# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# Form 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the Fiscal Year Ended December 31, 2019

o 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 Nasdag 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 o No x

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 o No x

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 x No o

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 x No o

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 o

Accelerated filer x

Non-accelerated filer o

Smaller reporting company x

Emerging growth company o

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. o

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

As of June 30, 2019, 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 \$118,248,358 (based on the closing price of \$2.08 per share as reported on the NASDAQ Global Select Market as of that date).

As of March 2, 2020, the registrant had 68,941,406 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 2, 2020, the registrant would have had approximately 92 million common shares outstanding at March 2, 2020.

# DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2020 Annual Meeting of Stockholders, 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 end of December 31, 2019, 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 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 drug candidates to improve upon the standard of care and contribute to a curative combination treatment regimen;
- the potential benefits of the reversion of the Ontario Municipal Employees Retirement System ("OMERS") royalty monetization transaction for our ONPATTRO<sup>TM</sup> (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;
- · expanding our HBV drug candidate pipeline through internal development, acquisitions and in-licenses;
- our expectation for AB-729 for preliminary results from our single-dose Phase 1 trial to be available late in the first quarter of 2020;
- our expectation for AB-729 for preliminary results from multiple-dose Phase 1 trial to be available late in the second half of 2020;
- 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;
- the potential for an oral HBsAg-reducing agent and potential all-oral combination therapy;
- our objective to complete IND/CTA-enabling studies for AB-836 by the end of 2020;
- the potential for AB-836 to be low-dose with a wide therapeutic window and to address known capsid resistant variants T33N and 1105T;
- 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;
- our expectation to pursue development of a next generation oral HBV RNA-destabilizer;
- · payments from the Gritstone Oncology, Inc. licensing agreement;
- 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 into mid-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.

# PART I

# 1. Business Overview

Arbutus Biopharma Corporation ("Arbutus", the "Company", "we", "us", and "our") is a publicly traded (Nasdaq Global Select Market: ABUS) biopharmaceutical company dedicated to developing a cure for patients suffering from chronic hepatitis B infection, a disease of the liver caused by the hepatitis B virus ("HBV"). HBV represents a significant, global unmet medical need. The World Health Organization estimates that over 250 million people worldwide suffer from HBV infection, while other estimates indicate that approximately 2 million people in the United States suffer from HBV infection. Chronic HBV ("CHB") infection has high rates of morbidity and mortality with a cure rate for HBV patients taking standard of care ("SOC") treatment regimens of less than 5%. Our objective is to develop safe and effective therapies that can be combined for a finite treatment period and lead to higher cure rates. We define a cure as a functional cure where HBV replication and hepatitis B surface antigen ("HBsAg") expression are reduced to undetectable levels six months after end of therapy.

To pursue our strategy of developing a treatment for chronic HBV, we are developing a diverse product pipeline consisting of multiple drug candidates with complementary mechanisms of action, which have the potential to improve upon the SOC and contribute to a curative combination regimen.

Additionally, we have a royalty entitlement on 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 from the sale of this royalty interest. The royalty interest will revert back to us after the buyer receives \$30 million in royalty payments from Alnylam. 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 Therapeutics, Inc. ("Acuitas"). The royalty from Acuitas has been retained by us and was not part of the royalty sale. Refer to Item 1 Business Overview - Strategic Alliances and Licensing Agreements for additional details.

#### Strategy

Our objective is to develop a curative combination regimen for patients with chronic HBV infection. We believe this can best be achieved by:

- developing a pipeline of proprietary therapeutic agents that target multiple elements of the HBV viral lifecycle, the most important of which we believe are HBV replication and HBsAg expression;
- developing compounds that target the host immune system; and
- identifying an effective combination of complementary proprietary therapeutic agents administered for a finite treatment duration.

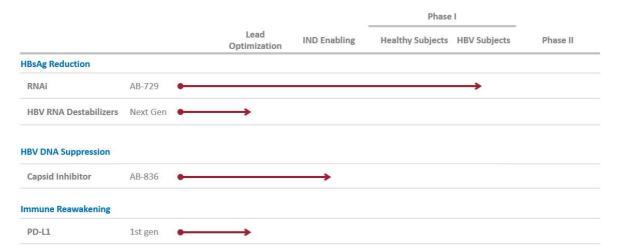
# Our primary focus is to:

- progress our clinical and pre-clinical product candidates through Phase 1 and Phase 2 clinical trials;
- identify a safe and effective combination regimen to support a Phase 3 clinical registration program;
- · obtain regulatory approval for such a combination regimen; and
- · commercialize such combination regimen.

We are currently conducting a Phase 1a/1b clinical trial and pre-clinical and investigational new drug ("IND")-enabling studies to evaluate proprietary HBV therapeutic agents alone, together with SOC therapies and in combination with each other. We expect to use the results from this clinical trial and the other studies to adaptively design future clinical trials to test the safety, efficacy, and duration of potential combination therapies.

Our HBV product pipeline consists of the following programs:

# **Arbutus HBV Pipeline**



We believe that AB-729, our subcutaneously administered RNA interference ("RNAi") product candidate, may be combinable with our lead capsid inhibitor product candidate, AB-836, and existing approved therapies, in our first combination therapy for HBV patients. We believe AB-836 has the potential for improved efficacy and an enhanced resistance profile relative to our previous generation capsid inhibitor product candidate, AB-506. In parallel, we are in lead optimization with several compounds for our PD-L1 program and next-generation HBV RNA destabilizer program. Our next-generation HBV RNA destabilizer product candidates have distinct chemical scaffolds from AB-452, our previous generation HBV RNA destabilizer.

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

# **HBV Background**

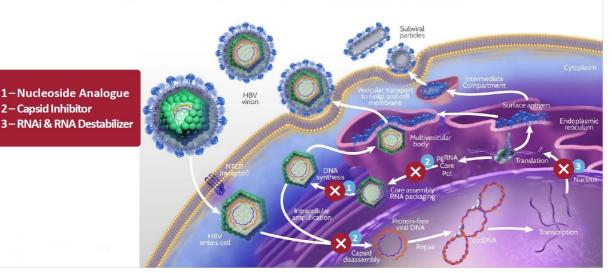
# **Agents for Combination Therapy**

Current treatments for HBV include pegylated interferon- $\alpha$  ("Peg-IFN $\alpha$ ") and nucleos(t)ide analogues ("NAs"). These treatments reduce viral load, but have low rates of cure (<5%). Peg-IFN $\alpha$ , 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 virus replication and inflammation and eliminate HBV DNA in the blood. However, virus replication resumes and liver inflammation and fibrosis may still progress once Peg-IFN $\alpha$  and NA therapies are stopped.

Given the biology of HBV, we believe combination therapies are the key to more effective HBV treatment and a potential cure. Additionally, we believe the development of an effective combination therapy can be accelerated when multiple components are controlled by a single company. Therefore, our R&D 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.

# **HBV Lifecycle Illustrates Key Points for Intervention**

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



- 1. Nucleos(t)ide analogues (NAs): NAs work by inhibiting HBV DNA polymerase activity and suppressing HBV replication. Oral NAs have become a mainstay of 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 lack of significant side effects. However, NAs 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 available 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.
- 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 hepatitis B surface antigen ("HBsAg") in preclinical models. 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.

# **HBsAg Reduction**

# **RNAi Agents**

The development of RNAi drugs, which utilize the RNA interference pathway, allows for a novel approach to treating disease. There is one approved RNAi product, ONPATTRO, another product candidate that has filed a New Drug Application ("NDA"), and there are a number of RNAi products currently advancing in human clinical trials. Our extensive experience in antiviral drug development has been applied to our RNAi program to develop therapeutics for chronic HBV infection.

Our RNAi HBV product candidate is designed to reduce HBsAg expression in patients 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.

#### GalNAc RNAi (AB-729)

Early in 2018, we nominated AB-729 for IND-enabling studies. AB-729 is a subcutaneously-delivered RNAi therapeutic targeted to hepatocytes using our novel covalently conjugated GalNAc delivery technology. AB-729 inhibits viral replication and reduces all HBV antigens, including HBsAg in preclinical models. Reducing HBsAg is thought to be a key prerequisite to enable reawakening of a patient's immune system to respond to the virus. The duration of HBsAg reduction with AB-729 supports once per month dosing.

We presented data from pre-clinical studies at the International Liver Congress of the European Association for the Study of the Liver ("EASL") meeting in April 2018 in a presentation titled, "Durable Inhibition of Hepatitis B Virus Replication and Antigenemia Using Subcutaneously Administered RNAi Agent AB-729 in Preclinical Models". This presentation showed robust HBsAg knockdown and more durable in vivo activity than earlier-generation RNAi agents for the treatment of chronic HBV infection.

We successfully completed IND-enabling studies for AB-729 which we filed as part of a clinical trial authorization ("CTA"). In July 2019, we initiated a single and multiple dose Phase 1a/1b clinical trial for AB-729, designed to investigate the safety, tolerability, pharmacokinetics, and pharmacodynamics of AB-729 in healthy subjects and in CHB subjects. Preliminary safety data in single-dose cohorts of healthy subjects and efficacy data in single-dose cohorts of patients with CHB infection are expected later this month. Additional single-dose data and preliminary multi-dose data are expected in the second half of 2020.

Our initial RNAi product candidate, ARB-1467, demonstrated the ability to reduce HBsAg in patients but utilized a lipid nanoparticle delivery vehicle which required intravenous delivery and bi-weekly administration. We discontinued development of ARB-1467 in 2018 to focus on AB-729, our subcutaneously-delivered product candidate that supports once per month dosing.

#### **HBV RNA Destabilizers**

HBV RNA destabilizers are small molecule orally active 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 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.

In October 2018, we announced the emergence of nonclinical safety findings in our AB-452 HBV RNA destabilizer program. Given the nature of these observations and the novel mechanism of action of this drug, additional studies were necessary to understand these findings and their implications before deciding whether to advance AB-452 into human clinical trials. Following careful assessment of the nonclinical safety findings, we noted several confounding observations which included observations with no histological correlation, a lack of dose response regarding some key findings and what we thought was an unexplained vehicle effect. Because of these confounding observations, we repeated the 90-day preclinical safety study in two species. Additionally, we evaluated AB-452 in a series of in vitro and in vivo studies to further characterize the compound, its mechanism of action, safety and pharmacokinetic profile. Based on the results from these repeat pre-clinical safety studies and additional characterization activities, in consultation with external regulatory and pre-clinical experts, we decided not to advance AB-452.

We remain committed to the development of oral HBV RNA destabilizers that have shown compelling anti-viral effects in multiple HBV pre-clinical models. Our effort is now focused on advancing a next-generation oral HBV specific RNA-destabilizer with chemical scaffolds distinct from AB-452 through lead optimization.

# **HBV Suppression**

# Capsid Inhibitors (AB-836)

HBV core protein assembles into a capsid structure, which is required for viral replication. The current SOC therapy (NAs or Peg-IFN) significantly reduces HBV DNA levels in the serum, but HBV replication continues in the liver, thereby enabling HBV infection to persist. More effective therapy for patients requires 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.

Our oral capsid inhibitor discovery effort generated promising next-generation compounds, which led to the nomination of AB-836 in January 2020 for IND/CTA-enabling studies. AB-836 has the potential for increased potency and an enhanced resistance profile compared to our previous capsid inhibitor product candidate, AB-506. AB-836 is a novel chemical series differentiated from AB-506 and other competitor compounds in the capsid inhibitor space. 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 agents and is also anticipated to be dosed once daily. We anticipate completing IND/CTA-enabling studies for AB-836 by the end of 2020.

Our previous capsid inhibitor product candidate, AB-506, was an orally administered, highly selective capsid inhibitor that had shown improved potency and pharmacokinetics ("PK") over our first generation capsid inhibitor, AB-423, in pre-clinical studies. In February 2020, we announced our decision to discontinue clinical development of AB-506, which at the time of the decision was in a Phase 1a/1b clinical trial. We made this decision after observing two cases of acute hepatitis in a 28-day healthy volunteer trial of AB-506. The liver enzyme levels in these two subjects subsequently normalized.

We remain committed to the development of oral capsid inhibitors that have shown compelling reductions in HBV DNA and HBV RNA levels. We are currently focused on advancing our promising next-generation oral capsid inhibitor product candidate, AB-836, through IND/CTA-enabling studies.

#### **Immune Modulators**

We have a number of research programs aimed at discovery and development of proprietary HBV candidates with different and complementary mechanisms of action. We are in lead optimization with compounds potentially capable of reawakening patients' HBV-specific immune response by inhibiting PD-L1. These compounds complement our pipeline of agents and could potentially form an effective combination therapy for the treatment of HBV.

# **Strategic Alliances and Licensing Agreements**

# **ONPATTRO**

In 2012, we entered into a license agreement with Alnylam that entitles Alnylam to develop and commercialize products with our LNP 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 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.

# Acuitas Therapeutics, Inc.

We have rights to a second 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 us and was not part of the royalty entitlement sale to OMERS.

# **Genevant Sciences**

In April 2018, we entered into an agreement with Roivant Sciences Ltd. ("Roivant"), our largest shareholder, to launch 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 have licensed exclusive rights to these delivery platforms to Genevant for RNA-based applications outside of HBV and any other pre-existing licensing obligations of Arbutus. Genevant plans to develop products in-house and to pursue industry partnerships in order to build a diverse pipeline of therapeutics across multiple modalities, including RNAi, mRNA, and gene editing.

Under the terms of the agreement, Roivant contributed \$37.5 million in transaction-related seed capital to Genevant, consisting of an initial \$22.5 million investment and a subsequent \$15 million investment at a pre-determined, stepped-up valuation. We retained all rights to our delivery platforms for HBV, and we are entitled to a tiered low single-digit royalty from Genevant on future sales of products enabled by the delivery platforms licensed to Genevant. We also retained the entirety of our royalty entitlement on the commercialization of Alnylam's ONPATTRO. As of December 31, 2019, we held an equity interest in Genevant of approximately 40%.

As of December 31, 2019, recovery of our remaining carrying value in Genevant was uncertain, and therefore we recorded a \$7.6 million impairment expense to reduce the carrying value of our investment in Genevant to zero.

# License 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. Through this transaction, Arbutus Inc. acquired a HBV surface antigen secretion inhibitor program and a capsid assembly inhibitor program.

Under the stock purchase agreement, we agreed to pay up to a total of \$21.0 million to Enantigen's selling shareholders upon the achievement of specified development and regulatory milestones for (a) the first two products that contain either a capsid compound or an HBV surface antigen compound that is covered by a patent acquired under this agreement, or (b) a capsid compound from an agreed upon list of compounds. The development milestones are tied to programs which are no longer under development by us, and therefore the contingency related to these milestones has been reduced to zero. 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 milestone payment obligations. Refer to note 3 - Fair Value Measurements in the Notes to the Consolidated Financial Statements.

#### **Margibo®**

Marqibo®, originally developed by us, is a novel, sphingomyelin/cholesterol liposome-encapsulated formulation of the FDA-approved anticancer drug Vincristine. Marqibo's approved indication is for the treatment of adult patients with Philadelphia chromosome-negative acute lymphoblastic leukemia (Ph-ALL) in second or greater relapse or whose disease has progressed following two or more lines of anti-leukemia therapy. We originally out-licensed Marqibo to Talon Therapeutics Inc. ("Talon") in 2006, and in July 2013, Talon was acquired by Spectrum Pharmaceuticals, Inc. ("Spectrum"). Spectrum initiated the commercial launch of Marqibo in September 2013 through its existing hematology sales force in the United States. In January 2019, Acrotech Biopharma, LLC, a subsidiary of Aurobindo Pharma USA, Inc., acquired the license for Marqibo from Spectrum.

We receive mid-single-digit royalty payments based on Marqibo's commercial sales. In addition, Marqibo is in ongoing clinical trials evaluating two additional indications, which are Pediatric acute lymphoblastic leukemia and Non-Hodgkin's lymphoma.

# **Gritstone Oncology**

In October 2017, we entered into an exclusive license agreement with Gritstone Oncology, Inc. ("Gritstone") that granted them worldwide access 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 will make payments for achievement of development, regulatory, and commercial milestones, royalties (which Genevant has a right to 50% of such royalty payments), and reimburses us for conducting technology development and for providing manufacturing and regulatory support for Gritstone's product candidates.

# University of British Columbia

Certain early work on LNP delivery systems and related inventions was undertaken at the University of British Columbia ("UBC"), as well as by us that was subsequently assigned to UBC. These inventions are licensed to us by UBC under a license agreement, initially entered in 1998 as amended in 2001, 2006 and 2007. We have granted sublicenses under the UBC license to certain third parties, including Alnylam. UBC subsequently filed a demand for arbitration against us for allegedly unpaid royalties associated with certain of said sublicenses, including the Alnylam sublicense. In the third quarter 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. We paid the \$5.9 million award to UBC in the third quarter of 2019. The arbitrator also held that the third phase of the arbitration, which would address patent validity, should we choose to pursue a third phase, would not provide a defense to the award. An award for costs and attorneys' fees is still to be determined. In December 2019, the arbitrator subsequently issued an interim decision concerning costs and attorneys' fees, holding that each party is to bear their own costs and attorneys' fees with the single exception of an award to UBC for reasonable costs and attorneys' fees incurred in defending against our counterclaim. The total of said costs and attorneys' fees is still to be determined. Please refer to "Item 3. Legal Proceedings" for additional information.

# **Patents and Proprietary Rights**

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our drug 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. A large number of patent applications filed with the United States and European Patent Offices have been granted. 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 64 patent families, in the United States and abroad, that are directed to our therapeutic HBV product candidates. The portfolio includes over 50 issued patents throughout the world and an extensive portfolio of pending patent applications.

#### **Scientific Advisers**

We seek advice from our scientific advisory board, which consists of a number of leading scientists and physicians, on scientific and medical matters.

#### **Site Consolidation**

In 2018, we substantially completed a site consolidation and organizational restructuring to align our HBV business in Warminster, PA, by reducing our global workforce and by closing our facility in Burnaby, Canada. For further detail, refer to note 10 "Site Consolidation" in the consolidated financial statements in Part II - Item 8.

# **Employees**

At December 31, 2019, Arbutus had 80 employees (78 full-time and 2 part-time), 62 of whom were engaged in research and development. 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.

# 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 pharmaceutical products, obtaining FDA and other regulatory approvals of products, 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 therapeutics for treatment of HBV. These companies include, but are not limited to Johnson and Johnson, Roche, Glaxo Smith Kline, Gilead, Assembly Biosciences, Dicerna, Replicor, Vir Biotechnology, Enanta and Aligos Therapeutics. Further, it is likely that additional drugs will become available in the future for the treatment of HBV. These companies are developing products such as capsid inhibitors, RNAi agents, immune modulators, NAs, surface antigen inhibitors, entry inhibitors and gene editing agents. These products are in various stages of pre-clinical and clinical development.

We anticipate that we will face competition as new products enter the marketplace and advanced technologies become available. Our competitors' products may be safer, more effective, or more effectively marketed and sold than any product we may commercialize. Competitive 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, complete the clinical trials and regulatory approval processes, and effectively market any products we develop. 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.

# **Government Regulation**

Regulation by governmental authorities in the United States and in other countries is a significant consideration in our product development, manufacturing and, upon approval of our product candidates, 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. United States federal laws and regulations govern the testing, development, manufacture, quality control, safety, effectiveness, approval, storage, labeling, record keeping, reporting, distribution, import, export 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 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 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 regulations following any such approvals will require the expenditure of significant financial and human resources not currently at our disposal.

# **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 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 studies, 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 ("cGCP") 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 before the study begins. 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 cGCP 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 http://clinicaltrials.gov.

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

In Phase 1, the drug 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). Although Phase 1 trials typically are conducted in healthy human subjects, in some instances (including, for example, with some cancer therapies) the study subjects are patients with the targeted disease or condition.

In Phase 2, the drug 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 drug's safety. Additional animal toxicology studies may precede this phase.

In Phase 3, the drug is administered to a larger group of patients, 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 drug'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 drug in the United States submits to the FDA a New Drug Application ("NDA"). The NDA is a comprehensive, multi-volume application intended to demonstrate the product's safety and effectiveness and includes, among other things, pre-clinical and clinical data, information about the drug'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 its 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 submission for products 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 drug 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. Products with Fast Track designation also may be eligible for more frequent meetings and correspondence with the FDA about the product's development. Another FDA program intended to expedite development is Accelerated Approval, which allows approval on the basis of a surrogate endpoint that is reasonably likely to predict clinical benefit. Breakthrough Therapy designation, which is available for drugs under development for serious or life-threatening conditions and where preliminary clinical evidence shows that the drug may have substantial improvement on at least one clinically significant endpoint over available therapy, means that a drug 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/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.

If the FDA concludes that an NDA does not meet the regulatory standards for approval, it typically issues a Complete Response letter, which communicates the reasons for the agency's decision not to approve the application and may request additional information, including additional clinical data. 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 or non-clinical studies or to conduct surveillance programs to monitor the drug's effects.

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.

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 under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"). The Hatch-Waxman Act provides periods of exclusivity for a branded drug product that would serve as a reference listed drug ("RLD") for a generic drug applicant filing an abbreviated new drug application ("ANDA") or for an applicant filing a 505(b)(2) NDA application. 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 below). Such a product that is not an NCE may qualify for a three-year period of exclusivity if its NDA contains new clinical data, 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 3-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.

Competition. The Hatch-Waxman Act establishes two abbreviated approval pathways for drug products that are in some way follow-on versions of already approved branded NDA products: (i) generic versions of the approved RLD, which may be approved under an 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 the RLD, which may be approved under a 505(b)(2) NDA, in which the sponsor relies to some degree on the FDA's finding that the RLD is safe and effective, but submits its own product-specific data to support the differences between the product and the RLD.

The sponsor of an ANDA or 505(b)(2) application seeking to rely on an approved product as the RLD 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 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 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.

# 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, including limiting, suspending 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 current Good Manufacturing Practice ("cGMP") 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. Failure to comply with applicable cGMP 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 drug products, 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, its advertising, promotion and marketing 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 ot
- 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 creates new data privacy rights for consumers. 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 n

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. CMS, the agency that administers the Medicare and Medicaid programs, has authority to revise reimbursement rates and to implement coverage restrictions for some drugs. 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. While Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payors.

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. In December 2018, the United States District Court for the Northern District of Texas ruled (i) that the "individual mandate" is unconstitutional as a result of the associated tax penalty being repealed by Congress as part of the Tax Cuts and Jobs Act; and (ii) the individual mandate is not severable from the rest of the Affordable Care Act, and as a result the entire Affordable Care Act is invalid. In December 2019, the United States Court of Appeals for the Fifth Circuit affirmed the district court's decision that the individual mandate is unconstitutional, but remanded the case to the district court to reconsider the severability question. It is unclear how the ultimate decision in this case, which is now pending before the United States Supreme Court, or other efforts to repeal, replace, 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, recent legislative enactments have resulted in Medicare payments to providers being subject to a reduction of, on average, two percent, referred to as sequestration, until 2029. Continuation of sequestration or enactment of other reductions in Medicare reimbursement for drugs could affect our ability to achieve a profit on any candidate products that are approved for marketing.

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 clinical trials, approval, manufacturing, 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**

Arbutus Biopharma Corporation is a publicly traded industry-leading therapeutic solutions company focused on discovering, developing and commercializing a curative combination regimen for patients suffering from chronic HBV infection.

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 have two wholly-owned subsidiaries as of December 31, 2019: Arbutus Biopharma, Inc. and Arbutus Biopharma US Holdings, Inc., which was formed in 2018.

Protiva was acquired on May 30, 2008. On January 1, 2018, Protiva was amalgamated with Arbutus Biopharma Corporation.

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.

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

# **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 <a href="http://www.arbutusbio.com">http://www.arbutusbio.com</a>. 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. Our reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, including our annual reports on Form 10-K (and our annual reports on Form 20-F up to the year ended December 31, 2012), our quarterly reports on Form 10-Q (and our quarterly reports on Form 6-K up to the quarter-ended September 30, 2013) and our current reports on Form 8-K, and amendments to those reports, are accessible through our website, free of charge, as soon as reasonably practicable after these reports are filed electronically with, or otherwise furnished to, the United States Securities and Exchange Commission ("SEC"). We also make available on our website the charters of our audit committee, executive compensation and human resources committee and corporate governance and nominating committee, whistleblower policy, insider trading policy, corporate disclosure policy, related persons transactions policy and majority voting policy, as well as our code of business conduct and ethics for directors, officers and employees. In addition, we intend to disclose on our web site any amendments to, or waivers from, our code of business conduct and ethics that are required to be disclosed pursuant to the SEC rules.

The SEC also maintains a website that contains reports, proxy and information statements, and other information regarding Arbutus and other issuers that file electronically with the SEC. The SEC's website address is <a href="http://www.sec.gov">http://www.sec.gov</a>.

# 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, financiongal 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 one 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 acceptance for the development and commercialization of any product candidates we develop;
- · conduct sales and marketing activities;
- · 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 curative combination regimen. 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 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 cure HBV. If we cannot develop compounds to achieve our goal of 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 curative combination regimen for HBV.

We will require substantial additional capital to fund our operations. If additional capital is not available, we may need to delay, limit or eliminate our research, development and commercialization processes and modify our business strategy.

Our principal sources of liquidity are cash, cash equivalents and marketable securities of \$90.8 million as of December 31, 2019. We believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operations into mid-2021. 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, Gritstone and Acrotech;
- 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, product candidates or technology for development;
- our ability to attract and retain corporate partners, and their effectiveness in carrying out the development and ultimate commercialization of one or more 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 product candidates;
- · competing 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 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 ore 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 sustained 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, 2019 and have not received any revenues other than from research and development collaborations, royalties, license fees and milestone payments. From inception to December 31, 2019, we have an accumulated net deficit of \$970.1 million. 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 sustained profits until such time as milestone payments, product sales 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.

# 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 a partner 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.

# We will seek to raise additional funds in the future, which may be dilutive to shareholders or impose operational restrictions.

We will need to raise additional capital in the future to help fund our pre-clinical studies, clinical trials and for the development and commercialization of our product candidates for which we obtain regulatory approval. If we raise additional capital through the issuance of equity securities, the percentage ownership of our current shareholders will be reduced. We may also issue equity as part of the consideration to our licensors, to compensate consultants or to settle outstanding payables. Our shareholders may experience additional dilution in net book value per share and any 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 cannot raise additional funds, we will have to delay our development activities or cease operations.

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.

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. Such testing is expensive and time-consuming and requires specialized knowledge and expertise.

Clinical trials are 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") before a clinical trial can be initiated at a given site;
- 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 patients in our clinical trials;
- delay or failure in having patients 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 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;
- · inability to monitor patients adequately during or after treatment;
- · 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. 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. Any of these occurrences may harm our business, financial condition, results of operations, cash flows and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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 candidate, and, correspondingly, our business and financial prospects, would be materially adversely affected. 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 such product candidate, 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 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.

We face risks related to health epidemics and outbreaks, including the coronavirus, which could significantly disrupt our preclinical studies and clinical trials.

In December 2019, a novel strain of coronavirus (COVID-19) was reported to have surfaced in Wuhan, China. The duration and the geographic impact of the business disruption and related financial impact resulting from the coronavirus cannot be reasonably estimated at this time and our business could be adversely impacted by the effects. We are currently conducting clinical trials in Moldova, Thailand, South Korea, Hong Kong, Australia and New Zealand. Enrollment of patients in these clinical trials and future clinical trials in these regions may be delayed due to the outbreak of COVID-19. In addition, we rely on independent clinical investigators, contract research organizations and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our preclinical studies and clinical trials, and the outbreak may affect their ability to devote sufficient time and resources to our programs. We also rely on third party suppliers and contract manufacturers to produce the drug product we utilize in our clinical trials, and the outbreak may cause delays in delivery of APIs and drug product. As a result, the expected timeline for data readouts of our preclinical studies and clinical trials and certain regulatory filings may be negatively impacted, which would adversely affect our business.

# Clinical trial results may fail to support approval of our product candidates.

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. This, in turn, would significantly adversely affect our business prospects.

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, 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 commercial our product candidates in jurisdictions outside the United States.

To obtain marketing approval, United States laws require:

- controlled research and human clinical testing;
- 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 Good Manufacturing Practice 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 other jurisdictions 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 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 a comparable regulatory authority outside the United States may require us to conduct additional pre-clinical and clinical testing, which may delay or prevent approval 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 clinical trials. 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 patient 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, 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 financial position. Even if our product candidates receive marketing approval, undesirable side effects may limit the 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.

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

Approved 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. If we or any of the third parties on which we rely fail to meet those requirements, it could lead to enforcement action, among other consequences, that 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 may find it difficult to enroll patients in our clinical trials, which could delay or prevent clinical trials of our product candidates.

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

We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a clinical trial, or complete our clinical trials in a timely manner. Patient enrollment is affected by a variety 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;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- · efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

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

# 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, 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;
- 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. 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 pharmaceutical 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. 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.

# If the market opportunities for our product candidates are smaller than we believe they are, our results of operations may be adversely affected and our business may suffer.

We focus our research and product development on treatments of chronic HBV. Our projections of the number of people who have chronic HBV are based on estimates. These estimates may prove to be incorrect and the number of patients in the United States and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some jurisdictions outside the United States, there have been, and continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act of 2010, or collectively the Affordable Care Act, was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The Affordable Care Act has substantially changed the way healthcare is financed by both governmental and private insurers and has significantly affected the pharmaceutical industry.

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 (TCJA) 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. Further, the Bipartisan Budget Act of 2018 among other things amended the Medicare statute, effective January 1, 2019, to reduce the coverage gap in most Medicare drug plans, commonly known as the "donut hole," by raising the manufacturer discount under the Medicare Part D coverage gap discount program to 70%. In addition, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, President Trump signed an Executive Order terminating the cost-sharing subsidies under the Affordable Care Act. In addition, CMS has issued regulations giving states greater flexibility, starting in 2020, in the identification of the essential health benefits benchmarks for non-grandfathered individual and small group market health insurance coverage, including plans sold through the health insurance exchanges established under the Affordable Care Act. Additional legislative changes, regulatory changes, and judicial challenges related to the Affordable Care Act remain possible, but the nature and extent of such potential changes or challenges are uncertain at this time. The implications of the Affordable Care Act, and efforts to repeal and replace, or invalid

We cannot predict what healthcare reform initiatives may be adopted in the future. Further federal and state legislative and regulatory developments are likely, and we expect ongoing initiatives in the United States to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Legislative and regulatory proposals have also been made to expand post approval requirements and restrict sales and promotional activities for pharmaceutical products. Any healthcare reforms enacted in the future may, like the Affordable Care Act, be phased in over a number of years but, if enacted, could reduce our revenue, increase our costs, or require us to revise the ways in which we conduct business or put us at risk for loss of business. We are not sure whether additional legislative changes will be enacted, or whether the current regulations, guidance or interpretations will be changed, or what the impact of such changes on our business, if any, may be.

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.

If we are able to successfully commercialize any of our products and if we participate in the Medicaid Drug Rebate Program or other governmental pricing programs, failure to comply with reporting and payment obligations under these programs could result in additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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 certain federal agencies and grantees, a manufacturer also must participate in the Federal Supply Schedule ("FSS") pricing program, established by Section 603 of the Veterans Health Care Act of 1992 ("VHCA"). Under this program, the manufacturer is obligated to make its covered drugs available for procurement on an FSS contract and charge a price to the Big Four agencies that is no higher than the statutory Federal Ceiling Price. Moreover, pursuant to Defense Health Agency ("DHA") regulations, manufacturers must provide rebates on utilization of their covered drugs 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 ("Non-FAMP") and the Federal Ceiling Price ("FCP") in effect on the dispense date (these price points are 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

The Medicaid Drug Rebate Program and other governmental pricing programs require participating manufacturers to report pricing data to the government. Pricing calculations vary among products and programs and include average manufacturer price and best price for the Medicaid Drug Rebate Program, and FCP and non-FAMP for the FSS pricing program.

If we successfully commercialize any of our products and participate in such governmental pricing programs, we will be liable for errors associated with our submission of pricing data. That liability could be significant. Pricing submissions and rebate calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies and the courts. If we fail to comply with any applicable reporting and payment obligations under governmental pricing programs that we participate in, we could be subject to additional reimbursement requirements, significant civil monetary penalties, sanctions and fines, and those could negatively impact our business, financial condition, results of operations and growth prospects. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. We cannot assure you that our submissions would not be found by the applicable governmental agency to be incomplete or incorrect.

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), 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 civil penalties,

- 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, Arbutus 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 will revert to Arbutus. 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; and

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 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 adversely affected.

We expect that we will depend in part on our licensing agreements with Alnylam, Gritstone, and Acrotech 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.

If conflicts arise between our licensing partners and us, our 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 licensing partners, including Alnylam, Gritstone, and Acrotech, 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 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 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, contract research organizations 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.

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 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 receives FDA approval, we expect to rely on third-party contractors to manufacture our drugs. 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 drugs 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 products, 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.

We have no experience selling, marketing or distributing drug products and currently have no internal capability to do so.

We currently have no sales, marketing or distribution capabilities. While we intend to have a role in the commercialization of our product candidates, if approved, we do not anticipate having the resources in the foreseeable future to develop global sales and marketing capabilities for all of our proposed products. Our future success depends, in part, on our ability to enter into and maintain

collaborative relationships with other companies that have sales, marketing and distribution capabilities, a strategic interest in the products under development, and the ability to successfully market and sell our products. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our proposed products, significant capital expenditures, management resources and time will be required to establish and develop an in-house marketing and sales force with the necessary expertise. We cannot make assurances that we will be able to establish or maintain relationships with third-party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, as well as the terms of our agreements with such third parties, which cannot be predicted at this early stage of our development. We cannot make assurances that such efforts will be successful. In addition, we cannot make assurances that we will be able to market and sell our products in the United States or in other locations around the world.

#### Risks Related to Patents, Licenses and Trade Secrets

# 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.

# 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 may not provide the holder with any competitive advantages;
- · patents could be challenged by third parties;
- the patents of others could impede our ability to do business;
- · 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, if patents that cover our activities are issued to other companies, there can be no assurance that we would be able to obtain licenses to these patents at a reasonable cost or be able to develop or obtain alternative technology. If we do not obtain such licenses, we could encounter delays in the introduction of products, or could find that the development, manufacture or sale of products requiring such licenses is prohibited. In addition, we could incur substantial costs in defending patent infringement suits brought against us or 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 may not effectively prevent disclosure of confidential information and 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 Competition**

The pharmaceutical market is intensely competitive. If we are unable to compete effectively with existing drugs, new treatment methods and new technologies, we may be unable to successfully commercialize any product candidates that we develop.

The pharmaceutical market is intensely competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are pursuing the development of novel drugs for the same diseases that we are targeting or expect to target. Many of our competitors have:

- much greater financial, technical and human resources than we have at every stage of the discovery, development, manufacture and commercialization process;
- more extensive experience in pre-clinical testing, conducting clinical trials, obtaining regulatory approvals, and in manufacturing, marketing and selling pharmaceutical products;
- product candidates that are based on previously tested or accepted technologies;
- · products that have been approved or are in late stages of development; and
- collaborative arrangements in our target markets with leading companies and research institutions.

We will face competition from products that have already been approved and accepted by the medical community for the treatment of the conditions for which we are currently developing products. We also expect to face competition from new products that enter the market. We believe a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may try to develop products. These products,

or other of our competitors' products, may be more effective, safer, less expensive or marketed and sold more effectively than any products we develop.

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 and Johnson, Roche, Glaxo Smith Kline, Gilead, Assembly Biosciences, Dicerna, Replicor, Vir Biotechnology, Enanta 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. Our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small number of our competitors.

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 obsolete or uncompetitive before we can recover the expenses of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and the ability to execute on our business plan. Furthermore, we also face competition from existing and new treatment methods that reduce or eliminate the need for drugs, such as the use of advanced medical devices. The development of new medical devices or other treatment methods for the diseases we are targeting and may target could make our product candidates non-competitive, obsolete or uneconomical.

# **Risks Related to Managing our Operations**

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 may have difficulty managing our growth and expanding our operations successfully as we continue to evolve from a company primarily involved in discovery and pre-clinical testing into one that develops products through clinical development and commercialization.

As product candidates we develop enter and advance through clinical trials, we will need to expand our development, regulatory, manufacturing, clinical and medical capabilities or contract with other organizations to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various collaborators, suppliers and other organizations. Our ability to manage our operations and growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems or controls.

# 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 Canadian Nuclear Safety Commission and the United States Nuclear Regulatory Commission 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 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 impact key business processes. Despite the implementation of security measures, 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, and telecommunication and electrical failures. Such events could result in exposure of confidential information, the modification of critical data, 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. To the extent that any disruption or security breach will result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the development of our product candidates could be delayed. While we have implemented security measures, including controls over unauthorized access, our internal computer systems and those of our contractors and consultants are vulnerable to damage from these events. 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 that could result in financial, legal, business or reputational harm to us or that our insurance would provide any or adequate coverage of any such loss.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial reports, which could have a material adverse effect on our share price and our ability to raise capital.

A failure to maintain effective internal control over financial reporting or disclosure controls and procedures could adversely affect our ability to report our financial results accurately and on a timely basis, which could result in a material misstatement in our financial statements, a loss of investor confidence in our financial reporting or adversely affect our access to sources of liquidity. Furthermore, because of the inherent limitations of any system of internal control over financial reporting, including the possibility of human error, the circumvention or overriding of controls and fraud, even effective internal controls may not prevent or detect all misstatements. Frequent or rapid changes in procedures, methodologies, systems and technology exacerbate the challenge of developing and maintaining a system of internal controls and can increase the cost and level of effort to develop and maintain such systems.

See Item 9A, "Controls and Procedures" in this Form 10-K for additional information and management's assessment of internal controls.

# 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 2, 2020, executive officers, directors, five percent or greater shareholders, and their respective affiliated entities beneficially own, in the aggregate, approximately 41% of our outstanding common shares.

Entities associated with Roivant Sciences Ltd. ("Roivant") collectively hold as a group approximately 23% of our outstanding common shares as of March 2, 2020. 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 22,589,601 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 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 2, 2020, Roivant would hold approximately 39 million common shares, or, 42% of our outstanding common shares.

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 acquiror 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". Roivant consented to increasing the size of the board to eight in connection with the appointment of Andrew Cheng, M.D., PhD., to the board of directors. 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.

# The trading price of the shares of our common shares has been highly volatile, and purchasers of our common shares could incur substantial losses.

The market price of our common shares has and may continue to fluctuate significantly in response to factors, some of which are beyond our control. The stock market in general has recently experienced extreme price and volume fluctuations. The market prices of securities of pharmaceutical and biotechnology companies have been extremely volatile, and have experienced fluctuations that often have been unrelated or disproportionate to the operating performance of these companies. These broad market fluctuations could result in extreme fluctuations in the price of our common shares, which could cause our investors to incur substantial losses. Our share price could be subject to wide fluctuations in response to a variety of factors, which include:

- · whether our product candidates can be advanced as expected;
- · whether our clinical trials can be conducted within the timeframe that we expect and whether such trials will yield positive results;
- · changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial requirements for approvals;
- unanticipated serious safety concerns related to the use of our product candidates;
- a decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions;
- · the introduction of new products or technologies offered by us or our competitors;
- the inability to effectively manage our growth;
- actual or anticipated variations in quarterly operating results;
- the failure to meet or exceed the estimates and projections of the investment community;
- the perception of the biopharmaceutical industry by the public, legislatures, regulators and the investment community;
- the overall performance of the United States equity capital markets and general political and economic conditions;
- announcements of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- the trading volume of our common shares; and
- other events or factors, many of which are beyond our control.

Our operating results may fluctuate significantly in the future, which may cause our results to fall below the expectations of securities analysts, shareholders and investors.

Our operating results may fluctuate significantly in the future as a result of a variety of factors, many of which are outside of our control. These factors include, but are not limited to:

- the timing, implementation and cost of our research, pre-clinical studies and clinical trials;
- our ability to attract and retain personnel with the necessary strategic, technical and creative skills required for effective operations;
- the amount and timing of expenditures by practitioners and their patients;

- · introduction of new technologies;
- product liability litigation, class action and derivative action litigation, or other litigation;
- the amount and timing of capital expenditures and other costs relating to the expansion of our operations;
- the state of the debt and/or equity capital markets at the time of any proposed offering we choose to initiate;
- our ability to successfully integrate new acquisitions into our operations;
- government regulation and legal developments regarding our product candidates in the United States and in the foreign countries in which we may
  operate in the future; and
- general economic conditions.

As a strategic response to changes in the competitive environment, we may from time to time make pricing, service, technology or marketing decisions or business or technology acquisitions that could have a material adverse effect on our operating results. Due to any of these factors, our operating results may fall below the expectations of securities analysts, shareholders and investors in any future period, which may cause our share price to decline.

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 those persons 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, 2019. 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.

We may be prohibited from fully using our United States net operating loss carryforwards, which could affect our financial performance.

As of December 31, 2019, we had \$11.7 million of net operating losses due to expire in 2035 and \$62.0 million of net operating loss ("NOL") carryforwards subject to an indefinite carryforward period which can be used to offset future taxable income in the United States. We also had research tax credit carryforwards of approximately \$3.9 million for United States federal income tax purposes, expiring in varying amounts through the year 2038. Under Section 382 of the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three year period,

the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. As of December 31, 2019, we had gross net operating losses of approximately \$164.9 million for Canadian federal income tax purposes, expiring in varying amounts through the year 2038. We also have research tax credit carryforwards of approximately \$60.6 million available for indefinite carryforward. Canadian tax law has similar restrictions as the United States Tax Code on a corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes. Consequently, our Canadian NOLs could be limited if the organization undergoes an ownership change.

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. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset United States and Canadian federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. Furthermore, these losses could expire before we generate sufficient income to utilize them.

# Future changes to tax laws could materially adversely affect our company and reduce net returns to our shareholders.

The tax treatment of the company is subject to changes in tax laws, regulations and treaties, or the interpretation thereof, tax policy initiatives and reforms under consideration and the practices of tax authorities in jurisdictions in which we operate, as well as tax policy initiatives and reforms related to the Organisation for Economic Co-Operation and Development's, or OECD, Base Erosion and Profit Shifting, or BEPS, Project, the European Commission's state aid investigations and other initiatives. Such changes may include (but are not limited to) the taxation of operating income, investment income, dividends received or (in the specific context of withholding tax) dividends paid. We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our financial position and overall or effective tax rates in the future in countries where we have operations, reduce post-tax returns to our shareholders, and increase the complexity, burden and cost of tax compliance.

# 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.

# Future sales of our common shares may depress our share price.

The market price of our common shares could decline as a result of sales of substantial amounts of our common shares in the public market, or as a result of the perception that these sales could occur, which could occur if we issue a large number of common shares (or securities convertible into our common shares) in connection with a future financing, as our common shares are trading at low levels. These factors could make it more difficult for us to raise funds through future offerings of common shares or other equity securities.

# An active market for our common shares may not be sustained.

Although our common shares are listed on the Nasdaq Global Select Market, an active trading market for our common shares may not be sustained, especially given the large percentage of our common shares held by our affiliates. If an active market for our common shares is not sustained, it may be difficult for our shareholders to sell shares without depressing the market price for our common shares.

Additional shares that may be issued upon the exercise of currently outstanding options or upon the conversion of Preferred Shares would dilute the voting power of our currently outstanding common shares and could cause our share price to decline.

As of March 2, 2020, we had outstanding options to acquire approximately 10.6 million common shares and outstanding Preferred Shares convertible into approximately 23 million common shares on October 18, 2021. The issuance of our common shares upon exercise of the stock options or conversion of the Preferred Shares would result in dilution to the interests of other holders of our common shares and could adversely affect our share price.

# We do not expect to pay dividends for the foreseeable future.

We have not paid any cash dividends to date and we do not intend to declare dividends for the foreseeable future, as we anticipate that we will reinvest future earnings, if any, in the development and growth of our business. Therefore, investors will not receive any funds unless they sell their common shares, and shareholders may be unable to sell their shares on favorable terms or at all. We cannot assure you of a positive return on investment or that you will not lose the entire amount of your investment in our common shares. Prospective investors seeking or needing dividend income or liquidity should not purchase our common shares.

The value of our securities, including our common shares, might be affected by matters not related to our operating performance and could subject us to securities litigation.

The value of our common shares may be reduced for a number of reasons, many of which are outside our control, including:

- general economic and political conditions in Canada, the United States and globally;
- governmental regulation of the health care and pharmaceutical industries;
- failure to achieve desired drug discovery outcomes by us or our collaborators;
- failure to obtain industry partner and other third party consents and approvals, when required;
- stock market volatility and market valuations;
- competition for, among other things, capital, drug targets and skilled personnel;
- the need to obtain required approvals from regulatory authorities;
- revenue and operating results failing to meet expectations in any particular period;
- investor perception of the health care and pharmaceutical industries;
- limited trading volume of our common shares;
- announcements relating to our business or the businesses of our competitors; and
- our ability or inability to raise additional funds.

If securities analysts do not publish research or reports about our business, or if they publish negative evaluations, the price of our common shares could decline.

The trading market for our common shares may be impacted by the availability or lack of research and reports that third-party industry or financial analysts publish about us. There are many large, publicly traded companies active in the biopharmaceutical industry, which may mean it will be less likely that we receive widespread analyst coverage. Furthermore, if one or more of the analysts who do cover us downgrade its shares, its share price would likely decline. If we do not receive adequate coverage by reputable analysts that have an understanding of our business and industry, it could fail to achieve visibility in the market, which in turn could cause our share price to decline.

# **Item 1B. Unresolved Staff Comments**

There are currently no unresolved staff comments.

# Item 2. Properties

In August 2016, we signed a lease agreement effective November 1, 2016, subsequently amended on October 7, 2016, to enable moving our headquarters to 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.

In November 2018, we signed a new lease agreement effective January 1, 2019, for 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 LNP delivery systems and related inventions was undertaken by UBC, as well as by us and assigned to UBC. These inventions were subsequently licensed 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 parties.

In November 2014, UBC filed a demand for arbitration against us and UBC also sought interest and costs, including legal fees. We filed our Statement of Defense to UBC's Statement of Claims, as well as a Counterclaim involving a patent application that we alleged UBC wrongly licensed to a third party. The proceedings were divided into three phases, with the first hearing taking place in June 2017. In the first phase, the arbitrator determined which agreements are sublicense agreements within UBC's claim. Also in the first phase, UBC updated its alleged entitlement from \$3.5 million originally claimed to seek \$10.9 million in alleged unpaid royalties, plus interest arising from payments as early as 2008. The arbitrator also held in the first phase of the arbitration that the patent application that is the subject of the Counterclaim was not required to be licensed to Arbutus. The second phase of arbitration took place in the second quarter of 2019. In the third quarter 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. We paid the \$5.9 million award to UBC in the third quarter of 2019. The arbitrator also held that the third phase of the arbitration, which would address patent validity, should we choose to pursue a third phase, would not provide a defense to the award. In December 2019, the arbitrator issued an interim decision concerning costs and attorneys' fees, holding that each party is to bear their own costs and attorneys' fees with the single exception of an award to UBC for reasonable costs and attorneys' fees incurred in defending against

our Counterclaim. The determination as to what costs and attorneys' fees are reasonable in defending against said Counterclaim is still to be determined.

# **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 2, 2020, there were 102 registered holders of common shares and 68,941,406 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, 2019.

# 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, 2019.

# 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

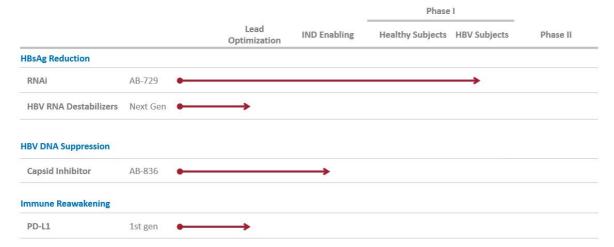
We are a biopharmaceutical company dedicated to discovering, developing, and commercializing a cure for patients suffering from chronic hepatitis B infection, a disease of the liver caused by the hepatitis B virus ("HBV"). HBV represents a significant, global unmet medical need. The World Health Organization estimates that over 250 million people worldwide suffer from HBV infection, while other estimates indicate that approximately 2 million people in the United States suffer from HBV infection. Chronic HBV infection has high rates of morbidity and mortality with a cure rate for HBV patients taking standard of care ("SOC") treatment regimens of less than 5%. Our objective is to develop safe and effective therapies that can be combined and lead to higher cure rates with finite treatment durations.

To pursue our strategy of developing a cure for chronic HBV, we are developing a diverse product pipeline consisting of multiple drug candidates with potential complementary mechanisms of action MOA, each of which has the potential to improve upon the SOC and contribute to a curative combination treatment regimen. Our clinical and pre-clinical pipeline includes agents that have the potential to form an effective proprietary combination therapy.

Our product pipeline is entirely focused on finding a curative combination regimen for chronic HBV infection, with the objective of developing a suite of products that intervene at different points in the viral life cycle and reactivate the host immune system. We are currently conducting one clinical trial and several pre-clinical studies to evaluate potential combinations of proprietary HBV therapeutic agents in addition to SOC therapies to support their clinical use in combination. We expect to use the results from these studies to adaptively design additional clinical trials to test the efficacy of the combination therapy and the duration of the result in patients. We plan to identify a combination regimen to conduct Phase III clinical trials intended to ultimately support regulatory filings for marketing approval.

Our HBV product pipeline consists of the following programs:

# **Arbutus HBV Pipeline**



We believe that AB-729, our subcutaneously administered RNA interference ("RNAi") product candidate, may be combinable with our lead capsid inhibitor product candidate, AB-836, and existing approved therapies, in our first combination therapy for HBV patients. We believe AB-836 has the potential for improved efficacy and an enhanced resistance profile relative to our previous generation capsid inhibitor product candidate, AB-506. In parallel, we are in lead optimization with several compounds for our PD-L1 program and next-generation HBV RNA destabilizer program. Our next-generation HBV RNA destabilizer product candidates have distinct chemical scaffolds from AB-452, our previous generation HBV RNA destabilizer.

Additionally, we have a royalty entitlement on ONPATTRO<sup>TM</sup> (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 from the sale of this royalty interest. The royalty interest will revert back to us after the buyer receives \$30 million in royalty payments from Alnylam. 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 Therapeutics, Inc. ("Acuitas"). The royalty from Acuitas has been retained by us and was not part of the royalty sale. Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources for additional details.

#### CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The significant accounting policies that we believe to be most critical in fully understanding and evaluating our financial results relate to stock-based compensation, goodwill and intangible assets and our contingent consideration. These accounting policies require us to make certain estimates and assumptions. We believe that the estimates and assumptions upon which we rely are reasonable, based upon information available to us at the time that these estimates and assumptions are made. Actual results may differ from our estimates. Our critical accounting estimates affect the calculation of our net income or loss.

# Stock-based compensation

The stock-based compensation expense that we record is a critical accounting estimate due to the value of compensation recorded, the volume of our stock option activity, and the many assumptions that are required to calculate compensation expense.

Compensation expense is recorded for stock options issued to employees and directors using the fair value method. We must calculate the fair value of stock options issued and amortize the fair value to stock compensation expense over the vesting period, and adjust the expense for stock option forfeitures and cancellations. We use the Black-Scholes model to calculate the fair value of stock options issued which requires that certain estimates, including the expected life of the option and expected volatility of the stock, be made at the time that the options are issued. This accounting estimate is reasonably likely to change from period to period as further stock options are issued and adjustments are made for stock option forfeitures and cancellations. Our accounting policy is to recognize forfeitures as they occur. The term "forfeitures" is distinct from "cancellations" or "expirations" and represents only the unvested portion of the surrendered stock option. For the purpose of calculating fair value, we estimate the expected life of stock options granted to be five years for employees and eight years for directors and executives, based on our historical experience. We amortize the fair value of stock options using the straight-line method over the vesting period of the options.

We recorded stock-based compensation expense for our equity-classified awards in 2019 of \$6.8 million (as compared to \$6.2 million in 2018). Stock-based compensation expense for 2019 includes \$1.1 million of non-cash compensation expense for the accelerated vesting of the stock options of our former President and Chief Executive Officer upon his departure in June 2019.

#### Goodwill and intangible assets

Intangible assets classified as indefinite-lived and goodwill are not amortized, but are evaluated for impairment annually. In addition, if there is a major event indicating that the carrying value of an asset may not be recoverable, then management will perform an impairment test in an interim period by comparing the discounted cash flow values to each asset's carrying value to determine if a write down is necessary.

In assessing impairment, significant judgments are required to be made by management to estimate the timing and extent of future net cash flows, appropriate discount rates, probability of program success 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: projected results of operations and forecast cash flows based on our corporate budgets as approved by our board of directors, third party forecasts and data and other macroeconomic indicators that forecasts market conditions and our estimated future revenues and growth, 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 cash flows related to these programs are highly uncertain due to the unpredictable nature of each phase of these programs, management risk adjusts the estimated cash flows to reflect these uncertainties.

During the year ended December 31, 2019, we recorded a \$43.8 million non-cash impairment expense to reduce the carrying value of our in-process research and development ("IPR&D") assets to zero. We also recognized a corresponding income tax benefit of \$12.7 million related to the decrease in our deferred tax liability associated with the IPR&D intangible assets. The impairment was due to a decision to delay indefinitely the further development of our covalently closed circular DNA ("cccDNA") program while we focus on our other development programs.

Also, during the year ended December 31, 2019, we recorded a \$22.5 million non-cash impairment expense to reduce the carrying value of our goodwill asset to zero. Due to a sustained decrease in our share price during 2019, 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 value of the goodwill asset.

During the year ended December 31, 2018, we recorded a \$14.8 million non-cash impairment expense to our intangible assets, less a corresponding income tax benefit of \$4.3 million. This impairment was related to the indefinite deferral of further development of our AB-423 program in the capsid inhibitor drug class.

# **Contingent Consideration**

In connection with the acquisition of Enantigen in October 2014, we have obligations to make potential future payments of up to \$21.0 million to the former shareholders of Enantigen contingent upon the achievement of certain development milestones and payments of up to \$102.5 million upon the achievement of certain commercial milestones. The development milestones are tied to programs which are no longer under development by us. 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 and the achievement of development milestones, 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, 2019 compared to the year ended December 31, 2018:

	Year Ended December 31,				
	2019	2019			
		n thousand	ls)		
Total revenue	\$ 6,0	11 \$	5,945		
Impairment of intangible assets	43,8	36	14,811		
Impairment of goodwill	22,4	71	_		
Total other operating expenses	83,7	78	80,914		
Loss from operations	(144,0	74)	(89,780)		
Other income (loss)	(22,3	05)	28,438		
Loss before income taxes	(166,3	<del>7</del> 9)	(61,342)		
Income tax benefit	12 <b>,</b> €	56	4,282		
Net loss	(153,7	23)	(57,060)		
Dividend accretion of convertible preferred shares	(11,1	49)	(10,091)		
Net loss attributable to common shares	\$ (164,8	72) \$	(67,151)		

For the fiscal year ended December 31, 2019, our net loss attributable to common shares was \$164.9 million, or a loss of \$2.89 per basic and diluted common share, as compared to a net loss of \$67.2 million, or \$1.21 per basic and diluted common share, for the year ended December 31, 2018.

# Revenue

Revenues for the years ended December 31, 2019 and 2018 are summarized in the following table:

	 Year ended December 31,					
	 2019 2018					
	(in thousands, except percentages)					
Revenue from collaborations and licenses						
Acuitas Therapeutics, Inc.	\$ 1,931	32% \$	1,009	17%		
Alnylam Pharmaceuticals, Inc.	_	—%	197	3%		
Gritstone Oncology, Inc.	1,819	30%	4,318	73%		
Acrotech Biopharma, LLC	605	10%	158	3%		
Other milestone and royalty payments	_	—%	263	4%		
Non-cash royalty revenue						
Alnylam Pharmaceuticals, Inc.	1,656	28%	_	—%		
Total revenue	\$ 6,011	100% \$	5,945	100%		

Revenues consist mainly of milestone payments, royalties and service fees.

Total revenue increased \$0.1 million for the year ended December 31, 2019 compared to 2018, primarily due to a \$2.4 million increase in license royalty revenue from Alnylam and Acuitas based on net global sales of ONPATTRO, which was approved by the FDA and EMA in the third quarter of 2018. This increase, along with net increases from Acrotech and other payments received, was partially offset by a \$2.5 million decrease in revenues from Gritstone in 2019, as 2018 included milestone payments. The royalty interest for ONPATTRO from Alnylam was sold to OMERS, effective as of January 1, 2019, for \$20 million in gross

proceeds before advisory fees. OMERS will retain this entitlement until it has received \$30 million in royalties, at which point 100% of such royalty interest on future global net sales of ONPATTRO will revert back to us. OMERS has assumed the risk of collecting up to \$30 million of future royalty payments from Alnylam and we are not obligated to reimburse OMERS if they fail to collect any such future royalties. During the term of this agreement, we recognize non-cash royalty revenue related to the sales of ONPATTRO. 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, 2019 and 2018 are summarized in the following table:

	 Year ended December 31,					
	201	9	2	2018		
		(in thousands, ex	ccept percentages)			
Research and development	\$ 57,601	38%	\$ 57,93	4 61%		
General and administrative	17,727	12%	16,00	2 17%		
Depreciation	2,028	1%	2,18	1 2%		
Site consolidation	156	—%	4,79	7 5%		
Impairment of intangible assets	43,836	29%	14,81	1 15%		
Impairment of goodwill	22,471	15%	_	%		
Arbitration	6,266	4%	_	%		
Total operating expenses	\$ 150,085	100%	\$ 95,72	5 100%		

# Research and development

Research and development expenses consist primarily of clinical and pre-clinical trial expenses, personnel expenses, consulting and third party expenses, consumables and materials, as well as a portion of stock-based compensation and general overhead costs.

Research and development expenses decreased \$0.3 million in 2019 primarily due to a decrease in costs for development and characterization activities for our HBV RNA destabilizer (AB-452) and a decrease in costs associated with a Phase 2 clinical trial for ARB-1467 that was discontinued in 2018. These decreases were partially offset by an increase in costs associated with a Phase 1a/1b clinical trial for our RNAi therapeutic product candidate (AB-729) and an increase in costs associated with a Phase 1a/1b clinical trial for our former capsid inhibitor product candidate (AB-506), which was discontinued in the fourth quarter of 2019.

A significant portion of our research and development expenses are not tracked by project, as they benefit multiple projects or our overall technology platform. However, our collaboration agreements contain cost-sharing arrangements pursuant to which certain costs incurred under the project are reimbursed. Costs reimbursed under collaborations typically include certain direct external costs and hourly or full-time equivalent labor rates for the actual time worked on the project. Therefore, we do track direct external costs attributable to and the actual time our employees worked on our collaborations.

# General and administrative

General and administrative expenses increased \$1.7 million in 2019 compared to 2018, primarily due to severance related to the departure of our former President and Chief Executive Officer in June of 2019, partially offset by a decrease in professional fees. 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.

# Site consolidation charges

In February 2018, we announced a site consolidation and organizational restructuring to better align our HBV business in Warminster, PA, by reducing our global workforce and 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 complete in 2018. We expect total site consolidation expenses to be approximately \$5.0 million, of which approximately \$4.9 million has been incurred as of December 31, 2019.

# 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 IPR&D intangible assets to zero. We 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 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.

During 2018, we recorded an impairment charge of \$14.8 million and a corresponding income tax benefit of \$4.3 million related to identified intangible assets, as a result of our decision to indefinitely delay further development of our AB-423 program.

# Arbitration

In the third quarter of 2019, the arbitrator in the arbitration proceedings between the University of British Columbia ("UBC") and us issued his decision for the second phase of the arbitration, awarding UBC approximately \$5.9 million, which includes interest of approximately \$2.6 million. The arbitrator also held that the third phase of the arbitration, which would address patent validity, should we choose to pursue a third phase, would not provide a defense to the award. 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. In the arbitration, UBC's claim was for \$10.9 million plus interest.

#### Other income (losses)

Other income (losses) for the years ended December 31, 2019 and 2018 are summarized in the following table:

	 Year ended December 31,							
	2019			2018				
	 (in thousands, except percentages)							
Interest income	\$ 2,111	(9)%	\$	3,047	11 %			
Interest expense	(2,108)	9 %		(226)	(1)%			
Net equity investment (loss) gain	(22,522)	101 %		19,322	68 %			
Decrease in fair value of contingent consideration	\$ 173	(1)%	\$	7,298	26 %			
Foreign exchange gains (losses)	41	—%		(1,003)	(4)%			
Total other income (loss)	\$ (22,305)	100 %	\$	28,438	100 %			

#### Interest income

Interest income decreased \$0.9 million in 2019 compared to 2018 primarily due to a lower average balance of cash, cash equivalents and investments and a decline in market interest rates.

#### Interest expense

Interest expense increased \$1.9 million in 2019 compared to 2018 due primarily to the non-cash amortization of discount and issuance costs related to the sale of a portion of our ONPATTRO royalty interest in 2019.

# Net equity investment (loss) gain

In 2018, together with Roivant, we launched Genevant, a company focused on the discovery, development, and commercialization of a broad range of RNA-based therapeutics enabled by our LNP Delivery Technologies. We account for our 40% ownership interest in Genevant using the equity method of accounting.

We recorded non-cash equity losses of \$22.5 million for the year ended December 31, 2019 and non-cash equity gains of \$19.6 million for the year ended December 31, 2018. Equity losses for 2019 included \$14.9 million of losses for our proportionate share of Genevant's net losses 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 our remaining carrying value in Genevant. Equity gains for 2018 included the \$24.9 million gain on our contribution of delivery technology licenses upon the formation of Genevant, partially offset by \$5.6 million of losses for our proportionate share of Genevant's net loss for the partial year.

# Decrease in fair value of contingent consideration

Contingent consideration is a liability we assumed from our acquisition of Arbutus Inc. in March 2015. In October 2014, Arbutus Inc. acquired all of the outstanding shares of Enantigen Therapeutics, Inc. ("Enantigen") pursuant to a stock purchase agreement. An additional \$102.5 million may also be paid to Enantigen's selling stockholders related to the achievement of certain sales performance milestones in connection with the sale of the first commercialized product by Arbutus Inc. for the treatment of HBV. 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 2018, the fair value of our contingent consideration liability decreased by \$7.3 million due to our decision to indefinitely delay further clinical development of AB-423, thereby reducing the probability of achieving future development milestones, as well as adjustments to the estimated timing of future sales milestones. In 2019, we re-evaluated the timing of the future sales milestones after the discontinuation of the AB-506 program, resulting in a \$0.2 million decrease in the fair value of our contingent consideration liability.

# 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 transaction 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. As a result of the site consolidation, we expect that the proportion of cash balances and expenses incurred in Canadian dollars, relative to US dollars, to continue to decrease.

During the year ended December 31, 2019, we recorded foreign exchange gains of less than \$0.1 million. During the year ended December 31, 2018, we recorded foreign exchange losses of \$1.0 million.

# Income tax benefit

For the years ended December 31, 2019 and 2018, we recorded an income tax benefits of \$12.7 million and \$4.3 million, respectively, 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, royalty monetization, interest income on funds available for investment, and government contracts, grants and tax credits.

As of December 31, 2019, we had cash and cash equivalents of \$31.8 million and investments in marketable securities of \$59.0 million, totaling \$90.8 million. We had no outstanding debt as of December 31, 2019.

In December 2018, we entered into an Open Market Sale Agreement ("Sale Agreement") with Jefferies LLC ("Jefferies"), under which we may issue and sell common shares, from time to time, for an aggregate sales price of up to \$50.0 million. For the twelve months ended December 31, 2019, we issued 9,138,232 of our common shares pursuant to the Sale Agreement, resulting in net proceeds of approximately \$18.6 million. There were no shares issued during the twelve months ended December 31, 2018 under the Sale Agreement. In December 2019, we entered into an amendment (the "Amendment") to the Sale Agreement with Jefferies in connection with our filing of a new shelf registration statement on Form S-3 (File No. 333-235674), filed with the SEC on December 23, 2019 (the "New Shelf Registration Statement"). The Amendment revised the Sale Agreement to reflect that we may sell our common shares, without par value, from time to time for an aggregate sales price of up to \$50.0 million, under the New Shelf Registration Statement. In 2020, through March 2, 2020, we issued 4,127,092 of our common shares pursuant to the Amendment, resulting in net proceeds of approximately \$12.3 million.

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 immediately upon approval in the US. 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, 2019 we held an aggregate of \$90.8 million in cash, cash equivalents and investments in marketable securities. We believe our cash resources as of December 31, 2019 will be sufficient to fund our operations into mid-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:

- 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 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 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 products.

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,			
	 2019 2018			
	(in thousa	nds)		
Net loss for the period	\$ (153,723) \$	(57,060)		
Items not involving cash	84,942	(6,531)		
Net change in non-cash operating items	(2,225)	(4,275)		
Net cash used in operating activities	\$ (71,006) \$	(67,866)		
Net cash provided by (used in) investing activities	28,338	(4,127)		
Net cash provided by financing activities	37,457	55,646		
Effect of foreign exchange rate changes on cash and cash equivalents	 68	(1,003)		
Decrease in cash and cash equivalents	\$ (5,143) \$	(17,350)		
Cash and cash equivalents, beginning of period	36,942	54,292		
Cash and cash equivalents, end of period	\$ 31,799 \$	36,942		

Net cash used in operating activities in 2019 increased \$3.1 million compared to 2018 primarily due to the payment of a \$5.9 million arbitration award to UBC and a \$2.3 million cash severance payment to our former CEO in 2019. These cash outflows in 2019 were partially offset by a \$2.1 million decrease in payments related to site consolidation activities and a \$1.6 million decrease in cash revenues from collaborations and licenses compared to 2018.

Net cash from investing activities in 2019 increased by \$32.5 million compared to 2018 primarily due to maturities of investments in marketable securities.

Net cash from financing activities in 2019 decreased \$18.2 million compared to 2018. Cash provided by financing activities in 2019 primarily consisted of \$18.6 million of proceeds from sales of common shares under our Open Market Sales Agreement and \$18.5 million of net proceeds from the sale a portion of our future royalties from sales of ONPATTRO. Cash provided by financing activities in 2018 primarily consisted of \$66.3 million of net proceeds from the second tranche of the Preferred Shares financing, offset by repayment of a \$12.0 million promissory note with a bank.

# **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 sheet of Arbutus Biopharma Corporation (the Company) as of December 31, 2019, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the year ended December 31, 2019, 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, 2019, and the results of its operations and its cash flows for the year ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 5, 2020 expressed an unqualified opinion thereon.

# **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 audit. We are a public accounting firm registered with the 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 audit 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. Our audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ Ernst Young LLP

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

Philadelphia, Pennsylvania

March 5, 2020

# Report of Independent Registered Public Accounting Firm

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

# **Opinion on Internal Control Over Financial Reporting**

We have audited Arbutus Biopharma Corporation's internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Arbutus Biopharma Corporation (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheet of the Company as of December 31, 2019, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the year ended December 31, 2019, and the related notes and our report dated March 5, 2020 expressed an unqualified opinion thereon.

# **Basis for Opinion**

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

# **Definition and Limitations of Internal Control Over Financial Reporting**

A company's 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of the financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's 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 material 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.

/s/ Ernst Young LLP Philadelphia, Pennsylvania March 5, 2020

# Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of Arbutus Biopharma Corporation

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Arbutus Biopharma Corporation (the Company) as of December 31, 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for the year ended December 31, 2018, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018, and the results of its operations and its cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles.

# Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We are a public accounting firm registered with the 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 audit 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 consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audit included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ KPMG LLP Chartered Professional Accountants

We served as the Company's auditor from 2002 to 2019. Vancouver, Canada

March 7, 2019

# **Consolidated Balance Sheets**

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

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 31,799	\$ 36,942
Investments in marketable securities	59,035	87,675
Accounts receivable	1,204	1,431
Prepaid expenses and other assets	1,790	3,181
Total current assets	93,828	129,229
Investment in Genevant	_	22,224
Property and equipment, net of accumulated depreciation	8,676	10,145
Right of use asset	2,738	_
Intangible assets	_	43,836
Goodwill	_	22,471
Other non-current assets	293	
Total assets	\$ 105,535	\$ 227,905
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 7,098	\$ 9,429
Site consolidation accrual	137	1,331
Liability-classified options	253	479
Lease liability, current	340	_
Total current liabilities	7,828	11,239
Liability related to sale of future royalties	18,992	_
Deferred rent and inducements, non-current	_	645
Contingent consideration	2,953	3,126
Lease liability, non-current	3,018	_
Deferred tax liability	_	12,661
Total liabilities	32,791	27,671
Stockholders' equity		
Preferred shares		
Authorized: unlimited number without par value		
Issued and outstanding: 1,164,000 (December 31, 2018: 1,164,000)	137,285	126,136
Common shares		
Authorized: unlimited number with no par value		
Issued and outstanding: 64,780,314 (December 31, 2018: 55,518,800)	898,535	879,405
Additional paid-in capital	55,246	48,084
Deficit	(970,093	(805,221)
Accumulated other comprehensive loss	(48,229	(48,170)
Total stockholders' equity	72,744	200,234
Total liabilities and stockholders' equity	\$ 105,535	\$ 227,905

# **Consolidated Statements of Operations and Comprehensive Loss**

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

Revenue         jenn         jenn           Revenue from collaborations and licenses         \$ 4,355         \$ 5,056           Non-cash royalty revenue         1,666         \$ 6,056           Total creven         2,666         \$ 5,056           Operating         \$ 5,061         \$ 5,094           General and development         \$ 2,028         \$ 1,000           Operacity         \$ 2,028         \$ 2,028           Size consolidation         \$ 1,000         \$ 4,000           Deporacian of intangible asets         \$ 2,021         \$ 4,000           Impairment of intangible asets         \$ 2,241         \$ 6,000           Impairment of goodwill         \$ 2,241         \$ 6,000           Impairment of goodwill         \$ 2,241         \$ 6,000           Impairment of intangible asets         \$ 3,000         \$ 5,000           Impairment of intangible asets         \$ 2,000         \$ 2,000           Impairment of intangible asets         \$ 2,000         \$ 2,000           Impairment of intangible asets         \$ 2,000         \$ 2,000           Impairment of intangible asets         \$ 2,111         \$ 3,000           Insert set come to set come in fair value of contingent consideration         \$ 2,251         \$ 2,200           In		 Year ended December 31,				
Revenue from collaborations and licenses         \$ 4,355         \$ 5,945           Non-each royalty revenue         1,656         — 6           Cital revenue         6,011         5,058           Operating expenses         35,061         5,7934           Research and development         57,061         5,7934           General and administrative         1,002         2,028         1,818           Depreciation         2,028         1,818         1,918           Site consolidation         15         4,797         1,910         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,918         1,91		2019		2018		
Non-cash nyaly revenue         1,656         — 1           Total revenue         6,011         5,055           Operating expenses         2         5,7601         5,7934           Research and development         5,7601         5,7934           General and administrative         1,7727         16,002           Deposition         2,028         2,181           Sile consolidation         15,05         4,383         1,481           Impairment of intangible assets         43,383         1,481         1           Impairment of goodwill         2,241         ————————————————————————————————————	Revenue	_				
Total revenue         6,011         5,958           Operating expenses         5,75,01         5,79,30           Research and development         5,75,01         5,79,30           General and administrative         11,727         16,002           Depreciation         1,56         4,78           Site consolidation         1,56         4,78           Impairment of intangible assets         4,38         1,811           Impairment of goodwill         2,247         ————————————————————————————————————	Revenue from collaborations and licenses	\$ 4,355	\$	5,945		
Operating expenses         Search and development         57,012         57,934           General and administrative         17,727         16,002           Depreciation         2,028         2,181           Site consolidation         156         4,797           Impairment of intangible assets         43,836         14,811           Impairment of goodwill         22,471         —           Arbitration         6,266         —           Arbitration         (10,407)         89,702           Loss from operations         150,008         95,725           Loss from operations         150,008         95,725           Loss from operations         2,111         3,047           Interest expense         2,111         3,047           Interest expense         2,111         3,042           Interest expense         2,111         3,042           Net capitity investment (loss) gain         2(2,522)         19,322           Decrease in fair value of contingent consideration         17         3,292           Poreign exchange gains (losses)         4         1,003           Torigin exchange gains (losses)         4         1,003           Loss fore income taxes         1,003         6,134	Non-cash royalty revenue	 1,656		_		
Research and development         57,601         57,934           General and administrative         17,272         16,002           Depreciation         2,028         2,181           Site consolidation         156         4,797           Impairment of intangible assets         43,836         14,811           Impairment of goodwill         22,471         —           Arbit atlon         6,266         —           Total operating expenses         150,008         59,725           Loss from operations         (140,07)         (89,780)           Other income (loss)         2,111         3,047           Interest income         2,111         3,047           Interest expense         (2,168)         (22,52)           Net equity investment (loss) gain         (22,522)         19,322           Decrease in fair value of contingent consideration         173         7,98           Foreign exchange gains (losses)         41         (1,003)           Total other income (loss)         (22,522)         19,322           Loss befor income taxes         166,379         (61,342)           Loss before income taxes         (166,379)         (57,000)           Net loss         (11,149)         (10,001)	Total revenue	6,011		5,945		
General and administrative         17,727         16,002           Depreciation         2,028         2,181           Site consolidation         156         4,797           Impairment of intangible asers         43,836         14,811           Impairment of goodwill         22,471         ————————————————————————————————————	Operating expenses					
Opereciation         2,028         2,181           Site consolidation         156         4,797           Impairment of intangible assets         43,336         14,811           Impairment of goodwill         22,471         ————————————————————————————————————	Research and development	57,601		57,934		
Sile consolidation         156         4,797           Impairment of intangible assets         43,836         14,811           Impairment of goodwill         22,471         —           Arbitation         6,266         —           Total operating expenses         15,085         95,725           Loss from operations         (14,407)         80,700           Other income (loss)         2,111         3,047           Interest supense         2,111         3,047           Net equity investment (loss) gain         (22,522)         19,225           Decrease in fair value of contingent consideration         173         7,298           Foreign exchange gains (losses)         41         (1,003)           Total other income (loss)         41         (1,003)           Loss before income taxes         166,379         61,342           Income tax benefit         12,656         4,282           Net loss applicable to preferred shares         11,104         (10,001)           Net loss applicable to preferred shares         11,104         (10,001)           Net loss activibutable to common shares         11,104         (10,001)           Net loss activibutable to common shares         1,002         (1,002)         (1,002)	General and administrative	17,727		16,002		
Impairment of intangible assets         43,836         14,811           Impairment of goodwill         22,471         ————————————————————————————————————	Depreciation	2,028		2,181		
Impairment of goodwill         22,471         —           Abitration         6,266         —           Total operating expenses         150,085         55,725           Loss from operations         (144,074)         (89,780)           Other income (loss)         2,111         3,047           Interest expense         2,111         3,047           Interest expense         2,211         3,042           Net equity investment (loss) gain         (22,522)         19,322           Decrease in fair value of contingent consideration         173         7,298           Foreign exchange gains (losses)         4         1(1,03)           Total other income (loss)         22,305         28,438           Loss before income taxes         (166,379)         61,342           Income tax benefit         12,656         4,282           Net loss         12,656         4,282           Net loss         13,53,732         5,75,060           Income tax benefit         1,1149         10,091           Net loss attributable to preferred shares         11,149         10,091           Net loss attributable to common shares         \$ (2,8)         (6,7,15)           Basic and diluted         5,7093,45         5,304,083	Site consolidation	156		4,797		
Arbitration         6,266         —           Total operating expenses         150,085         55,725           Loss from operations         (144,074)         (89,780)           Other income (loss)         2         3,047           Interest income         2,111         3,047           Interest expense         2,118         3,042           Net equity investment (loss) gain         22,522         19,322           Decrease in fair value of contingent consideration         173         7,298           Foreign exchange gains (losses)         41         (1,003)           Foreign exchange gains (losses)         41         (1,003)           Income tacken income taxes         (166,379)         (61,342)           Loss before income taxes         12,556         4,282           Net loss         12,556         4,282           Net loss         12,556         4,282           Polyidend accretion of convertible preferred shares         11,149         10,009           Net loss attributable to common shares         11,149         10,009           Net loss attributable to common shares         12,009         10,009           Resist and diluted         \$ (2,89)         1,215           Weighted average number of common shares	Impairment of intangible assets	43,836		14,811		
Total operating expenses         150,085         95,725           Loss from operations         (144,074)         (89,780)           Other income (loss)             Interest expense         2,111         3,047           Net equity investment (loss) gain         (22,522)         19,322           Decrease in fair value of contingent consideration         173         7,298           Foreign exchange gains (losses)         41         1,003           Foreign exchange gains (losses)         43         1,003           Total other income (loss)         43         1,003           Rose before income taxes         12,653         28,438           Loss before income taxes         11,653         4,282           Rose loss attributable to preferred shares         11,553         5,750,000           Rose loss attributable to common shares         11,149         10,009           Net loss stributable to common shares         \$ 1,283         (7,151)           Rose common shares         \$ 2,89         1,215           Basic and diluted         \$ 7,093,45         5,304,083           Competensive income         5,709,454         5,304,083           Competensive income         5,004,003         1,504,003		22,471		_		
Los from operations         (144,074)         (89,780)           Other income (loss)         Interest income         2,111         3,047           Interest expense         (2,108)         (225)           Net equity investment (loss) gain         (22,522)         19,322           Decrease in fair value of contingent consideration         173         7,298           Foreign exchange gains (losses)         41         (1,003)           Total other income (loss)         (22,305)         28,438           Los before income taxes         (166,379)         (61,342)           Income tax benefit         1,2656         4,282           Net loss         (153,723)         (57,006)           Tems applicable to preferred shares         (11,149)         (10,091)           Net loss attributable to common shares         (11,149)         (10,091)           Net loss attributable to common shares         (11,149)         (10,091)           Net loss attributable to common shares         (10,402)         (57,150)           Seas and diluted         5, 70,93,454         55,304,083           Competensive income         (5,09),454         55,304,083           Competensive income         (5,09),454         55,304,083	Arbitration	 6,266				
Other income (loss)         3,047           Interest income         2,111         3,047           Interest expense         (2,108)         (225)           Net equity investment (loss) gain         (22,522)         19,322           Decrease in fair value of contingent consideration         173         7,298           Foreign exchange gains (losses)         41         (1,003)           Total other income (loss)         (22,305)         28,438           Loss before income taxes         (166,379)         (61,342)           Income tax benefit         12,665         4,282           Net loss         (153,72)         (57,060)           Tems applicable to preferred shares         1(11,49)         (10,001)           Pivel loss attributable to common shares         (11,149)         (10,001)           Net loss per common shares         (11,149)         (10,001)           Basic and diluted         (2,80)         (1,21)           Weighted average number of common shares         (5,703,454)         55,304,083           Comprehensive income         (5,90)         15	Total operating expenses	 150,085		95,725		
Interest income         2,111         3,047           Interest expense         (2,108)         (226)           Net equity investment (loss) gain         (22,522)         19,322           Decrease in fair value of contingent consideration         173         7,298           Foreign exchange gains (losses)         41         (1,003)           Total other income (loss)         (22,305)         28,438           Loss before income taxes         (166,379)         (61,342)           Income tax benefit         1,265         4,282           Net loss         (153,723)         (57,060)           Items applicable to preferred shares         (11,149)         (10,091)           Net loss attributable to common shares         (164,872)         (67,151)           Net loss per common share         (289)         (1,212)           Basic and diluted         \$ (2,89)         (1,212)           Weighted average number of common shares         5,093,454         55,304,083           Comprehensive income         (5,93)         55,304,083	Loss from operations	(144,074)		(89,780)		
Interest expense         (2,108)         (226)           Net equity investment (loss) gain         (22,522)         19,322           Decrease in fair value of contingent consideration         173         7,298           Foreign exchange gains (losses)         41         (1,003)           Total other income (loss)         (22,305)         28,438           Loss before income taxes         (166,379)         (61,342)           Income tax benefit         12,656         4,282           Net loss         (153,723)         (57,006)           Items applicable to preferred shares         (11,149)         (10,091)           Net loss attributable to common shares         (164,872)         (67,151)           Net loss per common shares         (2,89)         (1,210)           Weighted average number of common shares         (2,89)         (1,210)           Weighted average number of common shares         57,093,454         55,304,083           Comprehensive income         (59)         55,304,083	Other income (loss)					
Net equity investment (loss) gain         (22,522)         19,322           Decrease in fair value of contingent consideration         173         7,298           Foreign exchange gains (losses)         41         (1,003)           Total other income (loss)         (22,305)         28,438           Loss before income taxes         (166,379)         (61,342)           Income tax benefit         12,656         4,282           Net loss         (153,723)         (57,060)           Items applicable to preferred shares         (11,149)         (10,091)           Net loss attributable to common shares         \$ (164,872)         (67,151)           Net loss per common share         \$ (2.89)         (1.21)           Weighted average number of common shares         \$ (2.89)         (1.21)           Basic and diluted         57,093,454         55,304,083           Comprehensive income         (59)         15	Interest income	2,111		3,047		
Decrease in fair value of contingent consideration         173         7,298           Foreign exchange gains (losses)         41         (1,003)           Total other income (loss)         (22,305)         28,438           Loss before income taxes         (166,379)         (61,342)           Income tax benefit         12,656         4,282           Net loss         (153,723)         (57,060)           Items applicable to preferred shares         (11,149)         (10,091)           Net loss attributable to common shares         (67,151)         (67,151)           Net loss per common shares         (2.89)         (1.21)           Basic and diluted         57,093,454         55,304,083           Comprehensive income         (59)         15	Interest expense	(2,108)		(226)		
Foreign exchange gains (losses)         41         (1,003)           Total other income (loss)         (22,305)         28,438           Loss before income taxes         (166,379)         (61,342)           Income tax benefit         12,656         4,282           Net loss         (153,723)         (57,060)           Items applicable to preferred shares         (11,149)         (10,091)           Net loss attributable to common shares         (164,872)         (67,151)           Net loss per common shares         (2.89)         (1.21)           Weighted average number of common shares         57,093,454         55,304,083           Comprehensive income         (59)         15	Net equity investment (loss) gain	(22,522)		19,322		
Total other income (loss)         (22,305)         28,438           Loss before income taxes         (166,379)         (61,342)           Income tax benefit         12,656         4,282           Net loss         (153,723)         (57,060)           Items applicable to preferred shares         (11,149)         (10,091)           Net loss attributable to common shares         (164,872)         (67,151)           Net loss per common share         (2.89)         (1.21)           Weighted average number of common shares         57,093,454         55,304,083           Basic and diluted         57,093,454         55,304,083           Comprehensive income         (59)         15	Decrease in fair value of contingent consideration	173		7,298		
Loss before income taxes         (166,379)         (61,342)           Income tax benefit         12,656         4,282           Net loss         (153,723)         (57,060)           Items applicable to preferred shares         (11,149)         (10,091)           Net loss attributable to common shares         (164,872)         (67,151)           Net loss per common shares         (2.89)         (1.21)           Weighted average number of common shares         57,093,454         55,304,083           Comprehensive income         (59)         15	Foreign exchange gains (losses)	 41		(1,003)		
Income tax benefit         12,656         4,282           Net loss         \$ (153,723)         \$ (57,060)           Items applicable to preferred shares         \$ (11,149)         \$ (10,091)           Net loss attributable to common shares         \$ (164,872)         \$ (67,151)           Net loss per common share         \$ (2.89)         \$ (1.21)           Weighted average number of common shares         \$ (2.89)         \$ (1.21)           Weighted average number of common shares         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         \$ (7,93,454)         <	Total other income (loss)	(22,305)		28,438		
Net loss         \$ (153,723)         \$ (57,060)           Items applicable to preferred shares         Usidend accretion of convertible preferred shares         (11,149)         (10,091)           Net loss attributable to common shares         \$ (164,872)         \$ (67,151)           Net loss per common share         Basic and diluted         \$ (2.89)         \$ (1.21)           Weighted average number of common shares         Basic and diluted         57,093,454         55,304,083           Comprehensive income         Currency translation adjustment         (59)         15	Loss before income taxes	(166,379)		(61,342)		
Items applicable to preferred sharesDividend accretion of convertible preferred shares(11,149)(10,091)Net loss attributable to common shares\$ (164,872)\$ (67,151)Net loss per common shareBasic and diluted\$ (2.89)\$ (1.21)Weighted average number of common sharesBasic and diluted57,093,45455,304,083Comprehensive incomeCurrency translation adjustment(59)15	Income tax benefit	12,656		4,282		
Dividend accretion of convertible preferred shares(11,149)(10,091)Net loss attributable to common shares\$ (164,872)\$ (67,151)Net loss per common sharesBasic and diluted\$ (2.89)\$ (1.21)Weighted average number of common sharesBasic and diluted57,093,45455,304,083Comprehensive incomeCurrency translation adjustment(59)15	Net loss	\$ (153,723)	\$	(57,060)		
Net loss attributable to common shares \$ (164,872) \$ (67,151)  Net loss per common share  Basic and diluted \$ (2.89) \$ (1.21)  Weighted average number of common shares  Basic and diluted \$ 57,093,454 \$ 55,304,083  Comprehensive income  Currency translation adjustment (59) 15	Items applicable to preferred shares					
Net loss per common share  Basic and diluted \$ (2.89) \$ (1.21)  Weighted average number of common shares  Basic and diluted 57,093,454 55,304,083  Comprehensive income  Currency translation adjustment (59) 15	Dividend accretion of convertible preferred shares	(11,149)		(10,091)		
Basic and diluted \$ (2.89) \$ (1.21)  Weighted average number of common shares  Basic and diluted 57,093,454 55,304,083  Comprehensive income  Currency translation adjustment (59) 15	Net loss attributable to common shares	\$ (164,872)	\$	(67,151)		
Weighted average number of common sharesBasic and diluted57,093,45455,304,083Comprehensive incomeCurrency translation adjustment(59)15	Net loss per common share					
Basic and diluted 57,093,454 55,304,083  Comprehensive income  Currency translation adjustment (59) 15	Basic and diluted	\$ (2.89)	\$	(1.21)		
Comprehensive income     (59)     15       Currency translation adjustment     (59)     15	Weighted average number of common shares					
Currency translation adjustment (59) 15	Basic and diluted	57,093,454		55,304,083		
	Comprehensive income					
<b>Comprehensive loss</b> \$ (153,782) \$ (57,045)	Currency translation adjustment	(59)		15		
	Comprehensive loss	\$ (153,782)	\$	(57,045)		

# Consolidated Statement of Stockholders' Equity

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

	Convertible Prefe	erred Shares	Common	Shares				
	Number of shares	Share capital	Number of shares	Share capital	Additional paid-in capital	Deficit	Accumulated other comprehensive loss	Total stockholders' equity
Balance at December 31, 2017	500,000	\$ 49,780	55,060,650	\$ 876,108	\$ 42,840	\$ (738,070)	\$ (48,185)	\$ 182,473
Issuance of Preferred Shares, net of issuance cost	664,000	66,265	_	_	_	_	_	66,265
Accretion of accumulated dividends on Preferred Shares	_	10,091	_	_	_	(10,091)	_	_
Stock-based compensation	_	_	_	_	6,687	_	_	6,687
Certain fair value adjustments to liability stock option awards	_	_	_	_	472	_	_	472
Issuance of common shares pursuant to exercise of options	_	_	458,150	3,297	(1,915)	_	_	1,382
Currency translation adjustment	_	_	_	_	_	_	15	15
Net loss			_	_	_	(57,060)	_	(57,060)
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 our 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

# **Consolidated Statements of Cash Flows**

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

	Year ended December 31,		
	 2019		2018
OPERATING ACTIVITIES			
Net loss for the period	\$ (153,723)	\$	(57,060)
Items not involving cash:			
Deferred income tax benefit	(12,661)		(4,282)
Depreciation	2,028		2,181
Loss (gain) on sale of property and equipment	20		(26)
Stock-based compensation expense	6,799		6,241
Unrealized foreign exchange (gains) losses	(68)		1,003
Change in fair value of contingent consideration	(173)		(7,298)
Impairment of intangible assets	43,836		14,811
Impairment of goodwill	22,471		_
Site consolidation non-cash portion	_		396
Net equity investment loss (gain)	22,522		(19,557)
Non-cash royalty revenue	(1,656)		_
Non-cash interest expense	2,099		_
Net accretion and amortization of investments in marketable securities	(275)		_
Net change in non-cash operating items:	` ´		
Accounts receivable	227		(1,029)
Accrued revenue	_		128
Investment tax credits receivable	_		(49)
Prepaid expenses and other assets	1,606		(648)
Accounts payable and accrued liabilities	(2,410)		(1,266)
Deferred revenue	(=, :10)		(2,742)
Site consolidation accrual	(983)		1,331
Other liabilities	(665)		
Net cash used in operating activities	 (71,006)		(67,866)
INVESTING ACTIVITIES	(71,000)		(07,000)
Acquisition of investments	(58,759)		(121,580)
Disposition of investments	87,675		118,566
Proceeds from sale of property and equipment	07,073		25
Acquisition of property and equipment	(589)		(1,138)
Net cash provided by (used in) investing activities	 28,338		(4,127)
FINANCING ACTIVITIES	20,330		(4,127)
Proceeds from the sale of future royalties	10 5 40		
·	18,549		(12,001)
Promissory note repayment	_		(12,001)
Proceeds from sale of Preferred Shares, net of issuance costs			66,265
Issuance of common shares pursuant to exercise of options	307		1,382
Issuance of common shares pursuant to Open Market Sales Agreement	 18,601		
Net cash provided by financing activities	37,457		55,646
Effect of foreign exchange rate changes on cash and cash equivalents	 68		(1,003)
Decrease in cash and cash equivalents	\$ (5,143)	\$	(17,350)
Cash and cash equivalents, beginning of period	\$ 36,942	\$	54,292
Cash and cash equivalents, end of period	\$ 31,799	\$	36,942
Supplemental cash flow information			
Preferred shares dividends accrued	\$ (11,149)	\$	(10,091)
Initial investment in Genevant	\$ _	\$	27,377
Interest paid	\$ _	\$	104

# **Notes to Consolidated Financial Statements**

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

# 1. Nature of business and future operations

Arbutus Biopharma Corporation (the "Company" or "Arbutus") is a biopharmaceutical business dedicated to discovering developing, and commercializing a cure for patients suffering from chronic hepatitis B infection, a disease of the liver caused by the hepatitis B virus ("HBV"). To pursue our strategy of developing a treatment for chronic HBV, we are developing a diverse product pipeline consisting of multiple drug candidates with complementary mechanisms of action, which have the potential to improve upon the SOC and contribute to a curative combination regimen. Our pipeline includes agents that have the potential to form an effective proprietary combination therapy.

The Company's pipeline includes:

- AB-729, a subcutaneously-delivered RNA interference ("RNAi") therapeutic product candidate currently in a Phase 1a/1b clinical trial with preliminary results anticipated in late March 2020;
- AB-836, a next-generation capsid inhibitor product candidate currently advancing through IND-enabling studies; and
- other compounds early in the development process, including back-up capsid inhibitors, next-generation oral HBV RNA destabilizers and compounds that inhibit PD-L1.

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.

#### 2. Significant accounting policies

# Basis of presentation and principles of consolidation

Tekmira Pharmaceuticals Corporation ("Tekmira") was incorporated in Canada on October 6, 2005 as an inactive wholly-owned subsidiary of Inex Pharmaceuticals Corporation ("Inex"). Pursuant to a "Plan of Arrangement" effective April 30, 2007, the business and substantially all of the assets and liabilities of Inex were transferred to Tekmira.

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

On July 31, 2015, Tekmira changed its corporate name to Arbutus Biopharma Corporation and OnCore changed its corporate name to Arbutus Biopharma, Inc. ("Arbutus Inc.").

The Company has two wholly-owned subsidiaries as of December 31, 2019: Arbutus Inc. and Arbutus Biopharma US Holdings, Inc., which was formed in 2018.

Protiva Biotherapeutics Inc. ("Protiva") was acquired by the Company on May 30, 2008. On January 1, 2018, Protiva was amalgamated with Arbutus Biopharma Corporation. The Company's former wholly-owned subsidiary, Protiva Agricultural Development Company Inc ("PADCo") was previously recorded by the Company using the equity method. On March 4, 2016, Monsanto Company exercised its option to acquire 100% of the outstanding shares of PADCo.

These consolidated financial statements include the accounts of the Company and its two wholly-owned subsidiaries, in accordance with U.S. generally accepted accounting principles ("GAAP"). All intercompany balances and transactions have been eliminated. Certain prior year amounts have been reclassified to conform to the current year presentation.

#### 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 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.

# 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 areas requiring the use of management estimates relate to valuation of intangible assets and goodwill, stock-based compensation, and the amounts recorded as accrued liabilities, contingent consideration, and income tax recovery.

# 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. 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, 2019, 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.

# Equity method investment

The Company accounts for its investment in Genevant Sciences Ltd. ("Genevant") in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 323, *Investments - Equity Method and Joint Ventures* ("ASC 323"). In accordance with ASC 323, associated companies are accounted for as equity method investments if the Company can exercise significant influence over the associated companies. Investments in and advances to Genevant are presented on a one-line basis in the caption "Investment in Genevant" in the Company's consolidated balance sheets, net of allowance for losses, which represents the Company's best estimate of probable losses inherent in such assets. The Company's proportionate share of Genevant's net income or loss is presented along with any other gains or losses associated with the investment on a one-line basis in the Company's consolidated statement of operations. Transactions between the Company and any associated companies are eliminated on a basis proportional to the Company's ownership interest. The Company's proportionate share of Genevant's financial results are recorded on a one-quarter lag basis.

As of December 31, 2019, recovery of the Company's remaining carrying value in Genevant was uncertain, and therefore the Company recorded a \$7.6 million impairment expense to reduce the carrying value of its investment in Genevant to zero.

# Property and equipment

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

	Usefu	Useful Life (Years)	
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.

# Goodwill and intangible assets

The balances related to acquired in-process research and development ("IPR&D") intangible assets related to the Company's covalently closed circular DNA ("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 in recent months, 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 by an amount in excess of the carrying value of the 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.

The costs incurred in establishing and maintaining patents for intellectual property developed internally are expensed in the period incurred.

## Revenue recognition

ASC 606, *Revenue From Contracts with Customers* ("ASC 606") became effective for the Company on January 1, 2018, and was adopted using the modified retrospective method under which previously presented financial statements are not restated and the cumulative effect of adopting ASC 606 on contracts in process is recognized by an adjustment to retained earnings at the effective date. The adoption of ASC 606 did not change recognized revenue under the Company's ongoing significant collaboration and license agreements and no cumulative effect adjustment was required.

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, including acquired in-process research and development expenses for which there is no alternative future use, are charged as an expense in the period in which they are incurred.

# 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 15, 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, 2019 and 2018, since the effect of the Company's stock options is anti-dilutive. For the year ended December 31, 2019, potential common shares of 8.9 million pertaining to stock options outstanding and approximately 19.4 million pertaining to if-converted preferred shares for a total of approximately 28.4 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 24.7 million potential common shares and if-converted preferred shares were excluded from the calculation for the year ended December 31, 2018.

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,						
		2019		2018			
		(in thousands, except sha	re and	d per share amounts)			
Numerator:							
Allocation of distributable earnings	\$	_	\$	_			
Allocation of undistributable loss		(164,872)		(67,151)			
Allocation of net loss attributed to common shareholders	\$	(164,872)	\$	(67,151)			
Denominator:							
Weighted average number of common shares - basic and diluted		57,093,454		55,304,083			
Basic and diluted net loss attributable to common shareholders per share	\$	(2.89)	\$	(1.21)			

In December 2018, the Company entered into an Open Market Sale Agreement ("2018 Sale Agreement") with Jefferies LLC

("Jefferies"), under which it may issue and sell common shares. In 2020, through March 2, 2020, we issued 4,127,092 common shares pursuant to the amendment to the Sale Agreement.

# Government grants and refundable investment tax credits

Government grants and tax credits provided for current expenses are included in the determination of income or loss for the year, as a reduction of the expenses to which they relate.

# 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.

# Equity-classified stock option awards

The Company grants stock options to employees, directors and consultants pursuant to share incentive plans described in note 16. Compensation expense is recorded for issued stock options using the fair value method with a corresponding increase in additional paid-in capital. Any consideration received on the exercise of stock options is credited to share capital.

The fair value of equity classified stock options is measured at the grant date and is amortized on a straight-line basis over the vesting period.

## Liability-classified stock option awards

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 November 2018, the FASB issued ASU No. 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606. The ASU provides more comparability in the presentation of revenue for certain transactions between collaborative arrangement participants and only allows a company to present units of account in collaborative arrangements that are within the scope of the revenue recognition standard together with revenue accounted for under the revenue recognition standard. The parts of the collaborative arrangement that are not in the scope of the revenue recognition standard should be presented separately from revenue accounted for under the revenue recognition standard. The amendments in ASU No. 2018-18 are effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The Company evaluated the impact of this pronouncement and concluded that the guidance does not have a material impact on its financial position and results of operations.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement, which removes, adds and modifies certain disclosure requirements for fair value measurements in Topic 820. The Company will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, and the valuation processes of Level 3 fair value measurements. However, the Company will be required to additionally disclose the changes in unrealized gains and losses included in other comprehensive income for recurring Level 3 fair value measurements, and the range and weighted average of assumptions used to develop significant unobservable inputs for Level 3 fair value measurements. The ASU is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The amendments relating to additional disclosure requirements will be applied prospectively for only the most recent interim or annual period presented in the initial year of adoption. All other amendments will be applied retrospectively to all periods presented upon their effective date. The Company is permitted to early adopt either the entire ASU or only the provisions that eliminate or modify the requirements. The Company evaluated the impact of this pronouncement and concluded that the guidance does not have a material impact on its financial position and results of operations.

#### 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, investments in marketable securities, 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 13), 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 \$3.0 million as of December 31, 2019 and the decrease of \$0.2 million has been recorded in other losses in the statement of operations and comprehensive loss for the year ended December 31, 2019. 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:

	Level 1	Lev	el 2	Level 3	Total
As of December 31, 2019			(in thous	sands)	
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

	Level 1	Leve	12	L	evel 3	Total
As of December 31, 2018			(in thou	sands)		
Assets						
Cash and cash equivalents	\$ 36,942		_		_	\$ 36,942
Investments in marketable securities	87,675		_		_	87,675
Total	\$ 124,617	\$	_	\$	_	\$ 124,617
Liabilities						
Liability-classified options	\$ _	\$	_	\$	479	\$ 479
Contingent consideration	_		_		3,126	3,126
Total	\$ _	\$	_	\$	3,605	\$ 3,605

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						iability at end of the period
				(in thousa	ıds)			
Year ended December 31, 2019	\$	479	\$	_	\$	(226)	\$	253
Year ended December 31, 2018	\$	1,239	\$	(93)	\$	(667)	\$	479

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

	Liability at	beginning of the period	Inc	crease (decrease) in fair value of liability	Liability at end of the period
				(in thousands)	
Year ended December 31, 2019	\$	3,126	\$	(173)	\$ 2,953
Year ended December 31, 2018	\$	10,424	\$	(7,298)	\$ 3,126

# 4. Investments in marketable securities

Investments in marketable securities consisted of the following:

	Amortized Cost Gross Unrealized Gain <sup>(1)</sup>		Gross Unrealized Loss(1)	Fair Value		
As of December 31, 2019			(in tho	usan	ds)	
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

 $<sup>^{(1)}</sup>$  Gross unrealized gain (loss) is pre-tax.

	Amortized Cost	Gr	oss Unrealized Gain <sup>(1)</sup>	Gro	ss Unrealized Loss(1)	Fair Value
As of December 31, 2018			(in tho	usands)		
Cash equivalents						
Individual savings account	\$ 20,420	\$	_	\$	_	\$ 20,420
Total	\$ 20,420	\$	_	\$	_	\$ 20,420
Investments in marketable securities						
Canadian guaranteed investment						
certificates	\$ 71,483	\$	_	\$	_	\$ 71,483
USD term deposit	 16,192			\$		\$ 16,192
Total	\$ 87,675	\$	_	\$	_	\$ 87,675

 $<sup>^{\</sup>left( 1\right) }Gross$  unrealized gain (loss) is pre-tax.

The contractual term to maturity of short-term marketable securities held by the Company as of December 31, 2019 is less than one year. There were no long-term marketable securities held by the Company as of December 31, 2019.

There were no realized gains or losses for the year ended December 31, 2019 or 2018.

## 5. Equity method investment

In April 2018, the Company entered into an agreement (the "Genevant Agreement") with Roivant Sciences Ltd. ("Roivant"), its largest shareholder, to launch 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. Genevant plans to develop products in-house and pursue industry partnerships to build a diverse pipeline of therapeutics across multiple modalities, including RNAi, mRNA and gene editing.

Under the terms of the Genevant Agreement, the Company contributed fixed assets with a carrying value of \$0.6 million and a license for the delivery technologies. The contributed license provides Genevant with exclusive rights to the LNP and ligand conjugate delivery platforms for RNA-based applications outside of HBV and any other pre-existing licensing obligations of Arbutus. The Company retains all rights to the LNP and ligand conjugate delivery platforms for HBV, and is entitled to a tiered low single-digit royalty from Genevant on future sales of products enabled by those delivery platforms. The Company also retained the entirety of its royalty entitlement on the commercialization of Alnylam Pharmaceuticals, Inc.'s ("Alnylam") ONPATTRO<sup>TM</sup> (Patisiran) ("ONPATTRO"). Roivant contributed \$37.5 million in transaction-related seed capital to Genevant, consisting of an initial capital contribution in April 2018 of \$22.5 million and a subsequent investment in June 2018 of \$15.0 million at a pre-determined, stepped-up valuation, as contemplated in the initial agreement. As a result of this subsequent investment in Genevant by Roivant and other parties, the Company's initial ownership interest in Genevant was reduced from 50% to approximately 40%. As of December 31, 2019, the Company's ownership interest in Genevant remained approximately 40%.

The Company's contribution of licenses related to the delivery technologies and fixed assets in exchange for an equity interest in Genevant resulted in a gain for the Company of \$24.9 million during the second quarter of 2018. The gain reflected the fair value of the equity in Genevant received by the Company, less the \$0.6 million carrying value of the fixed assets contributed by the Company and less \$1.9 million of goodwill allocated to Genevant based upon the relative fair value of Genevant to the Company as of the transaction date. The fair value of equity in Genevant received by the Company was based on a valuation performed by external valuation specialists. The basis difference between the Company's carrying value in Genevant and the Company's share of Genevant's net assets is attributed primarily to indefinite-lived IPR&D (the delivery technology transferred to Genevant).

The Company has significant influence over Genevant due to its ownership interest and accounts for its investment in Genevant using the equity method. The Company's proportionate share of Genevant's financial results are recorded on a one-quarter lag basis.

The Company recorded non-cash equity losses of \$22.5 million for the year ended December 31, 2019 and non-cash equity gains of \$19.6 million for the year ended December 31, 2018. 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. Equity gains for 2018 included the \$24.9 million gain on the Company's contribution of delivery technology licenses upon formation of Genevant, partially offset by \$5.6 million of losses for the Company's proportionate share of Genevant's net loss for the partial year.

## 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's lease agreements do not contain any material residual value guarantees or material restrictive covenants.

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, 2019, the Company incurred total operating lease expenses of \$1.2 million, which included lease expenses associated with fixed lease payments of \$0.9 million, and variable payments associated with common area maintenance and similar expenses of \$0.3 million. For the twelve months ended December 31, 2018, the straight-line fixed expense for leases was \$1.4 million. Sublease income for the twelve months ended December 31, 2019 was \$0.2 million, versus \$0.2 million for the twelve months ended December 31, 2018.

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

	As of December 31, 2019
Weighted-average remaining lease term (years)	7.0
Weighted average discount rate	8.9%

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:

	2	019	2018
		(in thousands)	
Cash paid for amounts included in the measurement of lease liabilities	\$	1,116 \$	_

Future minimum lease payments under operating leases that have remaining terms as of December 31, 2019 are as follows:

	As of D	ecember 31, 2019
	(in	thousands)
2020	\$	657
2021		677
2022		581
2023		598
2024		616
Thereafter		1,423
Total Lease Payments	\$	4,552
Less: interest		(1,193)
Present value of lease payments	\$	3,359

# 7. Property and equipment

The Company's property and equipment balances as of the years ended December 31, 2019 and 2018 are as follows:

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

	Cost			Accumulated depreciation		Net book value	
<u>December 31, 2018</u>			(in	thousands)			
Lab equipment	\$	5,420	\$	(2,455)	\$	2,965	
Leasehold improvements		9,308		(2,401)		6,907	
Computer hardware and software		2,313		(2,040)		273	
	\$	17,041	\$	(6,896)	\$	10,145	

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.

In 2018, the Company recorded a \$14.8 million intangible assets impairment charge, and a corresponding income tax benefit of \$4.3 million related to the decrease in deferred tax liability, for the indefinite delay of further development of its AB-423 program.

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 in recent months, 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.

## 9. Accounts payable and accrued liabilities

Accounts payable and accrued liabilities are comprised of the following:

	 December 31, 2019	Decer	nber 31, 2018
	(in the	ousands)	
Trade accounts payable	\$ 2,398	\$	3,192
Payroll accruals	2,314		2,341
Research and development accruals	1,433		2,716
Professional fee accruals	809		871
Other accrued liabilities	144		309
Total	\$ 7.098	\$	9,429

#### 10. Site consolidation

In 2018, the Company substantially completed a site consolidation and organizational restructuring to align its HBV business in Warminster, PA, including a reduction of its global workforce and closure of its Burnaby facility. The Company estimates that the total expenses to complete the site consolidation will be approximately \$5.0 million, of which \$4.9 million has been incurred as of December 31, 2019. Included in the site consolidation plan was the payment of one-time employee termination benefits, employee relocation costs, and site closure costs. The Company ceased the use of its Burnaby facility as of June 2018 and the Company entered into subleases with various tenants, including Genevant, for a portion of the Burnaby facility. The Company recorded the remaining committed cost, less sublease income under contract, in site consolidation expenses in 2018. The lease of the Burnaby facility expired on July 31, 2019.

The Company accounts for site consolidation expense in accordance with ASC 420, *Exit or Disposal Cost Obligations* ("ASC 420"). ASC 420 specifies that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred, except for a liability where employees are required to render service until they are terminated in order to receive termination benefits and will be retained to render service beyond the minimum retention period. A liability for such one-time termination benefits shall be measured initially at the communication date based on the fair value of the liability as of the termination date and recognized ratably over the future service period.

The following table shows the changes to the site consolidation accrual for the twelve months ended December 31, 2019:

		nths Ended December 31, 2019
	(in t	housands)
Accrual Balance December 31, 2018	\$	1,331
Employee severance and relocation expense		510
Lease and facility expense		(347)
Total site consolidation expense	\$	163
Amounts paid and adjustments		(1,357)
Accrual Balance December 31, 2019	\$	137

## 11. Loan payable

During 2018, the Company had a bank loan of \$12.0 million in the form of a promissory note for the purpose of financing its operations and expanding its laboratory facilities in the United States. The loan accrued interest daily at a rate of one-month London Interbank Offered Rate (LIBOR) plus 1.25% per annum. The maturity date of the loan was December 27, 2019. The loan was secured by the Company's cash of \$12.6 million and was restricted from use until the loan was settled in full. The Company invested the restricted cash in a two-year fixed certificate of deposit with a bank and was presented as restricted investment in the Company's balance sheet for the period ended December 31, 2017. In March 2018, the Company repaid the loan and accrued interest in full, resulting in the release of \$12.6 million from restricted cash to investments in marketable securities on the Company's condensed consolidated balance sheet.

## 12. 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 22%. Over the course of the Agreement, the actual interest rate will be affected by the amount and timing of royalty revenue recognized and changes in the timing of forecasted royalty revenue. On a quarterly basis, the Company will reassess the expected timing of the royalty revenue, recalculate the amortization and effective interest rate and adjust the accounting prospectively as needed.

The Company recognizes non-cash royalty revenue related to the sales of ONPATTRO during the term of the Agreement. As royalties are remitted to OMERS from Alnylam, the balance of the recognized liability is effectively repaid over the life of the

Agreement. There are a number of factors that could materially affect the amount and timing of royalty payments from Alnylam, none of which are within the Company's control.

During the year ended December 31, 2019, the Company recognized non-cash royalty revenue of \$1.7 million and \$2.1 million of related non-cash interest expense.

The table below shows the activity related to the net liability from inception of the Agreement through December 31, 2019:

	Twelve Months	Ended December 31, 2019
	(in t	housands)
Net liability related to sale of future royalties - beginning balance	\$	_
Initial recognition of liability		30,000
Debt discount and issuance costs		(11,451)
Non-cash interest expense		2,099
Net debt discount and issuance costs		(9,352)
Non-cash royalty revenue		(1,656)
Net liability related to sale of future royalties - ending balance	\$	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.

## 13. 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. For the years ended December 31, 2019 and 2018, the Company earned royalties on Marqibo sales in the amounts of \$0.3 million and \$0.2 million, respectively. 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, 2019 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 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 and in January 2015, filed a Statement of Claim, which alleged entitlement to \$3.5 million in allegedly unpaid royalties based on publicly available information, and an unspecified amount based on non-public information. UBC also sought interest and costs, including legal fees. The Company filed its Statement of Defense to UBC's Statement of Claims, as well as a Counterclaim involving a patent application that the Company alleged UBC wrongly licensed to a third party. The proceedings were divided into three phases, with the first hearing taking place in June 2017. In the first phase, the arbitrator determined which agreements are sublicense agreements within UBC's claim. Also in the first phase, UBC updated its alleged entitlement from \$3.5 million originally claimed to seek \$10.9 million in alleged unpaid royalties, plus interest arising from payments as early as 2008. The arbitrator also held in the first phase of the arbitration that the patent application that is the subject of the Counterclaim was not required to be licensed to Arbutus. The second phase of arbitration took place in the second quarter of 2019. 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. The arbitrator also held that the third phase of the arbitration, which would address patent validity, should the Company choose to pursue a third phas

The Company recorded a charge of \$6.3 million in 2019 consisting \$5.9 million for the award (including interest) and \$0.4 million for an estimate of a potential award for costs and attorneys' fees.

## License Agreements between Enantigen

In October 2014, Arbutus Inc. acquired all of the outstanding shares of Enantigen Therapeutics, Inc. ("Enantigen") pursuant to a stock purchase agreement. Through this transaction, Arbutus Inc. acquired a HBV surface antigen secretion inhibitor program and a capsid assembly inhibitor program.

Under the stock purchase agreement, Arbutus Inc. agreed to pay up to a total of \$21.0 million to Enantigen's selling stockholders upon the achievement of specified development and regulatory milestones for (a) the first two products that contain either a capsid compound or an HBV surface antigen compound that is covered by a patent acquired under this agreement, or (b) a capsid compound from an agreed-upon list of compounds. The development milestones are tied to programs which are no longer under development by us, and therefore the contingency related to these milestones has been reduced to zero.

An additional \$102.5 million may also be paid to Enantigen's selling stockholders related to the achievement of certain sales performance milestones in connection with the sale of the first commercialized product by Arbutus Inc. 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 Inc.'s milestone payment obligations.

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 \$3.0 million as of December 31, 2019.

## 14. Collaborations, contracts and licensing agreements

## Alnylam Pharmaceuticals, Inc.

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. During the third quarter of 2018, Alnylam's ONPATTRO, which utilizes the Company's LNP technology, was approved by the U.S. Food and Drug Administration ("FDA") and the European Medicines Agency. The Company is entitled to tiered low to mid single-digit royalty payments on global net sales of ONPATTRO and received its first royalty payment in the fourth quarter of 2018. In July 2019, the Company sold a portion of its royalty entitlement for Alnylam's ONPATTRO to OMERS. See note 12 for further details.

The Company recognized \$1.7 million of non-cash revenue and \$0.2 million of cash revenue based on global net sales of Alnylam's ONPATTRO for the year ended December 31, 2019 and 2018, respectively.

#### Acuitas Therapeutics, Inc.

The Company has rights to a second 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 us and was not part of the royalty entitlement sale to OMERS.

The Company recognized \$1.9 million and \$1.0 million of revenue from Acuitas based on global net sales of Alnylam's ONPATTRO for the years ended December 31, 2019 and 2018, respectively.

## Gritstone Oncology, Inc.

On October 16, 2017, the Company entered into a license agreement with Gritstone Oncology, Inc. ("Gritstone") that entitles Gritstone to research, develop, manufacture and commercialize products with the Company's LNP technology. The Company received an upfront payment in November 2017, and is eligible to receive future potential payments including development and commercial milestone payments, royalty payments on future product sales and payments for research services provided. 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. In 2018, Gritstone paid a development milestone payment of \$2.5 million pursuant to the license agreement and the Company recorded related revenue, net of the portion paid to Genevant, of \$1.3 million.

Milestone payments that are not within the control of the Company or the licensee, such as those that require regulatory approvals, are not considered probable of being achieved until those approvals are received.

The Company recognized \$1.8 million and \$4.3 million of revenue from Gritstone for the years ended December 31, 2019 and 2018, respectively.

## 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.) including the grant of worldwide licenses (the "Talon License Agreement") for three of the Company's chemotherapy products, Marqibo®, Alocrest <sup>TM</sup> (Optisomal Vinorelbine) and Brakiva <sup>TM</sup> (Optisomal Topotecan).

In 2012, Talon had 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 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 Biopharma LLC in January 2019. The acquisitions and license sale did not affect the terms of the license between Talon and the Company.

The Company recognized \$0.6 million and \$0.2 million of revenue related to sales of Marqibo for the years ended December 31, 2019 and 2018, respectively.

## 15. 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 the 2018 Sale Agreement with Jefferies, under which it may issue and sell common shares, from time to time, for an aggregate sales price of up to \$50.0 million. For the twelve months ended December 31, 2019, the Company issued 9,138,232 common shares pursuant to the Sale Agreement, resulting in gross proceeds of approximately \$19.5 million. There were no shares issued during the twelve months ended December 31, 2018 under the Sale Agreement.

In December 2019, the Company entered into an amendment to the Sale Agreement with Jefferies in connection with filing a new shelf registration statement on Form S-3 (File No. 333-235674), filed with the SEC on December 23, 2019 (the "New Shelf Registration Statement"). The Amendment revised the Sale Agreement to reflect that we may sell our common shares, without par value, from time to time for an aggregate sales price of up to \$50.0 million, under the New Shelf Registration Statement. In 2020, through March 2, 2020, we issued 4,127,092 common shares pursuant to the amendment to the Sale Agreement, resulting in net proceeds of approximately \$12.3 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 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, 2019 Roivant would hold 42% 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 under ASC 480, 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).

## 16. Stock-based compensation

## Awards outstanding and available for issuance

During the year ended December 31, 2019, the Company had stock options outstanding under the following plans: the 2016 Omnibus Share and Incentive Plan (the "2016 Plan"), the 2011 Omnibus Share Compensation Plan (the "2011 Plan"), the 2013 designated plans (the "Designated Plans"), the 2019 inducement grant and the OnCore Option Plan.

As of December 31, 2019, the aggregate number of shares authorized for awards under all Plans was 12,790,202. As of December 31, 2019, the Company had 8,576,584 options outstanding and a further 2,424,703 awards available for issuance.

The Company issues new shares of common 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.

Additionally, the Company granted a total of 200,000 options in 2013 to two executive officers in conjunction with their new appointments as executive officers. These options were granted in accordance with the policies of the Toronto Stock Exchange and pursuant to newly designated share compensation plans (the "Designated Plans"). The Designated Plans are governed by substantially the same terms as the 2011 Plan. No new options can be granted under the Designated Plans. There were 150,000 options outstanding for one of the Company's former executive officers as of December 31, 2018, all of which expired unexercised in February 2019.

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, the 2007 Plan, the Designated Plans 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 for the year ended December 31, 2019:

	Stock Options Outstanding		<b>Vested Stock Options</b>	Non-Vested Stock Options		Options	
	Number	1	Weighted-Average Exercise Price	Number	Number		eighted-Average nt-Date Fair Value
Balance as of December 31, 2018	6,331,088	\$	6.05	2,620,542	3,710,546	\$	3.39
Options granted	3,018,000	\$	3.41	_	3,018,000	\$	2.43
Options exercised	(83,000)	\$	3.25	(83,000)	_	\$	_
Options forfeit, canceled or expired	(1,016,995)	\$	6.98	(477,848)	(539,147)	\$	3.24
Options vested	_	\$	_	2,234,955	(2,234,955)	\$	3.10
Balance as of December 31, 2019	8,249,093	\$	5.00	4,294,649	3,954,444	\$	2.86

The intrinsic value of options exercised under the Arbutus plans during 2019 and 2018 are less than \$0.1 million and \$1.1 million, respectively.

The following table summarizes additional information related to the Company's equity-classified stock options as of December 31, 2019:

	As of D	ecember 31, 2019
Options outstanding and expected to vest		
Number of stock options outstanding		8,249,093
Weighted-average exercise price	\$	5
Intrinsic value (in \$000s)	\$	1,001
Weighted-average term remaining		6.9 years
<u>Vested stock options</u>		
Number of vested stock options		4,294,649
Weighted-average exercise price	\$	5.85
Intrinsic value (in \$000s)	\$	189
Weighted-average term remaining		5.0 years

On March 3, 2015, the Company voluntarily de-listed from the Toronto Stock Exchange. All stock options granted after March 3, 2015 were denominated in US dollars based on the Company's stock price on the Nasdaq Global Select Market. The methodology and assumptions used to estimate the fair value of stock options at date of grant under the Black-Scholes option-pricing model remain unchanged. 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. Assumptions about the Company's expected stock-price volatility are based on the historical volatility of the Company's publicly traded stock. The risk-free interest rate used for each grant is equal to the zero coupon rate for instruments with a similar expected life. Expected life assumptions are based on the Company's historical data.

The assumptions used in the Black-Scholes option-pricing for grants made during the years ended December 31, 2019 and 2018 are as follows:

	December 31, 2019	December 31, 2018
Expected average option term	7.3 years	6.7 years
Expected volatility	75.9%	75.2%
Expected dividends	—%	—%
Risk-free interest rate	2.27%	2.81%

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, 2019:

	Stock Options Vested and Outstanding		
	Number		Weighted-Average Exercise Price
Balance as of December 31, 2018	377,500	\$	5.81
Options exercised	<u> </u>	\$	_
Options forfeit, canceled or expired	(150,000)	\$	7.01
Balance as of December 31, 2019	227,500	\$	5.49

There were no exercises of liability-classified stock options during 2019. The intrinsic value of liability-classified options exercised during 2018 was \$0.1 million.

The following table summarizes additional information related to the Company's liability-classified stock options as of December 31, 2019:

	As of Dece	mber 31, 2019
Options outstanding and expected to vest		
Intrinsic value (in \$000s)	\$	96
Weighted-average term remaining		1.6 years

Liability options are re-measured to their fair values at each reporting date, using the Black-Scholes valuation model. The methodology and assumptions prevailing at the re-measurement date used to estimate the fair values of liability options remain unchanged from the date of grant of equity classified stock option awards. Assumptions about the Company's expected stock-price volatility are based on the historical volatility of the Company's publicly traded stock. The risk-free interest rate used for each grant is equal to the zero coupon rate for instruments with a similar expected life. Expected life assumptions are based on the Company's historical data.

The weighted average Black-Scholes option-pricing assumptions and the resultant fair values as of December 31, 2019 and December 31, 2018, are presented in the following table:

	Dece	mber 31, 2019	December 31, 2018
Stock price	\$	2.78	\$ 3.83
Expected average option term		1.6 years	2.2 years
Expected volatility		113.1%	75.2%
Expected dividends		—%	—%
Risk-free interest rate		1.59%	2.48%
Weighted-average fair value per share	\$	1.11	\$ 1.27
Total fair value of vested liability-classified options (in \$000s)	\$	253	\$ 479

# **OnCore Option Plan**

As of the acquisition date in March 2015, the Company reserved 184,332 shares for the future exercise of OnCore stock options. The total fair value of OnCore stock options at the date of acquisition was \$3.3 million, using the Black-Scholes pricing model with an assumed risk-free interest rate of 0.97%, volatility of 78%, a zero dividend yield and an expected life of 8.0 years, which are consistent with the assumption inputs used by the Company to determine the fair value of its options. Of the total fair value, \$1.1 million was attributed as pre-combination service and included as part of the total acquisition consideration. The post-combination attribution of \$2.2 million was recognized as compensation expense over the vesting period of the stock options through December 2018.

Following the merger, 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, 2019:

	Sto	Stock Options Vested and Outstanding			
	Number of OnCore Options	Number of Equivalent Company Common Shares	Weighted-Average Exercise Price		
Balance as of December 31, 2018	139,290	140,273	\$ 0.56		
Options exercised	(40,000)	(40,282)	\$ 0.58		
Options forfeit, canceled or expired	_	_	\$ —		
Balance as of December 31, 2019	99,290	99,991	\$ 0.56		

The intrinsic value of options exercised under the OnCore plan during 2019 and 2018 was \$0.1 million and \$0.3 million, respectively.

The following table summarizes additional information related to the OnCore stock options as of December 31, 2019:

	As	s of December 31, 2019
Vested stock options		
Intrinsic value (in \$000s)	\$	222,248
Weighted-average term remaining		4.9 years

## 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; and (2) fair value adjustments for the Company's liability-classified stock options.

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			
	 2019	2018		
	(in the	usands)		
Research and development	\$ 2,971	\$	2,670	
General and administrative	3,828		3,337	
Total	\$ 6,799	\$	6,007	

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, 2019, there remains \$6.8 million of unearned compensation expense related to unvested equity employee stock options to be recognized as expense over a weighted-average period of approximately 2.1 years.

## 17. Income taxes

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% (2018 - 27%) to the loss before income taxes as shown in the following tables:

	 Year ended December 31,			
	 2019	2018		
	(in thousand	s)		
Computed taxes (benefits) at Canadian federal and provincial tax rates	\$ (44,922) \$	(16,563)		
Difference between statutory rate and foreign rate	8,356	_		
Adjustments to prior year	(525)	_		
Permanent and other differences	3,458	(2,328)		
Change in valuation allowance - other	19,078	13,062		
Difference due to income taxed at foreign rates	(3,343)	(138)		
Stock-based compensation	523	1,685		
Impairment of goodwill	4,719	_		
Deferred income tax benefit	\$ (12,656) \$	(4,282)		

As of December 31, 2019, the Company has investment tax credits available to reduce Canadian federal income taxes of \$10.0 million, versus \$8.8 million as of December 31, 2018, which expire between 2027 and 2037, and provincial income taxes of \$4.5

million, versus \$4.0 million as of December 31, 2018, which expire between 2024 and 2027. In addition, the Company has research and development credits of \$3.9 million as of December 31, 2019, versus the \$4.3 million it had as of December 31, 2018, which expire between 2031 and 2038 and which can be used to reduce future taxable income in the United States.

As of December 31, 2019, the Company had scientific research and experimental development expenditures of \$60.6 million available for indefinite carry-forward, versus the \$61.5 million it had as of December 31, 2018. The Company also had net operating losses of \$164.9 million as of December 31, 2019 and \$182.3 million as of December 31, 2018, which are due to expire between 2031 and 2038 and which can be used to offset future taxable income in Canada.

As of December 31, 2019, the Company had \$11.7 million of net operating losses due to expire in 2035 and \$62.0 million of net operating losses subject to an indefinite carryforward period which can be used to offset future taxable income in the United States, versus the \$11.0 million the Company had as of December 31, 2018. Future use of a portion of the United States loss carry-forwards is subject to limitations under the Internal Revenue Code Section 382.

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 \$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 Dec	ember 3	31,
	 2019		2018
	(in tho	usands)	
Deferred tax assets (liabilities):			
Non-capital loss carryforwards	\$ 59,956	\$	51,575
Research and development deductions	16,349		15,803
Book amortization in excess of tax	(914)		(608)
Share issue costs	202		307
Revenue recognized for tax purposes in excess of revenue recognized for accounting purposes	5,128		_
Tax value in excess of accounting value in lease inducements	705		147
Federal investment tax credits	7,325		9,686
Provincial investment tax credits	4,535		3,955
In-process research and development	_		(12,664)
Upfront license fees	236		283
Equity accounted for investment	3,038		37
Other	6,202		2,503
Total deferred tax assets (liabilities)	102,762		71,024
Valuation allowance	(102,762)		(83,685)
Net deferred tax assets (liabilities)	\$ 	\$	(12,661)

# 18. Related Party Transactions

During 2018, the Company purchased certain research and development services from Roivant, which were billed at agreed hourly rates and reflective of market rates for such services. The total cost of these services was \$0.6 million during 2018 and was recorded in the income statement in research and development. There were no such purchases in 2019.

During 2018, the Company also purchased certain research and development services from its equity method investee, Genevant. These services were billed at agreed hourly rates and reflective of market rates for such services. The total cost of these services was \$0.4 million during 2018 and were included in the income statement in research and development. There were no such purchases during 2019.

Conversely, Genevant purchased certain administrative and transitional services from the Company totaling \$0.1 million and \$0.2 million during 2019 and 2018, respectively, 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 and \$0.2 million, in 2019 and 2018, respectively, which was netted against site consolidation costs in the income statement (note 10).

# 19. Interim financial data (unaudited)

Summarized unaudited quarterly financial data is presented below.

					Quarters Ended				
	March 31		June 30		September 30 <sup>1</sup>		December 31		Full Year
			(in th	iousai	nds, except per share	data	ı)		
\$	679	\$	653	\$	3,061	\$	1,618	\$	6,011
\$	(19,071)	\$	(20,515)	\$	(91,401)	\$	(13,087)	\$	(144,074)
\$	(23,251)	\$	(23,315)	\$	(82,503)	\$	(24,654)	\$	(153,723)
\$	(25,966)	\$	(26,077)	\$	(85,295)	\$	(27,534)	\$	(164,872)
per \$	(0.47)	\$	(0.46)	\$	(1.50)	\$	(0.46)	\$	(2.89)
	\$	\$ 679 \$ (19,071) \$ (23,251) \$ (25,966) per	\$ 679 \$ \$ (19,071) \$ \$ (23,251) \$ \$ (25,966) \$	\text{(in the control of the c	March 31         June 30           (in tbusing the body of the body	Cin thousands, except per share	March 31   June 30   September 301   September 302   September 303   September 303   September 304   September 304   September 304   September 304   September 305   September 306   September 306   September 306   September 306   September 307   September 307   September 308   Septemb	March 31   June 30   September 301   December 31	March 31   June 30   Sept

<sup>&</sup>lt;sup>1</sup> In the third quarter of 2019, the Company recorded non-cash impairment charges of \$43.8 million and \$22.5 million, respectively, to reduce the carrying value of its IPR&D intangible assets and goodwill 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. See note 8 for more information.

					Quarters Ended			
		March 31	June 30		September 30 <sup>1</sup>		December 31	Full Year
<u>2018</u>			(in th	ousa	nds, except per share	data	)	
Total revenue	\$	1,436	\$ 1,244	\$	1,587	\$	1,678	\$ 5,945
Loss from operations	\$	(18,405)	\$ (22,046)	\$	(32,426)	\$	(16,903)	\$ (89,780)
Net loss	\$	(17,429)	\$ 3,091	\$	(24,473)	\$	(18,249)	\$ (57,060)
Net income/(loss) attributable to common								
shares	\$	(19,765)	\$ 550	\$	(27,040)	\$	(20,896)	\$ (67,151)
Basic and diluted net income/(loss) per	r							
common share	\$	(0.36)	\$ 0.01	\$	(0.49)	\$	(0.38)	\$ (1.21)

<sup>&</sup>lt;sup>1</sup> In the third quarter of 2018, the Company recorded a \$14.8 million non-cash impairment charge to reduce the carrying value of its IPR&D intangible assets, as well as a corresponding income tax benefit of \$4.3 million related to the decrease in the related deferred tax liability.

## 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, 2019, 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, 2019.

# **Attestation Report of the Registered Public Accounting Firm**

The independent registered public accounting firm's report on the effectiveness of our internal control over financial reporting, is included in Item 8 of this annual report on Form 10-K and is incorporated herein by reference.

# **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, 2019 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 2020 Annual General Meeting of the Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2019.

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 and 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 2020 Annual General Meeting of the Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2019.

# 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 2020 Annual General Meeting of the Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2019.

## 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 2020 Annual General Meeting of the Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2019.

## Item 14. Principal Accounting Fees and Services

The information required by this item is incorporated herein by reference to our Proxy Statement for the 2020 Annual General Meeting of the Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2019.

# PART IV

# **Item 15. Exhibits and Financial Statement Schedules**

Exhibit	Description
2.1*	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).
3.1*	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).
3.2*	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).
4.1*	Governance Agreement between the Company and Roivant Sciences Ltd., a Bermuda exempted company, dated January 11, 2015 (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).
4.2**	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.
10.1†*	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).
10.2†*	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).
10.3†*	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).
10.4**#	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).
10.5†*	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).
10.6†*	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).
10.7†*	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).
10.8†*	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).
10.9*	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).

Settlement Agreement and General Release, by and among Tekmira Pharmaceuticals Corporation, Protiva Biotherapeutics Inc., Alnylam 10.10†\* 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). Cross-License Agreement by and among Alnylam Pharmaceuticals, Inc., Tekmira Pharmaceuticals Corporation and Protiva 10.11†\* 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\* Forms of Lock-Up 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 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). 10.14\* 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). Form of Representation Letter (incorporated herein by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K/A filed 10.15\* with the SEC on January 26, 2015). 10.16\* Executive Employment Agreement Elizabeth Howard, dated March 7, 2016 (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). 10.17\*# 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). 10.18†\* 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 10.1 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). Executive Employment Agreement, dated effective as of July 11, 2015, between OnCore Biopharma, Inc. and Michael J. Sofia 10.19\*# (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). 10.20\* 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). 2016 Omnibus Share and Incentive Plan (incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10.21\* 10-O for the guarter ended June 30, 2016, filed with the SEC on August 4, 2016). 10.22\*† 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 guarter ended September 30, 2016, filed with the SEC on November 3, 2016). First Amendment to Lease Agreement between Arbutus Biopharma, Inc. and ARE-PA Region No. 7, LLC dated October 7, 2016 10.23\*† (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). Acknowledgment of Commencement Date in connection with Lease Agreement between the Company and ARE-PA Region No. 7, LLC 10.24\* 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).

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

10.25\*

November 21, 2017).

10.26\* Governance Amendments between the Company and Roivant Sciences Ltd. (incorporated herein by reference to Exhibit B to the Registrant's Preliminary Proxy Soliciting Materials on Schedule Pre 14A for the Special Meeting, filed with the SEC on November 21, 2017). Amended and Restated Lockup Agreement between the Company and Roivant Sciences Ltd. (incorporated herein by reference to Exhibit 10.27\* 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). 10.28\* 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). 10.29\* 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). 10.30\*# 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). Exclusivity Agreement, dated February 13, 2018, by and between the Company and Roivant Sciences Ltd. (incorporated herein by 10.31\* reference to Exhibit 7.09 of the Schedule 13D filed with the SEC by Roivant Sciences Ltd. on February 14, 2018). 10.32\* 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). Open Market Sale AgreementSM, dated December 20, 2018, by and between the Company and Jefferies LLC. (incorporated herein by 10.33\* reference to Exhibit 1.1 of the Current Report on Form 8-K filed with the SEC on December 20, 2018). 10.34\*\* 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). Executive Employment Agreement, dated June 11, 2018, by and between the Company and David Hastings. (incorporated herein by 10.35\*# reference to Exhibit 10.52 of the Form 10-K filed with the SEC on March 7, 2019). 10.36\*# 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 Form10-K filed with the SEC on March 7, 2019). 10.37\*# 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). 10.38\* 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). 10.39\*# 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). 10.40\* 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). Executive Employment Agreement, dated July 10, 2015, by and between the Company and Michael McElhaugh, as amended by the First 10.41\* Amendment to Executive Employment Agreement, dated April 20, 2016, and the Second Amendment to Executive Employment

Q for the Quarter ended June 30, 2019, filed with the SEC on August 5, 2019).

Agreement dated December 11, 2018 (incorporated herein by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-

10.42*	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).
10.43*	Arbutus Biopharma Corporation 2016 Omnibus Share and Incentive Plan, as supplemented by the Committee on May 9, 2019 (incorporated herein by reference to Exhibit 10.7 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).
10.44*	Form of Arbutus Biopharma Corporation Option Agreement (incorporated herein by reference to Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q for the Quarter ended June 30, 2019, filed with the SEC on August 5, 2019).
10.45*	Option Agreement, dated June 24, by and between the Company and William H. Collier (incorporated herein by reference to Exhibit 10.9 to the Registrant's Quarterly Report on Form 10-Q for the Quarter ended June 30, 2019, filed with the SEC on August 5, 2019).
10.46*	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).
10.47*	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).
16.1*	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.)
21.1**	List of Subsidiaries.
23.1**	Consent of KPMG LLP, an Independent Registered Public Accounting Firm.
23.2**	Consent of Ernst and Young LLP, an Independent Registered Public Accounting Firm.
31.1**	Certification of Chief Executive Officer pursuant to Rule 13a-14 or 15d-14 of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2**	Certification of Chief Financial Officer pursuant to Rule 13a-14 or 15d-14 of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

<sup>\*</sup> Previously filed

<sup>\*\*</sup> Filed herewith

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

<sup>#</sup> Management Contract

# **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 5, 2020.

# 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 5, 2020.

Signatures	Capacity in Which Signed
/s/ Frank Torti, M.D.  Dr. Frank Torti, M.D.	Director (Chairman)
/s/ William Collier William Collier	President and Chief Executive Officer and Director (Principal Executive Officer)
/s/ David C. Hastings David C. Hastings	Chief Financial Officer (Principal Financial Officer)
/s/ Daniel Burgess Daniel Burgess	Director
/s/ Richard C. Henriques Richard C. Henriques	Director
/s/ Keith Manchester Keith Manchester	Director
/s/ Eric Venker, M.D., PharmD Eric Venker, M.D., PharmD	Director
/s/ James Meyers James Meyers	Director
/s/ Andrew Cheng, M.D., Ph. D 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 entierty 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 2, 2020 there were (a) 68,941,406 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 16, 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 2, 2020, Roivant would hold approximately 42% 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
Arbutus Biopharma US Holdings, Inc.	Delaware, United States of America

# CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors Arbutus Biopharma Corporation

We consent to the incorporation by reference in the registration statement (No. 333-235674) on Form S-3, and registration statements (No. 333-233192, No. 333-228919, No. 333-202762, No. 333-212115, and No. 333-186185) on Form S-8 of Arbutus Biopharma Corporation (the "Company") of our report dated March 7, 2019, with respect to the consolidated balance sheet of the Company as of December 31, 2018 and the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for the year then ended, and related notes, which report appears in the December 31, 2019 Form 10-K of the Company.

/s/ KPMG LLP Chartered Professional Accountants

Vancouver, Canada Date

# **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. 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,
- 2) Registration Statement (Form S-8 No. 333-233192) pertaining to the Inducement Plan of Arbutus Biopharma Corporation,
- 3) Registration Statement (Form S-8 No. 333-228919) pertaining to the 2011 Omnibus Share Compensation Plan,
- 4) Registration Statement (Form S-8 No. 333-212115) pertaining to the 2016 Omnibus Share and Incentive Plan,
- 5) Registration Statement (Form S-8 No. 333-202762) pertaining to the OnCore Biopharma, Inc. 2014 Equity Incentive Plan, and
- 6) 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 reports dated March 5, 2020, with respect to the consolidated financial statements of Arbutus Biopharma Corporation and the effectiveness of internal control over financial reporting of Arbutus Biopharma Corporation included in this Annual Report (Form 10-K) of Arbutus Biopharma Corporation for the year ended December 31, 2019.

/s/ Ernst Young LLP

Philadelphia, Pennsylvania March 5, 2020

## 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 5, 2020

/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. 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
    - 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 5, 2020

/s/ David Hastings

Name: David Hastings

Title: Chief 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, 2019, 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 5, 2020

/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, 2019, 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 5, 2020

/s/ David Hastings

Name: David Hastings

Title: Chief Financial Officer