$ —	\$ —	\$ 253	\$ 253
Contingent consideration	—	—	2,953	2,953
Total	\$ —	\$ —	\$ 3,206	\$ 3,206

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	Increase (decrease) in fair value of liability	Liability at end of the period
	(in thousands)			
Year ended December 31, 2020	\$ 253	\$ —	\$ (3)	\$ 250
Year ended December 31, 2019	\$ 479	\$ —	\$ (226)	\$ 253

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

	Liability at beginning of the period	Increase (decrease) in fair value of liability	Liability at end of the period
	(in thousands)		
Year ended December 31, 2020	\$ 2,953	\$ 473	\$ 3,426
Year ended December 31, 2019	\$ 3,126	\$ (173)	\$ 2,953

4. Investments in marketable securities

Investments in marketable securities consisted of the following:

<u>As of December 31, 2020</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	\$ 13,703	\$ —	\$ —	\$ 13,703
US government agency bonds	—	—	—	—
US treasury bills	2,000	—	—	2,000
Total	\$ 15,703	\$ —	\$ —	\$ 15,703
Investments in marketable securities				
US government agency bonds	\$ 11,550	\$ 7	\$ —	\$ 11,557
US treasury bills	21,990	2	—	21,992
US government bonds	37,463	6	(1)	37,468
Total	\$ 71,003	\$ 15	\$ (1)	\$ 71,017

⁽¹⁾ Gross unrealized gain (loss) is pre-tax.

<u>As of December 31, 2019</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	\$ 4,106	\$ —	\$ —	\$ 4,106
US government agency bonds	1,511	—	—	1,511
US treasury bills	1,499	—	—	1,499
Total	\$ 7,116	\$ —	\$ —	\$ 7,116
Investments in marketable securities				
US government agency bonds	\$ 19,863	\$ 2	\$ (1)	\$ 19,864
US treasury bills	15,926	2	(1)	15,927
US government bonds	23,246	—	(2)	23,244
Total	\$ 59,035	\$ 4	\$ (4)	\$ 59,035

⁽¹⁾ Gross unrealized gain (loss) is pre-tax.

There were no realized gains or losses for the year ended December 31, 2020 or 2019.

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 the discovery, development, and commercialization of a broad range of RNA-based therapeutics enabled by the Company’s lipid nanoparticle (“LNP”) and ligand conjugate delivery technologies. The Company licensed exclusive 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, the Company is entitled to receive tiered low single-digit royalties on future sales of Genevant products covered by the licensed patents. If Genevant sub-licenses the intellectual property licensed by the Company to Genevant, the Company is entitled to receive under the Genevant License, upon the commercialization of a product developed by such sub-licensee, the lesser of (i) twenty percent of the revenue received by Genevant for such sublicensing and (ii) tiered low single-digit royalties on product sales by the sublicensee.

On July 23, 2020, the United States Patent and Trademark Office before the Patent Trial and Appeal Board ("PTAB") announced its decision in Moderna Therapeutics, Inc.'s ("Moderna") challenge of the validity of U.S. Patent 8,058,069 ("the '069 Patent"). In this decision, the PTAB determined no challenged claims were unpatentable. On September 23, 2020, Moderna appealed the '069 Patent decision to the Federal Circuit Court of Appeals. Moderna filed its opening brief in that appeal on February 23, 2021, and the Company's responsive brief is due on May 4, 2021. While the Company is the patent holder, this patent has been licensed to Genevant. The '069 Patent was included in the exclusive rights licensed by the Company to Genevant under the Genevant License.

On July 31, 2020, Roivant recapitalized Genevant through an equity investment and conversion of previously issued convertible debt securities held by Roivant. The Company participated in the recapitalization of Genevant with an investment of \$2.5 million. The Company determined that this \$2.5 million additional investment in Genevant represented the funding of prior losses and accordingly, the Company recorded the amount as an equity investment loss on the Condensed Consolidated Statements of Operations and Comprehensive Loss in 2020.

Following the recapitalization, the Company owned approximately 16% of the common equity of Genevant. In connection with the recapitalization, Genevant, the Company and Roivant entered into an Amended and Restated Shareholders Agreement that provides Roivant with substantial control of Genevant. The Company has a non-voting observer seat on Genevant's Board of Directors. Due to the Company's loss of significant influence with respect to Genevant as a result of the recapitalization, the Company discontinued the use of the equity method of accounting for its interest in Genevant. Following the recapitalization, 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. The Company's entitlement to receive future royalties or sublicensing revenue under the Genevant License was not impacted by the recapitalization.

As of December 31, 2020, the carrying value of the Company's investment in Genevant was zero and the Company owned approximately 16% of the common equity of Genevant. During 2019, the Company recorded non-cash equity losses of \$22.5 million related to Genevant. Equity losses for 2019 included \$14.9 million of losses for the Company's proportionate share of Genevant's net losses and a \$7.6 million impairment charge to reduce the carrying value of the Company's investment in Genevant to zero. The impairment was due to uncertainty surrounding the recovery of the Company's remaining carrying value in Genevant.

6. Leases

The Company has two operating leases for office and laboratory space. 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 leases office space located at 626 Jacksonville Rd, Warminster, Pennsylvania under a lease that expires on December 31, 2021, and the Company has an option to extend the lease term to April 30, 2027. In connection with the Company's site consolidation in 2018, the Company ceased using its office and laboratory space located in Burnaby, British Columbia, Canada on June 30, 2018. The Company subleased a portion of the Burnaby facility to various tenants, including Genevant, until the lease expired on July 31, 2019. The Company recognized the remaining lease payments for the Burnaby facility, less sublease income under contract, in site consolidation expenses in 2018.

The Company adopted ASU No. 2016-02, *Leases* (Topic 842) on January 1, 2019 using the modified retrospective basis applied at the effective date of the new standard and elected to utilize a package of practical expedients. 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, 7.6% for the 626 Jacksonville Rd. lease and 5.0% for the Burnaby lease. The Company recognizes lease expense on a straight-line basis over the remaining lease term.

During the year ended December 31, 2020, 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. For the twelve months ended December 31, 2019, the Company incurred total operating lease expense of \$1.2 million, which included fixed lease payments of \$0.9 million, and variable payments of \$0.3 million. Sublease income for the Company's Burnaby site, which closed during that year, was \$0.2 million for the twelve months ended December 31, 2019.

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

	<u>As of December 31, 2020</u>
Weighted-average remaining lease term (years)	6.1
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:

	<u>2020</u>	<u>2019</u>
	<u>(in thousands)</u>	
Cash paid for amounts included in the measurement of lease liabilities	\$ 657	\$ 1,116

Future minimum lease payments under operating leases that have remaining terms as of December 31, 2020 are as follows:

	<u>As of December 31, 2020</u>	
	<u>(in thousands)</u>	
2021	\$	677
2022		581
2023		598
2024		616
2025		635
Thereafter		787
Total lease payments	\$	3,894
Less: interest		(911)
Present value of lease payments	\$	2,983

7. Property and equipment

The Company's property and equipment balances as of the years ended December 31, 2020 and 2019 are as follows:

	Cost	Accumulated depreciation (in thousands)	Net book value
December 31, 2020			
Lab equipment	\$ 5,669	\$ (4,369)	\$ 1,300
Leasehold improvements	8,555	(3,017)	5,538
Computer hardware and software	324	(235)	89
	<u>\$ 14,548</u>	<u>\$ (7,621)</u>	<u>\$ 6,927</u>

	Cost	Accumulated depreciation (in thousands)	Net book value
December 31, 2019			
Lab equipment	\$ 5,511	\$ (3,316)	\$ 2,195
Leasehold improvements	8,521	(2,152)	6,369
Computer hardware and software	286	(174)	112
	<u>\$ 14,318</u>	<u>\$ (5,642)</u>	<u>\$ 8,676</u>

During 2019, the Company closed its Burnaby facility and the lease expired according to its terms on July 31, 2019. In connection with the facility closure, the Company disposed of \$3.4 million of equipment, furniture and leasehold improvements. Most of the disposed assets were fully depreciated. The aggregate net book value of the disposed assets was less than \$0.1 million.

8. Intangible assets and goodwill

All IPR&D intangible asset balance related to the Company's cccDNA program. During 2019, the Company recorded a \$43.8 million non-cash impairment expense to reduce the carrying value of its IPR&D intangible assets to zero. The Company also recognized a corresponding income tax benefit of \$12.7 million related to the decrease in its deferred tax liability related to the IPR&D intangible assets. The impairment was due to a decision to delay indefinitely the further development of the Company's cccDNA program while the Company focuses on its other development programs.

The Company's goodwill balance represented the excess of purchase price over the value assigned to the net tangible and identifiable intangible assets in connection with the business combination that formed Arbutus. During 2019, the Company assessed its changes in circumstances to determine if it was more likely than not that the fair value of its single reporting unit was below its carrying amount. Due to a sustained decrease in the Company's share price during that time frame, the Company's market capitalization was reduced below the book value of its net assets and the Company concluded that the fair value of its single reporting unit was below its carrying amount in excess of the carrying value of goodwill. As a result, the Company recorded a \$22.5 million non-cash impairment expense to reduce the carrying value of its goodwill asset to zero in 2019.

9. Accounts payable and accrued liabilities

Accounts payable and accrued liabilities are comprised of the following:

	December 31, 2020	December 31, 2019
	(in thousands)	
Trade accounts payable	\$ 2,994	\$ 2,398
Payroll accruals	3,566	2,314
Research and development accruals	1,653	1,433
Professional fee accruals	679	809
Site consolidation accrual	—	137
Other accrued liabilities	9	144
Total	<u>\$ 8,901</u>	<u>\$ 7,235</u>

10. 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.

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 16%. 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. From the inception of the royalty sale through December 31, 2020, the Company has recorded an aggregate of \$5.1 million of non-cash royalty revenue for royalties earned by OMERS. 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, 2020, the Company recognized non-cash royalty revenue of \$3.4 million and \$4.0 million of related non-cash interest expense. During the year ended December 31, 2019, the Company recognized non-cash royalty revenue of \$1.7 million and related non-cash interest expense of \$2.1 million.

The table below shows the activity related to the net liability for the years ended December 31, 2020 and December 31, 2019:

	Twelve Months Ended December 31,	
	2020	2019
	(in thousands)	
Net liability related to sale of future royalties - beginning balance	\$ 18,992	\$ —
Initial recognition of liability	—	30,000
Debt discount and issuance costs	—	(11,451)
Non-cash royalty revenue	(3,395)	(1,656)
Non-cash interest expense	3,957	2,099
Net liability related to sale of future royalties - ending balance	\$ 19,554	\$ 18,992

In addition to the royalty from the Alnylam LNP License Agreement, the Company is also receiving 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 from Acuitas has been retained by the Company and was not part of the royalty sale to OMERS.

11. Contingencies and commitments

Product development partnership with the Canadian Government

The Company entered into a Technology Partnerships Canada (“TPC”) agreement with the Canadian Federal Government on November 12, 1999. Under this agreement, TPC agreed to fund 27% of the costs incurred by the Company, prior to March 31, 2004, in the development of certain oligonucleotide product candidates up to a maximum contribution from TPC of \$7.2 million (C\$9.3 million). The Company received a cumulative contribution of \$2.7 million (C\$3.7 million). In return for the funding provided by TPC, the Company agreed to pay royalties on the share of future licensing and product revenue, if any, that is received by the Company on certain non-RNAi oligonucleotide product candidates covered by the funding under the agreement. These royalties are payable until a certain cumulative payment amount is achieved or until a pre-specified date. In addition, until a cumulative amount equal to the funding actually received under the agreement has been paid to TPC, the Company agreed to pay 2.5% royalties on any royalties the Company receives for Marqibo, a chemotherapy product sold by Acrotech Biopharma LLC (“Acrotech”). For the years ended December 31, 2020 and 2019, the Company earned royalties on Marqibo sales in the amount of \$0.3 million in each period. The resulting royalties payable by the Company to TPC were not material in either period. The cumulative amount paid or accrued up to December 31, 2020 was less than \$0.1 million, resulting in the contingent amount due to TPC being \$2.7 million (C\$3.7 million).

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 Arbutus 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 his decision for the second phase of the arbitration, awarding UBC \$5.9 million, which includes interest of approximately \$2.6 million. The Company paid the \$5.9 million award to UBC in September 2019 and recorded a charge of \$6.3 million, consisting of \$5.9 million for the award (including interest) and \$0.4 million for an estimate of a potential award for costs and attorneys’ fees. An award for costs and attorneys’ fees is still to be determined.

On December 18, 2020, UBC delivered to the Company a notice of arbitration alleging that under the cross license between UBC and Arbutus, it is 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. The Company does not believe that any royalties are due to UBC and the Company intends to vigorously contest UBC’s allegation.

Stock Purchase Agreement with Enantigen

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 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 \$3.4 million as of December 31, 2020.

12. Collaborations, contracts and licensing agreements

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 lead HBV core inhibitor (capsid inhibitor) candidate vecicorvir (“VBR”) and standard-of-care NA therapy for the treatment of subjects with chronic HBV infection. The Company and Assembly will share in the costs of the collaboration. The Company incurred \$0.2 million of costs related to the collaboration during the year ended December 31, 2020 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 its AB-729 compound.

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 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 approved by the United States Food and Drug Administration (“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, 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. See note 10 for further details.

The Company also has rights to a second, lower royalty interest on global net sales of ONPATTRO originating from a settlement agreement and subsequent license agreement with 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 Oncology, Inc. (“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.

Acrotech Biopharma LLC and Spectrum Pharmaceuticals, Inc.

In May 2006, the Company signed a number of agreements with Talon Therapeutics, Inc. (“Talon,” formerly Hana Biosciences, Inc.) that granted Talon worldwide licenses to certain of its LNP technology (the “Talon License Agreement”) for three of Talon’s chemotherapy products, Marqibo®, Alocrest™ (Optisomal Vinorelbine) and Brakiva™ (Optisomal Topotecan).

In 2012, Talon received approval for Marqibo from the FDA for the treatment of adult patients with Philadelphia chromosome negative acute lymphoblastic leukemia in second or greater relapse or whose disease has progressed following two or more anti-leukemia therapies. Marqibo is a liposomal formulation of the chemotherapy drug, vincristine. In 2012, the Company received a milestone payment of \$1.0 million based on the FDA’s approval of Marqibo and receives royalty payments based on Marqibo’s commercial sales. There are no further milestones related to Marqibo but the Company is eligible to receive total milestone payments of up to \$18.0 million on Alocrest and Brakiva. Talon was acquired by Spectrum Pharmaceuticals, Inc. in July 2013, who subsequently sold the license of Marqibo to Acrotech in January 2019. The acquisitions and license sale did not affect the terms of the license between Talon and the Company.

Revenues are summarized in the following table:

	Year ended December 31,	
	2020	2019
	(in thousands)	
Revenue from collaborations and licenses		
Acuitas Therapeutics, Inc.	\$ 3,259	\$ 1,931
Gritstone Oncology, Inc.	—	1,819
Acrotech Biopharma, LLC	269	605
Non-cash royalty revenue		
Alnylam Pharmaceuticals, Inc.	3,386	1,656
Total revenue	\$ 6,914	\$ 6,011

13. Shareholders’ equity

Authorized share capital

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

Open Market Sale Agreement

In December 2018, the Company entered into an Open Market Sale Agreement (“the Sale Agreement”) with Jefferies LLC (“Jefferies”), under which it could issue and sell common shares, from time to time, for an aggregate sales price of up to \$50 million. In December 2019, the Company entered into an amendment to the Sale Agreement with Jefferies (the “2019 Amendment”) in connection with the filing of a shelf registration statement on Form S-3 (File No. 333-235674), filed with the SEC on December 23, 2019 (the “Shelf Registration Statement”). The 2019 Amendment revised the original Sale Agreement to reflect that the Company could sell its common shares, without par value, from time to time, for an aggregate sales price of up to \$50 million, under the Shelf Registration Statement. In July 2020, the Company fully utilized the remaining availability under the Sale Agreement, as amended by the 2019 Amendment. In August 2020, the Company entered into a new amendment to the Sale Agreement (the “2020 Amendment”) with Jefferies. Pursuant to the 2020 Amendment, the Company can issue and sell common shares, from time to time, for an aggregate sales price of up to \$75 million under the Sale Agreement, as amended.

For the year ended December 31, 2020, the Company issued 24,728,368 common shares pursuant to the Sale Agreement, resulting in net proceeds of approximately \$86.3 million. From January 1, 2021 through March 3, 2021, the Company received an additional \$24.3 million of net proceeds from the issuance of 5.8 million common shares under the ATM program.

For the year ended December 31, 2019, the Company issued 9,138,232 common shares pursuant to the Sale Agreement, resulting in net proceeds of approximately \$19.5 million.

Series A Preferred Shares

On October 2, 2017, the Company announced that it 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 are non-voting and are convertible into common shares at a conversion price of \$7.13 per share (which represents 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, will be subject to mandatory conversion into approximately 23 million common shares on October 18, 2021 (subject to limited exceptions in the event of certain fundamental corporate transactions relating to Arbutus’ capital structure or assets, which would permit earlier conversion at Roivant’s option). Assuming conversion of the Preferred Shares into common shares, based on the number of common shares outstanding on December 31, 2020 Roivant would hold 33% of the Company’s common shares. Roivant has agreed to a four year lock-up period for this investment and its existing holdings in Arbutus. Roivant has also agreed to a four year standstill whereby Roivant will not acquire greater than 49.99% of the Company’s common shares or securities convertible into common shares. The initial investment of \$50.0 million closed on October 16, 2017, and the remaining amount of \$66.4 million closed on January 12, 2018 following regulatory and shareholder approvals.

The Company records the Preferred Shares wholly as equity with no bifurcation of conversion feature from the host contract, given that the Preferred Shares cannot be cash settled and the redemption features are within the Company’s control, which include a fixed conversion ratio with predetermined timing and proceeds. The Company accrues 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).

14. Stock-based compensation

Awards outstanding and available for issuance

During the year ended December 31, 2020, 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, 2020, the aggregate number of shares authorized for awards under all Plans was 15,790,202. As of December 31, 2020, the Company had 10,669,776 options outstanding and 3,161,471 awards available for issuance under the Plans.

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

Under the 2016 and 2011 Plans, 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 or the prior day and the term may not exceed 10 years. Options granted generally vest over three or 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 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, 2020:

	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, 2019	8,249,093	\$ 5.00	4,294,649	3,954,444	\$ 2.86
Options granted	2,865,350	\$ 3.21	—	2,865,350	\$ 2.20
Options exercised	(125,649)	\$ 3.04	(125,649)	—	\$ —
Options forfeit, canceled or expired	(597,118)	\$ 5.10	(313,861)	(283,257)	\$ 2.53
Options vested	—	\$ —	2,529,247	(2,529,247)	\$ 2.69
Balance as of December 31, 2020	10,391,676	\$ 4.53	6,384,386	4,007,290	\$ 2.51

The intrinsic value of options exercised under the Arbutus Plans during 2020 and 2019 are \$0.3 million and less than \$0.1 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, 2020:

	As of December 31, 2020
Options outstanding and expected to vest	
Number of stock options outstanding	10,391,676
Weighted-average exercise price	\$ 4.53
Intrinsic value (in \$000s)	\$ 3,532
Weighted-average term remaining	6.7 years
Vested stock options	
Number of vested stock options	6,384,386
Weighted-average exercise price	\$ 5.11
Intrinsic value (in \$000s)	\$ 1,758
Weighted-average term remaining	5.5 years

The assumptions used in the Black-Scholes option-pricing for grants made during the years ended December 31, 2020 and 2019 are as follows:

	December 31, 2020	December 31, 2019
Expected average option term	6.2 years	7.3 years
Expected volatility	80.2 %	75.9 %
Expected dividends	— %	— %
Risk-free interest rate	1.2 %	2.27 %

Liability-classified stock options under the Arbutus Plans

Due to the change in the Company's functional currency as of January 1, 2016, certain stock option awards with exercise prices denominated in Canadian dollars changed from equity classification to liability classification (see note 2).

The following table summarizes activity related to the Company's liability-classified stock options for the year ended December 31, 2020:

	Stock Options Vested and Outstanding	
	Number	Weighted-Average Exercise Price
Balance as of December 31, 2019	227,500	\$ 5.49
Options exercised	(25,000)	\$ 3.02
Options forfeit, canceled or expired	(5,000)	\$ 3.02
Balance as of December 31, 2020	197,500	\$ 6.00

The intrinsic value of liability-classified options exercised during 2020 was less than \$0.1 million.

The following table summarizes additional information related to the Company's liability-classified stock options as of December 31, 2020:

	As of December 31, 2020
<u>Options outstanding and expected to vest</u>	
Intrinsic value (in \$000s)	\$ 158
Weighted-average term remaining	0.9 years

Liability options are re-measured to their fair values at each reporting date, using the Black-Scholes valuation model.

The weighted average Black-Scholes option-pricing assumptions and the resultant fair values as of December 31, 2020 and December 31, 2019, are presented in the following table:

	December 31, 2020	December 31, 2019
Stock price	\$ 3.55	\$ 2.78
Expected average option term	0.9 years	1.6 years
Expected volatility	105.66 %	113.1 %
Expected dividends	— %	— %
Risk-free interest rate	0.11 %	1.59 %
Weighted-average fair value per share	\$ 1.30	\$ 1.11
Total fair value of vested liability-classified options (in \$000s)	\$ 250	\$ 253

OnCore Option Plan

The Company has reserved shares for the future exercises of OnCore stock options that were granted prior to the merger in 2015. The Company is not permitted to grant any further options under the OnCore Option Plan.

The following table summarizes activity related to the OnCore stock options for the year ended December 31, 2020:

	Stock Options Vested and Outstanding		Weighted-Average Exercise Price
	Number of OnCore Options	Number of Equivalent Company Common Shares	
Balance as of December 31, 2019	99,290	99,991	\$ 0.56
Options exercised	(19,255)	(19,391)	\$ 0.56
Options forfeit, canceled or expired	—	—	\$ —
Balance as of December 31, 2020	80,035	80,600	\$ 0.56

The intrinsic value of options exercised under the OnCore plan during each of 2020 and 2019 was \$0.1 million.

The following table summarizes additional information related to the OnCore stock options as of December 31, 2020:

	As of December 31, 2020	
Vested stock options		
Intrinsic value (in \$000s)	\$	241
Weighted-average term remaining		3.8 years

Employee Stock Purchase Plan

In May 2020, the Company's stockholders approved the 2020 Employee Stock Purchase Plan (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 is September 1, 2020 through August 31, 2021 with purchase dates set on February 26, 2021 and August 31, 2021. All 1,500,000 common shares remained available for future issuance under the ESPP at December 31, 2020. For the year ended December 31, 2020, the Company recognized \$0.2 million 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 income (loss) as follows:

	Year Ended December 31	
	2020	2019
	(in thousands)	
Research and development	\$ 3,090	\$ 2,971
General and administrative	3,071	3,828
Total	\$ 6,161	\$ 6,799

During the year ended December 31, 2019, the Company recognized \$1.1 million of non-cash stock-based compensation expense for the accelerated vesting stock options, related to the departure of the Company's former President and Chief Executive Officer in June of 2019.

At December 31, 2020, there remains \$7.8 million of unearned compensation expense related to unvested equity employee stock options to be recognized as expense over a weighted-average period of approximately 2.3 years.

For the year ended December 31, 2020, the Company recognized \$0.3 million of performance based stock compensation expense which is included in the table above.

15. 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. The United States Internal Revenue service is currently examining the Company's federal tax return for 2018. The outcome of tax audits cannot be predicted with certainty, however the Company believes that an adequate provision has been made for any adjustments that may result from the examination. If any issues addressed in the Company's tax audits are resolved in a manner not consistent with management's expectations, the Company could be required to adjust its provision for income tax in the period such resolution occurs.

Income tax (benefit) expense varies from the amounts that would be computed by applying the combined Canadian federal and provincial income tax rate of 27% (2019 - 27%) to the loss before income taxes as shown in the following tables:

	Year ended December 31,	
	2020	2019
	(in thousands)	
Computed taxes (benefits) at Canadian federal and provincial tax rates	\$ (17,211)	\$ (44,922)
Difference due to change in tax rate on opening deferred taxes	—	8,356
Adjustment to prior year	390	(525)
Permanent and other differences	622	3,458
Change in valuation allowance - other	12,033	19,078
Difference due to income taxed at foreign rates	3,716	(3,343)
Stock-based compensation	450	523
Impairment of goodwill	—	4,719
Income tax expense (recovery)	\$ —	\$ (12,656)

As of December 31, 2020, the Company has investment tax credits available to reduce Canadian federal income taxes of \$8.0 million, versus \$10.0 million as of December 31, 2019, which expire between 2030 and 2037, and provincial income taxes of \$2.6 million, versus \$4.5 million as of December 31, 2019, which expire between 2024 and 2027. In addition, the Company has research and development credits of \$3.9 million as of December 31, 2020, and \$3.9 million as of December 31, 2019, which expire between 2031 and 2038 and which can be used to reduce future taxable income in the United States.

As of December 31, 2020, the Company had scientific research and experimental development expenditures of \$58.6 million available for indefinite carry-forward, versus the \$60.6 million it had as of December 31, 2019. The Company also had net operating losses of \$175.6 million as of December 31, 2020 and \$164.9 million as of December 31, 2019, 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, 2020 and December 31, 2019, 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 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 \$1.8 million and \$61.9 million in pre-tax domestic and foreign losses, respectively, for the year ended December 31, 2020. The Company generated \$27.1 million and \$139.3 million in pre-tax domestic and foreign losses, respectively, for the year ended December 31, 2019.

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

	As of December 31,	
	2020	2019
	(in thousands)	
Deferred tax assets (liabilities):		
Non-capital losses carryforwards	\$ 74,351	\$ 59,956
Research and development deductions	15,812	16,349
Book amortization in excess of tax	(737)	(914)
Revenue recognized for tax purposes in excess of revenue recognized for accounting purposes	5,279	5,128
Tax value in excess of accounting value in lease inducements	627	705
Federal investment tax credits	5,872	7,325
Provincial investment tax credits	2,644	4,535
Equity accounted for investment	3,375	3,038
Federal R&E credits	3,897	3,897
Deductible stock options	2,457	1,632
Other	1,218	1,111
Total deferred tax assets	\$ 114,795	\$ 102,762
Valuation allowance	(114,795)	(102,762)
Net deferred tax assets (liabilities)	\$ —	\$ —

16. Related party transactions

On July 31, 2020, Genevant was recapitalized through an equity investment and conversion of previously issued convertible debt securities held by Roivant. Arbutus participated in the recapitalization of Genevant with an investment of \$2.5 million. Arbutus determined that this \$2.5 million additional investment in Genevant represented the funding of prior losses and accordingly, the Company recorded the amount as an equity investment loss on the Condensed Consolidated Statements of Operations and Comprehensive Loss in 2020. See note 5 for further details.

Genevant purchased certain administrative and transitional services from the Company totaling less than \$0.1 million and \$0.1 million during 2020 and 2019, respectively. 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.

In addition, Genevant had a sublease for 17,900 square feet in the Company's Burnaby facility. Sublease income, including management fee reimbursements, from Genevant was \$0.2 million in 2019 the last year under the Burnaby facility lease, which was netted against site consolidation costs 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, 2020, 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, 2020.

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, 2020 that have materially affected or are reasonably likely to materially affect the Company’s internal control over financial reporting.

Item 9B. Other Information

None.

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 2021 Annual General Meeting of the Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2020.

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 2021 Annual General Meeting of the Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2020.

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 2021 Annual General Meeting of the Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2020.

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 2021 Annual General Meeting of the Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2020.

Item 14. Principal Accounting Fees and Services

The information required by this item is incorporated herein by reference to our Proxy Statement for the 2021 Annual General Meeting of the Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2020.

PART IV

Item 15. Exhibits and Financial Statement Schedules

<u>Exhibit</u>	<u>Description</u>
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>Amended and Restated Governance Agreement between the Company and Roivant Sciences Ltd., a Bermuda exempted company, dated October 16, 2017 (incorporated herein by reference to Exhibit C to the Registrant's Preliminary Proxy Soliciting Materials on Schedule Pre 14A for the Special Meeting, filed with the SEC on November 21, 2017).</u>
4.2**	<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 Indemnity Agreement (refiled herein with initial Agreement by reference to Exhibit 4.15 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>
10.5†*	<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†* [Settlement Agreement and General Release, by and among Tekmira Pharmaceuticals Corporation, Protiva Biotherapeutics Inc., Alnylam Pharmaceuticals, Inc., and AlCana Technologies, Inc., dated November 12, 2012 \(incorporated herein by reference to Exhibit 4.26 to the Registrant's Annual Report on Form 20-F for the year ended December 31, 2012 filed with the SEC on March 27, 2013\).](#)
- 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* [Form of Representation Letter \(incorporated herein by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K/A filed with the SEC on January 26, 2015\).](#)
- 10.14*# [Executive Employment Agreement, dated effective as of February 25, 2016, between Arbutus Biopharma, Inc. and Elizabeth Howard \(incorporated herein by reference to Exhibit 10.78 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC on March 9, 2016\).](#)
- 10.15*# [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 \(incorporated herein by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed with the SEC on November 5, 2015\).](#)
- 10.16†* [Stock Purchase Agreement by and among OnCore Biopharma, Inc. and each of the stockholders of Enantigen Therapeutics, Inc., dated as of October 1, 2014 \(incorporated herein by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed with the SEC on May 6, 2015\).](#)
- 10.17*# [Executive Employment Agreement, dated effective as of July 11, 2015, between OnCore Biopharma, Inc. and Michael J. Sofia \(incorporated herein by reference to Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed with the SEC on August 7, 2015\).](#)
- 10.18*# [Amended 2011 Omnibus Share Compensation Plan \(incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, filed with the SEC on August 4, 2016\).](#)
- 10.19†† [Lease Agreement between the Company and ARE-PA Region No. 7, LLC dated August 9, 2016 \(incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, filed with the SEC on November 3, 2016\).](#)
- 10.20†† [First Amendment to Lease Agreement between Arbutus Biopharma, Inc. and ARE-PA Region No. 7, LLC dated October 7, 2016 \(incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, filed with the SEC on November 3, 2016\).](#)
- 10.21* [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 \(incorporated herein by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, filed with the SEC on November 3, 2016\).](#)
- 10.22* [Subscription Agreement and Related Documents between the Company and Roivant Sciences Ltd. \(incorporated herein by reference to Exhibit A to the Registrant's Preliminary Proxy Soliciting Materials on Schedule Pre 14A for the Special Meeting, filed with the SEC on November 21, 2017\).](#)
- 10.23* [Amended and Restated Lockup Agreement between the Company and Roivant Sciences Ltd. \(incorporated herein by reference to Exhibit D to the Registrant's Preliminary Proxy Soliciting Materials on Schedule Pre 14A for the Special Meeting, filed with the SEC on November 21, 2017\).](#)
- 10.24* [Form of Registration Rights Agreement \(incorporated herein by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K/A filed with the SEC on January 26, 2015\).](#)
- 10.25* [Amendment to Registration Rights Agreement between the Company and Roivant Sciences Ltd. \(incorporated herein by reference to Exhibit E to the Registrant's Preliminary Proxy Soliciting Materials on Schedule Pre 14A for the Special Meeting, filed with the SEC on November 21, 2017\).](#)

- 10.26* [Amended and Restated Standstill Agreement between the Company and Roivant Sciences Ltd. \(incorporated herein by reference to Exhibit F to the Registrant's Preliminary Proxy Soliciting Materials on Schedule Pre 14A for the Special Meeting, filed with the SEC on November 21, 2017\).](#)
- 10.27* [Preferred Share Article Amendment between the Company and Roivant Sciences Ltd. \(incorporated herein by reference to Exhibit G to the Registrant's Preliminary Proxy Soliciting Materials on Schedule Pre 14A for the Special Meeting, filed with the SEC on November 21, 2017\).](#)
- 10.28* [Exclusivity Agreement, dated February 13, 2018, by and between the Company and Roivant Sciences Ltd. \(incorporated herein by reference to Exhibit 7.09 of the Schedule 13D filed with the SEC by Roivant Sciences Ltd. on February 14, 2018\).](#)
- 10.29* [Master Contribution And Share Subscription Agreement, by and between the Company, Genevant Sciences Ltd. and Roivant Sciences LTD. \(incorporated herein by reference Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the Quarter ended March 31, 2018 filed with the SEC on May 4, 2018\).](#)
- 10.30* [Open Market Sale AgreementSM, dated December 20, 2018, by and between the Company and Jefferies LLC. \(incorporated herein by reference to Exhibit 1.1 of the Current Report on Form 8-K filed with the SEC on December 20, 2018\).](#)
- 10.31* [Amendment No. 1 to the Open Market Sale AgreementSM, dated December 20, 2019, by and between the Company and Jefferies LLC. \(incorporated herein by reference to Exhibit 1.3 to the Registrant's Registration Statement on Form S-3 filed with the SEC on December 20, 2019\).](#)
- 10.32* [Amendment No. 2 to the Open Market Sale AgreementSM, dated August 7, 2020, by and between the Company and Jefferies LLC. \(incorporated herein by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K filed with the SEC on August 7, 2020\).](#)
- 10.33** [Executive Employment Agreement, dated June 11, 2018, by and between the Company and David Hastings. \(incorporated herein by reference to Exhibit 10.52 of the Form 10-K filed with the SEC on March 7, 2019\).](#)
- 10.34** [Executive Signing Bonus, dated May 28, 2018, by and between the Company and David Hastings. \(incorporated herein by reference to Exhibit 10.53 of the Form 10-K filed with the SEC on March 7, 2019\).](#)
- 10.35** [Executive Employment Agreement, dated October 8, 2018, by and between the Company and Gaston Picchio \(incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the Quarter ended September 30, 2018, filed with the SEC on November 7, 2018\).](#)
- 10.36* [Separation Agreement and Release, dated June 13, 2019, by and the Company and Mark J. Murray \(incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on June 18, 2019\).](#)
- 10.37** [Employment Agreement, dated June 13, 2019, by and between the Company and William H. Collier \(incorporated herein by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed with the SEC on June 18, 2019\).](#)
- 10.38** [Form of Indemnity Agreement \(incorporated herein by reference to Exhibit 10.4 the Registrant's Current Report on Form 8-K filed with the SEC on June 18, 2019\).](#)
- 10.39** [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 \(incorporated herein by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q for the Quarter ended June 30, 2019, filed with the SEC on August 5, 2019\).](#)
- 10.40* [Purchase and Sale Agreement, dated July 2, 2019, by and between the Company and OCM IP Healthcare Portfolio LP \(incorporated herein by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q for the Quarter ended June 30, 2019, filed with the SEC on August 5, 2019\).](#)
- 10.41** [Arbutus Biopharma Corporation 2016 Omnibus Share and Incentive Plan, as supplemented by the Committee on May 28, 2020 \(incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on June 1, 2020\).](#)
- 10.42** [Arbutus Biopharma Corporation 2020 Employee Stock Purchase Plan \(incorporated herein by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on June 1, 2020\).](#)

10.43**	<u>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).</u>
10.44**	<u>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).</u>
10.45**	<u>Form of Arbutus Biopharma Corporation Indemnity Agreement (incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the Quarter ended September 30, 2019, filed with the SEC on November 6, 2019).</u>
10.46**	<u>Offer Letter, dated August 8, 2019, by and between the Company and Andrew Cheng (incorporated herein by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the Quarter ended September 30, 2019, filed with the SEC on November 6, 2019).</u>
10.47†*	<u>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).</u>
10.48†*	<u>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).</u>
10.49†*	<u>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).</u>
16.1*	<u>Letter from KPMG LLP, dated April 23, 2019. (incorporated herein by reference to Exhibit 16.1 to the Registrant's Current Report on Form 8-K filed with the SEC on April 23, 2019.)</u>
21.1**	<u>List of Subsidiaries.</u>
23.1**	<u>Consent of Ernst and Young LLP, an Independent Registered Public Accounting Firm.</u>
31.1**	<u>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.</u>
31.2**	<u>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.</u>
32.1**	<u>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.</u>
32.2**	<u>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.</u>
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

† Portions of this exhibit have been omitted in compliance with Item 601 of Regulation S-K.

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

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on March 4, 2021.

ARBUTUS BIOPHARMA CORPORATION

By: /s/ William Collier
William Collier
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities indicated on March 4, 2021.

<u>Signatures</u>	<u>Capacity in Which Signed</u>
<u>/s/ Frank Torti, M.D.</u> Dr. Frank Torti, M.D.	Director (Chairman)
<u>/s/ William H. Collier</u> William H. Collier	President and Chief Executive Officer and Director (Principal Executive Officer)
<u>/s/ David C. Hastings</u> David C. Hastings	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)
<u>/s/ Daniel Burgess</u> Daniel Burgess	Director
<u>/s/ Richard C. Henriques</u> Richard C. Henriques	Director
<u>/s/ Keith Manchester, M.D.</u> Keith Manchester, M.D.	Director
<u>/s/ Eric Venker, M.D., PharmD</u> Eric Venker, M.D., PharmD	Director
<u>/s/ James Meyers</u> James Meyers	Director
<u>/s/ Andrew Cheng, M.D., Ph. D</u> Andrew Cheng, M.D., Ph. D	Director

**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 March 3, 2021 there were (a) 95,583,915 common shares outstanding and (b) 1,164,000 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.

Series A Participating Convertible Preferred Shares

In October 2017, we entered into a subscription agreement with Roivant Sciences Ltd., or Roivant, for the sale of 1,164,000 Series A participating convertible preferred shares, or the Preferred Shares, for gross proceeds of \$116.4 million. These Preferred Shares are non-voting and accrue an 8.75% per annum coupon in the form of additional Preferred Shares, compounded annually, until October 18, 2021, at which time all the Preferred Shares will be subject to mandatory conversion into common shares (subject to limited exceptions in the event of certain fundamental corporate transactions relating to our capital structure or assets, which would permit earlier conversion at Roivant's option). The conversion price is \$7.13 per share, which will result in the Preferred Shares being converted into approximately 23 million common shares. After conversion of the

Preferred Shares into common shares, based on the number of common shares outstanding as of March 3, 2021, Roivant would hold approximately 33% of our common shares. Roivant agreed to a four year lock-up period for this investment and its existing holdings in us. Roivant also agreed to a four year standstill whereby Roivant will not acquire greater than 49.99% of our common shares or securities convertible into common shares. The initial investment of \$50.0 million closed in October 2017, and the remaining amount of \$66.4 million closed in January 2018 following regulatory and shareholder approvals.

Registration Rights

On January 11, 2015, we entered into an Agreement and Plan of Merger and Reorganization, or the Merger Agreement, with OnCore Biopharma, Inc., or OnCore, pursuant to which OnCore became our wholly-owned subsidiary. In connection with the Merger Agreement, we entered into a Registration Rights Agreement, or the Registration Rights Agreement, with certain of OnCore's shareholders. On October 16, 2017, we entered into an Amending Agreement pursuant to which the common shares underlying the Preferred Shares purchased by Roivant were included as registrable securities under the Registration Rights Agreement.

Pursuant to the Registration Rights Agreement, certain holders of our common shares have registration rights. After registration of these common shares pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act. The registration rights will terminate with respect to each shareholder on the date on which such shareholder ceases to beneficially own more than three percent of our common shares then outstanding, if such shares may be sold pursuant to Rule 144 of the Securities Act.

An aggregate of approximately 42 million common shares are entitled to these registration rights, including approximately 23 million common shares issuable upon conversion of the Preferred Shares.

Director Nomination Rights

Pursuant to the terms of the Amended and Restated Governance Agreement, dated October 16, 2017, between us and Roivant and Part 28 of our Articles, for so long as Roivant has "beneficial ownership" (as defined pursuant Rule 13d-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act), or Beneficial Ownership, or exercises control or direction over not less than:

- thirty percent (30%) of our issued and outstanding common shares calculated on a partially diluted basis as of a particular date, Roivant has the right to nominate three (3) individuals for election to our Board of Directors at each shareholder meeting, one (1) of whom must satisfy the applicable independence standards;
- twenty percent (20%) of our issued and outstanding common shares calculated on a partially diluted basis as of a particular date, Roivant has the right to nominate two (2) individuals for election to our Board of Directors at each shareholder meeting; and
- ten percent (10%) of our issued and outstanding common shares calculated on a partially diluted basis as of a particular date, Roivant has the right to nominate one (1) individual for election to our Board of Directors at each shareholder meeting.

Upon Roivant having Beneficial Ownership or exercising control or direction over less than ten percent (10%) of our outstanding common shares calculated on a partially diluted basis as of a particular date, the nomination rights provided above will be of no further force and effect. The total number of common shares underlying the Preferred Shares beneficially owned by Roivant are included in the Beneficial Ownership calculations described above.

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 AST Trust Company (Canada).

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-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,
2. Registration Statement (Form S-3 No. 333-235674) pertaining to the offering, issuance and sale of up to \$150,000,000 of common shares, preferred shares, warrants, debt securities and units of Arbutus Biopharma Corporation,
3. Registration Statement (Form S-8 No. 333-239407) pertaining to the Arbutus Biopharma Corporation 2016 Omnibus Share and Incentive Plan and Arbutus Biopharma Corporation 2020 Employee Stock Purchase Plan,
4. Registration Statement (Form S-8 No. 333-233192) pertaining to the Inducement Stock Option Award of Arbutus Biopharma Corporation,
5. Registration Statement (Form S-8 No. 333-228919) pertaining to the Arbutus Biopharma Corporation 2011 Omnibus Share Compensation Plan,
6. Registration Statement (Form S-8 No. 333-212115) pertaining to the Arbutus Biopharma Corporation 2016 Omnibus Share and Incentive Plan,
7. Registration Statement (Form S-8 No. 333-202762) pertaining to the OnCore Biopharma, Inc. 2014 Equity Incentive Plan, and
8. 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 4, 2021, 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, 2020.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
March 4, 2021

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 Form 10-K;
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 the 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 4, 2021

/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 Hastings, Chief Financial Officer of Arbutus Biopharma Corporation, certify that:

1. I have reviewed this Form 10-K;
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 4, 2021

/s/ David Hastings

Name: David 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, 2020, 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 4, 2021

/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, 2020, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I David 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 4, 2021

/s/ David Hastings
Name: David Hastings
Title: Chief Financial Officer
(Principal Financial Officer)