# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

#### Form 10-K

**△** ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the Fiscal Year Ended December 31, 2021

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Transition Period from

to

Commission File Number: 001-34949

### **Arbutus Biopharma Corporation**

(Exact Name of Registrant as Specified in Its Charter)

British Columbia, Canada

(State or Other Jurisdiction of Incorporation or Organization)

98-0597776

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

701 Veterans Circle Warminster PA 18974

(Address of Principal Executive Offices)

267-469-0914

(Registrant's Telephone Number, Including Area Code) Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class

Trading Symbol(s)

Name of Each Exchange on Which Registered

Common shares, without par value

ABUS

The Nasdaq Stock Market LLC

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes 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 0

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	Accelerated filer	Non-accelerated filer	Smaller reporting company	Emerging growth company			
		$\boxtimes$	$\boxtimes$				
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. 0 Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. $\square$							
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes $\Box$ No x							
As of June 30, 2021, 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 \$238,483,586 based on the closing price of \$3.03 per share as reported on the Nasdaq Global Select Market as of that date).							
As of March 3, 2022, the registrant had 148,641,736 common shares, without par value, outstanding.							

#### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2022 Annual Meeting of Shareholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission no later than 120 days after the registrant's fiscal year ended December 31, 2021, are incorporated by reference into Part III of this Form 10-K.

#### ARBUTUS BIOPHARMA CORPORATION

#### TABLE OF CONTENTS

		<u>Page</u>
Risk Factors Sun	Regarding Forward-looking Statements	<u>4</u> <u>6</u>
<u> </u>	<del></del>	<u> </u>
<u>PART I</u>		<u>9</u>
<u>Item 1.</u>	<u>Business</u>	9 9 35 56 56 56
Item 1A.	Risk Factors	<u>35</u>
Item 1B.	<u>Unresolved Staff Comments</u>	<u>56</u>
<u>Item 2.</u>	<u>Properties</u>	<u>56</u>
<u>Item 3.</u>	<u>Legal Proceedings</u>	<u>56</u>
Item 4.	Mine Safety Disclosures	<u>56</u>
PART II		<u>58</u>
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	
Item 6.	<u>Reserved</u>	<u>58</u> <u>58</u>
<u>Item 7.</u>	Management's Discussion and Analysis of Financial Condition and Results of Operations	<u>59</u>
Item 7A.	Quantitative and Qualitative Disclosures about Market Risk	<u>68</u> <u>69</u>
<u>Item 8.</u>	Financial Statements and Supplementary Data	<u>69</u>
<u>Item 9.</u>	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	<u>99</u>
Item 9A.	Controls and Procedures	<u>99</u> <u>99</u>
<u>Item 9B.</u>	Other Information	
Item 9C.	<u>Disclosure Regarding Foreign Jurisdictions that Prevent Inspections</u>	<u>100</u>
PART III		<u>101</u>
<u>Item 10.</u>	Directors, Executive Officers and Corporate Governance	<u>101</u>
<u>Item 11.</u>	Executive Compensation	<u>101</u>
<u>Item 12.</u>	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	<u>101</u>
<u>Item 13.</u>	Certain Relationships and Related Transactions, and Director Independence	<u>101</u>
<u>Item 14.</u>	Principal Accountant Fees and Services	<u>101</u>
PART IV		<u>102</u>
Item 15.	Exhibits and Financial Statement Schedules	102

#### Cautionary Note Regarding Forward-looking Statements

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

- · our strategy, future operations, pre-clinical research, pre-clinical studies, clinical trials, prospects and the plans of management;
- · the potential for our product candidates to achieve their desired or anticipated outcomes;
- the expected cost, timing and results of our clinical development plans and clinical trials, including our clinical collaborations with third parties;
- the potential impact of the COVID-19 pandemic on our business and clinical trials;
- the discovery, development and commercialization of a curative combination regimen for chronic hepatitis B infection, a disease of the liver caused by the hepatitis B virus ("HBV");
- the potential of our product candidates to improve upon the standard of care and contribute to a functional curative combination treatment regimen;
- obtaining necessary regulatory approvals;
- obtaining adequate financing through a combination of financing activities and operations;
- · the potential for us to discover and/or develop new molecular entities for treating coronaviruses, including COVID-19;
- the expected returns and benefits from strategic alliances, licensing agreements, and research collaborations with third parties;
- our expectations regarding our technology licensed to third parties, and the timing thereof;
- our anticipated revenue and expense fluctuation and guidance;
- · our expectations regarding the timing of announcing data from our ongoing clinical trials
- our expectations regarding current patent disputes and litigation;
- our expectation of a net cash burn between \$90.0 million and \$95.0 million in 2022; and
- · our belief that we have sufficient cash resources to fund our operations into the second quarter of 2024,

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

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

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

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

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

#### Risk Factors Summary

The following is a summary of the principal risks that could adversely affect our business, operations and financial results. For more information, see "Item 1A. Risk Factors" in this Annual Report on Form 10-K for the year ended December 31, 2021.

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

- We are in the early stages of our development, and there is a limited amount of information about us upon which you can evaluate our product candidates.
- We will require substantial additional capital to fund our operations. Additional funds may be dilutive to shareholders or impose operational restrictions. Further, if additional capital is not available, we may need to delay, limit or eliminate our research, development and commercialization programs and modify our business strategy.
- We have incurred losses in nearly every year since our inception and we anticipate that we will not achieve profits for the foreseeable future. To date, we have had no product revenues, and we may never be profitable.
- The COVID-19 coronavirus could adversely impact our business, including our clinical development plans.

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

- Our product candidates are in early stages of development and must go through clinical trials, which are very expensive, time-consuming and difficult to design and implement. The outcomes of clinical trials are uncertain, and delays in the completion of or the termination of any clinical trial of our product candidates could harm our business, financial condition and prospects.
- Pre-clinical studies and 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.
- Because we have limited resources, we may decide to pursue a particular product candidate and fail to advance product candidates that later demonstrate a greater chance of clinical and commercial success.
- Several of our current pre-clinical studies and clinical trials are being conducted outside the United States, and the United States Food and Drug Administration (the "FDA") may not accept data from trials conducted in locations outside the United States.
- We cannot guarantee how long it will take regulatory agencies to review our applications for product candidates, and we may fail to obtain the
  necessary regulatory approvals to market our product candidates.
- If a particular product candidate causes undesirable side effects, then we may be unable to receive regulatory approval of or commercialize such product candidate.
- We may find it difficult to enroll patients in our clinical trials, which could delay or prevent our clinical trials.
- Several of our and our collaboration partner's clinical trials have been impacted and could be delayed or suspended as a result of the military
  action by Russia in Ukraine.
- · Even if our product candidates obtain regulatory approval, they will remain subject to ongoing regulatory requirements and oversight.
- We face significant competition from other biotechnology and pharmaceutical companies.
- · We are largely dependent on the future commercial success of our HBV and coronavirus product candidates.
- We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.
- Coverage and adequate reimbursement may not be available for our product candidates, which could make it difficult for us to sell our products profitably.

- We are subject to U.S. and Canadian healthcare laws and regulations. This could expose us to, among other things, criminal sanctions, civil
  penalties, contractual damages, exclusion from participation in government healthcare programs, curtailment or restricting of our operations and
  diminished profits and future earnings.
- Failure to comply with the United States Foreign Corrupt Practices Act ("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 adverse consequences.

#### **Risks Related to Our Dependence on Third Parties**

- We depend on our license agreement with Alnylam Pharmaceuticals, Inc. ("Alnylam") for the commercialization of ONPATTRO™ (Patisiran).
- We expect to depend in part on our licensing agreements for a significant portion of our revenues for the foreseeable future and to develop, conduct clinical trials with, obtain regulatory approvals for, and manufacture, market and sell some of our product candidates. If these licensing agreements are unsuccessful, or anticipated milestone or royalty payments are not received, our business could be materially adversely affected.
- We are dependent on collaboration and licensing partners and, therefore, are subject to the efforts of these parties and our ability to successfully collaborate with them.
- We will depend on Qilu Pharmaceuticals ("Qilu") for the development and commercialization of AB-729 in China, Hong Kong, Macau and Taiwan.
- If conflicts arise between our collaboration or licensing partners and us, our collaboration or licensing partners may act in their best interest and not in our best interest, which could adversely affect our business.
- We rely on third parties to conduct our clinical trials, and if they fail to fulfill their obligations, perform services in a satisfactorily manner, and/or comply with applicable legal or regulatory requirements, our development plans may be adversely affected.
- We rely exclusively on third parties to formulate and manufacture our product candidates, which exposes us to a number of risks that may delay development, regulatory approval and commercialization of our products or result in higher product costs.

#### **Risks Related to Our Intellectual Property**

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

#### Risks Related to the Ownership of our Common Shares

- The concentration of common share ownership with insiders, as well as director nomination rights held by the largest shareholder, will likely limit the ability of the other shareholders to influence corporate matters.
- We are incorporated in Canada, with our assets located both in Canada and the United States, with the result that it may be difficult for investors to enforce judgments obtained against us or some of our officers.
- If we are deemed a "passive foreign investment company" for the current or any future taxable year, investors subject to U.S. federal taxation would likely suffer materially adverse U.S. federal income tax consequences.
- Our articles and certain Canadian laws could delay or deter a change of control.

#### **General Risk Factors**

- If we are unable to attract and retain qualified key management, scientific staff, consultants and advisors, our ability to implement our business plan may be adversely affected.
- · We could face liability from our controlled use of hazardous and radioactive materials in our research and development processes.
- Our business, reputation, and operations could suffer in the event of information technology system failures.
- We may acquire other assets or businesses, or form strategic alliances or collaborations or make investments in other companies or technologies that could harm our financial condition, results of operations or cash flows, dilute our shareholders' ownership, incur debt or cause us to incur significant expense.

#### PART I

#### Item 1. Business

#### Overview

Arbutus Biopharma Corporation ("Arbutus", the "Company", "we", "us", and "our") is a clinical-stage, biopharmaceutical company leveraging its extensive virology expertise to develop novel therapeutics that target specific viral diseases. Our current focus areas include Hepatitis B virus (HBV), SARS-CoV-2 and other coronaviruses. In HBV, we are developing an RNA interference ("RNAi") therapeutic, oral capsid inhibitor, oral PD-L1 inhibitor, and oral RNA destabilizer that we intend to combine to provide a functional cure for patients with chronic HBV infection ("cHBV") by suppressing viral replication, reducing surface antigen and reawakening the immune system. We believe our lead compound, AB-729, is the only RNAi therapeutic with evidence of immune re-awakening, and is currently being evaluated in multiple phase 2 clinical trials. We have an ongoing drug discovery and development program directed to identifying novel, orally active agents for treating coronaviruses (including SARS-CoV-2). We are also exploring oncology applications for our internal PD-L1 portfolio.

#### Strategy

The core elements of our strategy include:

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

AB-729, our proprietary subcutaneously-delivered RNAi therapeutic product candidate that suppresses HBsAg expression, which is thought to be a key prerequisite to enable reawakening of a patient's immune system to respond to HBV, is currently in one ongoing Phase 1a/1b clinical trial and three Phase 2a proof-of-concept clinical trials in combination with other agents with potentially complementary mechanisms of action. Preliminary data from the Phase 1a/1b clinical trial has shown that treatment with AB-729 resulted in meaningful declines in HBsAg while being well tolerated with no serious adverse events (SAEs) noted after both single and repeat dosing. Preliminary data also suggests that long-term suppression of HBsAg with AB-729 results in increased HBV-specific immune response. We anticipate presenting long-term on- and off-treatment follow-up data from our Phase 1a/1b clinical trial at a medical conference in 2022.

AB-836, our proprietary next-generation oral capsid inhibitor that suppresses HBV DNA replication, is currently in an ongoing Phase 1a/1b clinical trial where preliminary data from healthy subjects and HBV patients have shown that AB-836 is generally safe and well-tolerated with robust antiviral activity. AB-836 is from a novel chemical series differentiated from competitor compounds and has the potential to provide increased efficacy and an enhanced resistance profile. We expect to announce additional data from this clinical trial in the first half of 2022.

AB-101, our oral PD-L1 inhibitor that has the potential to reawaken patients' HBV-specific immune response by inhibiting PD-L1, is advancing through lead optimization with the anticipation of completing investigational new drug ("IND")-enabling studies in the second half of 2022. We are also exploring potential oncology applications for our internal PD-L1 portfolio.

AB-161, our next-generation oral HBV specific RNA destabilizer, is advancing through lead optimization with the anticipation of completing IND-enabling studies in the second half of 2022. We have conducted extensive non-clinical safety evaluations with AB-161 that gives us confidence in this molecule's ability to circumvent the peripheral neuropathy findings seen in non-clinical safety studies with our first-generation oral RNA destabilizer, AB-452.

- Combining therapeutic product candidates with complementary mechanisms of action to find a functional cure for people with cHBV. We believe that our proprietary product candidates AB-729, AB-836, AB-101 and AB-161, along with existing approved therapies, may provide our first proprietary combination therapy for people with cHBV. In-line with our strategy to position AB-729 as a potential cornerstone therapeutic in future HBV combination regimens, and to help guide future development of combination therapies of AB-729 with other compounds from our proprietary HBV portfolio, we are evaluating AB-729 in combination with other agents with potentially complementary mechanisms of action, including the following:
  - We are currently enrolling patients with cHBV in a Phase 2a proof-of-concept clinical trial to evaluate AB-729 in combination with ongoing standard-of-care nucleos(t)ide analogues ("NA") therapy and short courses of Peg-IFN $\alpha$ -2a, with preliminary data anticipated in the second half of 2022.
  - Through our collaboration with Assembly BioSciences, Inc. ("Assembly"), patients with cHBV are being enrolled in a Phase 2a proof-of-concept clinical trial evaluating a triple combination of AB-729, Assembly's lead HBV core inhibitor (capsid inhibitor) product candidate, vebicorvir ("VBR"), and NA therapy. Assembly is conducting this clinical trial and expects preliminary data in the second half of 2022.
  - Through our collaboration with Antios Therapeutics, Inc. ("Antios"), enrollment is complete in a cohort of patients in Antios' ongoing Phase 2a proof-of-concept clinical trial evaluating a triple combination of AB-729, Antios' proprietary Active Site Polymerase Inhibitor Nucleotide (ASPIN), ATI-2173, and Viread (tenofovir disoproxil fumarate), a nucleos(t)ide reverse transcriptase inhibitor. With the majority of patients in this cohort enrolled in Ukraine, which is currently in a state of war, they may be lost to follow-up before completing the clinical trial. Therefore, we and Antios may report limited data on a reduced number of patients from this clinical trial.
  - Through our collaboration with Vaccitech plc ("Vaccitech"), we anticipate initiating in the first half of 2022 a Phase 2a clinical trial to evaluate a triple combination of AB-729 with Vaccitech's VTP-300, a proprietary T cell stimulating therapeutic vaccine, and NA therapy for the treatment of patients with cHBV. We filed a Clinical Trial Application (CTA) in the fourth quarter of 2021 and anticipate initiating the clinical trial in the first half of 2022.
- Advancing small molecule antiviral product candidates to treat COVID-19 and future coronavirus outbreaks. This program is focused on the discovery and development of new molecular entities for treating coronaviruses (including COVID-19) that address specific viral targets including the nsp12 viral polymerase and the nsp5 viral protease (nucleos(t)ide). Through our collaboration with X-Chem, Inc. ("X-Chem") and Proteros biostructures GmbH ("Proteros"), we have identified and obtained a worldwide exclusive license to several molecules that inhibit the SARS-CoV-2 nsp5 main protease ("Mpro"), a validated target for the treatment of COVID-19 and potential future coronavirus outbreaks. We expect to nominate a candidate that inhibits Mpro in the first half of 2022 and advance into IND-enabling studies. We are also continuing lead optimization activities for an Nsp12 viral polymerase candidate.

#### **Background on HBV**

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

#### Current treatments and their limitations

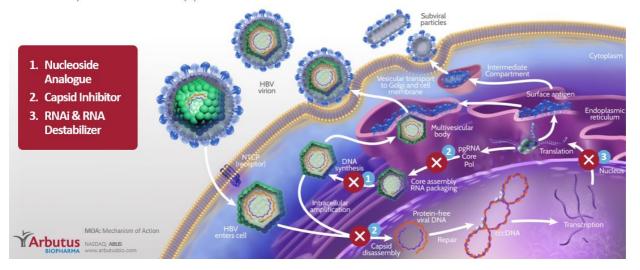
Today's current treatment options for cHBV include pegylated interferon- $\alpha$  regimens ("Peg-IFN $\alpha$ ") and NAs. Peg-IFN $\alpha$ , a synthetic version of a substance produced by the body to fight infection, is administered by injection and has numerous side effects including flu-like symptoms and depression. NAs are oral antiviral medications which, when taken chronically, reduce HBV virus replication and inflammation and significantly reduce HBV DNA in the blood. Oral NAs have become the standard-of-care for HBV treatment, mainly due to their ability to drive viral load to undetectable levels in the serum of patients, their easy single pill once-a-day dosing and favorable safety profile. However, in most cases, once Peg-IFN $\alpha$  and NA therapies are stopped, virus replication resumes and liver inflammation and fibrosis may still progress. While these treatments reduce viral load, less than 5% of patients are functionally cured after a finite treatment duration. With such low cure rates, most patients with cHBV are required to take NA therapy daily for the rest of their lives.

#### HBV Lifecycle and Key Points for Intervention

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

# A Combination of Agents with Complementary MOA is Needed for HBV Cure

HBV lifecycle illustrates key points for intervention



- 1. NAs: NAs work by inhibiting HBV DNA polymerase activity and suppressing HBV replication. However, NAs functionally cure only a small percentage of patients and typically require chronic dosing to maintain their benefits, which can be challenging for patients.
- 2. Capsid inhibitor (AB-836): this orally-delivered product candidate has the potential to inhibit HBV replication by preventing the assembly of functional viral capsids. HBV core protein assembles into a capsid structure, which is required for viral replication. The current standard-of-care therapy for HBV, primarily NAs that work by inhibiting the viral polymerase, significantly reduces virus replication, but not completely. Capsid inhibitors inhibit replication by

destabilizing core particle assembly or disassembly. Capsid inhibitors also have been shown to inhibit the uncoating step of the viral life cycle thus reducing the formation of new covalently closed circular DNA ("cccDNA"), the viral reservoir which resides in the cell nucleus and which is believed to play a role in viral persistence.

3. RNAi (AB-729): this subcutaneously-delivered RNAi therapeutic product candidate targeted to hepatocytes uses our novel covalently conjugated N-acetylgalactosamine ("GalNAc") subcutaneous delivery technology. AB-729 inhibits viral replication and reduces all HBV antigens, including HBsAg. Reducing HBsAg is thought to be a key prerequisite to enable reawakening of a patient's immune system to respond to the virus.

Oral HBV RNA destabilizer (AB-161): HBV RNA destabilizers have the potential to complement or replace subcutaneously delivered RNAi agents, such as AB-729, with an oral therapy in combination with a capsid inhibitor and an approved NA. 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.

Beyond addressing the key points of intervention described above, PD-L1 inhibitors could potentially be an important part of a combination therapy for the treatment of cHBV by reawakening the immune system. Highly functional HBV-specific T cells within our immune system are believed to be required for long-term HBV viral resolution. However, HBV-specific T cells become functionally defective, and greatly reduced in their frequency during cHBV. Our PD-L1 inhibitor product candidate, AB-101, is being developed to potentially boost HBV-specific T cells by preventing PD-L1 proteins from attaching to and inhibiting the HBV-specific T cells.

#### **Background on Coronaviruses**

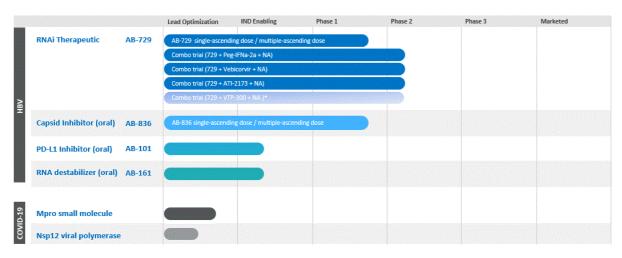
Coronaviruses are a large family of viruses that range from the common cold to more severe diseases such as severe acute respiratory syndrome (SARS), Middle East respiratory syndrome (MERS), and coronavirus disease 2019 (COVID-19). COVID-19 is defined as an illness caused by SARS-CoV-2 and was first identified in Wuhan, China in December 2019. This virus has been declared a pandemic by the World Health Organization and has spread to nearly every country in the world. The impact of this pandemic has been, and will likely continue to be, extensive in many aspects of society. COVID-19 has caused approximately 6.9 million deaths globally according to an analysis by the Institute for Health Metrics and Evaluation (IHME). COVID-19 spreads when an infected person breathes out droplets and very small particles that contain the virus. The CDC has recommended vaccinations, wearing masks, and social distancing to protect individuals from acquiring and transmitting COVID-19. Since its inception in December 2019, variant strains of COVID-19 have evolved and continue to impact the number of cases and deaths associated with this pandemic. It is well-accepted that in addition to the availability of vaccines, effective and safe therapies are needed to successfully combat the COVID-19 pandemic and any future coronavirus outbreaks.

#### **Our Product Candidates**

Our product pipeline includes multiple product candidates that target various steps in the HBV viral lifecycle and pan-coronavirus compounds that target essential enzymes for replication, the viral protease (Mpro) and polymerase (NA).

Our product pipeline consists of the following programs:

## **Pipeline**



\*Clinical trial to initiate in 1H 2022

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

#### GalNAc RNAi (AB-729)

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

AB-729 is a subcutaneously-delivered RNAi therapeutic targeted to hepatocytes using our proprietary covalently conjugated GalNAc delivery technology. AB-729 reduces all HBV antigens and inhibits viral replication. Our three-part Phase 1a/1b clinical trial was designed to investigate the safety, tolerability, pharmacokinetics, and pharmacodynamics of single- and multi-dose AB-729 in healthy subjects and in cHBV patients and to determine the most appropriate doses and dosing intervals to take forward into Phase 2 clinical development.

Part 1 of the trial dosed healthy subjects, and upon completion, supported advancing doses ranging from 60 mg to 180 mg into Part 2. Part 2 of the trial dosed patients with cHBV with single doses of AB-729, and upon completion, showed that single doses of AB-729 result in comparable mean HBsAg declines at week 12 followed by a sustained plateau phase. Part 3 of the trial is on-going and dosing HBV DNA negative and positive patients with multiple doses of AB-729 every 4, 8 or twelve weeks.

In November 2021, we presented a late breaker poster presentation at the 2021 AASLD liver meeting highlighting the most recent data from Part 3 of this clinical trial. Repeat dosing of 60 mg and 90 mg of AB-729 resulted in robust mean declines (ranging from 1.8-2.0 log10 at week 40) in HBsAg that were sustained up to 48 weeks, with no statistically significant differences observed to date between the 60 mg and 90 mg dose and/or dosing intervals. Data from the poster presentation also included long-term follow-up data for patients in cohort E (60 mg every four weeks) and cohort F (60 mg every eight weeks) who had been off AB-729 treatment for six months. Suppression of HBsAg to levels <100 IU/mL were maintained up to 24 weeks off-treatment in 3 of 7 patients in cohort E and 1 of 3 patients with available data in cohort F. Patients who remain below this clinically relevant threshold for six months after stopping AB-729 treatment could consider discontinuing their NA therapy

to assess the potential for functional cure. We anticipate presenting additional long-term on- and off-treatment follow-up data from Part 3 of this clinical trial at a medical conference in 2022.

Repeat dosing of both the 60 mg and 90 mg doses of AB-729 continues to be generally safe and well-tolerated. There were no treatment-related SAEs or discontinuations. The most common treatment emergent adverse events ("AEs") were injection site-related, of which all were grade one and did not appear to be dose or interval dependent. Alanine transaminase ("ALT") and Aspatate transaminase ("AST") elevations were asymptomatic and not considered AEs by the study investigators

The efficacy and safety data for AB-729, derived from up to one year of dosing, support our view that 60 mg every 8 weeks is an appropriate dose to move forward in our Phase 2a clinical trials. To advance our efforts to position AB-729 as a potential cornerstone therapeutic in future HBV combination regimens, we are evaluating AB-729 in three Phase 2a proof-of-concept combination clinical trials with other agents with potentially complementary mechanisms of action, including Peg-IFN $\alpha$ -2a and several investigational agents via clinical collaborations with other companies as described below.

Phase 2a proof-of-concept clinical trial to evaluate AB-729 in combination with Peg-IFN $\alpha$ -2a

In July 2021, we received authorization from the FDA to proceed with our Investigational New Drug (IND) application for AB-729 in a randomized, open label, multicenter Phase 2a clinical trial investigating the safety and antiviral activity of AB-729 in combination with ongoing NA therapy and short courses of Peg-IFN $\alpha$ -2a in patients with cHBV. We are currently enrolling up to 40 stably NA-suppressed, HBeAg negative, non-cirrhotic cHBV patients.

After 24-weeks of dosing with AB-729 (60 mg every 8 weeks), patients will be randomized into one of four groups to receive either AB-729 plus NA therapy plus Peg-IFN $\alpha$ -2a or NA therapy plus Peg-IFN $\alpha$ -2a for either 24 or 12 weeks. After completion of the assigned Peg-IFN $\alpha$ -2a treatment period, all patients will remain on NA therapy for the initial 24-week follow-up period, and will then discontinue NA treatment, provided they meet certain stopping criteria. If patients stop NA therapy, they will enter an intensive follow-up period for 48 weeks. We anticipate preliminary data from this clinical trial in the second half of 2022.

#### Collaboration with Assembly

In August 2020, we entered into a clinical collaboration agreement with Assembly to evaluate AB-729 in combination with Assembly's lead HBV core inhibitor (capsid inhibitor) candidate VBR and standard-of-care NA therapy for the treatment of patients with cHBV. Patients are being enrolled in a randomized, multi-center, open-label Phase 2a proof-of-concept clinical trial evaluating the safety, pharmacokinetics, and antiviral activity of the triple combination of AB-729, VBR, and an NA compared to the double combinations of VBR with an NA and AB-729 with an NA. We expect the clinical trial to enroll approximately 60 virologically-suppressed patients with HBeAg negative cHBV in the first cohort of the trial. Patients will be dosed for 48 weeks with AB-729 60 mg subcutaneously every 8 weeks and VBR (300 mg orally once daily), with a 48-week follow-up period. Both parties will share in the costs of the collaboration. Assembly is conducting the clinical trial and anticipates preliminary data in the second half of 2022. Under the terms of the collaboration, both parties may also add additional cohorts in the future to evaluate other patient populations and/or combinations. Except to the extent necessary to carry out Assembly's responsibilities with respect to the collaboration trial, we have not provided any license grant to Assembly for use of AB-729.

#### Collaboration with Vaccitech

In July 2021, we entered into a clinical collaboration agreement with Vaccitech to evaluate the safety, pharmacokinetics, immunogenicity, and antiviral activity of AB-729 followed by Vaccitech's VTP-300, a proprietary T cell stimulating therapeutic vaccine, in NrtI-suppressed patients with cHBV. We expect to enroll 40 NA-suppressed, HBeAg negative or positive, non-cirrhotic cHBV patients. Patients are expected to receive AB-729 + NA for 24 weeks. At week 24, patients will be randomized 1:1 to receive either NA + VTP-300 or NA + VTP-300 sham. At week 48, all patients are expected to be evaluated for eligibility to either discontinue all treatments or remain on their NA therapy only. Patients are expected to be followed for up to an additional 48 weeks. The Phase 2a proof-of-concept clinical trial will be managed by us, subject to oversight by a joint development committee comprised of representatives from us and Vaccitech. We and Vaccitech retain full rights to our respective product candidates and will split all costs associated with the clinical trial. We filed a CTA in the fourth quarter of

2021 and anticipate initiating the clinical trial in the first half of 2022. Pursuant to the agreement, the parties intend to undertake a larger Phase 2b clinical trial depending on the results of the initial Phase 2a clinical trial.

#### Collaboration with Antios

In June 2021, we entered into a clinical collaboration agreement with Antios to evaluate a triple combination of AB-729, Antios' proprietary Active Site Polymerase Inhibitor Nucleotide (ASPIN), ATI-2173, and Viread (tenofovir disoproxil fumarate), a nucleos(t)ide reverse transcriptase inhibitor which is currently approved by the FDA, for the treatment of patients with cHBV. The safety, pharmacokinetics, immunogenicity, and antiviral activity of the combination of ATI-2173, AB-729 and Viread is being evaluated in a single cohort in the ongoing Antios Phase 2a ANTT201 clinical trial. Antios is responsible for conducting this clinical trial. Antios is responsible for the manufacture and supply of AB-729. Except to the extent necessary to carry out Antios' responsibilities with respect to the collaboration trial, we have not provided any license grant to Antios for use of AB-729. This cohort has completed enrollment. With the majority of patients in this cohort enrolled in Ukraine, which is currently in a state of war, they may be lost to follow-up before completing the clinical trial. Therefore, we and Antios may report limited data on a reduced number of patients from this clinical trial.

#### Oral Capsid Inhibitor (AB-836)

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

AB-836 is a capsid inhibitor from a novel chemical series differentiated from competitor compounds with the potential for increased efficacy and an enhanced resistance profile. AB-836 leverages a novel binding site within the core protein dimer-dimer interface, has shown to be active against NA resistant variants and has the potential to address certain known capsid resistant variants. AB-836 is anticipated to be combinable with other mechanisms of action and is also anticipated to be dosed once daily.

We are enrolling patients in a double-blind, randomized, placebo-controlled Phase 1a/1b clinical trial designed to evaluate the safety, tolerability, pharmacokinetics and antiviral activity of single and multiple doses of AB-836 in healthy subjects and patients with cHBV. The trial consists of three parts. Part 1 evaluated alternating single doses of AB-836 or placebo ranging from 10 mg to 175 mg in a fasted or fed state in healthy subjects. Part 2 evaluated multiple ascending doses of 50 mg, 100 mg or 150 mg of AB-836 or placebo once daily for 10 days in healthy subjects. Part 3, which is still on-going, is currently randomizing HBV DNA positive cHBV patients who are HBeAg positive or negative to receive either 50 mg, 100 mg or 200 mg of AB-836 or placebo once daily for 28 days.

In December 2021, we announced preliminary data from this trial. In Parts 1 and 2, a total of 47 healthy subjects were enrolled and dosed. There were no deaths or SAEs observed. One healthy subject that received 50 mg once daily discontinued after treatment on day 13 due to an AE of agitation. All but three AEs were mild (Grade 2 headache, agitation and bronchitis), and only one was assessed as related to AB-836 (Grade 1 rash). There were no clinically significant abnormalities in clinical laboratory tests, ECGs, vital signs or physical exams noted.

In Part 3, 16 cHBV patients had been dosed thus far with enrollment continuing. Among those who received 100 mg once daily for the full 28 days (n=4), robust antiviral activity was observed at Day 28 of treatment with a mean (SE) log10 change from baseline of -3.1 (0.5). There have been no deaths or AEs. One cHBV patient that received 100 mg of AB-836 had a transient increase in ALT from baseline Grade 1 to Grade 3 at a single visit that resolved with continued dosing and had no associated symptoms. There were no clinically significant abnormalities in ECGs, vital signs or physical exams noted.

We are continuing to enroll and dose cHBV patients in Part 3 of this clinical trial and we anticipate reporting additional data in the first half of 2022.

#### Oral PD-L1 Inhibitor (AB-101)

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

AB-101 is an oral PD-L1 inhibitor that has the potential to reawaken patients' HBV-specific immune response by inhibiting PD-L1. We anticipate completing IND-enabling studies in the second half of 2022. We are also exploring potential oncology applications for our internal PD-L1 portfolio.

#### Oral HBV RNA Destabilizer (AB-161)

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

AB-161 is our next-generation oral HBV specific RNA destabilizer. We have conducted extensive non-clinical safety evaluations with AB-161 that gives us confidence in this molecule's ability to circumvent the peripheral neuropathy findings seen in non-clinical safety studies with our first-generation oral RNA destabilizer, AB-452. We anticipate completing IND-enabling studies for AB-161 in the second half of 2022.

#### **COVID-19 Research Efforts**

While our core mission is to find a cure for HBV, the magnitude of the coronavirus pandemic is undeniable. Given our science team's proven expertise in the discovery of new antiviral therapies, in 2020 we initiated a drug discovery effort for treating coronaviruses, including COVID-19. To that end, we have assembled an internal team of expert scientists under the direction of our Chief Scientific Officer, Dr. Michael Sofia, to identify novel small molecule therapies to treat COVID-19 and future coronavirus outbreaks. Dr. Sofia, who was awarded the Lasker-DeBakey Award for his discovery of sofosbuvir, brings extensive antiviral drug discovery experience to this new program. We are also a member of the COVID R&D consortium to address the SARS-CoV-2 pandemic and any future coronavirus outbreaks. Our COVID-19 research program is focused on the discovery and development of new molecular entities that address specific viral targets including the nsp12 viral polymerase and the nsp5 viral protease. These targets are essential viral proteins which our science team has experience in targeting.

#### Collaboration with X-Chem and Proteros

In March 2021, we entered into a discovery research and license agreement with X-Chem and Proteros to focus on the discovery of novel inhibitors targeting the SARS-CoV-2 nsp5 main protease (M<sup>pro</sup>). The agreement is designed to accelerate the development of pan-coronavirus agents to treat COVID-19 and potential future coronavirus outbreaks. This collaboration brought together our expertise in the discovery and development of antiviral agents with X-Chem's industry leading DNA-encoded library (DEL) technology and Proteros' protein sciences, biophysics and structural biology capabilities and provides important synergies to potentially identify safe and effective therapies against coronaviruses, including SARS-CoV-2. The collaboration allows for the rapid screening of one of the largest small molecule libraries against M<sup>pro</sup> (an essential protein required for the virus to replicate itself) and the use of state-of-the-art structure guided methods to rapidly optimize M<sup>pro</sup> inhibitors, which we could potentially progress to clinical candidates. The agreement provides for payments by us to X-Chem and Proteros upon satisfaction of certain development, regulatory and commercial milestones, as well as royalties on sales. Through this collaboration, we have identified and obtained a worldwide exclusive license to several molecules that inhibit M<sup>pro</sup>, a validated target for the treatment of COVID-19 and potential future coronavirus outbreaks. We expect to nominate an M<sup>pro</sup> product candidate in the first half of 2022 and advance into IND-enabling studies. We are also continuing lead optimization activities for an Nsp12 viral polymerase candidate.

#### **COVID-19 Impact**

The COVID-19 virus, first identified in December 2019, has been declared a pandemic by the World Health Organization and has spread to nearly every country in the world. The impact of this pandemic has been, and will likely continue to be, extensive in many aspects of society. The pandemic has resulted in and will likely continue to result in significant disruptions to businesses. A number of countries and other jurisdictions around the world have implemented extreme measures in attempts to slow the spread of the virus. These measures include the closing of businesses and requiring people to stay in their homes, the latter of which raises uncertainty regarding the ability to travel to hospitals in order to participate in clinical trials. Additional measures that have had, and will likely continue to have, a major impact on clinical development, at least in the near-term, include shortages and delays in the supply chain, and prohibitions in certain countries on enrolling patients in new clinical trials. While we have been able to progress with our clinical and preclinical activities to date, it is not possible to predict if the COVID-19 pandemic will materially impact our plans and timelines in the future.

#### **Other Collaborations and Royalty Entitlements**

#### Collaboration with Qilu Pharmaceuticals

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

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

Qilu is responsible for all costs related to developing, obtaining regulatory approval for, and commercializing AB-729 for the treatment or prevention of hepatitis B in the Territory. Qilu is required to use commercially reasonable efforts to develop, seek regulatory approval for, and commercialize at least one AB-729 product candidate in the Territory. A joint development committee will be established between us and Qilu to coordinate and review the development, manufacturing and commercialization plans. Both parties also agreed to negotiate in good faith the terms and conditions of a supply agreement and related quality agreement pursuant to which we will manufacture or have manufactured and supply Qilu with all quantities of AB-729 necessary for Qilu to develop and commercialize in the Territory until we have completed manufacturing technology

transfer to Qilu and approval of a product manufacturer by Qilu, or its designated contract manufacturing organization, by the National Medical Products Administration in China for AB-729.

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

#### Alnylam Pharmaceuticals, Inc. and Acuitas Therapeutics, Inc.

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

In 2012, we entered into a license agreement with Alnylam that entitles Alnylam to develop and commercialize products with our lipid nanoparticle ("LNP") delivery technology. Alnylam's ONPATTRO, which represents the first approved application of our LNP technology, was approved by the United States FDA and the European Medicines Agency ("EMA") during the third quarter of 2018 and was launched by Alnylam immediately upon approval in the United States. Under the terms of this license agreement, we are entitled to tiered royalty payments on global net sales of ONPATTRO ranging from 1.00% - 2.33% after offsets, with the highest tier applicable to annual net sales above \$500 million. This royalty interest was sold to the Ontario Municipal Employees Retirement System ("OMERS"), effective as of January 1, 2019, for \$20 million in gross proceeds before advisory fees. OMERS will retain this entitlement until it has received \$30 million in royalties, at which point 100% of this royalty entitlement on future global net sales of ONPATTRO will revert to us. OMERS has assumed the risk of collecting up to \$30 million of future royalty payments from Alnylam and we are not obligated to reimburse OMERS if they fail to collect any such future royalties. If this royalty entitlement reverts to us, it has the potential to provide an active royalty stream or to be otherwise monetized again in full or in part. From the inception of the royalty sale through December 31, 2021, an aggregate of \$11.2 million of royalties have been collected by OMERS.

We also have rights to a second, lower royalty interest on global net sales of ONPATTRO originating from a settlement agreement and subsequent license agreement with Acuitas Therapeutics, Inc. ("Acuitas"). This royalty entitlement from Acuitas has been retained by us and was not part of the royalty entitlement sale to OMERS.

#### Genevant Sciences, Ltd.

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

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

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

In July 2020, Roivant recapitalized Genevant through an equity investment and conversion of previously issued convertible debt securities held by Roivant. We participated in the recapitalization of Genevant with an equity investment of \$2.5 million. In connection with the recapitalization, the three parties entered into an Amended and Restated Shareholders Agreement that provides Roivant with substantial control of Genevant. We have a non-voting observer seat on Genevant's Board of Directors. As of December 31, 2021, we owned approximately 16% of the common equity of Genevant and the carrying value of our investment in Genevant was zero. Our entitlement to receive future royalties or sublicensing revenue from Genevant was not impacted by the recapitalization.

#### Moderna Inter Partes Review Petitions

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

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

With respect to the '127 Patent, the PTAB held all claims as invalid on September 10, 2019, by reason of anticipatory prior art. However, this decision was vacated and sent back (remanded) to the PTAB for a rehearing, pending the Supreme Court's decision whether to grant certiorari in a different case, United States v. Athrex, Inc. ("US v. Athrex"), the holding of which could impact the findings in the '127 Patent matter. The Supreme Court granted certiorari in US v. Athrex on October 13, 2020 (i.e., agreed to review the decision appealed from a lower court). Until the Supreme Court rendered its opinion in US v. Athrex, the '127 Patent hearing remained in abeyance, with no decision reached as to the validity of its claims. The Supreme Court decided on the US v. Athrex case on June 21, 2021, following which the Federal Circuit reinstated the appeal sua sponte, requiring the parties to brief how the case should proceed in light of the Supreme Court's opinion or for the appellant to waive the challenge. We elected to waive the challenge and proceed with the appeal at the Federal Circuit. The opening brief was filed on December 15, 2021. Moderna's responsive brief was due on February 24, 2022 and Arbutus' reply brief is due by March 17, 2022. No hearing date has been set for this matter.

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

its reply and responsive brief on October 5, 2020, and we filed our reply brief on November 9, 2020. An oral hearing on the '435 Patent was held on October 7, 2021 before the U.S. Court of Appeals for the Federal Circuit. On December 1, 2021, the Federal Circuit issued its opinion, leaving intact the PTAB's holding regarding the validity of certain claims in the '435 patent and the invalidity of other claims in the '435 patent.

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

The Federal Circuit's decision in the '069 appeal was rendered final by mandate on January 10, 2022. The decision in the '435 appeal was rendered final by mandate on January 25, 2022.

#### Moderna and Merck European Oppositions

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

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

#### Patent infringement lawsuit against Moderna

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

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

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

#### **Patents and Proprietary Rights**

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

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

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

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

Product candidate	Estimated Patent Expiration in US	Estimated Patent Expiration in EU
AB-729	2038	2038
AB-836	2039	2039

#### **Human Capital**

We are committed to an inclusive culture that values equality, opportunity, and respect. We seek to secure and develop top talent with a diversity of thought, experiences and backgrounds. Among the initiatives that Arbutus has introduced to promote and support diversity and inclusion, in addition to requiring mandatory annual training in unconscious bias and anti-harassment, is the formation of a diversity and inclusion committee, broadening the geographical reach of recruitment efforts, and addition of Juneteenth as a corporate holiday. Arbutus is also involved with local charities serving underserved communities in the Philadelphia area. Drug development is a complex endeavor that requires deep expertise and attracting and retaining qualified employees for specialized biopharmaceutical positions is very competitive. Our compensation programs are designed to attract and retain top talent. We offer every employee a total compensation package consisting of base salary, cash target bonus targeting the 50th to 75th percentile of market based on geography and company size, a comprehensive benefit package and equity compensation for every employee. Bonus opportunity and equity compensation generally increase as a percentage of total compensation based on level of responsibility. Actual bonus payout is based on company and individual performance. We also provide eligible employees the opportunity to participate in our employees tock purchase plan, employee rewards and recognition program, our wellness programs and company-hosted charitable events. We aim to allow our employees to maintain a work/life balance and find time to give back to the communities in which we work and live, all while striving to achieve company objectives and demonstrating our Arbutus values.

Arbutus also has a number of initiatives designed to reduce its environmental footprint, including the transition to the use of all LED lighting and timed parking lot lights, a building automation system that allows for controlling and scheduling of occupied/unoccupied space temperatures, repurposing substantially all shipping boxes and other packing material and donation of unused consumables to small start-up labs or local hospitals, among many other energy-saving initiatives.

We are invested in the development of our employees, including performance management and mentorship programs. In 2021, we experienced our lowest turnover in the previous six years, while many other companies experienced their highest in the midst of a historically competitive job market. Given our financial resources and our track record, we continue to be successful in filling vacated positions and in supporting our expanding pipeline of research programs and product candidates. We supplement our in-house expertise with outsourced capabilities when it would be cost prohibitive to build our own in-house capabilities. For example, we outsource a substantial portion of our clinical trial work to clinical research organizations and a majority of our drug manufacturing to contract manufacturers. Our in-house clinical development and manufacturing teams implement our development strategies and oversee the activities of our outside vendors.

At December 31, 2021, we had 87 employees (85 full-time and 2 part-time), 65 of whom were engaged in research and development, including three medical doctors, 34 individuals with Doctors of Philosophy (PhDs) degrees, and 14 scientists with Master of Science degrees. Substantially all of our employees are based out of our corporate headquarters in Warminster, PA. None of our employees are represented by a labor union or covered by a collective bargaining agreement, nor have we experienced any work stoppages. We believe that relations with our employees are good.

During the COVID-19 pandemic, approximately half of our employees have continued to work at our facilities, where we have adopted health screening, implemented social distancing and personal protective equipment requirements, enhanced cleaning and sanitation procedures, mandated the COVID-19 vaccine and booster for all onsite employees (with 100% compliance), and modified workspaces to reduce the potential for disease transmission. Our employees who do not require access to our facility to perform their work have been working from home during the pandemic. The change in protocols and working arrangements have not had a significant impact on productivity.

#### Competition

We face a broad range of current and potential competitors, from established global pharmaceutical companies with significant resources, to research-stage companies. In addition, we face competition from academic and research institutions and government agencies for the discovery, development and commercialization of novel therapeutics to treat HBV and coronavirus. Many of our competitors, either alone or with their collaborative partners, have significantly greater financial, product development, technical, manufacturing, sales, and marketing resources than we do. In addition, many of our direct competitors are large pharmaceutical companies with internal research and development departments that have significantly greater experience in testing product candidates, obtaining FDA and other regulatory approvals of product candidates, and achieving widespread market acceptance for those products.

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

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

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

We believe that our ability to compete depends, in part, upon our ability to develop products, successfully complete the clinical trials and regulatory approval processes, and effectively market any approved products. Further, we need to attract and retain

qualified personnel, obtain patent protection or otherwise develop proprietary product candidates or processes, and secure sufficient capital resources for the substantial time period between the discovery of lead compounds and their commercial sales, if any.

#### Manufacturing

We currently rely on third-party manufacturers to supply drug substance and drug products, including AB-729 and AB-836, for our ongoing and anticipated clinical trials and non-clinical studies. We currently have no plans to establish any large-scale internal manufacturing facilities for our product candidates.

#### **Government Regulation**

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

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

#### **Development and Approval**

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

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

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

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

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

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

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

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

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

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

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

FDA performance goals generally provide for action on an NDA within 10 months of the 60-day filing date, or within 12 months of the NDA submission. That deadline can be extended under certain circumstances, including by the FDA's requests for additional information. The targeted action date can also be shortened to 6 months of the 60-day filing date, or 8 months

after NDA submission for product candidates that are granted priority review designation because they are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. The FDA has other programs to expedite development and review of product candidates that address serious or life-threatening conditions. For example, the Fast Track program is intended to facilitate the development and review of new drugs that demonstrate the potential to address unmet medical needs involving serious or life-threatening diseases or conditions. If a product candidate receives Fast Track designation, the FDA may review sections of the NDA on a rolling basis, rather than requiring the entire application to be submitted to begin the review. Product candidates with Fast Track designation also may be eligible for more frequent meetings and correspondence with the FDA about the product candidate's development. Another FDA program intended to expedite development is the Accelerated Approval pathway, which allows approval on the basis of a surrogate endpoint that is reasonably likely to predict clinical benefit or on an intermediate clinical endpoint. To qualify for review under the Accelerated Approval pathway, a product candidate must treat a serious condition, provide a meaningful advantage over available therapies, and demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on an intermediate clinical endpoint. Breakthrough Therapy designation, which is available for product candidates under development for serious or life-threatening conditions and where preliminary clinical evidence shows that the product candidate may have substantial improvement on at least one clinically significant endpoint over available therapies, means that a product candidate will be eligible for all of the benefits of Fast Track designation, as well as more intensive guidance from the FDA on an efficient drug development program and a commitment from the agency to involve senior FDA managers in such guidance. Even if a product candidate qualifies for Fast Track designation or Breakthrough Therapy designation, the FDA may later decide that the product no longer meets the conditions for designation and may rescind the designation, and/or may determine that the product does not meet the standards for approval. As applicable, we anticipate seeking to utilize these programs to expedite the development and review of our product candidates, but we cannot ensure that our product candidates will qualify for such programs, or that we will be able to maintain such designations if we qualify for such programs.

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

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

*Competition.* The Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") establishes two abbreviated approval pathways for product candidates that are in some way follow-on versions of already approved branded

NDA products: (i) generic versions of the approved reference listed drug ("RLD"), which may be approved under an abbreviated new drug application ("ANDA") by showing that the generic product is the "same as" the approved product in key respects; and (ii) a product that is similar but not identical to a listed drug, which may be approved under a 505(b)(2) NDA, in which the sponsor relies to some degree on information from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference, and submits its own product-specific data to support the differences between the product and the listed drug.

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

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

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

*Emergency Use Authorization ("EUA").* The Secretary of Health and Human Services may authorize unapproved medical products to be marketed in the context of an actual or potential emergency that has been designated by the U.S. government. The COVID-19 pandemic has been designated as such a national emergency. After an emergency has been announced, the Secretary of Health and Human Services may authorize the issuance of and the FDA Commissioner may issue EUAs for the use of specific products based on criteria established by the FDCA, including that the product at issue may be effective in diagnosing, treating, or preventing serious or life-threatening diseases when there are no adequate, approved, and available alternatives. Although the criteria of an EUA differ from the criteria for approval of an NDA, EUAs nevertheless require the development and submission of data to satisfy the relevant FDA standards, and a number of ongoing compliance obligations.

The FDA expects EUA holders to work toward submission of full applications, such as an NDA, as soon as possible. An EUA is also subject to additional conditions and restrictions and is product-specific. An EUA terminates when the emergency determination underlying the EUA terminates. An EUA is not a long-term alternative to obtaining FDA approval, licensure, or clearance for a product. FDA may revoke an EUA for a variety of reasons, including where it is determined that the underlying health emergency no longer exists or warrants such authorization, so it is not possible to predict how long an EUA may remain in place.

#### Post-Approval Regulation

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

Good Manufacturing Practices. Companies engaged in manufacturing drug products or their components must comply with applicable GMP requirements, which include requirements regarding organization and training of personnel, building and facilities, equipment, control of components and drug product containers, closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls and reports. The FDA inspects equipment, facilities and manufacturing processes before approval and conducts periodic re-inspections after approval. If, after receiving approval, a company makes a material change in manufacturing equipment, location, or process (all of which are, to some degree, incorporated in the NDA), additional regulatory review and approval may be required. Failure to comply with applicable GMP requirements or the conditions of the product's approval may lead the FDA to take enforcement actions, such as issuing a warning letter, or to seek sanctions, including fines, civil penalties, injunctions, suspension of manufacturing operations, imposition of operating restrictions, withdrawal of FDA approval, seizure or recall of products, and criminal prosecution. Although we periodically monitor FDA compliance of the third parties on which we rely for manufacturing our product candidates, we cannot be certain that our present or future third-party manufacturers will consistently comply with GMP or other applicable FDA regulatory requirements.

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

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

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

• The federal Anti-Kickback Law, which prohibits, among other things, knowingly or willingly offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or in kind, to induce or reward the purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any health care items or service for which payment may be made, in whole or in part, by federal healthcare programs such as Medicare and Medicaid. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and prescribers, purchasers and formulary managers on the other. Liability may be established under the federal Anti-Kickback Law

without proving actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Law constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exemptions and regulatory safe harbors to the federal Anti-Kickback Law protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exemption or safe harbor, or for which no exception or safe harbor is available, may be subject to scrutiny.

- The federal civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government. Actions under the False Claims Act may be brought by the United States Attorney General or as a qui tam action by a private individual (a whistleblower) in the name of the government and the individual, and the whistleblower may share in any monetary recovery. Many pharmaceutical and other healthcare companies have been investigated and have reached substantial financial settlements with the federal government under the civil False Claims Act for a variety of alleged improper marketing activities, including: providing free product to customers with the expectation that the customers would bill federal programs for the product; providing sham consulting fees, grants, free travel and other benefits to physicians to induce them to prescribe the company's products; and inflating prices reported to private price publication services, which are used to set drug payment rates under government healthcare programs. In addition, in recent years the government has pursued civil False Claims Act cases against a number of pharmaceutical companies for causing false claims to be submitted as a result of the marketing of their products for unapproved, and thus non-reimbursable, uses. Because of the threat of treble damages and mandatory penalties per false or fraudulent claim or statement, healthcare and pharmaceutical companies often resolve allegations without admissions of liability for significant and material amounts. Pharmaceutical and other healthcare companies also are subject to other federal false claim laws, including, among others, federal criminal healthcare fraud and false statement statutes that extend to nongovernment health benefit programs.
- The fraud provisions of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which impose criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors, and prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry, in connection with the delivery of or payment for healthcare benefits, items or services.
- Analogous state and local laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs; and state and foreign laws that require drug manufacturers to report information related to clinical trials, or information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws and local ordinances that require identification or licensing of sales representatives.
- The 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 Federal Trade Commission Act ("FTC Act"), and the California Consumer Privacy Act ("CCPA")) govern the collection, use and disclosure of personal information. These laws may differ from each other in significant ways, thus complicating compliance efforts. Federal regulators, state attorneys general, and plaintiffs' attorneys have been and will likely continue to be active in this space. Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. The European Union's General Data Protection Regulation ("GDPR") and other data protection, privacy and similar national, state/provincial and local laws may restrict the access, use and disclosure of patient health information abroad. Compliance efforts will likely be an increasing and substantial cost in the future.

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

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

In California, the CCPA establishes certain requirements for data use and sharing transparency and provides California residents certain rights concerning the use, disclosure, and retention of their personal information. The CCPA and its

implementing regulations have already been amended multiple times since their enactment. In November 2020, California voters approved the California Privacy Rights Act ("CPRA") ballot initiative which introduced significant amendments to the CCPA and established and funded a dedicated California privacy regulator, the California Privacy Protection Agency ("CPPA"). The amendments introduced by the CPRA go into effect on January 1, 2023, and new implementing regulations are expected to be introduced by the CPPA. Failure to comply with the CCPA may result in, among other things, significant civil penalties and injunctive relief, or statutory or actual damages. In addition, California residents have the right to bring a private right of action in connection with certain types of incidents. These claims may result in significant liability and damages. Similarly, there are a number of legislative proposals in the United States, at both the federal and state level, that could impose new obligations or limitations in areas affecting our business. These laws and regulations are evolving and subject to interpretation, and may impose limitations on our activities or otherwise adversely affect our business.

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

#### **Coverage and Reimbursement**

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

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

A primary trend in the United States healthcare industry and elsewhere is cost containment. Government healthcare programs and other third-party payors are increasingly challenging the prices charged for medical products and services and examining

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

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

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

Medicare Part D generally provides coverage to enrolled Medicare patients for self-administered drugs (*i.e.*, drugs that are not administered by a physician). Medicare Part D is administered by private prescription drug plans approved by the U.S. government and, subject to detailed program rules and government oversight, each drug plan establishes its own Medicare Part D formulary for prescription drug coverage and pricing, which the drug plan may modify from time to time. The prescription drug plans negotiate pricing with manufacturers and pharmacies, and may condition formulary placement on the availability of manufacturer discounts. In addition, manufacturers are required to provide a 70% discount on brand name prescription drugs utilized by Medicare Part D beneficiaries when those beneficiaries are in the coverage gap phase of the Part D benefit design.

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

#### **United States Healthcare Reform**

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

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

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

Certain provisions of the Affordable Care Act have been subject to judicial challenges as well as efforts to modify them or to alter their interpretation and implementation. For example, the Tax Cuts and Jobs Act, enacted on December 22, 2017, eliminated the tax-based shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the individual mandate, effective January 1, 2019. Additional legislative changes, regulatory changes, and judicial challenges related to the Affordable Care Act remain possible. It is unclear how efforts modify or invalidate the Affordable Care Act or its implementing regulations, or portions

thereof, will affect our business. Any such changes could decrease the number of individuals with health coverage. It is possible that the Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to successfully commercialize our product candidates, if approved.

In addition, other legislative changes have been proposed since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction, which triggered the legislation's automatic reductions. In concert with subsequent legislation, this has resulted in aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2030 (with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, due to the COVID-19 pandemic). The law provides for 1% Medicare sequestration in the second quarter of 2022 and allows the full 2% sequestration thereafter until 2030. To offset the temporary suspension during the COVID-19 pandemic, in 2030, the sequestration will be 2.25% for the first half of the year, and 3% in the second half of the year. As long as these cuts remain in effect, they could adversely impact payment for any of our products that are reimbursed under Medicare, once commercialized.

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

#### Foreign Regulation

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

#### **Corporate Information**

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

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

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

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

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

We had one wholly-owned subsidiary as of December 31, 2021: Arbutus Biopharma, Inc.

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

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

#### **Investor Information**

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

#### Item 1A. Risk Factors

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

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

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

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

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

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

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

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

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

Our principal sources of liquidity are cash, cash equivalents and marketable securities, which were \$191.0 million as of December 31, 2021. In January 2022, we received a \$40 million upfront payment and \$15 million of proceeds resulting from the sale of common shares to Qilu as part of the technology transfer and exclusive licensing agreement to develop and commercialize AB-729 in China. We believe that our \$191.0 million of cash and investments in marketable securities as of

December 31, 2021 plus the \$55 million of proceeds received in January 2022 from our partnership with Qilu will be sufficient to fund our operations into the second quarter of 2024. However, changing circumstances may cause us to consume capital faster than we currently anticipate, and we may need to spend more money than currently expected because of such circumstances. Within the next several years, substantial additional funds will be required to continue with the active development of our pipeline product candidates and technologies. In particular, our funding needs may vary depending on a number of factors including:

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

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

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

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

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

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

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

With the exception of the years ended December 31, 2006 and December 31, 2012, we have incurred losses each fiscal year since inception through the year ended December 31, 2021 and have not received any revenues other than from research and development collaborations, royalties, license fees and milestone payments. From inception to December 31, 2021, we have an accumulated net deficit of approximately \$1.1 billion. Investment in drug development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. We continue to incur significant research, development and other expenses related to our ongoing operations, including development of our product candidates. We do not expect to achieve profits until such time as product sales, milestone payments and royalty payments, if any, generate sufficient revenues to fund our continuing operations. We cannot predict if we will ever achieve profitability and, if we do, we may not be able to remain consistently profitable or increase our profitability.

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

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

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

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

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

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

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

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

The global outbreak of COVID-19 continues to evolve, including with the emergence of new COVID-19 variants in 2021. The extent to which the COVID-19 pandemic may further impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the virus.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

To obtain marketing approval, United States laws require:

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

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

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

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

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

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

withdrawn. Any delay in, denial, or withdrawal of marketing approval for one of our product candidates will adversely affect our business, including our results of operations and financial position. Even if one or more of our product candidates receives marketing approval, undesirable side effects may limit such product's commercial viability. Patients may not wish to use our product, physicians may not prescribe our product, and our reputation may suffer. Any of these events may significantly harm our business and financial prospects.

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

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

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

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

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

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

A portion of our clinical trials evaluating AB-836 and AB-729 are being conducted in Ukraine. In addition, our collaboration partner, Antios, is conducting a Phase 2a proof-of-concept clinical trial that includes a cohort evaluating a triple combination of AB-729, ATI-2173 and Viread primarily in Ukraine. We had also planned to conduct a portion of our planned Phase 2a clinical trial to evaluate a triple combination of AB-729 with Vaccitech's VTP-300 and a NA in Ukraine.

In February 2022, Russia commenced a military invasion of Ukraine. Russia's invasion and the ensuing response by Ukraine has disrupted our and our collaboration partner's current clinical trials in such jurisdictions and could increase our costs and disrupt future planned clinical development activities. For example, we believe we and our collaboration partner may not be able to complete any additional dosing and/or follow-up visits of patients in Ukraine who are participating in these clinical trials. We may also be unable to ship additional clinical drug and other supplies necessary to complete the clinical trials in Ukraine. Although the route, length and impact of Russia's military action is highly unpredictable, clinical trial sites in Ukraine, could also suspend or terminate trials, and patients could be forced to evacuate or voluntarily choose to relocate far from clinical trial sites, making them unavailable for initial or further participation in these clinical trials. Alternative sites to fully and timely compensate for our clinical trial activities in Ukraine may not be available and we may need to find other countries to conduct these clinical trials. If these clinical trials are further interrupted, our clinical development plans for these product

candidates could be significantly delayed, which would increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

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

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

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

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

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

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

In addition, given the severity of the global COVID-19 pandemic, several companies are developing or commercializing therapeutics for the treatment of coronaviruses. These companies include, but are not limited to, Pfizer, Merck, Gilead, Vir Biotechnology, Shionogi, PardesBio, Enanta Pharmaceuticals, Aligos Therapeutics and Cocrystal Pharma.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory

approvals of those product candidates in the United States and other countries. Many of our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- the 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 falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry, in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA and its implementing regulations also impose obligations on certain covered entity health care providers, health plans and health care clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA other than with respect to providing certain employee benefits we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA;
- numerous federal and state laws and regulations that address privacy and data security, including state data breach notifications laws, state health information and/or genetic privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act, or FTC Act, and the CCPA), govern the collection, use, disclosure and protection of health-related and other personal information, many of which differ from each other in significant ways, thus complicating the compliance efforts. Compliance with these laws is difficult, constantly evolving, and time-consuming, and companies that do not comply with these laws may face government enforcement actions, civil and/or criminal penalties, or private action, as well as adverse publicity that could negatively affect our operating results and business;
- activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate
  additional risks of enforcement for non-compliance. The European Union's GDPR and other data protection, privacy and similar national,
  state/provincial and local laws may restrict the access, use and disclosure of patient health information abroad. Compliance efforts will likely be an
  increasing and substantial cost in the future;
- the 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;

- price reporting requirements under the Medicaid Drug Rebate Program and the 340B Program and with respect to average sales price reporting under the Medicare Part B program, and rebate or discount liability under the Medicaid Drug Rebate Program, the 340B Program, and Medicare Part D, with respect to which we could be subject to civil monetary penalties for a failure to comply with our reporting or rebate or discount obligations, or termination from the Medicaid Drug Rebate Program or 340B program, which, in turn, could jeopardize the availability of federal funds for our products under Medicaid and Medicare Part B; and
- analogous state laws and laws and regulations outside the United States, such as state anti-kickback and false claims laws, which may apply to
  sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including
  private insurers; state laws and laws outside the United States that require pharmaceutical companies to comply with the pharmaceutical industry's
  voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that
  may be made to certain healthcare providers; state laws and laws outside the United States that require drug manufacturers to report information
  related to clinical trials, or information related to payments and other transfers of value to physicians and other healthcare providers or marketing
  expenditures; state laws that restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs; and state laws
  and local ordinances that require identification or licensing of sales representatives.

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

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

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

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

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

#### **Risks Related to Our Dependence on Third Parties**

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

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

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

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

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

We expect that we will depend in part on our licensing agreements with Alnylam, Qilu and Gritstone to provide revenue to partially fund our operations, especially in the near term. Furthermore, our strategy is to enter into various additional arrangements with corporate and academic collaborators, licensors, licensees and others for the research, development, clinical testing, manufacturing, marketing and commercialization of our product candidates or other products based upon our technology. We may be unable to continue to establish such licensing agreements, and any licensing agreements we do establish may be unsuccessful, or we may not receive milestone payments or royalties as anticipated.

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

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

We have entered into a number of clinical collaboration agreements, including with Assembly, Vaccitech and Antios. We are responsible for managing the clinical trial under the collaboration agreement with Vaccitech, while Assembly and Antios are responsible for managing the clinical trials under the collaborations we have with each of them. The success of our collaborations depend on not only our efforts, but also on the efforts of our counterparties. Because we are not responsible for managing the clinical trials with Assembly and Antios, the success of those collaborations also depend on whether Assembly or Antios is successful in performance of its activities, to the extent it is responsible for performance of collaboration activities.

Additionally, these counterparties could change their strategic focus or pursue alternative technologies, which could materially and adversely affect our business. Similarly, we are dependent on X-Chem and Proteros pursuant to our discovery and research agreement to work toward the development of pancoronavirus agents to treat COVID-19 and potential future coronavirus outbreaks.

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

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

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

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

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

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

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

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

such third parties otherwise fail to meet deadlines or follow legal or regulatory requirements, our development plans may be delayed or terminated.

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

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

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

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

- we may be unable to contract with third-party manufacturers on acceptable terms, or at all, because the number of potential manufacturers is limited. Potential manufacturers of any product candidate that is approved will be subject to FDA compliance inspections and any new manufacturer would have to be qualified to produce our products;
- our third-party manufacturers might be unable to formulate and manufacture our product candidates and products in the volume and of the quality required to meet our clinical and commercial needs, if any;
- our third-party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply
  our clinical trials through completion or to successfully produce, store and distribute our commercial products, if approved;
- drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and other government agencies to ensure compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards, but we may ultimately be responsible for any of their failures;
- if any third-party manufacturer makes improvements in the manufacturing process for our product candidates, we may not own, or may have to share, the intellectual property rights to such improvements; and
- a third-party manufacturer may gain knowledge from working with us that could be used to supply one of our competitors with a product that
  competes with ours.

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

#### **Risks Related to Our Intellectual Property**

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

RNAi, capsid inhibitors and RNA destabilizer, as well as our other novel HBV assets, have generated many different patent applications from organizations and individuals seeking to obtain patents in the field. These applications claim many different methods, compositions and processes relating to the discovery, development and commercialization of these therapeutic products. It is likely that there could be litigation and other proceedings, such as inter partes review and opposition proceedings in various patent offices, relating to patent rights in RNAi, capsid inhibitors, RNA destabilizer and other small molecule compounds targeted at HBV. We are aware of patents and patent applications owned by third parties that may in the future be alleged by such third parties to cover the use of one or more of our products. We may need to acquire or obtain a license from

such third parties to any such issued patents to market or sell any such products, which may not be available on commercially acceptable terms or at all. If such third parties obtain valid and enforceable patents and successfully prove infringement of an approved Arbutus product, and we are not able to acquire such issued patents or negotiate a license on acceptable terms, and if such approved Arbutus product is determined to infringe any such issued patents, then we may be forced to pay royalties, damages and costs, or we may be prevented from commercializing such approved Arbutus product altogether, which could have a material adverse impact on our business.

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

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

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

A number of industry competitors and institutions have developed technologies, filed patent applications or received patents on various technologies that may be related to or affect our business. Some of these technologies, applications or patents may conflict with our technologies or patent applications. Such conflict could limit the scope of the patents, if any, that we may be able to obtain or result in the denial of our patent applications. In addition, we could incur substantial costs in filing suits against others to have such patents declared invalid. As publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain we or any licensor was the first creator of inventions covered by pending patent applications or that we or such licensor was the first to file patent applications for such inventions. Any future proceedings could result in substantial costs, even if the eventual outcomes are favorable. There can be no assurance that our patents, if issued, will be held valid or enforceable by a court or that a competitor's technology or product would be found to infringe such patents.

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

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

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

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

#### Risks Related to the Ownership of our Common Shares

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

As of March 3, 2022, executive officers, directors, five percent or greater shareholders, and their respective affiliated entities beneficially owned, in the aggregate, approximately 28% of our outstanding common shares.

Entities associated with Roivant Sciences Ltd. ("Roivant") collectively held as a group approximately 26% of our outstanding common shares as of March 3, 2022.

As a result, Roivant can significantly influence the outcome of matters requiring shareholder approval, including the election of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common shares that you may feel are in your best interest. The interests of Roivant may not always coincide with your interests or the interests of other shareholders and they may act in a manner that advances their best interests and not necessarily those of other shareholders, including seeking a premium value for their common shares. These actions might affect the prevailing market price for our common shares. In addition, Roivant and certain of our other principal shareholders that have held their shares for several years may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other shareholders. Such concentration of ownership control may also:

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

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

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

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

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

We generally will be a "passive foreign investment company" under the meaning of Section 1297 of the Code (a "PFIC") if (a) 75% or more of our gross income is "passive income" (generally, dividends, interest, rents, royalties, and gains from the disposition of assets producing passive income) in any taxable year, or (b) if at least 50% or more of the quarterly average value of our assets produce, or are held for the production of, passive income in any taxable year. We have determined that we have not been a PFIC for the three taxable years ended December 31, 2021, however recent changes to Treasury regulations under the Code have made this determination more challenging for us, and we cannot provide any assurances that we will not become a PFIC in the future. If we are a PFIC for any taxable year during which a United States person holds our common shares, it would likely result in materially adverse United States federal income tax consequences for such United States person, including, but not limited to, any gain from the sale of our common shares would be taxed as ordinary income, as opposed to capital gain, and such gain and certain distributions on our common shares would be subject to an interest charge, except in certain circumstances. It may be possible for United States persons to fully or partially mitigate such tax consequences by making a "qualifying electing fund election," as defined in the Code (a "QEF Election"), but although we have provided this information in the past, there is no requirement that we do so.

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

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

In addition, limitations on the ability to acquire and hold our common shares may be imposed by the Competition Act in Canada. This legislation permits the Commissioner of Competition of Canada to review any acquisition of a significant interest in us. This legislation grants the Commissioner jurisdiction to challenge such an acquisition before the Canadian Competition Tribunal if the Commissioner believes that it would, or would be likely to, result in a substantial lessening or prevention of competition in any market in Canada. The Investment Canada Act subjects an acquisition of control of a Canadian-company by a non-Canadian to government review if the value of our assets, as calculated pursuant to the legislation, exceeds a threshold amount. A reviewable acquisition may not proceed unless the relevant minister is satisfied that the investment is likely to result in a net benefit to Canada. Any of the foregoing could prevent or delay a change of control and may deprive or limit strategic opportunities for our shareholders to sell their shares.

#### **General Risk Factors**

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

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

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

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

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

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

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

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

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

resources that would otherwise focus on developing our existing business. We may not be able to find suitable collaboration partners or identify other investment opportunities, and we may experience losses related to any such investments.

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

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

There are currently no unresolved staff comments.

#### **Item 2. Properties**

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

From January 2019 through June 2021, we leased approximately 8,500 square feet of office space at 626 Jacksonville Rd, Warminster, Pennsylvania. In mid-2021, we amended the contract to relet a portion of the leased space. In addition, as the initial three-year lease term was set to expire on December 31, 2021, we extended the lease through December 31, 2022. We have an option to extend the lease term to April 30, 2027.

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**

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

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

## 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 us by UBC under a license agreement, initially entered into in 1998 and as amended in 2001, 2006 and 2007. We granted sublicenses under the UBC license to certain third parties, including Alnylam. In November 2014, UBC filed a demand for arbitration against us which alleged entitlement to unpaid royalties. In August 2019, the arbitrator issued his decision for the second phase or the arbitration, awarding UBC \$5.9 million, which included interest of approximately \$2.6 million. We paid the \$5.9 million award to UBC in September 2019 and paid an additional \$0.2 million award for costs and attorneys' fees in March 2021, and this matter is now fully resolved.

On December 18, 2020, UBC delivered to us a notice of arbitration alleging that under its cross license with us, it is due royalties of \$2.0 million plus interest arising from our sale to OMERS of part of our royalty interest on future global net sales of ONPATTRO, currently being sold by Alnylam. Oral hearings for this matter are currently scheduled to begin on April 25, 2022. We do not believe that any royalties are due to UBC and we intend to vigorously contest UBC's allegations.

## **Item 4. Mine Safety Disclosures**

#### PART II

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

Our common shares trade on the Nasdaq Global Select Market under the symbol "ABUS" following our name change to Arbutus Biopharma Corporation on July 31, 2015. As of March 3, 2022, there were 103 registered holders of common shares and 148,641,736 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, 2021.

## 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, 2021.

Item 6. Reserved

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

#### Overview

Arbutus Biopharma Corporation ("Arbutus", the "Company", "we", "us", and "our") is a clinical-stage biopharmaceutical company leveraging its extensive virology expertise to develop novel therapeutics that target specific viral diseases. Our current focus areas include Hepatitis B virus ("HBV"), SARS-CoV-2 and other coronaviruses. In HBV, we are developing an RNA interference ("RNAi") therapeutic, oral capsid inhibitor, oral PD-L1 inhibitor, and oral RNA destabilizer that we intend to combine to provide a functional cure for patients with chronic HBV infection ("cHBV") by suppressing viral replication, reducing surface antigen and reawakening the immune system. We believe our lead compound, AB-729, is the only RNAi therapeutic with evidence of immune re-awakening, and is currently being evaluated in multiple phase 2 clinical trials. We have an ongoing drug discovery and development program directed to identifying novel, orally active agents for treating coronaviruses (including SARS-CoV-2). We are also exploring oncology applications for our internal PD-L1 portfolio.

Our product pipeline consists of the following programs:

## **Pipeline**



\*Clinical trial to initiate in 1H 2022

AB-729, our proprietary subcutaneously-delivered RNAi therapeutic product candidate that suppresses HBsAg expression, which is thought to be a key prerequisite to enable reawakening of a patient's immune system to respond to HBV, is currently in one ongoing Phase 1a/1b clinical trial and three Phase 2a proof-of-concept clinical trials in combination with other agents with potentially complementary mechanisms of action. Preliminary data from the Phase 1a/1b clinical trial has shown that treatment with AB-729 resulted in meaningful declines in HBsAg while being well tolerated with no serious adverse events ("SAEs") noted after both single and repeat dosing. Preliminary data also suggests that long-term suppression of HBsAg with AB-729 results in increased HBV-specific immune response.

AB-836, our proprietary next-generation oral capsid inhibitor that suppresses HBV DNA replication, is currently in an ongoing Phase 1a/1b clinical trial where preliminary data from healthy subjects and HBV patients have shown that AB-836 is generally safe and well-tolerated with robust antiviral activity. AB-836 is from a novel chemical series differentiated from competitor compounds and has the potential to provide increased efficacy and an enhanced resistance profile.

AB-101, our oral PD-L1 inhibitor that has the potential to reawaken patients' HBV-specific immune response by inhibiting PD-L1, is advancing through lead optimization. We are also exploring potential oncology applications for our internal PD-L1 portfolio.

AB-161, our next-generation oral HBV specific RNA destabilizer, is advancing through lead optimization. We have conducted extensive non-clinical safety evaluations with AB-161 that gives us confidence in this molecule's ability to circumvent the peripheral neuropathy findings seen in non-clinical safety studies with our first-generation oral RNA destabilizer, AB-452.

Our coronavirus program is focused on the discovery and development of new molecular entities for treating coronaviruses (including COVID-19) that address specific viral targets including the nsp12 viral polymerase and the nsp5 viral protease (nucleos(t)ide).

#### **COVID-19 Impact**

We continue to monitor the effects of COVID-19, which has caused significant disruptions around the world. A number of countries and other jurisdictions around the world have implemented extreme measures in attempts to slow the spread of the virus. These measures include the closing of businesses and requiring people to stay in their homes, the latter of which raises uncertainty regarding the ability to travel to hospitals in order to participate in clinical trials. Additional measures that have had, and will likely continue to have, a major impact on clinical development, at least in the near-term, include shortages and delays in the supply chain, and prohibitions in certain countries on enrolling patients in new clinical trials. While we have been able to progress with our clinical and pre-clinical activities to date, it is not possible to predict if the COVID-19 pandemic will materially impact our plans and timelines in the future.

#### **Collaborations and Royalty Entitlements**

Qilu Pharmaceutical Co, Ltd.

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

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

Qilu is responsible for all costs related to developing, obtaining regulatory approval for, and commercializing AB-729 for the treatment or prevention of hepatitis B in the Territory. Qilu is required to use commercially reasonable efforts to develop, seek

regulatory approval for, and commercialize at least one AB-729 product candidate in the Territory. A joint development committee will be established between us and Qilu to coordinate and review the development, manufacturing and commercialization plans. Both parties also agreed to negotiate in good faith the terms and conditions of a supply agreement and

related quality agreement pursuant to which we will manufacture or have manufactured and supply Qilu with all quantities of AB-729 necessary for Qilu to develop and commercialize in the Territory until we have completed manufacturing technology transfer to Qilu and approval of a product manufactured by Qilu, or its designated contract manufacturing organization, by National Medical Products Administration in China for AB-729.

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

received \$15.0 million of gross proceeds from the Share Transaction on January 6, 2022. The Common Shares sold to the Investor in the Share Transaction represented approximately 2.5% of the Common Shares outstanding immediately prior to the execution of the Share Purchase Agreement.

Alnylam Pharmaceuticals, Inc. and Acuitas Therapeutics, Inc

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

Genevant Sciences, Ltd.

As of December 31, 2021, we owned approximately 16% of the common equity of Genevant Sciences Ltd. ("Genevant"), a company we launched with Roivant Sciences, Ltd. and to which we licensed rights to our lipid nanoparticle ("LNP") and ligand conjugate delivery platforms for RNA-based applications outside of HBV, except to the extent certain rights had already been licensed to other third parties (the "Genevant License"). We retained all rights to our LNP and conjugate delivery platforms for HBV. Under the Genevant License, as amended, if a third party sublicensee of intellectual property licensed by Genevant from us commercializes a sublicensed product, we become entitled to receive a specified percentage of certain revenue that may be received by Genevant for such sublicense, including royalties, commercial milestones and other sales-related revenue, or, if less, tiered low single-digit royalties on net sales of the sublicensed product. The specified percentage is 20% in the case of a mere sublicense (i.e., naked sublicense) by Genevant without additional contribution and 14% in the case of a bona fide collaboration with Genevant.

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

#### CRITICAL ACCOUNTING POLICIES AND ESTIMATES

#### **Contingent Consideration**

The significant accounting policy that we believe to be most critical in fully understanding and evaluating our financial results relates to our contingent consideration. This accounting policy requires us to make certain estimates and assumptions. We believe that the estimates and assumptions upon which we rely are reasonable, based upon information available to us at the time that these estimates and assumptions are made. Actual results may differ from our estimates. Our critical accounting estimates affect the calculation of our net income or loss.

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

In order to estimate the probability of program success, we evaluate the status and progress of our relevant programs and consider statistics and probabilities related to other relevant programs' success rates. As our relevant programs have advanced in clinical trials, we updated our assumptions related to probability of success in 2021. For the timing and extent of future product sales, we also consider the status and progress of our relevant programs, future forecasts and other macroeconomic indicators that forecast market conditions. The discount rate at which we calculate the present value of our potential future liability, is based on consideration of market-comparative data, market-based discount rates, and company-specific risk premiums.

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

#### RESULTS OF OPERATIONS

The following summarizes our results of operations for the year ended December 31, 2021 compared to the year ended December 31, 2020:

	Year Ended December 31,			
	2021			2020
	(in thousands)			
Total revenue	\$	10,988	\$	6,914
Total operating expenses		84,510		64,720
Loss from operations		(73,522)		(57,806)
Other income (loss)		(2,725)		(5,939)
Net loss		(76,247)		(63,745)
Dividend accretion of convertible preferred shares		(12,139)		(12,123)
Net loss attributable to common shares	\$	(88,386)	\$	(75,868)

For the fiscal year ended December 31, 2021, our net loss attributable to common shares was \$88.4 million, or a loss of \$0.83 per basic and diluted common share, as compared to a net loss of \$75.9 million, or a loss of \$1.00 per basic and diluted common share, for the year ended December 31, 2020.

#### Revenue

Revenue for the years ended December 31, 2021 and 2020 is summarized in the following table:

	 Year ended December 31,					
	 2021			2020		
	(in thousands, except percentages)					
Revenue from collaborations and licenses						
Acuitas Therapeutics, Inc.	\$ 4,675	42 %	\$ 3,259	47 %		
Acrotech Biopharma, LLC	205	2 %	269	4 %		
Non-cash royalty revenue						
Alnylam Pharmaceuticals, Inc.	6,108	56 %	3,386	49 %		
Total revenue	\$ 10,988	100 %	\$ 6,914	100 %		

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

Total revenue increased \$4.1 million for the year ended December 31, 2021 compared to 2020, due to a \$4.1 million increase in license royalty revenue from Alnylam and Acuitas due to the growth of Alnylam's sales of ONPATTRO.

The royalty interest for ONPATTRO from Alnylam was sold to OMERS, effective as of January 1, 2019, for \$20 million in gross proceeds before advisory fees. OMERS will retain this entitlement until it has received \$30 million in royalties, at which point 100% of such royalty interest on future global net sales of ONPATTRO will revert back to us. OMERS has assumed the risk of collecting up to \$30 million of future royalty payments from Alnylam and we are not obligated to reimburse OMERS if they fail to collect any such future royalties. During the term of this agreement, we recognize non-cash royalty revenue related to the sales of ONPATTRO. From the inception of the royalty sale through December 31, 2021, the Company has recorded an aggregate of \$11.2 million of non-cash royalty revenue for royalties earned by OMERS. The royalty interest for ONPATTRO from Acuitas was not part of the royalty sale to OMERS and we have retained the rights to receive those royalties. Revenue contracts are described in more detail in "Item 1. Business."

#### **Operating expenses**

Operating expenses for the years ended December 31, 2021 and 2020 are summarized in the following table:

	Year ended December 31,					
	 2021			2020		
	 (in thousands, except percentages)					
Research and development	\$ 65,502	78 %	\$ 49,338	76 %		
General and administrative	17,136	20 %	14,845	23 %		
Change in fair value of contingent consideration	1,872	2 %	473	1 %		
Site consolidation	_	— %	64	— %		
Total operating expenses	\$ 84,510	100 %	\$ 64,720	100 %		

#### Research and development

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

Research and development expenses increased \$16.2 million in 2021 compared to 2020 due primarily to an increase in expenses related to our ongoing AB-729 clinical trials, including our collaboration with Assembly, an increase in expenses for our ongoing AB-836 Phase 1a/1b clinical trial, and an increase in expenses for our early stage development programs, including our coronavirus program, AB-101 and AB-161.

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

#### General and administrative

General and administrative expenses increased \$2.3 million in 2021 compared to 2020, due primarily to an increase in employee compensation costs, stock-based compensation expense, insurance premiums and professional fees.

#### Change in fair value of contingent consideration

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

In general, increases in the fair value of the contingent consideration are related to the progress of our programs as they get closer to triggering these contingent payments. In 2021, the fair value of our contingent consideration liability increased \$1.9 million, primarily related to the progression of our programs through clinical trials and our assessment of the probability of commercialization. In 2020, the fair value of our contingent consideration liability increased by \$0.5 million, primarily related to the passage of time.

#### Site consolidation charges

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

#### Other income (losses)

Other income (losses) for the years ended December 31, 2021 and 2020 are summarized in the following table:

	Year ended December 31,					
	 2021			2020		
	 (in thousands, except percentages)					
Interest income	\$ 127	(5)% \$	\$ 741	(12)%		
Interest expense	(2,857)	105 %	(4,011)	68 %		
Equity investment loss	_	— %	(2,545)	43 %		
Foreign exchange gain (loss)	 5	— %	(124)	2 %		
Total other loss	\$ (2,725)	100 %	\$ (5,939)	100 %		

#### Interest income

Interest income decreased \$0.6 million in 2021 compared to 2020 due primarily to a general decline in market interest rates.

#### Interest expense

Interest expense decreased \$1.2 million in 2021 compared to 2020 due primarily to a decrease in the non-cash amortization of discount and issuance costs related to the sale of a portion of our ONPATTRO royalty interest to OMERS in July 2019.

#### Equity investment loss

In July 2020, we participated in the recapitalization of Genevant, led by Roivant, with an equity investment of \$2.5 million. We determined that this \$2.5 million additional investment in Genevant was funding prior losses and recorded the amount as an equity investment loss in 2020. Due to our loss of significant influence with respect to Genevant as a result of the recapitalization, we discontinued the use of equity method accounting for our interest in Genevant in 2020. Following the recapitalization, we account for our interest in Genevant as equity securities without readily determinable fair values. Accordingly, an estimate of the fair value of the securities is based on the original cost less previously recognized equity method losses, less impairments, plus or minus changes resulting from future observable price changes in orderly transactions for identical or similar Genevant securities. As of December 31, 2021, the carrying value of our investment in Genevant was zero and we owned approximately 16% of the common equity of Genevant.

## Foreign exchange gains (losses)

In connection with our site consolidation to Warminster, PA, our Canadian dollar-denominated expenses and cash balances have decreased significantly now that a majority of our business transactions are based in the United States. We continue to incur expenses and hold some cash balances in Canadian dollars, and as such, we will remain subject to risks associated with foreign currency fluctuations. During the year ended December 31, 2021, we recorded foreign exchange gains of less than \$0.1 million. During the year ended December 31, 2020, we recorded foreign exchange losses of \$0.1 million.

#### LIQUIDITY AND CAPITAL RESOURCES

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

As of December 31, 2021, we had cash and cash equivalents of \$109.3 million and investments in marketable securities of \$81.7 million, totaling \$191.0 million. In January 2022, we received a \$40 million upfront payment and a \$15 million equity investment from Qilu as part of a technology transfer and exclusive licensing agreement to develop and commercialize AB-729 in the Territory. We had no outstanding debt as of December 31, 2021.

## **Sources of Liquidity**

#### Sale Agreement

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

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

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

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

During the years ended December 31, 2021 and 2020, we issued 31,571,036 and 24,728,368 common shares, respectively, under the Sale Agreement, as amended, resulting in net proceeds of approximately \$134.7 million and \$86.3 million, respectively.

### Royalty Entitlements

Additionally, we have a royalty entitlement on ONPATTRO, a drug developed by Alnylam that incorporates our LNP technology and was approved by the FDA and the EMA during the third quarter of 2018 and was launched by Alnylam immediately upon approval in the United States. In July 2019, we sold a portion of this royalty interest to OMERS, effective as of January 1, 2019, for \$20 million in gross proceeds before advisory fees. OMERS will retain this entitlement until it has received \$30 million in royalties, at which point 100% of such royalty interest on future global net sales of ONPATTRO will revert to us. OMERS has assumed the risk of collecting up to \$30 million of future royalty payments from Alnylam and Arbutus is not obligated to reimburse OMERS if they fail to collect any such future royalties. If this royalty entitlement reverts to us, it has the potential to provide an active royalty stream or to be otherwise monetized again in full or in part. In addition to the royalty from the Alnylam LNP license agreement, we are also receiving a second, lower royalty interest on global net sales of ONPATTRO originating from a settlement agreement and subsequent license agreement with Acuitas. The royalty from Acuitas has been retained by us and was not part of the royalty sale to OMERS.

In December 2021, we entered into a technology transfer and exclusive licensing agreement with Qilu pursuant to which we granted Qilu an exclusive (with certain exceptions), sublicensable, royalty-bearing license, under certain intellectual property

owned by us, to develop, manufacture and commercialize AB-729 for the treatment or prevention of hepatitis B in the Territory. In partial consideration for the rights granted by us, Qilu paid us a one-time upfront cash payment of \$40 million and made an equity investment of \$15.0 million, both received in January 2022, and agreed to pay us milestone payments totaling up to \$245 million, net of withholding taxes, upon the achievement of certain technology transfer, development, regulatory and commercialization milestones. Qilu also agreed to pay us double digit royalties into the low twenties percent based upon annual net sales of AB-729 in the Territory.

#### **Cash requirements**

We believe that our \$191.0 million of cash and investments in marketable securities as of December 31, 2021, plus \$55.0 million of gross proceeds received in January 2022 from Qilu as part of our technology transfer and licensing agreement, will be sufficient to fund our operations into the second quarter of 2024 based on our expectation of a net cash burn between \$90.0 million and \$95.0 million in 2022. In the future, substantial additional funds will be required to continue with the active development of our pipeline products and technologies. In particular, our funding needs may vary depending on a number of factors including:

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

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

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

#### **Cash Flows**

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

	Year ended December 31,			
	 2021	2020		
	 (in thousand	ls)		
Net loss	\$ (76,247) \$	(63,745)		
Non-cash items	7,785	11,873		
Net change in operating items	930	431		
Net cash used in operating activities	\$ (67,532) \$	(51,441)		
Net cash used in investing activities	(12,678)	(14,909)		
Net cash provided by financing activities	137,236	86,746		
Effect of foreign exchange rate changes on cash and cash equivalents	5	56		
Increase in cash and cash equivalents	\$ 57,031 \$	20,452		
Cash and cash equivalents, beginning of period	52,251	31,799		
Cash and cash equivalents, end of period	\$ 109,282 \$	52,251		

Net cash used in operating activities in 2021 increased \$16.1 million compared to 2020 due primarily to an increase in research and development payments of approximately \$18.2 million, which was due primarily to an increase in research and development expenses for our clinical development and discovery programs.

Net cash used in investing activities in 2021 decreased by \$2.2 million compared to 2020 due primarily to the timing of maturities and acquisitions of investments in marketable securities.

Net cash from financing activities in 2021 increased \$50.5 million compared to 2020. Cash provided by financing activities in 2021 consisted primarily of \$134.7 million of proceeds from sales of common shares under the Sale Agreement, as amended. Cash provided by financing activities in 2020 consisted primarily of \$86.3 million of proceeds from sales of common shares under the Sale Agreement, as amended.

#### 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

## INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	Page
Report of Ernst & Young, LLP, Independent Registered Public Accounting Firm - PCAOB ID: 42	<u>70</u>
Consolidated Balance Sheets at December 31, 2021 and 2020	<u>72</u>
Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2021 and 2020	<u>73</u>
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2021 and 2020	<u>74</u>
Consolidated Statements of Cash Flows for the Years Ended December 31, 2021 and 2020	<u>75</u>
Notes to Consolidated Financial Statements	<u>76</u>

#### Report of Independent Registered Public Accounting Firm

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

#### **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Arbutus Biopharma Corporation (the Company) as of December 31, 2021 and 2020, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

#### **Basis for Opinion**

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

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

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

#### **Critical Audit Matter**

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

#### Valuation of contingent consideration liability

Description of the Matter

As discussed in Note 10 to the consolidated financial statements, the Company's contingent consideration liability, which consists of sales-based milestones and royalties, resulting from the acquisition of Enantigen in 2014, is remeasured to its estimated fair value each reporting period. As of December 31, 2021, the contingent consideration liability was \$5.3 million. Auditing the valuation of the contingent consideration liability was complex and highly judgmental due to the significant estimation required in determining the fair value. In particular, the fair value estimate was sensitive to significant assumptions such as the probability of successfully commercializing a treatment for the hepatitis B virus, the timing and amount of future revenues related to commercial sales, and the discount rate. These assumptions are affected by expectations about future industry, regulatory, market or economic conditions and are forward-looking and inherently uncertain.

How We Addressed the Matter in Our Audit

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

/s/ Ernst & Young LLP

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

Philadelphia, Pennsylvania

March 3, 2022

# **Consolidated Balance Sheets**

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

	December 31, 2021		De	cember 31, 2020
Assets				
Current assets:				
Cash and cash equivalents	\$	109,282	\$	52,251
Investments in marketable securities, current		46,035		71,017
Accounts receivable		899		1,312
Prepaid expenses and other current assets		4,445		3,124
Total current assets		160,661		127,704
Property and equipment, net of accumulated depreciation		5,983		6,927
Investments in marketable securities, non-current		35,688		_
Right of use asset		2,092		2,405
Other non-current assets		61		44
Total assets	\$	204,485	\$	137,080
Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable and accrued liabilities	\$	10,838	\$	9,151
Lease liability, current		383		390
Total current liabilities		11,221		9,541
Liability related to sale of future royalties		16,296		19,554
Contingent consideration		5,298		3,426
Lease liability, non-current		2,231		2,593
Total liabilities		35,046		35,114
Stockholders' equity				
Preferred shares				
Authorized: unlimited number without par value				
Issued and outstanding: 0 (December 31, 2020: 1,164,000)		_		149,408
Common shares				
Authorized: unlimited number without par value				
Issued and outstanding: 144,987,736 (December 31, 2020: 89,678,722)		1,286,636		985,939
Additional paid-in capital		65,485		60,751
Deficit		(1,134,347)		(1,045,961)
Accumulated other comprehensive loss		(48,335)		(48,171)
Total stockholders' equity		169,439		101,966
Total liabilities and stockholders' equity	\$	204,485	\$	137,080

# Consolidated Statements of Operations and Comprehensive Loss

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

	 Year ended December 31,				
	2021		2020		
Revenue					
Collaborations and licenses	\$ 4,880	\$	3,519		
Non-cash royalty revenue	 6,108		3,395		
Total revenue	10,988		6,914		
Operating expenses					
Research and development	65,502		49,338		
General and administrative	17,136		14,845		
Change in fair value of contingent consideration	1,872		473		
Site consolidation	 <u> </u>		64		
Total operating expenses	 84,510		64,720		
Loss from operations	(73,522)		(57,806)		
Other income (loss)					
Interest income	127		741		
Interest expense	(2,857)		(4,011)		
Equity investment loss	_		(2,545)		
Foreign exchange gain (loss)	 5		(124)		
Total other loss	(2,725)		(5,939)		
Net loss	\$ (76,247)	\$	(63,745)		
Items applicable to preferred shares					
Dividend accretion of convertible preferred shares	 (12,139)		(12,123)		
Net loss attributable to common shares	\$ (88,386)	\$	(75,868)		
Loss per share	 	<u> </u>			
Basic and diluted	\$ (0.83)	\$	(1.00)		
Weighted average number of common shares					
Basic and diluted	106,242,452		75,835,378		
Comprehensive income (loss)					
Unrealized (loss) gain on available-for-sale securities	\$ (164)	\$	14		
Currency translation adjustments	 		44		
Comprehensive loss	\$ (76,411)	\$	(63,687)		

# Consolidated Statement of Stockholders' Equity

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

	Convertible Pre	ferred Shares	Common	n 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, 2019	1,164,000	\$ 137,285	64,780,314	\$ 898,535	\$ 55,246	\$ (970,093)	\$ (48,229)	\$ 72,744
Accretion of accumulated dividends on Preferred Shares	_	12,123	_	_	_	(12,123)	_	_
Stock-based compensation	_	_	_	_	6,145	_	_	6,145
Certain fair value adjustments to liability stock option awards	_	_	_	_	18	_	_	18
Issuance of common shares pursuant to the Open Market Sales Agreement	_	_	24,728,368	86,297	_	_	_	86,297
Issuance of common shares pursuant to exercise of options	_	_	170,040	1,107	(658)	_	_	449
Unrealized gain on available-for-sale securities	_	_	_	_	_	_	14	14
Currency translation adjustment	_	_	_	_	_	_	44	44
Net loss						(63,745)		(63,745)
Balance at December 31, 2020	1,164,000	\$ 149,408	89,678,722	\$ 985,939	\$ 60,751	\$ (1,045,961)	\$ (48,171)	\$ 101,966
Accretion of accumulated dividends on Preferred Shares		12,139				(12,139)		_
Conversion of Preferred Shares into Common Shares	(1,164,000)	(161,547)	22,833,922	161,547	_	_	_	_
Stock-based compensation	_	_	_	_	6,385	_	_	6,385
Certain fair value adjustments to liability stock option awards	_	_	_	_	263	_	_	263
Issuance of common shares pursuant to the Open Market Sales Agreement	_	_	31,571,036	134,665	_	_	_	134,665
Issuance of common shares pursuant to exercise of ESPP options	_	_	196,335	817	(356)	_	_	461
Issuance of common shares pursuant to exercise of options	_	_	707,721	3,668	(1,558)	_	_	2,110
Unrealized loss on available-for-sale securities							(164)	(164)
Net loss	_	_	_	_	_	(76,247)	_	(76,247)
Balance at December 31, 2021		\$ <u> </u>	144,987,736	\$ 1,286,636	\$ 65,485	\$ (1,134,347)	\$ (48,335)	\$ 169,439

## **Consolidated Statements of Cash Flows**

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

	Year ended December 31,			
		2021		2020
OPERATING ACTIVITIES				
Net loss	\$	(76,247)	\$	(63,745)
Non-cash items:				
Depreciation		1,753		1,978
Stock-based compensation expense		6,424		6,161
Unrealized foreign exchange gains		(5)		(56)
Change in fair value of contingent consideration		1,872		473
Net equity investment loss		_		2,545
Non-cash royalty revenue		(6,108)		(3,395)
Non-cash interest expense		2,850		3,957
Net accretion and amortization of investments in marketable securities		999		210
Net change in operating items:				
Accounts receivable		413		(108)
Prepaid expenses and other assets		(1,025)		(752)
Accounts payable and accrued liabilities		1,911		1,666
Lease liabilities		(369)		(375)
Net cash used in operating activities		(67,532)		(51,441)
INVESTING ACTIVITIES				
Purchase of investments in marketable securities		(82,219)		(85,578)
Disposition of investments in marketable securities		70,350		73,398
Investment in Genevant		_		(2,500)
Acquisition of property and equipment		(809)		(229)
Net cash used in investing activities		(12,678)		(14,909)
FINANCING ACTIVITIES				
Issuance of common shares pursuant to exercise of options		2,110		449
Issuance of common shares pursuant to exercise of ESPP options		461		_
Issuance of common shares pursuant to the Open Market Sales Agreement		134,665		86,297
Net cash provided by financing activities		137,236		86,746
Effect of foreign exchange rate changes on cash and cash equivalents		5		56
Increase in cash and cash equivalents	\$	57,031	\$	20,452
Cash and cash equivalents, beginning of period	\$	52,251	\$	31,799
Cash and cash equivalents, end of period	\$	109,282	\$	52,251
Supplemental cash flow information				
Preferred shares dividends accrued	\$	(12,139)	\$	(12,123)

#### **Notes to Consolidated Financial Statements**

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

#### 1. Organization

## **Description of the Business**

Arbutus Biopharma Corporation ("Arbutus" or the "Company") is a clinical-stage biopharmaceutical company leveraging its extensive virology expertise to develop novel therapeutics that target specific viral diseases. The Company's current focus areas include Hepatitis B virus ("HBV"), SARS-CoV-2 and other coronaviruses. In HBV, the Company is developing an RNA interference ("RNAi") therapeutic, oral capsid inhibitor, oral PD-L1 inhibitor, and oral RNA destabilizer that it intends to combine to provide a functional cure for patients with chronic HBV infection ("cHBV") by suppressing viral replication, reducing surface antigen and reawakening the immune system. The Company believes its lead compound, AB-729, is the only RNAi therapeutic with evidence of immune re-awakening, and is currently being evaluated in multiple phase 2 clinical trials. The Company has an ongoing drug discovery and development program directed to identifying novel, orally active agents for treating coronaviruses (including SARS-CoV-2). The Company is also exploring oncology applications for its internal PD-L1 portfolio.

## Liquidity

At December 31, 2021, the Company had an aggregate of \$191.0 million in cash, cash equivalents and investments in marketable securities. In January 2022, the Company received a \$40 million upfront payment and a \$15 million equity investment from Qilu Pharmaceuticals Co., Ltd. ("Qilu") as part of a technology transfer and exclusive licensing agreement to develop and commercialize AB-729 in China. The Company had no outstanding debt as of December 31, 2021. The Company believes it has sufficient cash resources to fund its operations for at least the next 12 months.

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

## **COVID-19 Impact**

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

#### 2. Significant accounting policies

## Basis of presentation and principles of consolidation

These consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") and include the accounts of Arbutus Biopharma Corporation and its two wholly-owned subsidiaries, Arbutus Biopharma, Inc. and Arbutus Biopharma U.S. Holdings, Inc. All intercompany balances and transactions have been eliminated. Certain prior year amounts have been reclassified to conform to the current year presentation, such as the reclassification of depreciation expense to research and development and general and administrative expenses. In February 2021, Arbutus Biopharma US Holdings, Inc. merged into Arbutus Biopharma, Inc. with Arbutus Biopharma, Inc. continuing its legal existence and Arbutus Biopharma US Holdings, Inc. ceasing to exist.

#### Use of estimates

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

#### Cash and cash equivalents

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

#### Investments in marketable securities

The Company's short-term investments consist of marketable securities that have original maturities exceeding three months and remaining maturities of less than one year. The Company classifies investments with remaining maturities of one year or longer as non-current. These investments are accounted for as available-for-sale securities and are reported at fair value, with unrealized gains and losses reported in other comprehensive loss, until their disposition. Realized gains and losses from the sale of marketable securities, if any, are calculated using the specific-identification method, and are recorded as a component of other income or loss. The Company reviews its available-for-sale securities at each period end to determine if they remain available-for-sale based on the Company's current intent and ability to sell the security if it is required to do so. Declines in value judged to be other-than-temporary are included in interest income or expense in the Company's statements of operations and comprehensive loss. As of December 31, 2021, the recorded value of the Company's investments in marketable securities was deemed to be recoverable in all respects.

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

#### Foreign currency translation and functional currency conversion

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

#### **Investment in Genevant**

As the result of a recapitalization of Genevant in July 2020, Arbutus' ownership interest in Genevant decreased to approximately 16%. Due to Arbutus' loss of significant influence with respect to Genevant as a result of the recapitalization, Arbutus discontinued the use of the equity method of accounting for its interest in Genevant. Ownership interests that do not confer the ability to exercise significant influence are accounted for at fair value, except when the investment does not have a readily-determinable fair value. In that case, the investment is carried at cost, less any impairment. The carrying value is subsequently adjusted to fair value based on any observable price changes. Following the recapitalization, Arbutus accounts for its interest in Genevant as equity securities without readily determinable fair values. Accordingly, an estimate of the fair value of the securities is based on the original cost less previously recognized equity method losses, less impairments, plus or minus changes resulting from observable price changes in orderly transactions for identical or similar Genevant securities. As of December 31, 2021, the carrying value of Arbutus' investment in Genevant was zero and Arbutus owned approximately 16% of the common equity of Genevant.

See note 5 for more information.

#### Property and equipment

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

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	Usefu	I 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.

## Revenue from collaborations and licenses

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

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

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

In contracts where the Company has more than one performance obligation to provide its customer with goods or services, each performance obligation is evaluated to determine whether it is distinct based on whether (i) the customer can benefit from the

good or service either on its own or together with other resources that are readily available and (ii) the good or service is separately identifiable from other promises in the contract. The consideration under the contract is then allocated between the distinct performance obligations based on their respective relative stand-alone selling prices. The estimated stand-alone selling price of each deliverable reflects the Company's best estimate of what the selling price would be if the deliverable was regularly sold on a stand-alone basis and is determined by reference to market rates for the good or service when sold to others or by using an adjusted market assessment approach if the selling price on a stand-alone basis is not available.

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

## Leases

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

# Research and development costs

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

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

#### Net loss attributable to common shareholders per share

Net loss attributable to common shareholders per share is calculated based on the weighted average number of common shares outstanding. Diluted net loss attributable to common shareholders per share does not differ from basic net loss attributable to common shareholders per share for the years ended December 31, 2021 and 2020, since the effect of including potential common shares would be anti-dilutive. For the year ended December 31, 2021, potential common shares of 11.4 million pertaining to outstanding stock options were excluded from the calculation of net loss attributable to common shareholders, per share. A total of approximately 31.8 million outstanding stock options and if-converted Series A participating convertible preferred shares ("Preferred Shares") were excluded from the calculation for the year ended December 31, 2020.

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

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,					
		2021		2020			
	(in thousands, except share and per share amounts)						
Numerator:							
Allocation of distributable earnings	\$	_	\$	_			
Allocation of undistributable loss		(88,386)		(75,868)			
Allocation of net loss attributed to common shareholders	\$	(88,386)	\$	(75,868)			
Denominator:							
Weighted average number of common shares - basic and diluted		106,242,452		75,835,378			
Basic and diluted net loss attributable to common shareholders per share	\$	(0.83)	\$	(1.00)			

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

#### Deferred income taxes

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

#### Stock-based compensation

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

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

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

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

#### **Preferred Shares**

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

#### Segment information

The Company operates in a single reporting segment. Substantially all of the Company's revenues to date were earned from customers or collaborators based in the United States. Substantially all of the Company's premises, property and equipment are located in the United States.

#### Comprehensive loss

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

## Concentrations of Credit Risk

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

## Recent accounting pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-13, Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments (ASC 326). The guidance is effective for the Company beginning January 1, 2023 and it changes how entities account for credit losses on financial assets and other instruments that are not measured at fair value through net income, including available-for-sale debt securities. The Company is currently evaluating the impact of the new standard on its consolidated financial statements.

#### 3. Fair value measurements

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

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

factors market participants would use to value an asset or liability. The three levels of inputs that may be used to measure fair value are as follows:

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

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

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

To determine the fair value of the contingent consideration (note 10), the Company uses a probability weighted assessment of the likelihood the milestones would be met and the estimated timing of such payments, and then the potential contingent payments were discounted to their present value using a probability adjusted discount rate that reflects the early stage nature of the development program, time to complete the program development, and overall biotech indices. The Company determined the fair value of the contingent consideration was \$5.3 million as of December 31, 2021 and the increase of \$1.9 million has been recorded within operating expenses in the statement of operations and comprehensive loss for the year ended December 31, 2021. 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		Level 2	Level 2 Level 3			Total		
As of December 31, 2021	· <u></u>	(in thousands)								
Assets										
Cash and cash equivalents	\$	109,282	\$	_	\$	_	\$	109,282		
Investments in marketable securities		_		81,723		_		81,723		
Total	\$	109,282	\$	81,723	\$		\$	191,005		
Liabilities										
Liability-classified options	\$	_	\$	_	\$	26	\$	26		
Contingent consideration		_		_		5,298		5,298		
Total	\$		\$		\$	5.324	\$	5.324		

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

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

	· ·	t beginning of period	alue of liability-classified as exercised in the period	Dec	rease in fair value of liability	Lia	ability at end of the period
			(in thousar	ıds)			
Year ended December 31, 2021	\$	250	\$ (96)	\$	(128)	\$	26
Year ended December 31, 2020	\$	253	\$ _	\$	(3)	\$	250

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

	Liability at l	peginning of the period	In	crease in fair value of liability	Liability at end of the period			
	-			(in thousands)				
Year ended December 31, 2021	\$	3,426	\$	1,872	\$	5,298		
Year ended December 31, 2020	\$	2,953	\$	473	\$	3,426		

#### 4. Investments in marketable securities

Investments in marketable securities consisted of the following:

	Amortized Cost	Gro	oss Unrealized Gain <sup>(1)</sup>	Gross Unrealized Loss <sup>(1)</sup>			Fair Value			
As of December 31, 2021	 (in thousands)									
Cash equivalents										
Money market fund	\$ 62,836	\$		\$		\$	62,836			
Total	\$ 62,836	\$	_	\$	_	\$	62,836			
Investments in marketable securities										
US government agency bonds	\$ 21,198	\$	_	\$	(39)	\$	21,159			
US government bonds	60,675		_		(111)		60,564			
Total	\$ 81,873	\$	_	\$	(150)	\$	81,723			

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

	Amortized Cost		Gross Unrealized Gain <sup>(1)</sup>		Gross Unrealized Loss <sup>(1)</sup>	Fair Value	
As of December 31, 2020							
Cash equivalents							
Money market fund	\$ 13,703	\$	_	\$	_	\$	13,703
US treasury bills	2,000		_		_		2,000
Total	\$ 15,703	\$	_	\$	_	\$	15,703
Investments in marketable securities							
Us government agency bonds	\$ 11,550	\$	7	\$	_	\$	11,557
US treasury bills	21,990		2		_		21,992
US government bonds	37,463		6		(1)		37,468
Total	\$ 71,003	\$	15	\$	(1)	\$	71,017

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

There were no realized gains or losses for the year ended December 31, 2021 or 2020.

## 5. Investment in Genevant

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

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

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

On July 31, 2020, Roivant recapitalized Genevant through an equity investment and conversion of previously issued convertible debt securities held by Roivant. The Company participated in the recapitalization of Genevant with an investment of \$2.5 million. The Company determined that this \$2.5 million additional investment in Genevant represented the funding of prior losses and accordingly, the Company recorded the amount as an equity investment loss on the Condensed Consolidated Statements of Operations and Comprehensive Loss in 2020. Following the recapitalization, the Company owned approximately 16% of the common equity of Genevant. In connection with the recapitalization, Genevant, the Company and Roivant entered into an Amended and Restated Shareholders Agreement that provides Roivant with substantial control of Genevant. The Company has a non-voting observer seat on Genevant's Board of Directors. Due to the Company's loss of significant influence with respect to Genevant as a result of the recapitalization, the Company discontinued the use of the equity method of accounting for its interest in Genevant. Following the recapitalization, the Company accounts for its interest in Genevant as equity securities without readily determinable fair values. Accordingly, an estimate of the fair value of the securities is based on the original cost less previously recognized equity method losses, less impairments, plus or minus changes resulting from observable price changes in orderly transactions for identical or a similar Genevant securities. The Company's entitlement to receive future royalties or sublicensing revenue under the Genevant License was not impacted by the recapitalization.

As of December 31, 2021, the carrying value of the Company's investment in Genevant was zero and the Company owned approximately 16% of the common equity of Genevant.

#### 6. Leases

The Company 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, 2022, and the Company has an option to extend the lease term to April 30, 2027.

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

During each of the years ended December 31, 2021 and 2020, the Company incurred total operating lease expenses of \$0.7 million, which included lease

During each of the years ended December 31, 2021 and 2020, the Company incurred total operating lease expenses of \$0.7 million, which included lease expenses associated with fixed lease payments of \$0.6 million, and variable payments associated with common area maintenance and similar expenses of \$0.1 million.

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

	As of December 31, 2021
Weighted-average remaining lease term (years)	5.2
Weighted average discount rate	9.0%

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

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

	2021		2020
		(in thousands)	
Cash paid for amounts included in the measurement of lease liabilities	\$	650 \$	657

Future minimum lease payments under operating leases that have remaining terms as of December 31, 2021 are as follows:

	As of De	cember 31, 2021
	(in	thousands)
2022	\$	641
2023		598
2024		616
2025		635
2026		654
Thereafter		134
Total lease payments	\$	3,278
Less: interest		(664)
Present value of lease payments	\$	2,614

# 7. Property and equipment

The Company's property and equipment balances as of the years ended December 31, 2021 and 2020 are as follows:

	Cost	Accumulated depreciation	Net book value
<u>December 31, 2021</u>		(in thousands)	
Lab equipment	\$ 6,408	\$ (5,178)	\$ 1,230
Leasehold improvements	8,563	(3,883)	4,680
Computer hardware and software	386	(313)	73
	\$ 15,357	\$ (9,374)	\$ 5,983

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

Depreciation expense for the years ended December 31, 2021 and 2020 was \$1.8 million and \$2.0 million, respectively.

## 8. Accounts payable and accrued liabilities

Accounts payable and accrued liabilities are comprised of the following:

	Γ	December 31, 2021	December 31, 2020	
		usands)		
Trade accounts payable	\$	3,174	\$ 2,99	4
Payroll accruals		4,279	3,56	6
Research and development accruals		2,371	1,65	3
Professional fee accruals		983	679	9
Liability options		26	25	0
Other accrued liabilities		5		9
Total	\$	10,838	\$ 9,15	1

#### 9. Sale of future royalties

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

ONPATTRO utilizes Arbutus's LNP technology, which was licensed to Alnylam pursuant to the Cross-License Agreement, dated November 12, 2012, by and between the Company and Alnylam (the "LNP License Agreement"). Under the terms of the LNP License Agreement, the Company is entitled to tiered royalty payments on global net sales of ONPATTRO ranging from 1.00% to 2.33% after offsets, with the highest tier applicable to annual net sales above \$500 million. This royalty interest was sold to OMERS, effective as of January 1, 2019, for \$20 million in gross proceeds before advisory fees. OMERS will retain this entitlement until it has received \$30 million in royalties, at which point 100% of such royalty interest on future global net sales of ONPATTRO will revert to the Company. OMERS has assumed the risk of collecting up to \$30 million of future royalty payments from Alnylam and Arbutus is not obligated to reimburse OMERS if they fail to collect any such future royalties. From the inception of the royalty sale through December 31, 2021, an aggregate of \$11.2 million of royalties have been earned by OMERS.

The \$30 million in royalties to be paid to OMERS is accounted for as a liability, with the difference between the liability and the gross proceeds received accounted for as a discount. The discount, as well as \$1.5 million of transaction costs, will be amortized as interest expense based on the projected balance of the liability as of the beginning of each period. Management estimated an effective annual interest rate of approximately 12%. Over the course of the Agreement, the actual interest rate will be affected by the amount and timing of royalty revenue recognized and changes in the timing of forecasted royalty revenue. On a quarterly basis, the Company will reassess the expected timing of the royalty revenue, recalculate the amortization and effective interest rate and adjust the accounting prospectively as needed.

The Company recognizes non-cash royalty revenue related to the sales of ONPATTRO during the term of the Agreement. As royalties are remitted to OMERS from Alnylam, the balance of the recognized liability is effectively repaid over the life of the Agreement. From the inception of the royalty sale through December 31, 2021, the Company has recorded an aggregate of \$11.2 million of non-cash royalty revenue for royalties earned by OMERS. There are a number of factors that could materially affect the amount and timing of royalty payments from Alnylam, none of which are within the Company's control.

During the year ended December 31, 2021, the Company recognized non-cash royalty revenue of \$6.1 million and \$2.9 million of related non-cash interest expense. During the year ended December 31, 2020, the Company recognized non-cash royalty revenue of \$3.4 million and related non-cash interest expense of \$4.0 million.

The table below shows the activity related to the net liability for the years ended December 31, 2021 and December 31, 2020:

	Twelve Months Ended December 31,			
		2021	2020	
Net liability related to sale of future royalties - beginning balance	\$	19,554 \$	18,992	
Non-cash royalty revenue		(6,108)	(3,395)	
Non-cash interest expense		2,850	3,957	
Net liability related to sale of future royalties - ending balance	\$	16,296 \$	19,554	

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.

#### 10. Contingencies and commitments

#### Product development partnership with the Canadian Government

The Company entered into a Technology Partnerships Canada ("TPC") agreement with the Canadian Federal Government on November 12, 1999. Under this agreement, TPC agreed to fund 27% of the costs incurred by the Company, prior to March 31, 2004, in the development of certain oligonucleotide product candidates up to a maximum contribution from TPC of \$7.2 million (C\$9.3 million). The Company received a cumulative contribution of \$2.7 million (C\$3.7 million). In return for the funding provided by TPC, the Company agreed to pay royalties on the share of future licensing and product revenue, if any, that is received by the Company on certain non-RNAi oligonucleotide product candidates covered by the funding under the agreement. These royalties are payable until a certain cumulative payment amount is achieved or until a pre-specified date. In addition, until a cumulative amount equal to the funding actually received under the agreement has been paid to TPC, the Company agreed to pay 2.5% royalties on any royalties the Company receives for Marqibo, a chemotherapy product sold by Acrotech Biopharma LLC ("Acrotech"). For the years ended December 31, 2021 and 2020, the Company earned royalties on Marqibo sales in the amount of \$0.2 million in each period. The resulting royalties payable by the Company to TPC were not material in either period. The cumulative amount paid or accrued up to December 31, 2021 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 the Company that was subsequently assigned to UBC. These inventions are licensed to the Company by UBC under a license agreement, initially entered into in 1998 and as amended in 2001, 2006 and 2007. The Company has granted sublicenses under the UBC license to certain third parties, including Alnylam. In November 2014, UBC filed a demand for arbitration against the Company which alleged entitlement to unpaid royalties. In August 2019, the arbitrator issued its decision for the second phase of the arbitration, awarding UBC \$5.9 million, which included interest of approximately \$2.6 million. The Company paid the \$5.9 million award to UBC in September 2019 and paid an additional \$0.2 million for costs and attorneys' fees in March 2021, and this matter is now fully resolved.

On December 18, 2020, UBC delivered to the Company a notice of arbitration alleging that under the cross license between UBC and Arbutus, it is due royalties of \$2.0 million plus interest arising from the Company's sale to OMERS of part of its royalty interest on future global net sales of ONPATTRO, currently being sold by Alnylam. Oral hearings for this matter are currently scheduled to begin on April 25, 2022. The Company does not believe that any royalties are due to UBC and the Company intends to vigorously contest UBC's allegation.

#### Stock Purchase Agreement with Enantigen

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

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

The fair value of the contingent consideration was \$5.3 million as of December 31, 2021.

## 11. Collaborations and royalty entitlements

#### **Collaborations**

Qilu Pharmaceuticals Co, Ltd.

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

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

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

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

The License Agreement falls under the scope of ASC Topic 808, Collaborative Arrangements, ("ASC 808") as both parties are active participants in the arrangement that are exposed to significant risks and rewards. While this arrangement is in the scope of ASC 808, the Company analogizes to ASC 606 for some aspects of this arrangement, including for the delivery of a good or service (i.e., a unit of account). Revenue recognized by analogizing to ASC 606 will be recorded as revenue from collaborations and licenses on the consolidated statements of operations as the Company satisfies its performance obligations under the License Agreement which is expected to begin in 2022.

#### Assembly Biosciences, Inc.

In August 2020, the Company entered into a clinical collaboration agreement with Assembly Biosciences, Inc. ("Assembly") to evaluate AB-729 in combination with Assembly's lead HBV core inhibitor (capsid inhibitor) candidate vebicorvir ("VBR") and standard-of-care NA therapy for the treatment of subjects with HBV infection. The Company and Assembly will share in the costs of the collaboration. The Company incurred \$2.6 million and \$0.2 million of costs related to the collaboration during the years ended December 31, 2021 and 2020, respectively and reflected those costs in research and development in the statements of operations and comprehensive loss. Except to the extent necessary to carry out Assembly's responsibilities with respect to the collaboration trial, the Company has not provided any license grant to Assembly for use of AB-729.

## Vaccitech plc

In July 2021, the Company entered into a clinical collaboration agreement with Vaccitech plc ("Vaccitech") to evaluate AB-729 followed by Vaccitech's VTP-300, a proprietary T cell stimulating therapeutic vaccine, in NrtI-suppressed patients with cHBV. The Company is responsible for managing this Phase 2a proof-of-concept clinical trial, subject to oversight by a joint development committee comprised of representatives from the Company and Vaccitech. The Company and Vaccitech retain full rights to their respective product candidates and will split all costs associated with the clinical trial. The Company incurred \$0.5 million of costs related to the collaboration, net of Vaccitech's 50% share, during the year ended December 31, 2021 and reflected those net costs in research and development in the statements of operations and comprehensive loss.

## Antios Therapeutics, Inc.

In June 2021, the Company entered into a clinical collaboration agreement with Antios Therapeutics, Inc. ("Antios") to evaluate a triple combination of AB-729, Antios' proprietary active site polymerase inhibitor nucleotide (ASPIN), ATI-2173, and Viread (tenofovir disoproxil fumarate), a nucleos(t)ide reverse transcriptase inhibitor which is currently approved by the FDA, for the treatment of patients with cHBV. Antios is responsible for the costs of adding a single cohort to its clinical trial. The Company is responsible for the manufacture and supply of AB-729, the cost of which is not material.

#### X-Chem, Inc. and Proteros biostructures GmbH

In March 2021, the Company entered into a discovery research and license agreement with X-Chem, Inc. ("X-Chem") and Proteros biostructures GmbH ("Proteros") to focus on the discovery of novel inhibitors targeting the SARS-CoV-2 nsp5 main protease (M<sup>pro</sup>). The agreement is designed to accelerate the development of pan-coronavirus agents to treat COVID-19 and potential future coronavirus outbreaks. This collaboration brought together the Company's expertise in the discovery and development of antiviral agents with X-Chem's industry leading DNA-encoded library (DEL) technology and Proteros' protein sciences, biophysics and structural biology capabilities and provides important synergies to potentially identify safe and effective therapies against coronaviruses including SARS-CoV-2. The collaboration allows for the rapid screening of one of the largest small molecule libraries against M<sup>pro</sup> (an essential protein required for the virus to replicate itself) and the use of state-of-the-art structure guided methods to rapidly optimize M<sup>pro</sup> inhibitors, which the Company could potentially progress to clinical candidates. The agreement provides for payments by the Company to X-Chem and Proteros upon satisfaction of certain development, regulatory and commercial milestones, as well as royalties on sales. Through this collaboration, the Company has identified and obtained a worldwide exclusive license to several molecules that inhibit M<sup>pro</sup>, a validated target for the treatment of COVID-19 and potential future coronavirus outbreaks. The Company incurred \$1.9 million of costs related to the collaboration during the year ended December 31, 2021 and reflected those costs in research and development in the statements of operations and comprehensive loss.

#### **Royalty Entitlements**

Alnylam Pharmaceuticals, Inc. and Acuitas Therapeutics, Inc.

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

In 2012, the Company entered into a license agreement with Alnylam Pharmaceuticals, Inc. ("Alnylam") that entitles Alnylam to develop and commercialize products with the Company's LNP technology. Alnylam's ONPATTRO, which represents the first approved application of the Company's LNP technology, was launched by Alnylam in 2018. Under the terms of this license agreement, the Company is entitled to tiered royalty payments on global net sales of ONPATTRO ranging from 1.00% - 2.33% after offsets, with the highest tier applicable to annual net sales above \$500 million. This royalty interest was sold to OMERS, effective as of January 1, 2019, for \$20 million in gross proceeds before advisory fees. OMERS will retain this entitlement until it has received \$30 million in royalties, at which point 100% of this royalty entitlement on future global net sales of ONPATTRO will revert back to the Company. OMERS has assumed the risk of collecting up to \$30.0 million of future royalty payments from Alnylam and the Company is not obligated to reimburse OMERS if they fail to collect any such future royalties. If this royalty entitlement reverts to the Company, it has the potential to provide an active royalty stream or to be otherwise monetized again in full or in part. From the inception of the royalty sale through December 31, 2021, an aggregate of \$11.2 million of royalties have been earned by OMERS. See note 9 for further details.

The Company also has rights to a second, lower royalty interest on global net sales of ONPATTRO originating from a settlement agreement and subsequent license agreement with Acuitas. This royalty entitlement from Acuitas has been retained by the Company and was not part of the royalty entitlement sale to OMERS.

#### Gritstone Oncology, Inc.

On October 16, 2017, the Company entered into a license agreement with Gritstone that granted them worldwide access to its portfolio of proprietary and clinically validated LNP technology and associated intellectual property to deliver Gritstone's self-replicating, non-mRNA, RNA-based neoantigen immunotherapy products. Gritstone paid the Company an upfront payment, and will make payments for achievement of development, regulatory, and commercial milestones and royalties. As a result of the Company's agreement with Genevant (see note 5 for details), from April 11, 2018 going forward, Genevant is entitled to 50% of the revenues earned by the Company from Gritstone. The Company is the agent in this arrangement and records revenue on a net basis. Milestone payments that are not within the control of the Company or the licensee, such as those that require regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company did not receive any payments from Gritstone during the years ended December 31, 2021 or 2020.

# Acrotech Biopharma LLC

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

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

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

		Year ended December 31,		r 31,
		2021		2020
	_	(in tho	usands)	
Revenue from collaborations and licenses				
Acuitas Therapeutics, Inc.	\$	4,675	\$	3,259
Acrotech Biopharma, LLC		205		269
Non-cash royalty revenue				
Alnylam Pharmaceuticals, Inc.		6,108		3,386
Total revenue	\$	10,988	\$	6.914

#### 12. 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**

The Company has an Open Market Sale Agreement with Jefferies LLC ("Jefferies") dated December 20, 2018, as amended by Amendment No. 1, dated December 20, 2019, Amendment No. 2, dated August 7, 2020 and Amendment No. 3, dated March 4, 2021 (as amended, the "Sale Agreement"), under which the Company may issue and sell common shares, from time to time, under a shelf registration statement on Form S-3 (File No. 333-248467), filed with the SEC on August 28, 2020 (the "Registration Statement"). On March 4, 2021, the Company filed a prospectus supplement with the SEC (the "March 2021 Prospectus Supplement") in connection with the offering of up to an additional \$75.0 million of the Company filed a prospectus supplement with the SEC (the "October 2021 Prospectus Supplement") in connection with the offering of up to an additional \$75.0 million of the Company's common shares pursuant to the Sale Agreement under the Registration Statement.

During the years ended December 31, 2021 and 2020, the Company issued 31,571,036 and 24,728,368 common shares, respectively, under the Sale Agreement, as amended, resulting in net proceeds of approximately \$134.7 million and \$86.3 million, respectively.

As of December 31, 2021, there was approximately \$52.3 million remaining available under the October 2021 Prospectus Supplement.

## Series A Preferred Shares

In October 2017, the Company entered into a subscription agreement with Roivant for the sale of Preferred Shares to Roivant for gross proceeds of \$116.4 million. The Preferred Shares were non-voting and were convertible into common shares at a conversion price of \$7.13 per share (which represented a 15% premium to the closing price of \$6.20 per share). The purchase price for the Preferred Shares plus an amount equal to 8.75% per annum, compounded annually, was subject to mandatory conversion into common shares on October 18, 2021, at which time the Preferred Shares were converted into 22,833,922 common shares and both the lockup and standstill periods that Roivant had previously agreed to expired. Immediately following the conversion, Roivant owned approximately 27% of the Company's outstanding common shares as of December 31, 2021.

The Company recorded the Preferred Shares wholly as equity with no bifurcation of conversion feature from the host contract, given that the Preferred Shares could not be cash settled and the redemption features were within the Company's control, which included a fixed conversion ratio with predetermined timing and proceeds. The Company accrued for the 8.75% per annum compounding coupon at each reporting period end date as an increase to share capital, and an increase to deficit (see statement of stockholder's equity).

## 13. Stock-based compensation

## Awards outstanding and available for issuance

During the year ended December 31, 2021, the Company had stock options outstanding under the following plans (collectively, the "Plans"): the 2016 Omnibus Share and Incentive Plan (the "2016 Plan"), the 2011 Omnibus Share Compensation Plan (the "2011 Plan"); the 2019 inducement grant; and the OnCore Option Plan.

As of December 31, 2021, the aggregate number of shares authorized for awards under all Plans was 24,790,202. As of December 31, 2021, the Company had 11,410,574 options outstanding and 9,519,084 awards available for issuance under the Plans.

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

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

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

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

## Stock options under the Arbutus Plans

Equity-classified stock options under the Arbutus Plans

The following table summarizes activity related to the Company's equity-classified stock options, including its performance options, for the year ended December 31, 2021:

	Stock Options Outstanding		Vested Stock Options	Non-Vested S	tock Options		
	Number	'	Weighted-Average Exercise Price	Number	Number		Veighted-Average ant-Date Fair Value
Balance as of December 31, 2020	10,391,676	\$	4.53	6,384,386	4,007,290	\$	2.51
Options granted	3,531,050	\$	4.17	_	3,531,050	\$	3.06
Options exercised	(637,721)	\$	3.13	(637,721)	_	\$	_
Options forfeited, canceled or expired	(1,975,031)	\$	6.54	(1,698,338)	(276,693)	\$	2.84
Options vested	_	\$	_	2,496,021	(2,496,021)	\$	2.88
Balance as of December 31, 2021	11,309,974	\$	4.14	6,544,348	4,765,626	\$	2.71

The intrinsic value of options exercised under the Arbutus Plans during 2021 and 2020 are \$0.2 million and \$0.3 million, respectively.

The following table summarizes additional information related to the Company's equity-classified stock options, including its performance options, as of December 31, 2021:

	As of 1	December 31, 2021
Options outstanding and expected to vest		
Number of stock options outstanding		11,309,974
Weighted-average exercise price	\$	4.14
Intrinsic value (in \$000s)	\$	5,117
Weighted-average term remaining		7.6 years
<u>Vested stock options</u>		
Number of vested stock options		6,544,348
Weighted-average exercise price	\$	4.43
Intrinsic value (in \$000s)	\$	3,233
Weighted-average term remaining		6.9 years

The assumptions used in the Black-Scholes option-pricing for grants made during the years ended December 31, 2021 and 2020 are as follows:

	December 31, 2021	December 31, 2020
Expected average option term	5.6 years	6.2 years
Expected volatility	93.4 %	80.2 %
Expected dividends	— %	— %
Risk-free interest rate	0.67 %	1.2 %

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

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, 2021:

	Stock Options Vested and Outstanding			
	Number		Weighted-Average Exercise Price	
Balance as of December 31, 2020	197,500	\$	6.00	
Options exercised	(70,000)	\$	1.62	
Options forfeit, canceled or expired	(107,500)	\$	7.65	
Balance as of December 31, 2021	20,000	\$	12.98	

All of the outstanding liability-classified options are vested and the intrinsic value of those options exercised during 2021 was less than \$0.1 million. The weighted average term remaining for the liability-classified options is 2.1 years as of December 31, 2021 and the fair value was less than \$0.1 million.

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

## **OnCore Option Plan**

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

The following table summarizes activity related to the OnCore stock options for the year ended December 31, 2021:

	Stock Options Vested and Outstanding			
	Number of OnCore Options	Number of Equivalent Company Common Shares	Weighted-Average Exe Price	rcise
Balance as of December 31, 2020	80,035	80,600	\$	0.56
Options exercised	_	_	\$	_
Options forfeit, canceled or expired	_	_	\$	_
Balance as of December 31, 2021	80,035	80,600	\$	0.56

The following table summarizes additional information related to the OnCore stock options as of December 31, 2021:

	As	As of December 31, 2021	
Vested stock options			
Intrinsic value (in \$000s)	\$	183	
Weighted-average term remaining		2.8 years	

### **Employee Stock Purchase Plan**

In May 2020, the Company's stockholders approved the 2020 Employee Stock Purchase Plan (ESPP) which became effective on May 28, 2020. A total of 1,500,000 common shares were reserved for issuance under the ESPP. Company employees contribute funds via payroll deductions, which are used to buy Company common shares at a discount of up to 15% based on the lower of the price at the start of the offering period and at the end of the relevant purchase period within such offering

period. The initial offering period under the ESPP was September 1, 2020 through August 31, 2021 with purchase dates set on February 26, 2021 and August 31, 2021, with subsequent offering periods beginning on September 1 and ending on August 31. A total of 196,335 ESPP shares were issued under the plan and the balance remaining for issuance under the ESPP plan is 1,303,665 at December 31, 2021. For the years ended December 31, 2021 and 2020, the Company recognized \$0.3 million and \$0.2 million, respectively, of stock-based compensation expense related to the ESPP. The fair value of the right to acquire stock at a discounted price under the ESPP is calculated using the Black-Scholes valuation model and recorded as stock-based compensation. Expense is recognized over the period the employee contributes to the plan through payroll deductions.

#### Stock-based compensation expense

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

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

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

	 Year Ended December 31,		
	2021		2020
	(in thou	ısands)	
Research and development	\$ 2,777	\$	3,090
General and administrative	3,647		3,071
Total	\$ 6,424	\$	6,161

At December 31, 2021, there remained \$11.6 million of unearned compensation expense related to unvested equity employee stock options to be recognized as expense over a weighted-average period of approximately 2.7 years.

For the year ended December 31, 2020, the Company recognized \$0.3 million of performance based stock compensation expense, which is included in the table above. There was no performance based stock compensation expense in 2021.

#### 14. Income taxes

The Company is subject to taxation and files income tax returns in Canadian federal and provincial, United States federal and several state jurisdictions. The United States Internal Revenue service is currently examining the Company's federal tax return for 2018 and the Canada Revenue Agency is currently examining the Company's Canadian tax returns for 2018 and 2019. The outcome of tax audits cannot be predicted with certainty, however the Company believes that an adequate provision has been made for any adjustments that may result from the examination. If any issues addressed in the Company's tax audits are resolved in a manner not consistent with management's expectations, the Company could be required to adjust its provision for income tax in the period such resolution occurs.

Income tax (benefit) expense varies from the amounts that would be computed by applying the combined Canadian federal and provincial income tax rate of 27% (2020 - 27%) to the loss before income taxes as shown in the following tables:

		Year ended December 31,		
		2021 2020		
		(in thousands)		
Computed taxes (benefits) at Canadian federal and provincial tax rates	\$	(23,864)	(17,211)	
Adjustment to prior year		(1,041)	390	
Permanent and other differences		4,292	622	
Change in valuation allowance - other		15,928	12,033	
Federal and Provincial ITCs applied		(611)	_	
Difference due to income taxed at foreign rates		4,840	3,716	
Stock-based compensation		456	450	
Income tax expense (recovery)	\$		5 —	

As of December 31, 2021, the Company had investment tax credits available to reduce Canadian federal income taxes of \$7.4 million, versus \$8.0 million as of December 31, 2020, which expire between 2030 and 2037, and provincial income taxes of \$2.1 million, versus \$2.6 million as of December 31, 2020, which expire between 2024 and 2027. The investment tax credits are accounted for under a flow-through method. In addition, the Company had research and development credits of \$3.8 million as of December 31, 2021, and \$3.9 million as of December 31, 2020, which expire between 2031 and 2038 and which can be used to reduce future taxable income in the United States.

As of December 31, 2021, the Company had scientific research and experimental development expenditures of \$62.8 million available for indefinite carry-forward, versus the \$58.6 million it had as of December 31, 2020. The Company also had net operating losses of \$177.7 million as of December 31, 2021 and \$175.6 million as of December 31, 2020, which are due to expire between 2028 and 2038 and which can be used to offset future taxable income in Canada.

As of December 31, 2021 and December 31, 2020, the Company had \$11.7 million of net operating losses due to expire in 2035 which can be used to offset future taxable income in the United States. Future use of a portion of the United States loss carryforwards are subject to limitations under Internal Revenue Code Section 382. United States net operating loss carryforwards arising in 2019 and future periods have an indefinite carryforward period. As of December 31, 2021 and December 31, 2020, the Company had \$197.8 million and \$124.6 million, respectively, of total regular net operating losses which can be used to offset future taxable income in the United States.

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

The Company generated \$7.7 million and \$80.7 million in pre-tax domestic and foreign losses, respectively, for the year ended December 31, 2021. The Company generated \$1.8 million and \$61.9 million in pre-tax domestic and foreign losses, respectively, for the year ended December 31, 2020.

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

	As of December 31,		
		2021	2020
	(in thousands)		
Deferred tax assets (liabilities):			
Non-capital losses carryforwards	\$	90,255	\$ 74,351
Research and development deductions		16,968	15,812
Book amortization in excess of tax		(634)	(737)
Revenue recognized for tax purposes in excess of revenue recognized for accounting purposes		4,400	5,279
Tax value in excess of accounting value in lease inducements		549	627
Federal investment tax credits		5,301	5,872
Provincial investment tax credits		2,119	2,644
Equity accounted for investment		3,375	3,375
Federal R&E credits		3,741	3,897
Deductible stock options		3,309	2,457
Other		1,341	1,218
Total deferred tax assets	\$	130,724	\$ 114,795
Valuation allowance		(130,724)	(114,795)
Net deferred tax assets (liabilities)	\$		\$ _

## 15. Related party transactions

Pursuant to a financing and related subscription agreement, the Company issued Roivant the Preferred Shares in October 2017. On October 18, 2021, the Preferred Shares were converted into 22,833,922 common shares. Immediately following the conversion, Roivant owned approximately 27% of the Company's outstanding common shares. See note 12 for further details.

On July 31, 2020, Genevant was recapitalized through an equity investment and conversion of previously issued convertible debt securities held by Roivant. Arbutus participated in the recapitalization of Genevant with an investment of \$2.5 million. Arbutus determined that this \$2.5 million additional investment in Genevant represented the funding of prior losses and accordingly, the Company recorded the amount as an equity investment loss on the Consolidated Statements of Operations and Comprehensive Loss in 2020. As of December 31, 2021, the carrying value of the Company's investment in Genevant was zero and the Company owned approximately 16% of the common equity of Genevant. See note 5 for further details.

During each of the years ended December 31, 2021 and 2020, Genevant purchased certain administrative and transitional services from the Company totaling less than \$0.1 million. These services were billed at agreed hourly rates and reflective of market rates for such services and these costs were netted in research and development in the income statement.

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

None.

## **Item 9A. Controls and Procedures**

#### **Disclosure Controls and Procedures**

Our management, including our principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of the end of the period covered by this Annual Report on Form 10-K. Based upon that evaluation, our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer), concluded that, as of December 31, 2021, 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, 2021.

#### **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, 2021 that have materially affected or are reasonably likely to materially affect the Company's internal control over financial reporting.

	None.
Item 9C	. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.
	Not applicable.

Item 9B. Other Information

#### 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 2022 Annual General Meeting of the Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2021.

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

## **Item 11. Executive Compensation**

The information required by this item is incorporated herein by reference to our Proxy Statement for the 2022 Annual General Meeting of the Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2021.

#### 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 2022 Annual General Meeting of the Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2021.

#### 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 2022 Annual General Meeting of the Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2021.

## Item 14. Principal Accounting Fees and Services

The information required by this item is incorporated herein by reference to our Proxy Statement for the 2022 Annual General Meeting of the Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2021.

# **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**	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 Arbutus Biopharma Corporation Indemnity Agreement.
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).
10.10†*	Settlement Agreement and General Release, by and among Tekmira Pharmaceuticals Corporation, Protiva Biotherapeutics Inc., Alnylam Pharmaceuticals, Inc., and AlCana Technologies, Inc., dated November 12, 2012 (incorporated herein by reference to Exhibit 4.26 to the Registrant's Annual Report on Form 20-F for the year ended December 31, 2012 filed with the SEC on March 27, 2013).
10.11†*	Cross-License Agreement by and among Alnylam Pharmaceuticals, Inc., Tekmira Pharmaceuticals Corporation and Protiva Biotherapeutics Inc., dated November 12, 2012 (incorporated herein by reference to Exhibit 4.27 to the Registrant's Annual Report on Form 20-F for the year ended December 31, 2012 filed with the SEC on March 27, 2013).

- 10.12\* Form of Standstill Agreement (incorporated herein by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K/A filed with the SEC on January 26, 2015).

  10.13\*# Executive Employment Agreement, dated effective as of February 25, 2016, between Arbutus Biopharma, Inc. and Elizabeth Howard
- 10.13\*# Executive Employment Agreement, dated effective as of February 25, 2016, between Arbutus Biopharma, Inc. and Elizabeth Howard (incorporated herein by reference to Exhibit 10.78 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC on March 9, 2016).
- 10.14\*#

  Amending Agreement, dated as of November 2, 2015, among Arbutus Biopharma Corporation, Roivant Sciences Ltd., Patrick T. Higgins, Michael J. McElhaugh, Michael J. Sofia and Bryce A. Roberts (incorporated herein by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed with the SEC on November 5, 2015).
- 10.15†\*

  Stock Purchase Agreement by and among OnCore Biopharma, Inc. and each of the stockholders of Enantigen Therapeutics, Inc., dated as of October 1, 2014 (incorporated herein by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed with the SEC on May 6, 2015).
- 10.16\*# Executive Employment Agreement, dated effective as of July 11, 2015, between OnCore Biopharma, Inc. and Michael J. Sofia (incorporated herein by reference to Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed with the SEC on August 7, 2015).
- 10.17\*# Amended 2011 Omnibus Share Compensation Plan (incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, filed with the SEC on August 4, 2016).
- 10.18\*†

  Lease Agreement between the Company and ARE-PA Region No. 7, LLC dated August 9, 2016 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, filed with the SEC on November 3, 2016).
- 10.19\*† First Amendment to Lease Agreement between Arbutus Biopharma, Inc. and ARE-PA Region No. 7, LLC dated October 7, 2016
  (incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, filed with the SEC on November 3, 2016).
- 10.20\*
  Acknowledgment of Commencement Date in connection with Lease Agreement between the Company and ARE-PA Region No. 7, LLC dated August 9, 2016 and as amended on October, 7, 2016 (incorporated herein by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, filed with the SEC on November 3, 2016).
- 10.21\* Master Contribution And Share Subscription Agreement, by and between the Company, Genevant Sciences Ltd. and Roivant Sciences LTD. (incorporated herein by reference Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the Quarter ended March 31, 2018 filed with the SEC on May 4, 2018).
- 10.22\* Open Market Sale AgreementSM, dated December 20, 2018, by and between the Company and Jefferies LLC (incorporated herein by reference to Exhibit 1.1 of the Current Report on Form 8-K filed with the SEC on December 20, 2018).
- 10.23\* Amendment No. 1 to the Open Market Sale AgreementSM, dated December 20, 2019, by and between the Company and Jefferies LLC (incorporated herein by reference to Exhibit 1.3 to the Registrant's Registration Statement on Form S-3 filed with the SEC on December 20, 2019).
- 10.24\* Amendment No. 2 to the Open Market Sale AgreementSM, dated August 7, 2020, by and between the Company and Jefferies LLC (incorporated herein by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K filed with the SEC on August 7, 2020).
- Amendment No. 3 to the Open Market Sale AgreementSM, dated March 4, 2021, by and between Arbutus Biopharma Corporation and Jefferies LLC (incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on March 4, 2021.)
- 10.26\*# Executive Employment Agreement, dated June 11, 2018, by and between the Company and David Hastings. (incorporated herein by reference to Exhibit 10.52 of the Form 10-K filed with the SEC on March 7, 2019).
- 10.27\*# 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).

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). Executive Employment Agreement, dated July 10, 2015, by and between the Company and Michael McElhaugh, as amended by the First Amendment to Executive Employment Agreement, dated April 20, 2016, and the Second Amendment to Executive Employment Agreement dated December 11, 2018 (incorporated herein by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10.29\*# 10-Q for the Quarter ended June 30, 2019, filed with the SEC on August 5, 2019). 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 10.30\* the SEC on August 5, 2019). Arbutus Biopharma Corporation 2016 Omnibus Share and Incentive Plan, as supplemented by the Committee on May 28, 2020 10.31\*# (incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on June 1, 2020). Arbutus Biopharma Corporation 2020 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 10.2 to the 10.32\*# Registrant's Current Report on Form 8-K filed with the SEC on June 1, 2020). 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). 10.33\*# 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). 10.34\*# 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, 10.35\*# 2019). Cross License Agreement, dated April 11, 2018, by and between the Company and Genevant Sciences Ltd. (incorporated herein by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the Quarter ended June 30, 2020, filed with the SEC on 10.36†\* August 7, 2020). 10.37 +\* First Amendment to Cross License Agreement, dated June 27, 2018, by and among the Company, Genevant Sciences Ltd and Genevant Sciences GmbH. (incorporated herein by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the Quarter ended June 30, 2020, filed with the SEC on August 7, 2020). Second Amendment to Cross License Agreement, dated June 27, 2018, by and among the Company, Genevant Sciences Ltd. and Genevant Sciences GmbH. (incorporated herein by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q for the Quarter ended June 30, 2020, filed with the SEC on August 7, 2020). 10.38†\* <u>License Agreement, dated December 9, 2021, by and between the Company and Genevant Sciences GmbH (incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on December 10, 2021).</u> 10.39† Arbutus Biopharma Corporation 2016 Omnibus Share and Incentive Plan, as supplemented and amended (incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on June 1, 2021). 10.40\* Technology Transfer and Exclusive License Agreement, dated December 13, 2021, by and between the Company and Qilu 10.41 †\*\* Pharmaceutical Co., Ltd. 21.1\*\* List of Subsidiaries. 23.1\*\* Consent of Ernst and Young LLP, an Independent Registered Public Accounting Firm. 31.1\*\* Certification of Chief Executive Officer pursuant to Rule 13a-14 or 15d-14 of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

10.28\*#

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

<sup>\*</sup> Previously filed

## **Financial Statements**

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

## **Financial Statement Schedules**

None

None

# Item 16. Form 10-K Summary

<sup>\*\*</sup> Filed or furnished herewith, as applicable

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

<sup>#</sup> Management Contract or Compensatory Arrangement.

## **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 3, 2022.

# 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 3, 2022.

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

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

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

#### **CAPITAL STOCK**

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

## **Authorized and Outstanding Shares**

Our authorized share capital consists of (i) an unlimited number of common shares, without par value, (ii) an unlimited number of preferred shares, without par value, and (iii) 1,164,000 Series A Participating Convertible Preferred Shares. As of March 3, 2022 there were (a) 148,641,736 common shares outstanding and (b) 0 Series A Participating Convertible Preferred Shares outstanding. None of our common shares or preferred shares are held by us or on behalf of us.

# **Voting Rights**

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

#### **Dividends**

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

## **Liquidation Rights**

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

# Other Rights and Preferences.

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

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

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

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

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

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

# The Nasdaq Global Select Market

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

# **Transfer Agent and Registrar**

The transfer agent and registrar for our common shares is AST Trust Company (Canada).

#### INDEMNITY AGREEMENT

THIS AGRE	<b>EMENT</b> , having an effective date of (" <b>Effective Date</b> "), is entered into <b>BY</b> and <b>BETWEEN</b> :
	<b>ARBUTUS BIOPHARMA CORPORATION</b> , a company duly incorporated under the laws of the Province of British Columbia, and having an office at 701 Veterans Circle, Warminster, PA 18974
	(the "Indemnitor")
AND:	
	<b>[insert name]</b> , with an address c/o 701 Veterans Circle, Warminster, PA 18974 USA
	(the "Indemnitee")

#### WHEREAS:

- (A) the Indemnitor has requested the Indemnitee to act as a director or officer of the Indemnitor and may ask the Indemnitee to act in a similar capacity with affiliates of the Indemnitor; and
- (B) the Indemnitee has agreed, subject to the granting of the indemnities and releases herein provided for, to act as a director or officer of the Indemnitor and act in a similar capacity with affiliates of the Indemnitor if requested;

**NOW THEREFORE** in consideration of these premises, the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which is acknowledged by each of the parties hereto, the parties hereto covenant and agree as set forth below.

#### 1. INDEMNITY

- 1.1 Subject to §1.2, and §2.6(b) below the Indemnitor shall indemnify and save harmless the Indemnitee, and the Indemnitee's successors, heirs and personal representatives (together with the Indemnitee, the "Indemnified Parties") against and from:
  - (a) any and all actions and claims, whether current, threatened, pending or completed, whether civil, criminal, quasicriminal or administrative, of every nature and kind whatsoever which may be brought or made by any person, firm, corporation or government, or by any governmental department, body, commission, board, bureau, agency or instrumentality against the Indemnified Parties in connection with the Indemnitee's execution of the duties of his office held as a director or officer with the Indemnitor or any affiliate of the Indemnitor from time to time;
  - (b) any and all costs, damages, charges, expenses (including legal fees and disbursements, on a full indemnity basis), fines, liabilities (statutory or otherwise), losses and penalties which the Indemnitee may sustain, incur or be liable for in consequence of his acting as a director or officer of the Indemnitor or any affiliate of the Indemnitor from

time to time, whether sustained or incurred by reason of the Indemnitee's negligence, default, breach of duty, breach of trust, failure to exercise due diligence or otherwise in relation to the Indemnitor or any of its affiliates from time to time, or any of their respective affairs;

- (c) without in any way limiting the generality of the foregoing, any and all costs, damages, charges, expenses (including legal fees and disbursements on a full indemnity basis), fines, liabilities, losses and penalties which the Indemnified Parties may sustain, incur or be liable for as a result of or arising by operation of statute and incurred by or imposed upon the Indemnified Parties in relation to the affairs of the Company in the Indemnitee's capacity as director or officer, including but not limited to, all statutory obligations to creditors, employees, suppliers, contractors, subcontractors and any government or agency or division of any government, whether federal, provincial, state, regional or municipal whether existing at the date hereof or incurred hereafter; and
- (d) without in any way limiting the generality of the foregoing, the Indemnitor agrees that should any payment or reimbursement made pursuant to this Agreement, including without limitation the payment of insurance premiums or any payment made by an insurer under an insurance policy, be deemed to constitute a taxable benefit or otherwise be or become subject to any tax or levy upon the Indemnified Parties, then the Indemnitor shall pay such amount as may be necessary to ensure that the amount received by or on behalf of the Indemnified Parties, after the payment of or withholding for such tax, fully reimburses the Indemnified Parties for the actual cost, expense or liability incurred by or on his or her behalf.
- 1.2 Notwithstanding the provisions of §1.1, the Indemnitor shall not be obligated to indemnify or save harmless the Indemnified Parties against and from any action, claim, cost, damage, charge, expense, fine, liability, loss or penalty:
  - (a) if in respect thereof the Indemnitee failed to act honestly and in good faith with a view to the best interests of the Indemnitor or its affiliate as the case may be;
  - (b) in the case of a criminal or administrative action or proceeding, if the Indemnitee did not have reasonable grounds for believing that his conduct was lawful;
  - (c) arising out of any act, error or omission of the Indemnitee that is fraudulent or malicious and that is committed by the Indemnitee with actual fraudulent or malicious purpose or intent; or
  - (d) for which he is entitled to indemnity pursuant to any valid and collectible policy of insurance, to the extent of such insurance. Where partial indemnity is provided by such policy of insurance, the obligation of the Indemnitor under §1.1 shall continue in effect but be limited to that portion of the liability for which indemnity is not provided by such policy.
- 1.3 The determination of any claim by judgment, order, settlement or conviction, or upon a plea of "nolo contendere" or its equivalent, will not, of itself, create any presumption for the purposes of this Agreement that the Indemnitee did not act honestly and in good faith with a view to the best interests of the Indemnitor or with the care, diligence, and skill of a reasonably prudent person or, in the case of a criminal or administrative action or proceeding, that he did not have reasonable grounds for believing that his conduct was lawful (unless the judgment or order of a court specifically finds otherwise) or that the Indemnitee had committed wilful neglect or gross default.

#### 2. DEFENSE

- 2.1 For the purposes of this section 2:
  - "**Action**" means any action, inquiry, investigation, suit or other proceeding before a court or other tribunal in which a Claim is brought, made or advanced by or against the Indemnitee;
  - "Claim" means any allegation of charge, claim, cost, damage, expense, fine, liability, loss or penalty contemplated by §1.1:
  - "Judgment" means an award of damages or other monetary compensation made in an Action or any amounts the Indemnitee is ordered to pay by any court or other tribunal or any government, governmental department, body, commission, board, bureau, agency or instrumentality having proper jurisdiction as a result of any Claim brought, made or advanced of or against the Indemnitee; and
  - "Settlement" means an agreement to compromise a Claim or an Action.
- 2.2 Upon the Indemnitee becoming aware of any pending or threatened Claim or Action, the Indemnitee must provide written notice of it to the Indemnitor as soon as is reasonably practicable.
- 2.3 The Indemnitor shall have full power and authority to conduct such investigation of each Claim as is reasonably necessary in the circumstances and shall pay all costs of such investigation.
- 2.4 Subject to this subsection and §2.6(b), the Indemnitor shall defend, on behalf of the Indemnitee, any Claim or Action, even if the basis for the Claim or Action is groundless, false or fraudulent. If the Indemnitor has reasonable grounds for believing that any of the circumstances described in §1.2 apply to the Claim or Action, then the Indemnitor, upon giving the Indemnitee written notice of its belief and the grounds therefore, may refuse to so defend the Claim or Action, but such refusal shall not relieve the Indemnitor from any of its obligations of indemnity hereunder if it has determined that none of the provisions of §1.2 apply to the Claim or Action.
- 2.5 The Indemnitor shall consult with and pay reasonable heed to the Indemnitee concerning the appointment of any defence counsel to be engaged by the Indemnitor in fulfillment of its obligation to defend a Claim or Action, pursuant to §2.4.
- 2.6 With respect to a Claim or Action for which the Indemnitor is obliged to indemnify the Indemnitee hereunder:
  - (a) the Indemnitor may conduct negotiations towards a Settlement and, with the written consent of the Indemnitee (which the Indemnitee agrees not to unreasonably withhold), the Indemnitor may make such Settlement as it (in its sole judgment) deems appropriate or expedient in the circumstances, provided, however, that the Indemnitee shall not be required, as part of any proposed Settlement, to admit liability or agree to indemnify the Indemnitor in respect of, or make contribution to, any compensation or other payment for which provision is made by such Settlement; and
  - (b) if the Indemnitee fails to give his consent to the terms of a proposed Settlement which is otherwise acceptable to the Indemnitor and the claimant, the Indemnitor may require the Indemnitee to negotiate or defend the Claim or Action independently of the Indemnitor and in such event any amount recovered by such claimant in excess of the

amount for which Settlement could have been made by the Indemnitor, shall not be recoverable under this Indemnity, it being further agreed by the parties that the Indemnitor shall only be responsible for legal fees and costs up to the time at which such Settlement could have been made.

- 2.7 The Indemnitor shall have the right to negotiate a Settlement in respect of any Claim or Action which is founded upon any of the acts specified in §1.2. In the event that the Indemnitor negotiates a Settlement in respect of any of the acts specified in §1.2, the Indemnitee shall pay any compensation or other payment for which provision is made under the Settlement and shall not seek indemnity or contribution from the Indemnitor, within 60 days of the Indemnitor making demand therefor, all fees, costs and expenses (including legal fees and disbursements on a full indemnity basis) which result from the defence of the Claim or the Action in respect of which the Settlement was made, including the cost of any investigation undertaken by the Indemnitor in connection therewith, to the date the Settlement was made.
- 2.8 The Indemnitor shall pay any Judgment which may be given against the Indemnitee unless any of the circumstances set out in §1.2 applies to the Action in respect of which the Judgment is given or unless and to the extent the Indemnitee is otherwise entitled to indemnity under the policy of insurance as contemplated by §1.2(d) in either case, the Indemnitee shall pay to the Indemnitor, within 60 days of the Indemnitor making demand therefore, all, fees, costs and expenses (including legal fees and disbursements on a full indemnity basis) which result from the defence and appeal of the Action, including the costs of any investigation undertaken by the Indemnitor in connection with the Action.
- 2.9 Upon the request of the Indemnitee and subject to the restrictions set out in the *Business Corporations Act* (British Columbia), the Indemnitor shall pay the expenses of the Indemnitee incurred in relation to a Claim or an Action indemnified hereunder, provided the Indemnitee hereby gives an undertaking to repay such expenses if it is finally determined that such payments are not indemnifiable under this agreement or prohibited by the *Business Corporations Act* (British Columbia).

### 3. GENERAL

- 3.1 Nothing herein contained shall in any way affect the Indemnitee's right to resign from his position as director or officer of the Indemnitor at any time.
- 3.2 The indemnity and release herein provided for shall survive the termination of the Indemnitee's position as director or officer of the Indemnitor, the termination of this Agreement, and shall continue in full force and effect thereafter.
- 3.3 This Agreement supersedes all prior agreements between the parties with respect to its subject matter. Notwithstanding the forgoing, nothing in this Agreement shall be deemed to diminish or otherwise restrict an Indemnified Party's right to indemnification under any provision of the Indemnitor's articles or under applicable corporate law.
- 3.4 Unless stated otherwise, all monies to be paid hereunder shall be paid within 10 days of becoming payable.
- 3.5 The Indemnitee acknowledges that he has been advised to obtain independent legal advice with respect to entering into this Agreement, that he has obtained such independent legal advice or has expressly waived such advice, and that he is entering into this Agreement with full knowledge of the contents hereof, of his own free will and with full capacity and authority to do so.

- 3.6 If any provision of this Agreement is determined to be invalid or unenforceable in whole or in part, such invalidity or unenforceability shall attach only to such provision or part thereof and the remaining part of such provision and all other provisions hereof shall continue in full force and effect. The parties hereto agree to negotiate in good faith to agree to a substitute provision which shall be as close as possible to the intention of any invalid or unenforceable provision as may be valid or enforceable. The invalidity or unenforceability of any provision in any particular jurisdiction shall not affect its validity or enforceability in any other jurisdiction where it is valid or enforceable.
- 3.7 Each party hereto agrees to do all such things and take all such actions as may be necessary or desirable to give full force and effect to the matters contemplated by this Agreement.
- 3.8 This Agreement shall enure to the benefit of and be binding upon the parties hereto and their respective heirs, executors, administrators, legal representatives, successors and permitted assigns.
- 3.9 Time shall be of the essence of this Agreement.
- 3.10 This Agreement and the application or interpretation hereof shall be governed exclusively by its terms and by the laws of the Province of British Columbia and the laws of Canada applicable therein and the parties hereto hereby irrevocably attorn to the jurisdiction of the courts of the Province of British Columbia.

**IN WITNESS WHEREOF** parties hereto have duly executed this Agreement as of the date first written above.

#### ARBUTUS BIOPHARMA CORPORATION

Per:	
Authorized	Signatory

Signed, Sealed and Delivered by[insert name] in the presence of:	
Witness (Signature)	) ) [insert name and sign above]
Name (please print)	) )
Address	
City, Province	
Occupation	

# Schedule to Exhibit 10.4

The following directors and executive officers are parties to an Indemnity Agreement with the Company, each of which are substantially identical in all material respects to the representative Indemnity Agreement filed herewith as Exhibit 10.4 except as to the name of the signatory and the effective date of each signatory's Indemnity Agreement. The name of each signatory to the Indemnity Agreement is set forth below. The actual Indemnity Agreements are omitted pursuant to Instruction 2 to Item 601 of Regulation S-K.

# **INDEMNITEE**

William H. Collier David C. Hastings Michael J. McElhaugh Gaston Picchio PhD Michael J. Sofia PhD Elizabeth Howard PhD, JD

Frank Torti, MD
James Meyers
Daniel Burgess
Richard C. Henriques
Keith Manchester MD
Eric Venker MD, Pharm D
Andrew Cheng MD, PhD
Tram Tran, MD

**Exhibit 10.41** 

# TECHNOLOGY TRANSFER AND EXCLUSIVE LICENSE AGREEMENT

between

**Arbutus Biopharma Corporation** 

and

Qilu Pharmaceutical Co., Ltd.

**December 13, 2021** 

# TABLE OF CONTENTS

Page

# ARTICLE 1 DEFINITIONS 1

#### ARTICLE 2 LICENSE 17

- 2.1 License Grant to Qilu 17
- 2.2 Right of First Negotiation Granted to Qilu 18
- 2.3 Right to Sublicense. 18
- 2.4 Right to Subcontract 19
- 2.5 Technology Transfer 19
- 2.6 No Implied Licenses 19

# ARTICLE 3 GOVERNANCE 20

- 3.1 Alliance Managers 20
- 3.2 Joint Steering Committee 20
- 3.3 Membership 21
- 3.4 Meetings; Reports 21
- 3.5 Decision-Making; Escalation to Executive Officers 21

# ARTICLE 4 DEVELOPMENT AND REGULATORY MATTERS 22

- 4.1 Development Obligations 22
- 4.2 Development Reports 25
- 4.3 Regulatory Activities 25
- 4.4 Right of Reference and Use 27
- 4.5 Data Exchange and Use 27
- 4.6 Adverse Events Reporting 27
- 4.7 No Harmful Actions 28
- 4.8 Notice of Regulatory Action 28
- 4.9 Arbutus Support 28

#### ARTICLE 5 MANUFACTURE AND SUPPLY 29

- 5.1 Supply Obligations 29
- 5.2 Clinical Supply Agreement 30
- 5.3 Commercial Supply Agreement 30
- 5.4 Supply to Arbutus 30
- 5.5 Manufacturing Technology Transfer. 30
- 5.6 Transfer of the Arbutus Materials 32

#### ARTICLE 6 COMMERCIALIZATION 32

- 6.1 Commercialization Obligations 32
- 6.2 Commercialization Reports 33
- 6.3 Licensed Product Trademarks 33

i

- 6.4 No Other Trademark Rights 34
- 6.5 Diversion 34

#### ARTICLE 7 PAYMENTS 35

- 7.1 Upfront Payment 35
- 7.2 Development and Regulatory Milestones 35
- 7.3 Manufacturing Technology Transfer Completion Payment 36
- 7.4 Sales Milestones 36
- 7.5 Royalty Payments to Arbutus 37
- 7.6 Taxes 39
- 7.7 Financial Audits 40
- 7.8 Form of Payment 40

#### ARTICLE 8 CONFIDENTIALITY; PUBLICATION 41

- 8.1 Confidential Information 41
- 8.2 Non-Disclosure and Non-Use Obligation 42
- 8.3 Return of Confidential Information 42
- 8.4 Exemption 42
- 8.5 Permitted Disclosures 42
- 8.6 Disclosure of Agreement 43
- 8.7 Publicity; Use of Name and Logo 44
- 8.8 Publications 44
- 8.9 Engaging Individuals 44
- 8.10 Survival 44

### ARTICLE 9 REPRESENTATIONS, WARRANTIES, AND COVENANTS 45

- 9.1 Representations and Warranties of Each Party 45
- 9.2 Representations and Warranties of Arbutus 45
- 9.3 Debarment; Exclusion; Disqualification 47
- 9.4 Covenants of Arbutus 47
- 9.5 Covenants of Qilu 48
- 9.6 Compliance with Anti-Corruption Laws 49
- 9.7 Compliance with Law 50
- 9.8 Data Protection 50
- 9.9 NO OTHER WARRANTIES 51

#### **ARTICLE 10 INDEMNIFICATION 51**

- 10.1 By Qilu 51
- 10.2 By Arbutus 51
- 10.3 Indemnification Procedure 52
- 10.4 Mitigation of Loss 53
- 10.5 Limitation of Liability 53

ii

#### 10.6 Insurance 53

## ARTICLE 11 INTELLECTUAL PROPERTY 53

- 11.1 Ownership 53
- 11.2 Patent Prosecution 55
- 11.3 Patent Enforcement 56
- 11.4 Infringement of Third Party Rights 57
- 11.5 Qilu Territory Trademarks 59
- 11.6 Common Interest Agreement 60
- 11.7 Registration Obligations 60

# ARTICLE 12 TERMS AND TERMINATION 60

- 12.1 Term 60
- 12.2 Termination 61
- 12.3 Effect of Termination 62
- 12.4 Rights in Insolvency 64
- 12.5 Accrued Rights 64
- 12.6 Survival 64
- 12.7 Certain Additional Remedies of Qilu in Lieu of Termination 64

## ARTICLE 13 MISCELLANEOUS 64

- 13.1 Force Majeure 64
- 13.2 Assignment 65
- 13.3 Severability 65
- 13.4 Notices 65
- 13.5 Governing Law 66
- 13.6 Internal Resolution 66
- 13.7 Binding Arbitration 66
- 13.8 Headings 67
- 13.9 Independent Contractors 67
- 13.10 Waiver 68
- 13.11 Waiver of Rule of Construction 68
- 13.12 Cumulative Remedies; Recovery of Damages 68
- 13.13 Business Day Requirements 68
- 13.14 Further Actions 68
- 13.15 Construction 68
- 13.16 Entire Agreement; Amendments 69
- 13.17 Counterparts 69

#### TECHNOLOGY TRANSFER AND EXCLUSIVE LICENSE AGREEMENT

This **Technology Transfer and Exclusive License Agreement** (this "*Agreement*") is made as of December 13, 2021 (the "*Execution Date*"), by and between **Arbutus Biopharma Corporation**, a British Columbia corporation ("*Arbutus*"), having a place of business at 701 Veterans Circle, Warminster, PA 18974, USA, and **Qilu Pharmaceutical Co., Ltd.**, a company established pursuant to applicable laws and regulations of the People's Republic of China ("*Qilu*"), having a place of business at No. 8888 Lvyou Road, Jinan, Shandong 250104 China. Arbutus and Qilu are referred to in this Agreement individually as a "*Party*" and collectively as the "*Parties*."

#### **Recitals**

**Whereas**, Arbutus, a publicly-traded clinical-stage biopharmaceutical company primarily focused on discovering, developing and commercializing a cure for people with chronic hepatitis B virus ("*HBV*") infection, Controls (as defined below) the intellectual property and other rights related to AB-729, a subcutaneously-delivered RNAi therapeutic targeted to hepatocytes using Arbutus' novel covalently conjugated GalNAc delivery technology that is currently being developed for the treatment of HBV; and

**Whereas**, Qilu is interested in obtaining an exclusive license under such intellectual property and other rights to Exploit Licensed Products in the Field in the Territory as defined below, and Arbutus is willing to grant such an exclusive license to Qilu, subject to the terms and conditions set forth herein.

**Now, Therefore**, in consideration of the foregoing premises and the covenants contained herein, the Parties hereby agree as follows:

# ARTICLE 1 DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below:

**1.1** "Accounting Standards" means, (a) with respect to Arbutus, its Affiliates and Third Party Licensees, generally accepted accounting principles as practiced in the United States ("US GAAP"); (b) with respect to Qilu and its Affiliates, Accounting Standards for Business Enterprises as promulgated by Chinese Accounting Standards Committee of Ministry of Finance of PRC or its successor organization ("China GAAP"); or (c) with respect to Sublicensees, US GAAP, China GAAP, International Financial Reporting Standards, or other generally accepted accounting principles as adopted by such Sublicensees under the Applicable Laws of the respective jurisdictions of their incorporation, as applicable, in each case of (a)-(c), which principles or standards are currently used at the relevant time and consistently applied by the applicable Person.

- **1.2** "Acquiring Entity" means a Third Party (the "Acquiror") that acquires a Party (and is therefore deemed to be an Affiliate of such Party) through a Change of Control, together with any Affiliates of such Acquiror existing immediately prior to the consummation of the Change of Control. For purposes of clarity, an "Acquiring Entity" of a Party shall exclude (a) the Party and all of its Affiliates existing immediately prior to the consummation of the Change of Control and (b) any Person that becomes an Affiliate of the Acquiror following the consummation of the Change of Control, and not as a result of the Change of Control.
  - **1.3** "*Acquiror*" has the meaning set forth in <u>Section 1.2</u>.
  - **1.4** "Additional Cure Period" has the meaning set forth in Section 12.2(b)(ii).
- **1.5** "*Additional Compound*" means any RNAi compound (other than the Licensed Compound) (i) which contains AB-729 [\*\*\*], and (ii) the Development, Manufacture, use or sale of which would infringe any Valid Claim within the Arbutus Patents but for ownership thereof or a license granted thereto.
- **1.6** "*Additional Product*" means any drug substance materials and pharmaceutical product containing an Additional Compound, in all forms, presentations, formulations and dosage forms.
- **1.7** "Affiliate" means, with respect to any Person, any entity controlling, controlled by or under common control with such first Person, at the time that the determination of affiliation is made and for as long as such control exists. For the purpose of this definition only, "control" (including, with correlative meaning, the terms "controlled by" and "under the common control") means (a) direct or indirect ownership of fifty percent (50%) or more of the stock or shares having the right to vote for the election of directors of such Person (or if the jurisdiction where such Person is domiciled prohibits foreign ownership of such entity, the maximum foreign ownership interest permitted under such Applicable Laws; <u>provided</u>, <u>however</u>, that such ownership interest provides actual control over such Person), (b) status as a general partner in any partnership, or (c) the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise.
  - **1.8** "*Agreement*" has the meaning set forth in the Preamble.
  - **1.9** "*Alliance Manager*" has the meaning set forth in Section 3.1.
- **1.10** "Annual Net Sales" means total Net Sales by Qilu, its Affiliates and Sublicensees in the Territory of all Licensed Products in a particular Calendar Year, calculated in accordance with Accounting Standards consistently applied.
  - **1.11** "Anti-Corruption Laws" has the meaning set forth in Section 9.6(a)(i).

- 1.12 "Applicable Laws" means individually and collectively, any federal, state, local, national and supra-national laws, treaties, statutes, ordinances, rules and regulations, including any rules, regulations, guidance, guidelines or requirements having the binding effect of law of national securities exchanges, automated quotation systems or securities listing organizations, Regulatory Authorities, courts, tribunals, Governmental Authorities other than Regulatory Authorities, legislative bodies and commissions that are in effect from time to time during the Term and applicable to a particular activity hereunder. Applicable Laws shall include cGCP, cGLP, cGMP and cGVP, as defined below.
- **1.13** "*Applicable Territory*" means (a) with respect to Qilu, the Territory, and (b) with respect to Arbutus, the ROW Territory.
- **1.14** "*Approval*" means any consent, authorization, order, confirmation, qualification, permission, certification, approval, record-filing, registration, license, permit, designation and/or declaration or other act by a Governmental Authority approving or consenting to a request or application.
  - **1.15** "*Arbutus*" has the meaning set forth in the Preamble.
  - **1.16** "Arbutus Indemnitees" has the meaning set forth in Section 10.1.
  - **1.17** "*Arbutus IP*" means the Arbutus Know-How and the Arbutus Patents.
- **1.18** "*Arbutus Know-How*" means all Know-How Controlled by Arbutus or its Affiliates as of the License Effective Date or that comes into the Control of Arbutus or its Affiliates at any time during the Term, including Arbutus Materials and any Know-How included within the Arbutus New IP and the Joint New IP, that is necessary or reasonably useful to Exploit the Licensed Compound or the Licensed Products in the Field in the Territory.
- **1.19** "*Arbutus Materials*" means any materials included within the Arbutus Know-How to be provided by Arbutus to Qilu that are set forth on Exhibit 1.19.
  - **1.20** "*Arbutus New IP*" has the meaning set forth in Section 11.1(b)(ii).
- **1.21** "*Arbutus Patents*" means all Patent Rights that are Controlled by Arbutus or its Affiliates as of the License Effective Date or that come into the Control of Arbutus or its Affiliates at any time during the Term, including any Patent Rights included within the Arbutus New IP and the Joint New IP, that Cover the Licensed Compound or Licensed Products (including composition of matter and methods of using or making the Licensed Compound or Licensed Products), or are otherwise necessary or reasonably useful to Exploit the Licensed Compound or Licensed Products in the Field in the Territory. The Arbutus Patents as of the Execution Date are set forth in Exhibit 1.21, which shall be updated by Arbutus on a quarterly basis.
  - **1.22** "*Arbutus Support*" has the meaning set forth in <u>Section 4.9</u>.

- **1.23** "*Arbutus Support Cap*" has the meaning set forth in <u>Section 4.9</u>.
- **1.24** "Arbutus Territory Regulatory Documents" has the meaning set forth in Section 4.3(a).
- **1.25** "*Arbutus Unlicensed Compounds*" means any proprietary compounds or therapeutic agents owned or controlled by Arbutus or its Affiliates other than AB-729.
  - **1.26** "*Auditor*" has the meaning set forth in <u>Section 7.7</u>.
- **1.27** "Bankruptcy Code" means Title 11, U.S. Code or foreign equivalent laws, including the PRC Enterprise Bankruptcy Law.
- **1.28** "*Batch Records*" means the final executed batch production records for a single batch of Licensed Compound Manufactured for use by Arbutus in Clinical Trials.
- **1.29** "Biosimilar Product" means, with respect to a Licensed Product in a Relevant Region, any product (including a "generic product," "biogeneric," "follow-on biologic," "follow-on biological product," "follow-on protein product," "similar biological medicinal product," or "biosimilar product") (a) approved by the relevant Regulatory Authority in such Relevant Region based on a determination by such Regulatory Authority or by Applicable Law that such product is "similar," "comparable," "interchangeable," "bioequivalent," or "biosimilar" to such Licensed Product in such Relevant Region, and (b) that is (i) sold in the same Relevant Region (or is commercially available in the same Relevant Region via import from another country or region) as such Licensed Product by any Third Party that is not a Sublicensee, and (ii) not Manufactured by or on behalf of Qilu or any of its Affiliates or Sublicensees.
- **1.30** "*Business Day*" means a day other than a Saturday, Sunday or a day on which banking institutions in Philadelphia, Pennsylvania or in the Territory are required by Applicable Laws to remain closed.
- **1.31** "*Calendar Quarter*" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.
  - **1.32** *"Calendar Year"* means each twelve (12) month period commencing on January 1.
  - **1.33** "*CDE*" means the Chinese Center for Drug Evaluation of the NMPA, or any successor entity thereto.
- 1.34 "cGCP" means current Good Clinical Practices as defined in Parts 50, 56 and 312 of Title 22 of the U.S. Code of Federal Regulations, as may be amended from time to time, or any successor thereto or foreign equivalents thereof, including Good Clinical Practice for Drugs (i.e. 药物临床试验质量管理规范) promulgated by NMPA and the National Health Commission effective as of July 1, 2020, together with any guidelines and/or implementation rules issued by NMPA in connection therewith, in each case as amended from time to time.

- **1.35** "*cGLP*" means current Good Laboratory Practices as defined in Part 58 of Title 21 of the U.S. Code of Federal Regulations, as may be amended from time to time, or any successor thereto and foreign equivalents thereof.
- 1.36 "cGMP" means current Good Manufacturing Practices as defined in Parts 210 and 211 of Title 21 of the U.S. Code of Federal Regulations, as may be amended from time to time, or any successor thereto and foreign equivalents thereof, including Good Manufacturing Practice for Drugs (i.e.药品生产质量管理规范) promulgated by the Ministry of Health of China effective as of March 1, 2011, as may be amended from time to time.
- 1.37 "cGVP" means current Good Pharmacovigilance Practices applicable to the conduct of specific pharmacovigilance activities by a Person in the European Union based upon Article 108a of Directive 2001/83/EC (until repealed in its entirety), 536/2014/EU, by the European Medicines Agency, all other applicable rules, regulations, orders, guidances, guidelines (including those issued by the International Council on Harmonization or other industry or nongovernmental standards), in the United States pursuant to the Federal Food, Drug, and Cosmetics Act, as may be amended and supplemented from time to time, and implementing regulations, including such extraterritorial jurisdiction as may be applicable to adverse events or experience or medical device reports required to be reported to the USFDA (including access to original data as may be requested from time to time by USFDA), the reporting and data management and storage requirements of the World Health Organisation and the World Health Organisation Collaborating Centre for International Drug Monitoring Centre located in Uppsala Sweden (Uppsala Monitoring Centre) and equivalent or comparable non-United States and non-European Union regulations, rules, orders, guidances and standards, as applicable, including Good Pharmacovigilance Practices (药物警戒质量管理规范) promulgated by NMPA and effective as of December 1, 2021, in each case as may be amended from time to time.
- 1.38 "Change of Control" means, with respect to a Party, any of the following: (a) the sale or disposition of all or substantially all of the assets of such Party or its direct or indirect controlling Affiliate to a Third Party, other than to a Person of which more than fifty percent (50%) of the voting capital stock are owned after such sale or disposition by the Persons that were shareholders of such Party or its direct or indirect controlling Affiliate (in either case, whether directly or indirectly through any other Person) immediately prior to such transaction; or (b) (i) the acquisition by a Third Party, alone or together with any of its Affiliates, of more than fifty percent (50%) of the outstanding shares of voting capital stock of such Party or its direct or indirect controlling Affiliate, or (ii) the acquisition, merger or consolidation of such Party or its direct or indirect controlling Affiliate with or into another Person, other than, in the case of this clause (b), an acquisition or a merger or consolidation of such Party or its controlling Affiliate, as the case may be, immediately prior to such acquisition, merger or consolidation will beneficially own, directly or indirectly, at least fifty percent (50%) of the shares of voting capital stock of the acquiring Third Party or the surviving corporation in such acquisition, merger or consolidation, as the case may be, immediately after such acquisition, merger or consolidation. Notwithstanding the foregoing, any transaction or series of transactions effected for the sole purpose of changing the form or jurisdiction of organization of such Party will not be deemed a "Change of Control" for purposes of this Agreement.

- **1.39** "*China*" or "*PRC*" means, for the purpose of this Agreement, the People's Republic of China, excluding Hong Kong, Macau and Taiwan.
  - **1.40** *"China GAAP"* has the meaning set forth in <u>Section 1.1</u>.
  - **1.41** *"Clinical Supply Agreement"* has the meaning set forth in <u>Section 5.2</u>.
  - **1.42** *"Clinical Trial"* means any clinical trial in humans of a pharmaceutical or biological compound or product.
  - **1.43** "*CMO*" means a Third Party contract manufacturing organization.
- **1.44** "Combination Product" means a Licensed Product that, in addition to containing the Licensed Compound as an active pharmaceutical ingredient, is co-formulated with at least one other active pharmaceutical ingredient or therapeutic agent that is not the Licensed Compound (the "Other Component").
  - **1.45** "*Commercial Supply Agreement*" has the meaning set forth in <u>Section 5.3</u>.
- **1.46** "*Commercialize*" or "*Commercialization*" means to market, promote, advertise, exhibit, distribute (including storage for distribution or inventory), detail, sell (including to offer for sale or contract to sell) or otherwise commercially exploit (including to conduct pricing and reimbursement activities) a pharmaceutical or biological compound or product, or to conduct any activities directed to any of the foregoing (including importing and exporting activities in connection therewith).
- **1.47** "*Commercially Reasonable Efforts*" means, with respect to a Party, efforts that are consistent with the efforts and resources commonly used in the pharmaceutical industry by a company of comparable size in connection with the research, development and commercialization of a pharmaceutical product owned by it or to which it has exclusive rights, with similar product characteristics, which is of similar market potential at a similar stage in its development or product life.
  - **1.48** "*Confidential Information*" has the meaning set forth in <u>Section 8.1</u>.
- **1.49** "Control" or "Controlled" means, with respect to any Patent Rights, Know-How, other intellectual property right, compounds, molecules or Confidential Information, the ability of a Party (whether through ownership, license or sublicense (other than a license, sublicense or other right granted pursuant to this Agreement)) to grant to the other Party the licenses, sublicenses or rights as provided herein, or to otherwise disclose or provide such intellectual property, compounds, molecules or Confidential Information to the other Party, without violating the terms of any then-existing agreement with any Third Party at the time such Party would be required hereunder to grant the other Party such license, sublicenses or rights as provided herein or to otherwise disclose or provide such intellectual property, compounds, molecules or Confidential Information to the other Party. Notwithstanding the foregoing, a Party will be deemed not to Control any intellectual property (including Patent Rights or Know-How), compounds, physical, biological or chemical materials or Confidential Information that are owned or in-licensed by an

Acquiring Entity except (1) with respect to any such intellectual property (including Patent Rights or Know-How) arising as a result of activities of employees or consultants of the Acquiring Entity who participate in activities or have access to Confidential Information of either Party under this Agreement after a Change of Control; (2) to the extent that any such intellectual property (including Patent Rights or Know-How) is included in or used in furtherance of a Party's activities under this Agreement by the Acquiring Entity or its Affiliates after a Change of Control; or (3) to the extent that any such intellectual property (including Patent Rights or Know-How) is used by the acquired Party or the Acquiring Entity or their respective Affiliates to Exploit the Licensed Compound or Licensed Products.

- **1.50** "*Cover*" means, with respect to a product, technology, process, method or mode of administration that, in the absence of ownership of or a license granted under a particular Patent Right, the Manufacture, use, offer for sale, sale or importation of such product or composition of matter or the practice of such technology, process, method or mode of administration would infringe a claim of such Patent Right or, in the case of a claim of a Patent Right that has not yet issued, would infringe such claim if it were to issue without change.
  - **1.51** "*CRO*" means a contract research organization.
  - **1.52** "*CSO*" means a contract sales organization.
  - **1.53** "*Debarred*" has the meaning set forth in <u>Section 9.3</u>.
  - **1.54** "*Defaulting Party*" has the meaning set forth in <u>Section 12.2(b)(ii)</u>.
- **1.55** "*Develop*" or "*Development*" means to conduct any non-clinical, CMC or clinical drug research or development activities, whether before or after Regulatory Approval, including drug metabolism and pharmacokinetics, translational research, toxicology, pharmacology, test method development and stability testing, process and packaging development and improvement, process validation, process scale-up, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, conduct of Clinical Trials, regulatory affairs, the preparation and submission of regulatory filings, Clinical Trial regulatory activities, or any other activities directed towards obtaining or maintaining Regulatory Approval of any pharmaceutical or biological compound or product. Development includes use and importation of the relevant compound or product to conduct such Development activities. Development does not include Commercialization activities.
  - **1.56** "*Development Milestone Event*" has the meaning set forth in <u>Section 7.2</u>.

- **1.57** "*Development Milestone Payment*" has the meaning set forth in <u>Section 7.2</u>.
- **1.58** "*Development Participation Right*" has the meaning set forth in <u>Section 4.1(f)</u>.
- **1.59** "*Development Plan*" has the meaning set forth in <u>Section 4.1(b)</u>.
- **1.60** "*Disclosing Party*" has the meaning set forth in <u>Section 8.1</u>.
- **1.61** "*Disqualified*" has the meaning set forth in <u>Section 9.3</u>.
- **1.62** "*Dollar*" or "\$" means the U.S. dollar, and "\$" shall be interpreted accordingly.
- **1.63** "*Excluded*" has the meaning set forth in <u>Section 9.3</u>.
- **1.64** "*Execution Date*" has the meaning set forth in the Preamble.
- **1.65** "*Executive Officers*" means the Chief Executive Officer of Arbutus and the Chief Executive Officer of Qilu, or their respective designees.
- **1.66** "*Existing Confidentiality Agreement*" means that certain Mutual Non-Disclosure Agreement, dated May 24, 2021, between Arbutus and Qilu.
- **1.67** "*Exploit*" or "*Exploitation*" means, with respect to any pharmaceutical or biological compound or product, to Develop, Manufacture, have Manufactured, use, Commercialize, import, export, obtain and maintain Regulatory Approvals and applicable pricing or reimbursement approvals.
  - **1.68** "*Field*" means the treatment or prevention of HBV infection.
- **1.69** "*First Commercial Sale*" means, with respect to a given Licensed Product in a Relevant Region, the first sale of such Licensed Product by Qilu, its Affiliates or Sublicensees in an arm's length transaction to a Third Party (other than a Sublicensee) in such Relevant Region in exchange for cash (or some equivalent to which value can be assigned) after Regulatory Approval for such Licensed Product has been granted in such Relevant Region.
- **1.70** "*Generic Competition*" with respect to a particular Licensed Product in a particular Relevant Region shall exist if, during any [\*\*\*], there is one or more Biosimilar Products with respect to such Licensed Product being sold in such Relevant Region and the sales of such Biosimilar Product(s) in such Relevant Region account for [\*\*\*] or more of the market share in such Relevant Region. Market share shall be based on the aggregate market in such Relevant Region of such Licensed Product and such Biosimilar Product(s) (based on the number of units of such Licensed Product and such Biosimilar Product(s) in the aggregate sold in such Relevant Region, as reported by a well-known reporting service agreed between the Parties acting reasonably (e.g., IQVIA)).
  - **1.71** *"Global Trial"* has the meaning set forth in Section 4.1(f).

- **1.72** *"Global Trial Notice"* has the meaning set forth in Section 4.1(f).
- **1.73** "*Governmental Authority*" means any federal, state, national, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, or any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).
  - **1.74** "*HBV*" has the meaning set forth in the Recitals.
  - **1.75** "*Hong Kong*" has the meaning set forth in <u>Section 1.145</u>.
  - **1.76** "*ICC*" has the meaning set forth in <u>Section 13.7</u>.
  - 1.77 "Imported Drug License" means an imported drug license (进口药品注册证) issued by the NMPA.
- **1.78** "*IND*" means any investigational new drug application filed with the USFDA pursuant to Part 312 of Title 21 of the U.S. Code of Federal Regulations prior to beginning clinical trials in humans in the United States, or any equivalent filing in a country or regulatory jurisdiction other than the United States with the applicable Regulatory Authority.
  - **1.79** *"Indemnification Claim Notice"* has the meaning set forth in <u>Section 10.3.</u>
  - **1.80** "*Indemnified Party*" has the meaning set forth in Section 10.3.
  - **1.81** *"Indemnifying Party"* has the meaning set forth in <u>Section 10.3</u>.
  - **1.82** "*Initial Documentation*" has the meaning set forth in Section 4.3(a).
  - **1.83** "*Insolvency Event*" has the meaning set forth in Section 12.2(d).
- **1.84** "*Invention*" means any invention, discovery, technology, know-how, information or idea, trade secrets, knowledge, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, specifications data and results not generally known to the public (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, preclinical, clinical, safety, manufacturing, and quality control data and know-how, including study designs and protocols) in all cases, whether or not patentable, in written, electronic or any other form, that is conceived, discovered, developed or first actually reduced to practice by or on behalf of a Party, or by the Parties together, arising from or in the scope of activities to be conducted under this Agreement, but excluding any Product Data. For clarity, Inventions do not include any invention, discovery, technology, know-how, information or idea conceived, discovered, developed or first actually reduced to practice prior to the License Effective Date, or after the License Effective Date through activities conducted by a Party outside of the purpose of this Agreement.

- **1.85** "*Joint New IP*" has the meaning set forth in Section 11.1(b)(iii).
- **1.86** "JSC" has the meaning set forth in Section 3.2(a).
- **1.87** "*Know-How*" means any and all information or materials, including discoveries, improvements, modifications, processes, methods, assays, designs, protocols (including Clinical Trial protocols), formulas, data, inventions, algorithms, forecasts, profiles, strategies, plans, results, know-how and trade secrets (in each case, regardless of whether patentable, copyrightable or otherwise), but excluding any Patent Rights. For the avoidance of doubt, "Know-How" shall include Product Data and Regulatory Documents.
  - **1.88** "*License*" means the license granted by Arbutus to Qilu and its Affiliates pursuant to Section 2.1.
- **1.89** "*Licensed Compound*" means Arbutus' proprietary HBV RNAi agent known as AB-729, having the sequence and structure set forth on <u>Exhibit 1.89</u>.
  - **1.90** "*License Effective Date*" has the meaning set forth in Section 12.1.
- **1.91** "*Licensed Product*" means any pharmaceutical product that contains the Licensed Compound, either alone or in combination with one or more other active pharmaceutical ingredients or therapeutic agents, delivery systems or devices. For the avoidance of doubt, a Licensed Product does not include a pharmaceutical product that contains an Arbutus Unlicensed Compound.
- **1.92** "*Licensed Product Trademarks*" means the Trademark(s) used or anticipated to be used by a Party or its Affiliates or its Third Parties Licensees (in the case of Arbutus) or Sublicensees (in the case of Qilu) for the Exploitation of Licensed Products in such Party's Applicable Territory, and any registrations thereof or any pending applications relating thereto with any Governmental Authority.
  - **1.93** "*Licensed Product-Specific Trademarks*" has the meaning set forth in Section 6.3(b).
  - **1.94** "*Losses*" has the meaning set forth in <u>Section 10.1</u>.
- **1.95** "*MAA*" means a marketing authorization application, new drug application, biologics license application or similar application, as applicable, and all amendments and supplements thereto, submitted to the USFDA, NMPA, or any equivalent filing in a country or regulatory jurisdiction other than the U.S. or China with the applicable Regulatory Authority, to obtain marketing approval for a pharmaceutical or biologic product, in a country or in a group of countries, including in China, an application for an Imported Drug License and a domestic Drug Registration Certificate.

- **1.96** "*Macau*" has the meaning set forth in <u>Section 1.145</u>.
- **1.97** "*Manufacture*" or "*Manufacturing*" means to conduct or have conducted any activities directed to producing, making, scaling up, processing, formulating, filling, finishing, packaging, labeling, quality assurance testing and release, shipping, and storage at manufacturing facilities of any pharmaceutical or biological compound or product, or any component thereof (including production of drug substance and drug product, in bulk form, whether for Development or Commercialization).
  - **1.98** "Manufacturing Cost" means, [\*\*\*].
  - **1.99** "*Manufacturing Technology*" has the meaning set forth in <u>Section 5.5(a)</u>.
  - **1.100** "Manufacturing Technology Transfer" has the meaning set forth in Section 5.5(a).
- **1.101** "*Manufacturing Technology Transfer Completion*" means (a) delivery by Arbutus (or Arbutus' CMO(s) on behalf of Arbutus) to Qilu (or its permitted CMO or permitted Sublicensee) of the Manufacturing Technology in accordance with the Manufacturing Technology Transfer Plan, and (b) using the Manufacturing Technology transferred from Arbutus, completion of manufacturing of at least [\*\*\*] by Qilu (or its permitted CMO or permitted Sublicensee) at scale of at least [\*\*\*] of the Licensed Compound that is Manufactured timely and without regard to supply needs, with the quality of the manufactured Licensed Compound meeting the specifications approved by NMPA.
  - **1.102** "*Manufacturing Technology Transfer Plan*" has the meaning set forth in <u>Section 5.5(a)</u>.
  - **1.103** "*Negotiation Period*" has the meaning set forth in Section 2.2.
- **1.104** "Net Sales" means, with respect to a Licensed Product for any period, the total gross amount billed or invoiced on sales of such Licensed Product during such period by Qilu, its Affiliates, or Sublicensees in the Territory to Third Parties, in bona fide arm's length transactions, less the following deductions, in each case related specifically to the Licensed Product and actually incurred, paid or accrued by Qilu, its Affiliates or Sublicensees and not otherwise recovered by or reimbursed to Qilu, its Affiliates, or Sublicensees: [\*\*\*].

Subject to the above, Net Sales will be calculated in accordance with the applicable Accounting Standards, consistently applied.

**1.105** "*NMPA*" means the National Medical Products Administration in China, including its internal institutions such as the CDE, or any successor agency with a similar scope of responsibility regarding the regulation of human pharmaceutical and biological products in China.

- **1.106** "*Non-Defaulting Party*" has the meaning set forth in <u>Section 12.2(b)(ii)</u>.
- **1.107** "Other Component" has the meaning set forth in Section 1.44.
- **1.108** "*Participation Notice*" has the meaning set forth in <u>Section 4.1(f)</u>.
- **1.109** "*Parties*" or "*Party*" have the meaning set forth in the Preamble.
- **1.110** "*Party Vote*" has the meaning set forth in <u>Section 3.5</u>.
- **1.111** "*Patent Prosecution*" means activities directed to (a) preparing, filing and prosecuting applications (of all types) for any Patent Right, (b) managing any interference, opposition, re-issue, reexamination, supplemental examination, invalidation proceedings (including *inter partes* or post-grant review proceedings), revocation, nullification, or cancellation proceeding relating to the foregoing Patent Rights, (c) maintaining issued Patent Right(s), (d) listing in regulatory publications such as the Orange Book and its equivalents (as applicable), (e) obtaining patent term extensions, supplementary protection certificates and the like for issued Patent Right(s), and maintenance thereof, and (f) managing, including settling, any interference, opposition, reexamination, invalidation, revocation, nullification or cancellation proceeding relating to issued Patent Right(s).
- **1.112** "Patent Right" means (a) all patents and patent applications in any country or supranational jurisdiction, (b) any substitutions, divisionals, continuations, continuations-in-part, provisional applications, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates and the like of any such patents or patent applications, (c) foreign counterparts of any of the foregoing, (d) all applications claiming priority to any of the foregoing and (e) any patents issuing on any patent application identified in clauses (a) through (d).
- **1.113** "*Person*" means any individual, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture, unincorporated organization or association, or Governmental Authority.
  - **1.114** "*Pharmacovigilance Agreement*" has the meaning set forth in <u>Section 4.6</u>.
- **1.115** "*Phase I Clinical Trial*" means a clinical study for the first introduction into humans of a pharmaceutical or biological product to get information on product safety, tolerability, immunogenicity, pharmacological activity or pharmacokinetics, as described in federal regulation 21 C.F.R. § 312.21(a) or its foreign equivalents.
- **1.116** "*Phase II Clinical Trial*" means a clinical study in humans of the safety, dose ranging and efficacy of a pharmaceutical or biological product, as described in federal regulation 21 C.F.R. § 312.21(b) or its foreign equivalents.

- 1.117 "Phase III Clinical Trial" means a controlled clinical study, or a portion of a controlled study, in humans of the efficacy and safety of a pharmaceutical or biological product, which study (in its entirety or portion, as applicable), is prospectively designed to demonstrate statistically whether such pharmaceutical or biological product is effective and safe for use in a particular indication in a manner sufficient to file an application to obtain Regulatory Approval, as further defined in federal regulation 21 C.F.R. § 312.21(c) or its foreign equivalents. For clarity, with respect to what is commonly called a phase 2/3 study, the Phase III Clinical Trial definition is met upon the first patient, first visit in the portion of such study that is prospectively designed to demonstrate statistically whether such pharmaceutical or biological product is effective and safe for use in a particular indication in a manner sufficient to file an application to obtain Regulatory Approval, as further defined in federal regulation 21 C.F.R. § 312.21(c) or its foreign equivalents.
- **1.118** "*Product Data*" means any and all data relating to or arising out of the Development or Manufacture of the Licensed Compound or Licensed Products, or that is otherwise necessary or useful for the Exploitation of the Licensed Compound or Licensed Products in the Field in the Applicable Territory, including data collected or resulting from pre-clinical studies or Clinical Trials, CMC data, Manufacturing records and information, and supporting documentation (*e.g.*, protocols, format of case report forms, analysis plans) relating to pre-clinical studies, Clinical Trials or other Development or Manufacturing activities with respect to the Licensed Compound or Licensed Products.
  - **1.119** "*Product Infringement*" has the meaning set forth in <u>Section 11.3(b)(i)</u>.
  - **1.120** "*Qilu*" has the meaning set forth in the Preamble.
  - **1.121** "*Qilu Indemnitees*" has the meaning set forth in <u>Section 10.2</u>.
  - **1.122** "Qilu New IP" has the meaning set forth in Section 11.1(b)(i).
  - **1.123** "*Qilu Territory Trademarks*" has the meaning set forth in <u>Section 6.3(c)</u>.
  - **1.124** "*Receiving Party*" has the meaning set forth in <u>Section 8.1</u>.
- **1.125** "*Regulatory Approval*" means all Approvals, including if required by Applicable Laws, pricing Approvals, necessary for the marketing and sale of a pharmaceutical or biological product in a particular country or regulatory jurisdiction, which may include satisfaction of all applicable regulatory and notification requirements.
- **1.126** "*Regulatory Authority*" means any federal, national, supranational, state, provincial, directly administered municipality or local regulatory agency, department, bureau or other Governmental Authority, including the USFDA, the CDE and the NMPA, that has authority over the manufacture, development, commercialization or other use or exploitation (including the granting of Regulatory Approval) of any Licensed Product in any applicable regulatory jurisdiction.

- **1.127** "*Regulatory Documents*" means any filing, application or submission with any Regulatory Authority, including authorizations, approvals or clearances arising from the foregoing, including INDs, MAAs and Regulatory Approvals or their equivalents in any jurisdiction, and all written correspondence or written communication with or from the relevant Regulatory Authority, as well as minutes of any material meetings, telephone conferences or discussions with the relevant Regulatory Authority, in each case, with respect to the Licensed Compound or a Licensed Product.
- **1.128** "Regulatory-Based Exclusivity" means, on a Licensed Product-by-Licensed Product and Relevant Region-by-Relevant Region basis, that (a) Qilu or any of its Affiliates or Sublicensees has been granted the exclusive legal right by a Regulatory Authority (or is otherwise entitled to the exclusive legal right by operation of Applicable Law) in such Relevant Region to market and sell the Licensed Product or the active ingredient in such Licensed Product in such country, or (b) the data and information submitted by Qilu or any of its Affiliates or Sublicensees to the relevant Regulatory Authority in such Relevant Region for purposes of obtaining Regulatory Approval for such Licensed Product may not be disclosed, referenced or relied upon in any way by any Person to support the Regulatory Approval or marketing of any product by a Third Party in such country other than Qilu or its Affiliate or Sublicensee.
  - **1.129** "*Related Agreements*" has the meaning set forth in <u>Section 10.1</u>.
  - **1.130** "*Relevant Persons*" has the meaning set forth in <u>Section 9.5(d)</u>.
  - **1.131** "*Relevant Region*" has the meaning set forth in <u>Section 1.145</u>.
  - **1.132** "*Review Period*" has the meaning set forth in Section 4.1(f).
  - **1.133** "*ROW Territory*" means all countries of the world outside of the Territory.
- **1.134** "*Royalty Term*" means, with respect to a given Licensed Product in a Relevant Region, the period commencing on the First Commercial Sale of such Licensed Product in such Relevant Region and ending upon the later to occur of (a) the expiration of the last-to-expire Valid Claim of the Arbutus Patents that Cover such Licensed Product in such Relevant Region, (b) the expiration of Regulatory-Based Exclusivity for such Licensed Product in such Relevant Region, or (c) the tenth (10<sup>th</sup>) anniversary of the First Commercial Sale of such Licensed Product in such Relevant Region.
  - **1.135** "Sales Milestone Event" has the meaning set forth in Section 7.4.
  - **1.136** "Sales Milestone Payment" has the meaning set forth in Section 7.4.
  - **1.137** "Section 9.6 Representatives" has the meaning set forth in Section 9.6(a).
- **1.138** "*Subcontractor*" means CROs, CMOs, CSOs, distributors, wholesalers or similar vendors engaged by a Party to perform on such Party's behalf its activities under this Agreement.

- **1.139** "*Sublicensee*" means any Third Party to whom Qilu or any of its Affiliates grants a sublicense of the License, or any further sublicensee of such rights (regardless of the number of tiers, layers or levels of sublicenses of such rights).
  - **1.140** "Supply End Date" has the meaning set forth in Section 5.1.
- **1.141** "*Tax*" or "*Taxes*" means all forms of preliminary or finally imposed taxation, domestic and foreign taxes, fees, levies, duties and other assessments or charges of whatever kind (including sales, use, excise, stamp, transfer, property, value added, goods and services, withholding and franchise taxes but, for clarity, excluding income taxes and, except as may be agreed by the Parties otherwise, any other taxes levied on Arbutus or its Affiliates by any tax authority in the United States) together with any interest, penalties or additions payable in connection with such taxes, fees, levies duties and other assessments or charges.
  - **1.142** "*Technical Assistance*" has the meaning set forth in <u>Section 5.5(a)</u>.
  - **1.143** "Technical Assistance Cap" has the meaning set forth in Section 5.5(a).
  - **1.144** "*Term*" has the meaning set forth in <u>Section 12.1</u>.
- **1.145** "*Territory*" means the Greater Area of China, including (a) China, (b) the Hong Kong Special Administrative Region ("*Hong Kong*"), (c) the Macau Special Administrative Region ("*Macau*"), and (d) Taiwan (each of the foregoing a "*Relevant Region*").
  - **1.146** "*Third Party*" means any Person other than a Party or an Affiliate of a Party.
  - **1.147** "*Third Party Claims*" has the meaning set forth in <u>Section 10.1</u>.
  - **1.148** "*Third Party Components*" has the meaning set forth in <u>Section 1.104</u>.
  - **1.149** "*Third Party Offer*" has the meaning set forth in Section 2.2.
  - **1.150** "*Third Party License*" has the meaning set forth in Section 7.5(c).
- **1.151** "*Third Party Licensee*" means any Third Party holding a license (whether exclusive or non-exclusive) under the Know-How and Patent Rights Controlled by Arbutus or its Affiliates during the Term that is necessary or useful in the Exploitation of the Licensed Compound and the Licensed Products in the Field in the ROW Territory.
- **1.152** "*Trademark*" means any word, name, symbol, color, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo, business symbol or domain names, whether or not registered.
  - **1.153** "*US GAAP*" has the meaning set forth in <u>Section 1.1</u>.

- 1.154 [\*\*\*].
- **1.155** "*United States*" or "*U.S.*" means the United States of America, including its territories and possessions.
- **1.156** "*Upfront Payment*" has the meaning set forth in <u>Section 7.1</u>.
- **1.157** "*USFDA*" means the United States Food and Drug Administration or any successor agency(ies) or authority thereto having substantially the same function.
- **1.158** "Valid Claim" means either (a) a claim of an issued and unexpired patent or a supplementary protection certificate, which has not been held permanently revoked, unenforceable or invalid by a decision of a court, patent office or other forum of competent jurisdiction, unappealable or unappealed within the time allowed for appeal and that is not admitted to be invalid or unenforceable through reissue, disclaimer or otherwise (i.e., only to the extent the subject matter is disclaimed or is sought to be deleted or amended through reissue), dedicated to the public or abandoned, or (b) a claim of a pending patent application being prosecuted in good faith where the earliest priority date of which claim is less than [\*\*\*], that has not been abandoned, finally rejected or expired without the possibility of appeal or refiling.

#### ARTICLE 2 LICENSE

License Grant to Qilu. Arbutus agrees to grant and hereby grants to Qilu and its Affiliates during the Term an 2.1 exclusive (even as to Arbutus and its Affiliates, except as necessary for Arbutus to perform its obligations under this Agreement, or to exercise the retained rights expressly set forth in this <u>Section 2.1</u>), royalty-bearing, non-transferable (except in accordance with <u>Section 13.2</u>) license, with the right to grant sublicenses through multiple tiers (in accordance with <u>Section 2.3</u>), under the Arbutus IP to Exploit the Licensed Compound and Licensed Products in the Field in the Territory to the extent, and only to the extent, said license is necessary or reasonably useful to Exploit the Licensed Compound included in Licensed Products. For clarity, said grant includes the right to use the Arbutus Materials but does not include any license or other grant of rights to Exploit Arbutus Unlicensed Compounds. Subject to Section 2.2, Arbutus retains a right under the Arbutus IP, with the right to grant licenses through multiple tiers, to (a) Develop, Manufacture, have Manufactured, use, import, and export Licensed Products anywhere in the world for the purpose of Exploiting the Licensed Compound and Licensed Products in the ROW Territory, including, notwithstanding the foregoing exclusive license grant, the non-exclusive right to Develop, Manufacture and have Manufactured Licensed Compound and Licensed Products in the Field in the Territory (including importing and exporting activities in connection therewith) for Exploiting Licensed Products in the ROW Territory in all fields of use, but excluding, for the avoidance of doubt, any right to Commercialize Licensed Products in the Field in the Territory, (b) Exploit the Licensed Compound and Licensed Products in the Territory outside the Field, and (c) Exploit Arbutus Unlicensed Compounds worldwide in all fields of use.

2.2 Right of First Negotiation Granted to Qilu. During the Term of this Agreement, if (a) Arbutus or any of its Affiliates intends to Exploit the Licensed Product outside the Field in any Relevant Region in the Territory, (b) Arbutus or any of its Affiliates invents or develops any Additional Compound, as contained in any Additional Product, and Arbutus or any of its Affiliates intends to license the rights to a Third Party in any Relevant Region in the Territory to Exploit such Additional Compound and Additional Product, or (c) Arbutus or any of its Affiliates intends to contract with a Third Party to Manufacture the Licensed Compound and/or Licensed Product in any Relevant Region in the Territory for the purpose of Exploiting the Licensed Compound and Licensed Products in the ROW Territory, Arbutus shall notify Qilu of such intent in writing. If Arbutus provides written notice under clause (c), such notice shall include the price received by Arbutus from a well-known CMO in the Territory agreed between the Parties (e.g., [\*\*\*]) to Manufacture the Licensed Compound and/or Licensed Product in the Territory (the "Third Party Offer"). Arbutus agrees to grant and hereby grants Qilu the exclusive right of first negotiation to, in the case of the foregoing clause (a) and clause (b), obtain an exclusive license on commercially reasonable terms to Exploit the Licensed Compound and/or Licensed Product outside the Field in such Relevant Region in the Territory, or the Additional Compound and Additional Product in such Relevant Region in the Territory, or in the case of the foregoing clause (c), to Manufacture the Licensed Compound and/or Licensed Product in such Relevant Region in the Territory for Arbutus on commercially reasonable terms, including a price of the Licensed Compound and/or Licensed Product that is lower than the price provided in the Third Party Offer. For clarity, Qilu's exclusive right of first negotiation under clause (c) above shall only apply if Qilu or its Affiliate will Manufacture the Licensed Compound and/or Licensed Product in such Relevant Region in the Territory, and not if a Third Party subcontracted by Qilu or its Affiliate will Manufacture the Licensed Compound and/or Licensed Product on their behalf. Qilu shall have [\*\*\*]. [\*\*\*](the "Negotiation Period"). If Qilu does not exercise its right of first negotiation during such [\*\*\*] period, or if the Parties fail to enter into a definitive agreement within the Negotiation Period, then Arbutus shall be entitled to negotiate and enter into agreement with any Third Party for the relevant transaction without any further obligation to Qilu under this Section 2.2.

# 2.3 Right to Sublicense.

- (a) Qilu shall have the right to grant sublicenses of the License to its Affiliates to fulfill any of its obligations or exercise any of its rights under this Agreement. Each sublicense granted pursuant to this <u>Section 2.3(a)</u> shall be consistent with the terms and conditions of this Agreement. Notwithstanding any such sublicense, Qilu shall remain directly responsible for all of its obligations under this Agreement.
- (b) Qilu and its Affiliates shall have the right to grant sublicenses of the License to Third Parties; <u>provided</u>, that any sublicense of the License to a Sublicensee that includes the right to Commercialize or Manufacture the Licensed Compound or the Licensed Product shall require the prior written consent of Arbutus, which consent shall not be unreasonably withheld, conditioned or delayed. Each sublicense granted pursuant to this <u>Section 2.3(b)</u> shall be subject to a written agreement that is consistent with the terms and conditions of this Agreement. Qilu shall provide Arbutus with a copy of any sublicense it enters into with a Sublicensee within thirty (30) days after the execution thereof. Notwithstanding any such sublicense, Qilu will remain directly responsible for all of its obligations under this Agreement.

- **2.4 Right to Subcontract.** Qilu shall have the right to engage Subcontractors to perform on Qilu's behalf its activities under this Agreement; <u>provided</u>, that (i) if a Subcontractor requires a sublicense of the License to perform the subcontracted activities, such sublicense complies with the requirements of <u>Section 2.3(b)</u>, (ii) if such Subcontractor is a CMO, Qilu may only engage such CMO with the prior written consent of Arbutus, which consent shall not be unreasonably withheld, conditioned or delayed, (iii) Qilu shall cause its Subcontractors to be bound by (x) written obligations of confidentiality and non-use at least as restrictive as those set forth in this Agreement, and (y) other obligations consistent with this Agreement to the extent applicable to the activities being performed by such Subcontractor, and (iv) Qilu shall remain directly responsible for any obligations that have been subcontracted to a Subcontractor as if the Subcontractor were a party hereto.
- 2.5 Technology Transfer. Subject to Qilu's payment of the Upfront Payment, within [\*\*\*] after receipt by Arbutus of the Upfront Payment, Arbutus shall provide Qilu with complete and accurate copies of all of the Arbutus Know-How set forth in Exhibit 2.5, including any Batch Records, which shall be delivered in its existing format, and in a secure and commercially reasonable manner. If, following such initial delivery, any additional necessary or reasonably necessary Arbutus Know-How comes into Arbutus' or any of its Affiliates' Control during the Term (including any Product Data included within the Arbutus Know-How resulting from the Development of the Licensed Compound or Licensed Products in the ROW Territory), Arbutus shall deliver an electronic copy (which may be through access to a secured electronic database) of any tangible embodiments thereof to Qilu without charging Qilu any additional fees. In addition, if at any time during the Term, Qilu identifies particular documents, data or information that are within the Arbutus Know-How, but were not previously delivered to Qilu, including materials requested in connection with an audit or other inquiry by a Regulatory Authority relating to the Development, Manufacture or Commercialization of the Licensed Products, then upon the request of Qilu Arbutus shall use reasonable efforts to promptly deliver an electronic copy of such material (which may be through access to a secured electronic database) to Qilu free of charge to the extent that such material is within Arbutus' Control. The Parties shall cooperate in good faith to enable Qilu to receive access to any Arbutus Know-How that is necessary or reasonably useful to Exploit the Licensed Compound and Licensed Products in the Field in the Territory.
- **2.6 No Implied Licenses**. Except as expressly set forth herein, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, under any Patent Rights, Know-How, Trademarks, or other intellectual property rights of the other Party.

# ARTICLE 3 GOVERNANCE

**3.1 Alliance Managers**. Each Party shall appoint an English-speaking individual to act as its alliance manager under this Agreement as soon as practicable after the License Effective Date (each Party's appointed individual, its "*Alliance Manager*"). The Alliance Managers shall (a) serve as the primary points of contact between the Parties for the purpose of providing the other Party with information on the progress of a Party's activities under this Agreement, (b) be responsible for facilitating the flow of information and otherwise promoting communication, coordination and collaboration between the

Parties, and (c) facilitate the prompt resolution of any disputes. Each Party may replace its Alliance Manager at any time upon written notice to the other Party.

# 3.2 **Joint Steering Committee.**

- (a) **Formation; Purposes and Principles**. Promptly following the License Effective Date, but in no event later than thirty (30) days thereafter, the Parties will form a joint steering committee (the "*JSC*") to provide oversight and to facilitate information sharing between the Parties with respect to the activities of the Parties under this Agreement.
  - (b) **Specific Responsibilities.** In addition to the responsibilities set forth in <u>Section 3.2(a)</u>, the JSC will:
  - (i) coordinate and share information with respect to the Development, Manufacturing and Commercialization of Licensed Products undertaken by Qilu and its Affiliates and Sublicensees under this Agreement, including Development activities undertaken in accordance with the Development Plan;
  - (ii) review and approve (x) the initial Development Plan and subsequent amendments to the Development Plan proposed by Qilu, and (y) the protocol for each Clinical Trial of the Licensed Product in the Field in the Territory proposed to be conducted by Qilu, its Affiliates or Sublicensees;
  - (iii) discuss at a high-level and exchange relevant information relating to the Development, Manufacture and Commercialization activities for the Licensed Products undertaken by Arbutus and its Affiliates and Third Party Licensees in the ROW Territory (x) to the extent relevant to the Development, Manufacture and Commercialization of the Licensed Products in the Field in the Territory, and (y) to the extent that Arbutus Controls such information and has the right to disclose such information to Qilu;
    - (iv) attempt to resolve in the first instance all matters between the Parties that are in dispute; and
  - (v) perform such other functions as are assigned to it in this Agreement or as appropriate to further the purposes of this Agreement to the extent agreed to by the Parties.
- **3.3 Membership**. The JSC will be composed of three (3) representatives appointed by each of Arbutus or Qilu, or such other number as the Parties may agree in writing. Each individual appointed by a Party as a representative to the JSC will be an English-speaking employee of such Party, or an employee of such Party's Affiliate, and shall possess qualifications and experience and decision-making authority appropriate for the matters before the JSC. Each Party may replace any of its JSC representatives at any time upon written notice to the other Party, which notice may be given by e-mail, sent to the other Party's co-chairperson. The JSC will be co-chaired by one designated representative of each Party. The co-chairperson of the JSC will cast its Party Vote (as defined below) on the JSC. The co-chairpersons will be responsible for (a) calling

meetings, (b) preparing and circulating an agenda in advance of each meeting; <u>provided</u>, <u>however</u>, that the co-chairpersons will include any agenda items proposed by either Party on such agenda, and (c) preparing and issuing minutes of each meeting promptly thereafter. Each JSC representative will be subject to confidentiality obligations no less stringent than those set forth in <u>ARTICLE 8</u>.

- **3.4 Meetings; Reports.** The JSC will hold meetings on a Calendar Quarter basis during the Term or more or less frequently as may be agreed by the Parties. The JSC may meet in person or by audio or video conference as its representatives may mutually agree. Other representatives of the Parties, their Affiliates and Third Parties involved in the Development, Manufacture or Commercialization of Licensed Products may be invited by the members of the JSC to attend meetings as nonvoting observers; provided, however, that such representatives are subject to confidentiality obligations no less stringent than those set forth in <u>ARTICLE 8</u>. No action taken at a meeting will be effective unless at least one representative of each Party is present or participating. Neither Party will unreasonably withhold attendance of at least one representative of such Party at any meeting of the JSC for which reasonable advance notice was provided.
- **Decision-Making**; Escalation to Executive Officers. The Parties will endeavor in good faith to reach unanimous agreement with respect to all matters within the JSC's authority. Each Party's representatives on the JSC shall collectively have one vote (the "Party Vote") and no action or decision shall be taken by the JSC on such matters without unanimous Party Vote (i.e., the affirmative Party Vote of each Party), except as expressly provided in this <u>Section 3.5</u>, which will be documented in the minutes of the applicable JSC meeting or by a written consent signed by each Party's co-chairperson. Should the JSC not be able to reach agreement with respect to a matter at a duly called meeting of the JSC, either Party may refer such matter to the Executive Officers for resolution, and the Executive Officers will attempt to resolve the matter in good faith. If the Executive Officers fail to resolve such matter within [\*\*\*] after the date on which the matter is referred to the Executive Officers (unless a longer period is agreed to by the Parties), then: (a) Arbutus shall have final decision-making authority with respect to [\*\*\*]; and (b) Qilu shall have final decision-making authority with respect to [\*\*\*]. Each Party shall at all times exercise its final decision-making authority using reasonable scientific and business judgment, in compliance with Applicable Laws, and with respect to Qilu in accordance with its diligence and other obligations under this Agreement. The JSC shall not have responsibility for, oversight over or decision-making authority with respect to, the Development, Manufacture or Commercialization of the Licensed Products by Arbutus, its Affiliates or Third Party Licensees, either in the Territory or in the ROW Territory. Neither the JSC nor either Party, in exercising its decision-making authority, shall have the authority or power to (1) amend or modify the terms of this Agreement, (2) avoid or seek to avoid any obligation of such Party under this Agreement, (3) waive compliance with the terms of this Agreement, (4) permit a Party to take an action that requires the prior written consent or other approval of the other Party under this Agreement, or (5) impose additional financial or other obligations on a Party that are not otherwise specified in this Agreement or agreed to by such Party.

# ARTICLE 4 DEVELOPMENT AND REGULATORY MATTERS

### 4.1 Development Obligations.

- (a) Qilu shall at its sole expense use Commercially Reasonable Efforts to, by itself or through its Affiliates or Sublicensees, Develop and seek Regulatory Approval for at least one (1) Licensed Product in the Field in the Territory.
- Without limiting Qilu's obligations under Section 4.1(a), Qilu shall use Commercially Reasonable Efforts to Develop the Licensed Products in the Field in the Territory pursuant to a development plan that will include a description of the Development activities to be performed in support of obtaining Regulatory Approval for the Licensed Products in the Field in the Territory, including Clinical Trial designs (as such development plan may be amended, the "Development Plan"). The Development Plan shall include projected timelines for the completion of material Development activities, including the following: [\*\*\*]. An outline of the initial Development Plan is attached hereto as <u>Exhibit 4.1</u>. Within [\*\*\*] after the License Effective Date, Qilu shall submit to the JSC an initial draft of the Development Plan for the JSC's review and approval. Once approved by the JSC, all amendments to the initial Development Plan shall not be effective unless and until approved by the JSC, [\*\*\*]. Not later than [\*\*\*] days prior to the commencement of each Calendar Year during the Term when Development of the Licensed Products in the Field in the Territory is ongoing, Qilu shall submit to the JSC an updated Development Plan for the subsequent Calendar Year for its review and approval. Such update shall take into account completion, commencement, changes in or cessation of Development activities not contemplated by the then-current Development Plan in sufficient detail to reflect the continued diligence of Qilu and its Affiliates and Sublicensees. If, from time to time during the Term, there are any material changes to the proposed Development activities to be conducted by Qilu and its Affiliates and Sublicensees that are not reflected in the then-current Development Plan, including the addition of any Clinical Trials or any material changes to any Clinical Trial already included therein, Qilu shall promptly submit to the JSC an amendment to the Development Plan for the JSC's review and approval.
- (c) Without limiting Qilu's obligations under <u>Section 4.1(a)</u> and <u>Section 4.1(b)</u>, Qilu, by itself or through its Affiliates or Sublicensees, shall achieve each of the following diligence milestones by the corresponding diligence deadline, <u>provided</u> that (i) with respect to diligence milestone 2 listed below, Arbutus has timely supplied the Licensed Product (with sufficient quantities and quality) in accordance with the terms of the Clinical Supply Agreement, and (ii) with respect to diligence milestones 1 and 2 listed below, Arbutus has timely provided the material Arbutus Know-How then in the Control of Arbutus or its Affiliates in accordance with <u>Sections 2.5</u> and <u>9.4(c)</u> in order to enable Qilu to achieve the diligence milestones by the applicable diligence deadlines, the receipt of which shall be confirmed by Qilu in writing:

	Diligence Milestone	<u>Diligence Deadline</u>
1	[***]	[***]
2	[***]	[***]

If Qilu anticipates that it will not be able to achieve one or both of the diligence milestones set forth above by the corresponding diligence deadline, Qilu shall provide Arbutus with written notice thereof. The Parties, through the JSC, shall discuss Qilu's expectations regarding timing relating to achievement of the applicable milestone(s) and the factors relating thereto. Arbutus shall consider in good faith, and shall not unreasonably withhold its consent to, any reasonable extension to the diligence deadlines set forth above proposed by Qilu. For clarity, any amendment to the diligence deadlines set forth above shall require the written agreement of the Parties. Notwithstanding the foregoing, if Qilu is not able to achieve one or both of the diligence milestones set forth above by the corresponding diligence deadline because (x) additional pre-clinical studies not previously conducted by or on behalf of Arbutus, or (y) additional data not included within the Arbutus Know-How, are required by NMPA in order to support submission of an IND, then the Parties shall extend the relevant diligence deadline(s) by a reasonable period of time necessary for Qilu to conduct such additional pre-clinical studies or generate such additional data.

- (d) Qilu will perform its Development obligations under this Agreement in good scientific manner and in compliance with all Applicable Laws, including with respect to each such activity that will or would reasonably be expected to be submitted to a Regulatory Authority in support of a regulatory filing or application for Regulatory Approval, cGLP and cGCP.
- (e) Qilu shall maintain complete and accurate records of all work conducted by or on behalf of Qilu or its Affiliates, and shall require its Sublicensees to maintain complete and accurate records of all work conducted by or on behalf of such Sublicensees, as applicable, in each case in furtherance of the Development of the Licensed Products in the Territory and together with all material results, data and developments made in conducting such activities. Such records shall be maintained in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes and in accordance with Applicable Law.
- (f) In the event that Arbutus decides to conduct a global Phase III Clinical Trial for a Licensed Product in the Field (a "Global Trial"), Qilu shall have the right to participate in such Global Trial by including Clinical Trial sites in the Territory on the terms set forth in this Section 4.1(f) ("Development Participation Right"). In advance of any Global Trial, Arbutus shall provide written notice thereof to Qilu (a "Global Trial Notice"). Qilu shall have [\*\*\*] days from receipt of the Global Trial Notice (the "Review Period") to exercise its Development Participation Right by providing written notice thereof to Arbutus (the "Participation Notice"). If Qilu exercises its Development Participation Right within the Review Period, the Parties shall negotiate in good faith for up to [\*\*\*] days an agreement setting forth the terms of Qilu's participation in the Global Trial, which shall include (A) Qilu's obligation to support Arbutus in connection with the Global Trial by (i) recommending Clinical Trial sites in the Territory; provided, that Arbutus shall have the right to reject any Clinical Trial sites that do not meet the regulatory, quality or other standards of Arbutus, in Arbutus's sole discretion, (ii) bearing all costs and expenses incurred by or on behalf of Qilu for its participation in such Global Trial conducted in the Territory, and (iii) reimbursing Arbutus for a pro rata portion of its internal and external expenses, including the expenses of any CRO or other Third Party service providers, to oversee and manage the Global Trial to the extent attributable to the Territory; and (B) Qilu's rights and entitlements in connection with the Global Trial. For clarity, Arbutus shall have the right to control, in its sole discretion, the study design and

study protocol for the Global Trial. If Qilu does not deliver a Participation Notice to Arbutus during the Review Period, or if the Parties are unable to execute an agreement providing for Qilu's participation in the Global Trial within [\*\*\*] days of the Participation Notice, then Qilu will be deemed to have waived its Development Participation Right for the Global Trial and Arbutus shall have no further obligation to Qilu under this Section 4.1(f) with respect to participation in the Global Trial. Notwithstanding the foregoing, Qilu may elect to develop, at its own cost and expense, the Licensed Products in any indication in the Field in the Territory as approved under the Development Plan, even if Qilu does not exercise its Development Participation Right with respect to the same indication in the Field in the Territory. For the avoidance of doubt, Arbutus shall share any and all Arbutus Know-How arising from all Global Trials with Qilu pursuant to Section 4.5, regardless of whether Qilu agrees to participate in and be responsible for the costs of any such global Clinical Trials. This Section 4.1(f) shall also not be deemed to limit or impose obligations on either Party with respect to the development of the Licensed Product in their Applicable Territory.

**4.2 Development Reports.** Within [\*\*\*] days following the end of each Calendar Quarter during the Term in which activities described in the Development Plan are ongoing, Qilu shall submit to Arbutus a report summarizing in reasonable detail Qilu's and its Affiliates' and Sublicensees' activities related to (a) the Development of the Licensed Products during the preceding Calendar Quarter, including any material pre-clinical and clinical activities undertaken with respect thereto, and (b) the Manufacture of the Licensed Compound and Licensed Products during the preceding Calendar Quarter, including (i) an update on Qilu's plans for the Manufacture and supply of the Licensed Compound and Licensed Products, including supply for raw materials and components and any Third Party suppliers and CMOs to be included as part of such plans, and (ii) a summary of any material Manufacturing-related milestones that were in process or were achieved during the preceding Calendar Quarter, including the status of any technology transfer, process validation, etc. Arbutus shall have the opportunity to discuss each such report and its contents with Qilu, either through the JSC or in any other manner reasonably acceptable to both Parties, and Qilu shall provide to Arbutus any additional documentation or information reasonably requested by Arbutus relating to such reports.

## 4.3 Regulatory Activities.

Qilu shall apply for and maintain, at Qilu's sole cost and expense, all Regulatory Documents relating to the Licensed Products in the Field in the Territory. All Regulatory Documents relating to the Licensed Products in the Field in the Territory shall be owned by Qilu and held in Qilu's name, except for any Regulatory Documents, including any IND or Imported Drug License, that are required under Applicable Laws to be filed in Arbutus' name, which Regulatory Documents will be owned by Arbutus, but shall be prepared, filed and maintained by Qilu on Arbutus' behalf (such Regulatory Documents owned by Arbutus, the "Arbutus Territory Regulatory Documents"). Arbutus shall, at the direction of and with the assistance of Qilu, execute any documentation prepared by Qilu necessary to appoint Qilu as Arbutus' local regulatory agent to perform regulatory actions on its behalf in connection with the Arbutus Territory Regulatory Documents. Qilu shall be responsible, at Qilu's sole cost and expense, for all communications and interactions with Regulatory Authorities with respect to the Licensed Products in the Field in the Territory, both prior to and subsequent to receipt of any Regulatory Approvals. At least thirty (30) days in advance of filing any material Regulatory Document relating to a Licensed Product with any Regulatory Authority in the Territory, including any IND or MAA (or, if a Regulatory Authority requires that a filing be made in a period that does not allow for such thirty (30) day advance review period, then at a mutually agreed upon time in advance of such filing), Qilu shall provide to Arbutus for Arbutus' review and comment (i) the then-current draft of such Regulatory Document in full in Chinese, (ii) an English translation of the following portions of any such material Regulatory Document: (w) any protocol synopsis included therein; (x) any clinical overview or any clinical summary for the Licensed Compound, including any summaries of clinical safety, biopharmaceutics or efficacy data; (y) any data from any independent nonclinical pharmacology or toxicology studies with the Licensed Compound conducted by Qilu or its Affiliates or Sublicensees; and (z) any data relating to the Manufacture of the Licensed Compound or Licensed Product by or on behalf of Qilu or its Affiliates or Sublicensees, whether in the form of drug substance or drug product (excluding any data relating to any Licensed Compound or Licensed Product Manufactured and supplied by Arbutus under the Clinical Supply Agreement), and (iii) a summary of the other material parts thereof in English (the "Initial Documentation"). Arbutus shall provide its comments to the Initial Documentation in good faith within [\*\*\*] of receipt thereof, which comments shall include (A) Arbutus' written consent to the filing of any Arbutus Territory Regulatory Documents within the Initial Documentation or (B) if no such consent is so included, comments on specific revisions to the Arbutus Territory Regulatory Documents so that consent may be granted. Additionally, if Qilu makes any material changes to any protocol synopsis included in the Initial Documentation or the material parts of such Regulatory Document as previously summarized by Qilu in the Initial Documentation, then Qilu shall provide Arbutus with an updated version of such Initial Documentation at least three (3) Business Days prior to filing the applicable Regulatory Document. Qilu will consider in good faith Arbutus' comments to any material Regulatory Documents relating to a Licensed Product prior to filing such Regulatory Documents with the applicable Regulatory Authorities; provided, that no Arbutus Territory Regulatory Document relating to a Licensed Product may be filed in the Territory without the prior written consent of Arbutus, such consent not to be unreasonably withheld, conditioned or delayed. Within thirty (30) days after the filing of any material Regulatory Document relating to a Licensed Product with any Regulatory Authority in the Territory, Qilu shall provide to Arbutus a complete electronic copy of the Regulatory Document original as filed in Chinese. In

addition, after receiving Arbutus' written request, Qilu shall provide to Arbutus, within a reasonable time, an English translation of such Regulatory Document to the extent the original as filed is not written in English and an English translation thereof has not been provided to Arbutus previously, together with an invoice for the cost of translation, and Arbutus shall pay Qilu the amount as invoiced within thirty (30) days after receiving the invoice. Qilu shall notify Arbutus in writing at least ten (10) Business Days in advance of any material meeting with Regulatory Authorities in the Territory relating to the Licensed Products, and Arbutus shall have the right, but not the obligation, to have a representative of Arbutus accompany Qilu to each such meeting in an observational capacity if such attendance is permitted by the applicable Regulatory Authorities in the Territory; provided, that, with respect to any meeting with Regulatory Authorities in the Territory pertaining to an Arbutus Territory Regulatory Document, Arbutus' representative shall have the right to attend such meeting as a representative of the applicant/owner of such Arbutus Territory Regulatory Document, unless Arbutus agrees in writing prior to such meeting that such representative shall be in attendance in an observational capacity only.

- (b) Within thirty (30) days of receipt or filing, Qilu shall provide Arbutus with an electronic copy (in Chinese) and an English translation of all correspondence with Regulatory Authorities or Governmental Authorities (other than, for clarity, any material Regulatory Document, copies of which are required to be provided in accordance with Section 4.3(a) above). For clarity, the English translation shall not include the translation of any attachments, appendices or other enclosures to or with the correspondence. After receiving Arbutus' written request, Qilu shall provide to Arbutus, within a reasonable time, an English translation of such attachments, appendices or other enclosures to the extent the original is not written in English and an English translation thereof has not been provided to Arbutus previously, together with an invoice for the cost of translation, and Arbutus shall pay Qilu the amount as invoiced within thirty (30) days after receiving the invoice. Additionally, upon the reasonable request of Arbutus, Qilu shall promptly provide Arbutus with an electronic copy (in Chinese) and an English written summary of all other interactions with Regulatory Authorities and Governmental Authorities, in each case by or on behalf of Qilu or its Affiliates or, to Qilu's knowledge, Sublicensees with respect to the Development of the Licensed Products in the Field in the Territory.
- **4.4 Right of Reference and Use.** Arbutus agrees to grant and hereby grants to Qilu (and any Affiliate of Qilu or Sublicensee) a right of reference to all Regulatory Documents pertaining to Licensed Products in the Field submitted to a Regulatory Authority by or on behalf of Arbutus or its Affiliates or Third Party Licensees that are Controlled by Arbutus or its Affiliates for the purpose of seeking, obtaining and maintaining Regulatory Approval of Licensed Products in the Field in the Territory. If requested by Qilu, Arbutus will, and will cause its Affiliates and Third Party Licensees to, provide a signed statement to this effect in accordance with Applicable Laws. Qilu agrees to grant and hereby grants to Arbutus (and any Affiliate of Arbutus or Third Party Licensee) a right of reference to all Regulatory Documents pertaining to Licensed Products submitted to Regulatory Authorities by or on behalf of Qilu, its Affiliates or Sublicensees that are Controlled by Qilu or its Affiliates for the purpose of seeking, obtaining and maintaining Regulatory Approval of Licensed Products in the ROW Territory (or to seek any approvals from a Regulatory Authority required for the Development or Manufacturing of the Licensed Product in the Territory in accordance with Arbutus' retained rights). If requested by Arbutus, Qilu will, and will cause its Affiliates and its Sublicensees, to provide a signed statement to this effect in accordance with Applicable Laws.

### 4.5 Data Exchange and Use.

- (a) **For the ROW Territory**. During the Term, Qilu shall provide prompt high-level updates to Arbutus through the JSC regarding any newly generated Product Data that has been generated and finalized by or on behalf of Qilu or its Affiliates or Sublicensees with respect to the Licensed Compound and the Licensed Products in the Field in the Territory. Upon Arbutus' reasonable request, Qilu shall promptly provide Arbutus with electronic copies of, or reasonable access to, such Product Data to the extent that such Product Data has not been previously provided or made accessible to Arbutus. Arbutus shall have the right to use such Product Data to Exploit the Licensed Compound and the Licensed Products in the ROW Territory (or to seek any approvals from a Regulatory Authority required for the Development or Manufacturing of the Licensed Product in the Territory in accordance with Arbutus' retained rights). To the extent legally possible and permitted, Qilu shall be responsible for obtaining any Approvals required by the Applicable Law in order to allow Arbutus to legally access and use the Product Data.
- (b) **For the Territory**. During the Term, Arbutus shall provide prompt high-level updates to Qilu through the JSC regarding any newly generated Product Data that has not been previously provided or made accessible to Qilu. Upon Qilu's reasonable request, an electronic copy of any such Product Data included within the Arbutus Know-How not previously delivered to Qilu shall be delivered to Qilu in accordance with Section 2.5.
- 4.6 Adverse Events Reporting. Within ninety (90) days following the License Effective Date, or as otherwise agreed by the Parties, Qilu and Arbutus shall develop and agree in a separate written agreement to worldwide safety and pharmacovigilance procedures for the Parties with respect to Licensed Products, such as safety data sharing and exchange, adverse events reporting and prescription events monitoring (the "Pharmacovigilance Agreement"). Such Pharmacovigilance Agreement shall describe the obligations of both Parties with respect to the coordination of collection, investigation, reporting and exchange of information between the Parties concerning adverse events or any other safety issue of any significance and product quality and product complaints involving adverse events, in each case with respect to Licensed Products and sufficient to permit each Party and its Affiliates, Third Party Licensees and Sublicensees to comply with its legal obligations with respect thereto. The Pharmacovigilance Agreement shall be promptly updated if required by changes in Applicable Law. Each Party hereby agrees to comply with its respective obligations under the Pharmacovigilance Agreement and to cause its Affiliates, Third Party Licensees and Sublicensees to comply with such obligations. Without limiting the foregoing, Arbutus will be responsible for and shall have the sole right to maintain a global adverse event database for the Licensed Compound and the Licensed Products.

- **4.7 No Harmful Actions**. Each Party shall not, and shall use Commercially Reasonable Efforts to cause its Affiliates, Sublicensees (with respect to Qilu), Third Party Licensees (with respect to Arbutus) and Subcontractors not to, take any action with respect to the Licensed Compound or a Licensed Product that could reasonably be expected to have an adverse impact upon the other Party's Regulatory Approval status of the Licensed Compound or any Licensed Product in the other Party's Applicable Territory. If a Party believes that the other Party is or any of its Affiliates, Sublicensees (with respect to Qilu), Third Party Licensees (with respect to Arbutus) or Subcontractors are taking or intends to take any action with respect to the Licensed Compound or a Licensed Product that could have an adverse impact upon other Party's Regulatory Approval status of the Licensed Compound or any Licensed Product in such Party's Applicable Territory, then the Parties shall discuss in good faith a resolution of such concern.
- **4.8 Notice of Regulatory Action**. Each Party shall promptly, but in any event within two (2) Business Days of receipt of relevant information, notify the other Party of any information that it receives regarding any threatened or pending action, inspection or communication by or from a Third Party, including a Regulatory Authority, that would reasonably be expected to materially adversely affect the Exploitation of the Licensed Compound or Licensed Products in the Territory or the ROW Territory.
- **Arbutus Support.** In addition to Arbutus' express obligations to provide certain information under this Agreement, including under Section 2.5, the Parties understand and agree that it may be necessary for Oilu from time to time to seek support from Arbutus with respect to the following matters: (a) becoming familiar with and being able to understand and use the Product Data included in the Arbutus Know-How; and (b) answering questions necessary to enable Qilu to (i) prepare Regulatory Documents relating to the Licensed Compound or Licensed Products in the Field in the Territory, and (ii) prepare responses to any requests made by Regulatory Authorities in the Territory relating to the Licensed Compound or Licensed Products in the Field (the "Arbutus Support"). Upon the request of Qilu, Arbutus shall provide the Arbutus Support to Qilu, subject to the following terms and conditions: (1) all Arbutus Support shall be provided through employees of Arbutus, and Arbutus shall have no obligation to (x) provide any Arbutus Support that requires Arbutus to utilize any CRO, CMO or other Third Party service provider or incur any out-of-pocket costs, including any fees charged by any CRO, CMO or other Third Party service provider, unless Arbutus agrees to provide such Arbutus Support in writing, such Arbutus Support not to be unreasonably rejected or withheld, and Qilu timely pays (or reimburses Arbutus for) all such out-of-pocket costs, or (y) require any Arbutus employees to travel in-person to the Territory (except as may be agreed by the Parties otherwise, in which case, the Parties shall also agree on the specific travel arrangements and Qilu's responsibility for the costs therefor); (2) [\*\*\*]; and (3) [\*\*\*](the "Arbutus Support Cap"). If Oilu requires Arbutus Support in excess of the Arbutus Support Cap, Arbutus agrees not to unreasonably withhold its agreement to provide such additional Arbutus Support. Within thirty (30) days after the end of each Calendar Quarter when Arbutus Support is provided, Arbutus shall deliver to Qilu an invoice setting forth the number of hours of Arbutus Support provided during the prior Calendar Quarter and the amounts owed to Arbutus with respect thereto, including any out-of-pocket costs to be paid by Qilu. Each such invoice shall be paid by Qilu within thirty (30) days of the date of such invoice and otherwise in accordance with Sections 7.5(g), 7.5(h) and 7.6.

## ARTICLE 5 MANUFACTURE AND SUPPLY

- **Supply Obligations.** Subject to the terms of this Agreement, Arbutus, by itself or through an Affiliate or one or more Third Parties, shall be responsible for Manufacturing and supplying to Qilu all quantities of the Licensed Compound and Licensed Products necessary for Qilu to Develop and Commercialize the Licensed Compound and Licensed Products in the Field in the Territory until Qilu has received all Approvals required for Qilu or its designated CMO to Manufacture the Licensed Compound and Licensed Products in the Territory (the "Supply End Date"). Qilu shall use Commercially Reasonable Efforts to obtain all Approvals required for Qilu or its designated CMO to Manufacture the Licensed Products in the Territory as soon as reasonably practicable following the License Effective Date. After the Supply End Date, Qilu shall be responsible at its sole cost for Manufacturing all quantities of the Licensed Products necessary for Qilu and its Affiliates and Sublicensees to Develop and Commercialize Licensed Products in the Field in the Territory, and Arbutus' obligation to Manufacture and supply quantities of the Licensed Products for Qilu shall terminate. Qilu acknowledges and agrees that Arbutus has engaged certain CMOs to Manufacture the Licensed Products on behalf of Arbutus and that Arbutus' ability to conduct the Manufacturing Technology Transfer and to supply quantities of the Licensed Products to Qilu are subject to, and limited by, the terms of Arbutus' agreements with such CMOs. Arbutus shall use Commercially Reasonable Efforts to, or to cause its CMOs to, complete the Manufacturing Technology Transfer and supply the Licensed Products in a timely manner. Notwithstanding the foregoing, Arbutus will remain directly responsible for its obligations under this Agreement that have been subcontracted to its CMO. Arbutus hereby represents and warrants to Qilu that, as of the Execution Date, the terms of Arbutus' agreements with its CMOs (i) do not conflict in any material respect with its supply obligations for the Licensed Compound and Licensed Products as contemplated hereunder; and (ii) do not limit its ability or otherwise conflict with its obligations to conduct the Manufacturing Technology Transfer as contemplated hereunder.
- **5.2 Clinical Supply Agreement.** Within ninety (90) days following the License Effective Date, which time period may be extended upon mutual agreement of the Parties, the Parties shall negotiate in good faith and enter into a clinical supply agreement and related quality agreement pursuant to which Arbutus will supply to Qilu Licensed Compound and Licensed Products, at Arbutus' Manufacturing Cost, for use in Development of the Licensed Product in the Field in the Territory (the "Clinical Supply Agreement"). The Clinical Supply Agreement shall contain supply terms and conditions consistent with the principles set forth on Exhibit 5.2 hereto and such other terms as are customary for such agreements.
- **5.3 Commercial Supply Agreement**. At a time specified by Qilu, but in any event as soon as practicable after submission of an MAA for a Licensed Product to a Regulatory Authority in the Territory <u>provided</u> that the Supply End Date has not occurred, the Parties shall negotiate in good faith a commercial supply agreement and related quality agreement for the commercial supply of Licensed Compound and Licensed Products by Arbutus to Qilu, at a price to be agreed between the Parties, for use in Commercialization of the Licensed Products in the Field in the Territory (the "Commercial Supply Agreement"). The Commercial Supply Agreement shall provide for purchase of Licensed

28

Compound and Licensed Products and shall contain such other terms as are customary and commercially reasonable for such agreements.

- **5.4 Supply to Arbutus**. Subject to the Manufacturing Technology Transfer Completion, upon the request of Arbutus, the Parties shall negotiate in good faith:
- (a) a clinical supply agreement and related quality agreement for the clinical supply of Licensed Compound by Qilu to Arbutus for use in Development of the Licensed Product in the Field in the ROW Territory on commercially reasonable terms, including a price to Arbutus which shall be identical to Arbutus' Manufacturing Cost for the Licensed Compound under Section 5.2; and/or
- (b) a commercial supply agreement and related quality agreement for the commercial supply of Licensed Compound by Qilu to Arbutus for use in Commercialization of the Licensed Products in the ROW Territory, on commercially reasonable terms, including a price to be agreed between the Parties that is less than the price available to Arbutus from a well-known CMO in the Territory agreed between the Parties (e.g., [\*\*\*]).

#### 5.5 Manufacturing Technology Transfer.

Upon request by Qilu made after receipt by Arbutus of the Upfront Payment, Arbutus shall, and shall use Commercially Reasonable Efforts to cause its CMO(s) to, commence the Manufacturing technology transfer (the "Manufacturing Technology Transfer") to Qilu or its permitted CMO or permitted Sublicensees in accordance with a manufacturing technology transfer plan ("Manufacturing Technology Transfer Plan") to be negotiated in good faith and entered into by the Parties, which shall set forth the process by which Arbutus shall transfer to Qilu (or its permitted CMO or permitted Sublicensees) all of the Arbutus IP that is necessary or reasonably useful for the Manufacturing of the Licensed Compound and Licensed Products ("*Manufacturing Technology*"). In addition to the Manufacturing Technology Transfer, Arbutus shall provide reasonable technical assistance and support for Qilu to Manufacture or have Manufactured the Licensed Compound and Licensed Products until Manufacturing Technology Transfer Completion in accordance with the terms of this Section 5.5(a) ("Technical Assistance"). Arbutus and Qilu shall each use Commercially Reasonable Efforts to perform their respective obligations necessary to achieve Manufacturing Technology Transfer Completion as soon as reasonably possible. Qilu shall be responsible for reimbursing Arbutus for any out-of-pocket costs, including any fees charged by any CMO or other Third Party service provider, required to perform the Manufacturing Technology Transfer or the Technical Assistance, to the extent not otherwise reimbursed under this Agreement. Upon the request of Qilu, Arbutus shall provide the Technical Assistance to Qilu, subject to the following terms and conditions: (1) the Technical Assistance shall not require any Arbutus employee to travel in-person to the Territory (except as may be agreed by the Parties otherwise, in which case, the Parties shall also agree on the specific travel arrangements and Qilu's responsibility for the costs therefor); (2) the Technical Assistance shall include the time spent by Arbutus employees to oversee any activities in connection with the Manufacturing Technology Transfer and the Technical Assistance provided by any CMO or other Third Party service provider; (3) [\*\*\*]; and (4) [\*\*\*](the "*Technical Assistance Cap*"). If Qilu requires Technical Assistance in excess of the Technical Assistance Cap, Arbutus agrees not to unreasonably withhold its agreement

to provide such additional Technical Assistance. Within thirty (30) days after the end of each Calendar Quarter when the Manufacturing Technology Transfer is ongoing or the Technical Assistance is provided, Arbutus shall deliver to Qilu an invoice setting forth the number of hours of Technical Assistance provided during the prior Calendar Quarter and the amounts owed to Arbutus with respect thereto, including any out-of-pocket costs to be paid by Qilu, together with any out-of-pocket costs incurred by Arbutus in connection with the Manufacturing Technology Transfer to be paid by Qilu, in each case to the extent not otherwise reimbursed or paid for by Qilu under this Agreement. Each such invoice shall be paid by Qilu within thirty (30) days of the date of such invoice and otherwise in accordance with Sections 7.5(g), 7.5(h) and 7.6.

- (b) After the Supply End Date, Qilu will have the right and responsibility to Manufacture or have Manufactured Licensed Product in the Territory for clinical or commercial use, as the case may be, using the Manufacturing Technology transferred under the Manufacturing Technology Transfer Plan.
- (c) If there is any additional Arbutus Know-How pertaining to Manufacturing Technology that comes into Arbutus' or any of its Affiliates' Control during the Term after Manufacturing Technology Transfer Completion (including any data resulting from the Manufacture of the Licensed Products in the ROW Territory after the Manufacturing Technology Transfer Completion), Arbutus shall promptly notify Qilu and provide copies thereof to Qilu in accordance with Section 2.5 at no additional cost.
- 5.6 Transfer of the Arbutus Materials. Following Arbutus' receipt of the Upfront Payment, Arbutus shall use Commercially Reasonable Efforts to arrange and conduct the shipment of the Arbutus Materials in accordance with the schedule set forth on <a href="Exhibit 1.19">Exhibit 1.19</a>. The Parties shall sign material transfer agreements in a form reasonably acceptable to both Parties before each shipment of the Arbutus Materials, which material transfer agreement shall include a price for the applicable Arbutus Materials that reflects the fair market value thereof as mutually agreed by the Parties. Risk of loss, damage and delay shall pass to Qilu [\*\*\*] at Arbutus's shipping dock and Qilu shall be responsible for arranging for shipment and importation of the Arbutus Materials into the Territory. For the avoidance of doubt, Arbutus shall not be required to deliver any materials or information pursuant to this <a href="Section 5.6">Section 5.6</a> that have been transferred electronically with other Arbutus Know-How or provided pursuant to the Clinical Supply Agreement.

## ARTICLE 6 COMMERCIALIZATION

#### 6.1 Commercialization Obligations.

- (a) Upon receipt of Regulatory Approval for a Licensed Product in the Field in the Territory, Qilu (directly, or through its Affiliates and Sublicensees) shall use Commercially Reasonable Efforts to Commercialize such Licensed Product in the Field in the Territory. Subject to the terms and conditions of this Agreement, including this <u>ARTICLE 6</u> and <u>ARTICLE 3</u>, Qilu will be solely responsible for Commercializing Licensed Products in the Field in the Territory at its sole expense, and will have sole discretion with respect to Commercializing Licensed Products in the Field in the Territory.
- (b) Qilu will perform its Commercialization obligations under this Agreement in good scientific manner and in compliance with all Applicable Laws.
- (c) Qilu will not under any circumstances use the Licensed Compound or Licensed Products as a "loss leader" to generate sales for its other products.
- (d) Qilu shall not sell a Licensed Product as part of a bundle including one or more active pharmaceutical ingredients or therapeutic agents other than those contained in the Licensed Product that is invoiced as a single product for a single price without the prior written consent of Arbutus as to the calculation of Net Sales relating thereto. For clarity, subject to the foregoing provisions of this Section 6.1(d), Qilu may Exploit the Licensed Compound and Licensed Products in any product or treatment regimen that comprises, or is a combination of, (i) a Licensed Product, and (ii) another product, where (i) and (ii) are labeled for use together either simultaneously or in a separate or sequential administration, whether or not sold for a single price. For clarity, the other product may be a small molecule drug or a biological drug.

31

#### **6.2** Commercialization Reports.

- (a) (i) Within [\*\*\*] days following the end of each Calendar Quarter for the first [\*\*\*] Calendar Years occurring after Regulatory Approval for the first Licensed Product in the Territory is obtained, and (ii) within [\*\*\*] days following the end of the [\*\*\*] Calendar Quarter during each Calendar Year thereafter until the end of the Term, Qilu shall submit to Arbutus a report summarizing in reasonable detail Qilu's and its Affiliates' and permitted Sublicensees' activities related to (x) the Commercialization of the Licensed Products during the preceding Calendar Quarter(s), and (y) the Manufacture of the Licensed Compound and Licensed Products, including (A) an update on Qilu's plans for the Manufacture and supply of the Licensed Compound and Licensed Products, including supply for raw materials and components and any Third Party suppliers and CMOs to be included as part of such plans, and (B) a summary of any material Manufacturing-related milestones that were in process or were achieved during the preceding Calendar Quarter, including the status of any technology transfer, process validation, etc. Arbutus shall have the opportunity to discuss each such report and its contents with Qilu, either through the JSC or in any other manner reasonably acceptable to both Parties, and Qilu shall provide to Arbutus any additional documentation or information reasonably requested by Arbutus relating to such reports.
- (b) At least [\*\*\*] prior to the anticipated First Commercial Sale of a Licensed Product in the Field in the Territory, Qilu shall submit to Arbutus its proposed commercial launch plan for such Licensed Product for Arbutus' review. Following the delivery of the initial commercial launch plan, Qilu shall submit to Arbutus an annual update to such plan within [\*\*\*] days after the end of each Calendar Year. The initial commercial launch plan and each subsequent annual update shall include promotional plans, projected timelines, pricing and contracting strategy, product position statement, communications strategy, and promotional efforts commitments. Upon the request of Arbutus from time to time after receipt of Regulatory Approval for the first Licensed Product in the Field in the Territory, Qilu shall provide to Arbutus (i) a copy of Qilu's then-current marketing plan for the Licensed Products in the Field in the Territory, and (ii) copies of any marketing materials then being used by Qilu to market and promote the Licensed Products in the Field in the Territory, in each case of (i) and (ii), as then currently available and to the extent not previously provided.

#### 6.3 Licensed Product Trademarks.

- (a) Each Party shall be solely responsible for developing, selecting, searching, registering and maintaining, and shall be the exclusive owner of, all Licensed Product Trademarks in such Party's Applicable Territory, except as expressly set forth in this Section 6.3.
- (b) Arbutus hereby grants to Qilu and its Affiliates an exclusive, royalty-free, non-transferable (except in accordance with Section 13.2) license, with the right to grant sublicenses solely in connection with a permitted sublicense pursuant to Section 2.3 with respect to a Licensed Product in the Field in the Territory, under any Licensed Product Trademarks Controlled by Arbutus or its Affiliates other than any Trademarks that include any corporate name or logo of Arbutus or its Affiliates (such Licensed Product Trademarks, the "Licensed Product-Specific Trademarks") for all uses in the Field in the Territory. A complete and accurate list of the Licensed Product-Specific Trademarks existing as of the

Execution Date is set forth in <u>Exhibit 6.3(b)</u>. During the Term, Arbutus and its Affiliates shall not use any Licensed Product-Specific Trademark or any other Trademark that is confusingly similar to any Licensed Product-Specific Trademark in the Territory (except the use of the Licensed Product-Specific Trademarks in the Territory solely in connection with the performance of Arbutus' obligations or exercise of its retained rights in the Territory pursuant to <u>Section 2.1</u>), or register or attempt to register any such Licensed Product-Specific Trademark or any other Trademark that is confusingly similar to any Licensed Product-Specific Trademark with any Governmental Authority in the Territory.

- (c) Qilu shall have the right to brand the Licensed Products in the Territory using any Trademarks (including Chinese character trademarks and trade names, including Chinese translation or transliteration of the Licensed Product-Specific Trademarks) Qilu determines appropriate other than any Trademarks that include any corporate name or logo of Arbutus or its Affiliates. As between the Parties, Qilu shall own all rights in the Trademarks specific to the Licensed Product in the Field in the Territory other than the Licensed-Product Specific Trademarks (the "*Qilu Territory Trademarks*"), and all goodwill therein shall accrue to Qilu. Qilu shall register, maintain and enforce, at its own cost and expense, the Qilu Territory Trademarks as Qilu determines reasonably necessary.
- **6.4 No Other Trademark Rights.** For the avoidance of doubt, except as expressly permitted by this Agreement or as otherwise agreed in writing by the Parties, neither Party will have any right to use the other Party's or the other Party's Affiliates' corporate names or logos in connection with Exploitation of Licensed Products, without first obtaining the other Party's written consent. Notwithstanding anything to the contrary herein, to the extent and only to the extent required by Applicable Laws, Qilu may include Arbutus' name and corporate logo on the Licensed Product label, packaging and promotional/marketing materials to indicate that the Licensed Product is in-licensed from Arbutus.
- **6.5 Diversion**. Subject to Applicable Law, each Party covenants and agrees that it shall not, and shall ensure that its Affiliates, Third Party Licensees (with respect to Arbutus) and Sublicensees (with respect to Qilu) do not, either directly or indirectly, promote, market, distribute, import, sell or have sold any Licensed Products, including via the Internet or mail order, to any Third Party or to any address or Internet Protocol address or the like in the other Party's Applicable Territory; provided, that each Party shall have the right to attend conferences and meetings of congresses in the other Party's Applicable Territory and to promote and market, for their Applicable Territory, Licensed Products to Third Party attendees at such conferences and meetings, subject to this Section 6.5. Neither Party shall engage, or shall permit its Affiliates, Third Party Licensees (with respect to Arbutus) or Sublicensees (with respect to Qilu) to engage, in any advertising or promotional activities relating to any Licensed Products for use directed primarily to customers or users of Licensed Products located in any country, jurisdiction or region in the other Party's Applicable Territory, or solicit orders from any prospective purchaser that such Party has reason to believe intends to distribute such Licensed Product in any country, jurisdiction or region in the other Party's Applicable Territory. If a Party or any of its Affiliates, Third Party Licensees (with respect to Arbutus) or Sublicensees (with respect to Qilu) receives any order for Licensed Products for use from a prospective purchaser that intends to distribute such Licensed Product in a country, jurisdiction or region in the other Party's Applicable Territory, then such Party shall promptly, but in any event within [\*\*\*],

refer that order to such other Party and shall not accept any such orders. Except as otherwise provided herein, neither Party shall, or shall permit its Affiliates, Third Party Licensees (with respect to Arbutus) or Sublicensees (with respect to Qilu) to, deliver or tender (or cause or knowingly permit to be delivered or tendered) any Licensed Products for use in the other Party's Applicable Territory. Notwithstanding the foregoing, this Section 6.5 is not intended to limit, and shall not limit, Arbutus' retained rights as set forth in Section 2.1, including Arbutus' right to Exploit Licensed Products in the Territory outside the Field.

# ARTICLE 7 PAYMENTS

- **7.1 Upfront Payment**. Within thirty (30) days of the Execution Date, and subject to receipt of Arbutus' invoice for the Upfront Payment issued on the Execution Date, Qilu shall pay to Arbutus a one-time, non-refundable, non-creditable upfront payment of Forty Million Dollars (\$40,000,000.00) (the "*Upfront Payment*").
- **7.2 Development and Regulatory Milestones**. Subject to the terms and conditions of this Agreement, Qilu shall make each of the one-time, non-refundable, non-creditable milestone payments to Arbutus that are set forth below (each such payment, a "**Development Milestone Payment**") upon the first achievement of the corresponding milestone event by or on behalf of Qilu or its Affiliate or Sublicensee with respect to a Licensed Product (each such milestone event, a "**Development Milestone Event**") in accordance with this <u>Section 7.2</u>. For clarity, each Development Milestone Payment under this <u>Section 7.2</u> shall be paid only once with respect to the first time the corresponding Development Milestone Event is achieved. In the event that a Development Milestone Event is achieved and an earlier Development Milestone Event has not been achieved (e.g., Development Milestone Event 4 is achieved but Development Milestone Event 3 has not been achieved), then such earlier Development Milestone Event shall be deemed to have been achieved at the same time as the later Development Milestone Event at the same time that the Development Milestone Payment for the earlier Development Milestone Event at the Arbutus in writing promptly, but in no event later than two (2) Business Days, after the achievement of each Development Milestone Event set forth in this <u>Section 7.2</u>. After receiving such notice, Arbutus shall invoice Qilu for the applicable Development Milestone Payment in accordance with the notice. Qilu shall pay the applicable Development Milestone Payment due to Arbutus in Dollars within twenty (20) Business Days following Qilu's receipt of such invoice.

34

	Development Milestone Event	<u>Development Milestone</u> <u>Payment (Dollars)</u>
1	[***]	\$[***]
2	[***]	\$[***]
3	[***]	\$[***]
4	[***]	\$[***]
5	[***]	\$[***]

[\*\*\*]

- **7.3 Manufacturing Technology Transfer Completion Payment**. Within two (2) Business Days of Manufacturing Technology Transfer Completion, Qilu shall provide notice to Arbutus of the Manufacturing Technology Transfer Completion. After receiving such notice, Arbutus shall invoice Qilu for a one-time, non-refundable, non-creditable payment of [\*\*\*] Dollars (\$[\*\*\*]). Within twenty (20) Business Days following Qilu's receipt of such invoice, Qilu shall pay such [\*\*\*] Dollars (\$[\*\*\*]) to Arbutus.
- **7.4 Sales Milestones**. Subject to the terms and conditions of this Agreement, Qilu shall make each of the one-time, non-refundable, non-creditable milestone payments to Arbutus set forth below (each such milestone payment, a "**Sales Milestone Payment**") following the end of the first Calendar Year in which Annual Net Sales of the Licensed Products by Qilu, its Affiliates and Sublicensees in the Territory achieve the sales threshold (set forth in the table below) corresponding to such Sales Milestone Payment (each such sales threshold, a "**Sales Milestone Event**") in accordance with this <u>Section 7.4</u>. In the event that more than one Sales Milestone Event is first achieved in the same Calendar Year, then Qilu shall pay to Arbutus each of the corresponding Sales Milestone Payments for each of the Sales Milestone Events that has first been achieved in such Calendar Year. Qilu shall notify Arbutus in writing of the first achievement of each Sales Milestone Event set forth in this <u>Section 7.4</u> as part of the royalty reports delivered in accordance with <u>Section 7.5(f)</u>. After receiving such notice, Arbutus shall invoice Qilu for the applicable Sales Milestone Payment in accordance with the notice. Qilu shall make payment to Arbutus of the corresponding Sales Milestone Payment within twenty (20) Business Days after Qilu's receipt of such invoice.

Sales Milestone Event (in Dollars)	Sales Milestone Payment (Dollars)
Annual Net Sales in a given Calendar Year are equal to or greater than \$[***]	\$[***]
Annual Net Sales in a given Calendar Year are equal to or greater than \$[***]	\$[***]
Annual Net Sales in a given Calendar Year are equal to or greater than \$[***]	\$[***]
Annual Net Sales in a given Calendar Year are equal to or greater than \$[***]	\$[***]
Annual Net Sales in a given Calendar Year are equal to or greater than \$[***]	\$[***]

## 7.5 Royalty Payments to Arbutus.

(a) **Royalty Rates**. Subject to the terms of this <u>Section 7.5</u>, Qilu shall pay to Arbutus tiered royalties on Annual Net Sales in a given Calendar Year as provided below. Royalties shall be payable on a Licensed Product-by-Licensed Product and Relevant Region-by-Relevant Region basis during the applicable Royalty Term. For clarity, the royalties (and royalty tiers) set forth below shall be calculated on an aggregate basis based on Net Sales of all Licensed Products in the Territory in a Calendar Year.

Annual Net Sales in a Given Calendar Year (in Dollars)	Royalty Rate
Portion of Annual Net Sales in a given Calendar Year above \$0 and up to and including \$[***]	[***]%
Portion of Annual Net Sales in a given Calendar Year greater than $\{***\}$ up to and including $\{***\}$	[***]%
Portion of Annual Net Sales in a given Calendar Year greater than $\{***\}$ up to and including $\{***\}$	[***]%
Portion of Annual Net Sales in a given Calendar Year greater than $\{***\}$ up to and including $\{***\}$	[***]%
Portion of Annual Net Sales in a given Calendar Year greater than \$[***]	[***]%

The applicable royalty rate set forth in the table above will apply only to that portion of the Annual Net Sales during a given Calendar Year that falls within the indicated range.

- (b) **Royalty Termination Date**. Following expiration of the Royalty Term for a given Licensed Product in a Relevant Region: (i) no further royalties shall be payable in respect of sales of such Licensed Product in such Relevant Region; and (ii) the License granted to Qilu hereunder with respect to such Licensed Product in such Relevant Region shall automatically become fully paid-up, perpetual, irrevocable and royalty-free.
- (c) **Royalty Stacking**. If it is necessary to obtain a license from any Third Party to any Patent Rights owned or controlled by such Third Party to Develop, Manufacture or Commercialize a Licensed Product in the Field in the Territory (a "*Third Party License*"), then Qilu shall have the right to obtain such Third Party License and may deduct from Qilu's royalty obligations under <u>Section 7.5(a)</u>, on a Calendar Quarter-by-Calendar Quarter basis, [\*\*\*] of any royalties paid under such Third Party License for such Patent Rights during the applicable Calendar Quarter; [\*\*\*].
- (d) **Royalty Reduction**. The royalty rate payable with respect to Annual Net Sales of a Licensed Product shall be reduced on a Relevant Region-by-Relevant Region basis, to [\*\*\*] of the rate otherwise payable pursuant to <u>Section 7.5(a)</u> during the portion of the applicable Royalty Term with respect to such Licensed Product in such Relevant Region which remains in effect after the earlier of (i) the expiration of the last Valid Claim of an Arbutus Patent that Covers such Licensed Product in such Relevant Region or (ii) the first full Calendar Quarter following the existence of Generic Competition for such Licensed Product in such Relevant Region.
- (e) **Minimum Royalty**. In no event, after taking into account the deductions set forth in <u>Section 7.5(c)</u> and the reductions set forth in <u>Section 7.5(d)</u>, will any royalties payable by Qilu to Arbutus under this <u>Section 7.5</u> for any Licensed Product in any Relevant Region in any Calendar Quarter be less than [\*\*\*] of the amount of royalties that would otherwise be payable with respect thereto under <u>Section 7.5(a)</u> without taking into account such deductions and reductions.
- (f) **Royalty Reports and Payments**. Within forty-five (45) days after the end of each Calendar Quarter, commencing with the Calendar Quarter of the First Commercial Sale of the first Licensed Product in the Territory, Qilu shall provide Arbutus with a report that contains the following information for the applicable Calendar Quarter, on a Licensed Product-by-Licensed Product and Relevant Region-by-Relevant Region basis: (i) gross sales and Net Sales (including reasonable detail for deductions from gross sales to Net Sales and any calculations relating to conversion of foreign currency into Dollar equivalents); and (ii) the royalties payable under this <u>Section 7.5</u> (including reasonable detail for any deductions to such royalties or reductions to royalty rates taken pursuant to <u>Section 7.5(c)</u> or <u>Section 7.5(d)</u>) for such Calendar Quarter and (iii) if applicable with respect to any report relating to the last Calendar Quarter of a Calendar Year, a notification of any Sales Milestone Events first achieved during such Calendar Year and the amount of the corresponding Sales Milestone Payments payable under <u>Section 7.4</u>. After receiving the report, Arbutus shall invoice Qilu for the royalties payable under this <u>Section 7.5</u> for such Calendar Quarter in accordance with the report. Within twenty (20) Business Days after receipt of such invoice, Qilu shall pay to Arbutus the royalties payable under this <u>Section 7.5</u> for such Calendar Quarter.

- (g) **Payment Method, Currency, and Exchange Rate.** All payments to be made by Qilu to Arbutus under this Agreement shall be made in U.S. Dollars by electronic funds transfer in immediately available funds to a bank account designated in writing by Arbutus. For the purposes of calculating any sums due under this Agreement, Qilu shall convert any amount expressed in a foreign currency into U.S. Dollar equivalents, calculated using the applicable currency conversion rate as published by State Administration of Foreign Exchange of People's Republic of China on the last Business Day of the month immediately preceding the month in which the applicable payment is due.
- (h) **Interest**. Any undisputed payments not made when due under this Agreement as provided herein will bear interest at [\*\*\*]. If the is no longer published, the Parties will agree upon another internationally recognized rate which has historically been substantially equivalent to the and utilize such rate retroactively to such time as [\*\*\*] was no longer available.
- **Taxes.** If Qilu, its Affiliates, or Sublicensees, as applicable, are required by Applicable Law to deduct any Taxes from or in respect of any sum payable under this Agreement to Arbutus: (a) the sum payable will be increased as necessary so that after making all required deductions or withholdings for Taxes Arbutus receives a net amount equal to the sum it would have received had no such deductions or withholdings been made (i.e., Arbutus has received the actual stated amount as set forth under <u>ARTICLE 7</u> or other applicable provision of this Agreement); (b) Qilu, its Affiliates, or Sublicensees, as applicable, shall make such deductions or withholdings; and (c) Qilu, its Affiliates, or Sublicensees, as applicable, shall pay the amount deducted or withheld to the relevant Tax authority or other Governmental Authority in accordance with Applicable Law, and pay the remainder to Arbutus. Qilu shall be responsible for (i) applying for any tax exemption or reduction under Applicable Law with regard to its payments to Arbutus under this Agreement, and (ii) preparation and filing of all applicable Tax returns relating thereto. Arbutus shall cooperate, to the extent reasonably required, with the filing of any such Tax returns. Qilu shall indemnify Arbutus for any Taxes imposed on Arbutus with respect to such payments if Arbutus directly pays any Taxes on such payments, and Qilu shall promptly reimburse Arbutus for such Taxes, including all reasonable related costs. If Arbutus determines that it is required to report any such Taxes, Qilu shall promptly provide Arbutus with applicable receipts and other documentation necessary or appropriate for such report. Arbutus will issue the corresponding invoices reflecting the full amount due under other provisions of this Agreement and any such withholding or similar Taxes collected at the source as separate line items in the notes section of the said invoices, following the format provided by Qilu for such invoices. Except as set forth in this Section 7.6, each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the efforts of the Parties under this Agreement.
- **7.7 Financial Audits**. Qilu shall keep (and shall cause its Affiliates and Sublicensees to keep) complete and accurate records pertaining to the sale or other disposition of Licensed Products in reasonable detail to permit Arbutus to confirm the accuracy of all royalty payments reported under Section 7.5 and Sales Milestone Events and corresponding Sales Milestones Payments reported under Section 7.4, for at least [\*\*\*] following the end of the Calendar Year to which such records pertain. Arbutus shall have the right to cause an independent, certified public accountant of internationally recognized standing which shall be mutually agreed by the Parties (the "Auditor") to audit such

records solely to confirm Net Sales, royalty payments and commercial sales milestones for a period covering not more than the preceding [\*\*\*]. Such audits shall be performed during normal business hours upon [\*\*\*] days' prior written notice to Qilu, and in a manner that does not interfere with Qilu's or its applicable Affiliate's or Sublicensee's business activities for a period of [\*\*\*]. The Auditor will execute a written confidentiality agreement that is acceptable to Qilu with Qilu and will disclose to Arbutus only such information as is reasonably necessary to provide Arbutus with information regarding any actual or potential discrepancies between amounts reported and amounts actually paid or payable under this Agreement. The report of the Auditor will include the methodology and calculations used to determine the results, will be delivered to Arbutus and Qilu at the same time, and will be final after delivery to both Parties. Qilu shall pay the amount of any underpayment disclosed in any Auditor's report, together with any interest owed thereon (calculated in accordance with Section 7.5(h)) within thirty (30) days after delivery to the Parties of the final Auditor's report. If such final Auditor's report discloses an overpayment by Qilu of the royalties or other amounts payable hereunder, Qilu shall have the right to offset such overpayment against future payments owed to Arbutus under this Agreement, Arbutus shall refund the amount of such overpayment to Qilu within thirty (30) days after written request by Qilu. Any disclosures or reports disclosed to Arbutus under this Section 7.7 shall be Qilu's Confidential Information.

**7.8 Form of Payment.** All payments to be made by Qilu to Arbutus under this Agreement shall be made in United States Dollars and may be paid by bank wire transfer in immediately available funds to the bank account of Arbutus as Arbutus may from time to time designate by written notice to Qilu. Arbutus shall provide wire instructions for such designated bank account in writing to Qilu at least thirty (30) days prior to the payment due date, and shall notify Qilu by written notice of any changes to Arbutus's designated bank account and wire instructions. As of the Execution Date, the designated bank account of Arbutus for receiving all payments payable to Arbutus hereunder is as follows:

FOR FUNDS COMING IN US CURRENCY ONLY: [\*\*\*]

# ARTICLE 8 CONFIDENTIALITY; PUBLICATION

**8.1** Confidential Information. "Confidential Information" means all non-public Know-How or other confidential or proprietary information, including proprietary materials or information, ideas, inventions, discoveries, concepts, compounds, compositions, formulations, formulas, practices, procedures, processes, methods, knowledge, know-how, trade secrets, technology, inventories, machines, techniques, development, designs, drawings, computer programs, skill, experience, documents, apparatus, results, clinical and regulatory strategies, regulatory documentation, information and submissions pertaining to or made in association with Regulatory Documents, data (including pharmacological, toxicological, and clinical data, raw data, analytical and quality control data, manufacturing data and descriptions, patent and legal data, market data, financial data or descriptions), devices, assays, chemical formulations, specifications, material, product samples and other samples, physical, chemical and biological materials and compounds, and the like, transferred, disclosed or otherwise made available by or on behalf of a Party (the "Disclosing Party") to the other Party or its representatives (the "Receiving Party") prior to, on or after the Execution Date, whether or not patentable and

whether or not disclosed in written, oral graphical, machine-readable, electronic or other form or otherwise observed by the Receiving Party, and whether or not such information is marked as confidential or proprietary; provided that, in the event such information is not marked as confidential or proprietary, the circumstances of its disclosure or observation are such that a reasonable person should know that it is confidential or proprietary. It is understood and agreed by the Parties that the terms and conditions of this Agreement will be considered Confidential Information of both Parties and kept confidential by each of the Parties as set forth in this <u>ARTICLE 8</u>. For clarity, the Arbutus Know-How and Arbutus Patents (prior to their publication) will be Confidential Information of Arbutus.

- 8.2 Non-Disclosure and Non-Use Obligation. Except as otherwise expressly set forth herein, the Receiving Party shall keep the Confidential Information of the Disclosing Party confidential using at least the same degree of care with which the Receiving Party holds its own confidential information, but in no event less than a commercially reasonable degree of care, and shall not (a) disclose such Confidential Information to any person or entity without the prior written approval of the Disclosing Party, except, solely to the extent necessary to exercise its rights or perform its obligations under this Agreement, to its employees, Affiliates, Sublicensees or potential Sublicensees (with respect to Qilu), Third Party Licensees (with respect to Arbutus) and contractors, consultants or agents who have a need to know such Confidential Information, all of whom will be similarly bound by the provisions of this <u>ARTICLE 8</u> and for whose compliance herewith the Disclosing Party will be responsible, or (b) use such Confidential Information for any purpose other than for the purposes contemplated by this Agreement. The Receiving Party will use diligent efforts to cause the foregoing Persons to comply with the restrictions on use and disclosure of the Disclosing Party's Confidential Information set forth in this <u>Section 8.2</u>, and shall be responsible for ensuring that such Persons maintain the Disclosing Party's Confidential Information in accordance with this <u>ARTICLE 8</u>.
- **8.3 Return of Confidential Information**. Upon the expiration or termination of this Agreement, the Receiving Party shall return to the Disclosing Party unused tangible materials, or, as directed by the Disclosing Party, destroy all Confidential Information of the Disclosing Party that is in the Receiving Party's possession or control; <u>provided</u>, <u>however</u>, that one (1) copy of any Confidential Information of the Disclosing Party may be retained and stored solely for the purpose of determining its obligations under this Agreement, <u>provided</u> that the non-disclosure and non-use obligation under this <u>ARTICLE 8</u> shall continue to apply to any such copy. In addition, the Receiving Party shall not be required to return or destroy Confidential Information contained in any computer system back-up records made in the ordinary course of business, <u>provided</u> that such Confidential Information may not be accessed without the Disclosing Party's prior written consent or except as required by Applicable Law, and that such Confidential Information remains subject to the non-disclosure and non-use obligations under this <u>ARTICLE 8</u>.

- **8.4 Exemption**. The foregoing confidentiality and non-use obligations shall not apply to: (a) information already in the possession of the Receiving Party prior to its disclosure by the Disclosing Party as evidenced by contemporaneous written records; (b) information that is already in the public domain as of the date of disclosure to the Receiving Party or that comes into the public domain thereafter by publication or otherwise through no breach of the obligations of confidentiality and non-use hereunder by the Receiving Party, including with respect to Section 8.8; (c) information that has been disclosed to the Receiving Party from another source free from any obligation of confidentiality to the Disclosing Party; or (d) information that is developed independently by employees, contractors, consultants or agents of the Receiving Party or any of its Affiliates without use of or reliance upon the Disclosing Party's Confidential Information, as evidenced by contemporaneous written records.
- **8.5 Permitted Disclosures.** In addition to the exceptions contained in <u>Section 8.2</u> and <u>Section 8.4</u>, the Receiving Party may disclose Confidential Information of the Disclosing Party to the extent (and solely to the extent) that such disclosure is reasonably necessary in the following instances:
- (a) to comply with Applicable Law (including any securities law or regulation or the rules of a securities exchange pursuant to Section 8.6 below) or the order of a court of competent jurisdiction, provided that, where legally permissible, the Receiving Party promptly notifies the Disclosing Party of such obligation sufficiently prior to making such disclosure, so as to allow the Disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information to be disclosed, and fully cooperates with the Disclosing Party, if so requested, in maintaining the confidentiality of such information by applying for a protective order or any similar legal instrument. In any event, the Receiving Party shall only disclose such Confidential Information to the extent required under Applicable Law and shall continue to treat such information as Confidential Information for all other purposes under this Agreement;
- (b) to prosecute or defend litigation or to otherwise exercise its rights or perform its obligations in Section 11.4, to obtain or maintain Regulatory Approvals and other regulatory filings and communications, to file or prosecute patent applications as contemplated by this Agreement and to enforce Patent Rights in connection with the Receiving Party's rights and obligations pursuant to this Agreement; and
- (c) to allow the Receiving Party to exercise its rights and perform its obligations under this Agreement, provided that such disclosure is covered by terms of confidentiality and non-use at least as restrictive as those set forth herein.
  - **8.6 Disclosure of Agreement**. Either Party may disclose the terms of this Agreement:

- (a) to the extent required or advisable to comply with the rules and regulations promulgated by the United States Securities and Exchange Commission or any equivalent governmental agency in the Territory, <u>provided</u> that such disclosing Party shall (i) except where impracticable, give reasonable advance notice to the other Party of such required disclosure and a copy of the proposed disclosure, including any request for confidential treatment or redactions proposed by the disclosing Party, and (ii) consider in good faith any requests by the other Party to seek confidential treatment for or redactions of any portions of such proposed disclosure, it being understood and agreed that the disclosing Party shall have the right, if so advised by such Party's counsel, to disclose the terms of this Agreement if required or advisable to comply with the rules and regulations promulgated by the United States Securities and Exchange Commission or any equivalent governmental agency in the Territory;
- (b) to actual acquirers, permitted assignees, merger partners, existing investment bankers, investors and lenders or financing sources, <u>provided</u>, that such Third Party has executed with such Party, and such Party has provided to the other Party, a copy of a confidentiality agreement (redacted for name of party, economic terms or other competitive information) with terms at least as protective with respect to Confidential Information as those contained herein, in a form reasonably acceptable to the other Party (which acceptance shall not be unreasonably withheld, conditioned or delayed);
- (c) for customary discussions and other disclosures with and to *bona fide* prospective acquirers, permitted assignees or merger candidates or to *bona fide* potential investment bankers, investors and lenders, or financing sources, <u>provided</u>, that such Third Party has executed with such Party, and such Party has provided to the other Party, a copy of a confidentiality agreement (redacted for name of party, economic terms or other competitive information) with terms at least as protective with respect to Confidential Information as those contained herein, in a form reasonably acceptable to the other Party (which acceptance shall not be unreasonably withheld, conditioned or delayed); and
- (d) to the extent necessary to perform such Party's obligations or exercise its rights under this Agreement, to any actual or potential licensee or sublicensee of such Party with respect to the Licensed Compound or Licensed Products in a redacted form of this Agreement or its terms which shall be redacted in respect of financial terms, including payment amounts, provided, that (1) any such actual or potential, licensee or sublicensee agrees in writing to be bound by obligations of confidentiality and non-use no less protective of the Disclosing Party than those set forth in this <u>ARTICLE 8</u>.
- **8.7 Publicity; Use of Name and Logo**. The Parties have agreed on a press release announcing this Agreement, which shall be issued by the Parties on such date and time as may be agreed by the Parties. Except to the extent expressly permitted under this Agreement or, if executed, the Clinical Supply Agreement, the Commercial Supply Agreement or the Pharmacovigilance Agreement, or as required by Applicable Laws, each Party will not use the other Party's or its Affiliates' name or logo in any label, press release or product advertising, or for any other promotional purpose, without first obtaining the other Party's written consent.

- **8.8 Publications.** If Qilu wishes to publish or present in a public forum the scientific or technical results of any Development activities with respect to the Licensed Compound or Licensed Products in the Territory, Qilu shall provide Arbutus the opportunity to review any proposed abstracts, manuscripts or scientific presentations (including verbal presentations) with respect thereto by delivering a copy thereof (if applicable) to Arbutus at least thirty (30) days prior to Qilu's intended submission for publication. Arbutus shall have thirty (30) days from its receipt of any such copy of the proposed disclosure in which to notify Qilu in writing of (a) any request to modify or delay the timing of any publication or presentation for up to ninety (90) days for bona fide patenting reasons, or (b) any request to delete Arbutus' Confidential Information prior to such publication. Qilu shall promptly comply with any such request made by Arbutus prior to proceeding with such publication.
- **8.9 Engaging Individuals.** Each Party hereby agrees that all Persons engaged to perform any activities under this Agreement shall be contractually bound by confidentiality obligations at least as restrictive as the obligations of confidentiality and non-use set forth in this <u>ARTICLE 8</u> prior to performing such activities.
- **8.10 Survival**. This <u>ARTICLE 8</u> shall survive the expiration or termination of this Agreement and shall remain in full force and effect for seven (7) years after such expiration or termination; <u>provided</u>, that each Party's obligations with respect to any trade secret included in the Confidential Information of the other Party shall continue for so long as such trade secret is protected under Applicable Law.

# ARTICLE 9 REPRESENTATIONS, WARRANTIES, AND COVENANTS

- **9.1 Representations and Warranties of Each Party**. Each Party represents and warrants to the other Party as of the Execution Date that:
- (a) it is validly existing and in good standing under the Applicable Laws of the jurisdiction of its incorporation;
- (b) it has the full right, power and authority to (i) enter into this Agreement, (ii) conduct the activities allocated to it under this Agreement, (iii) grant the licenses under this Agreement, (iv) grant and assign the rights under this Agreement, and (v) disclose the information and Know-How that is to be disclosed under this Agreement, in each case to the extent applicable to such Party;
- (c) this Agreement has been duly executed by it and is legally binding upon it, enforceable in accordance with its terms, subject to bankruptcy, insolvency, reorganization, arrangement, winding-up, moratorium and similar laws of general application affecting the enforcement of creditors' rights generally, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it or its assets may be bound, nor violate any Applicable Law of any court, governmental body or administrative or other agency having jurisdiction over it;

- (d) neither it, nor any of its Affiliates are party to any agreements, instruments or understanding, oral or written, that conflict with its obligations under this Agreement; and
- (e) except as otherwise provided herein, no government authorization, consent, approval, license, exemption of or filing or registration with any Governmental Authority, domestic or foreign, under any Applicable Laws currently in effect, on the part of such Party, is necessary for the transactions contemplated by this Agreement or any other agreement or instrument executed in connection herewith.
- **9.2 Representations and Warranties of Arbutus**. Arbutus represents and warrants to Qilu as of the Execution Date that:
- (a) all Arbutus Patents existing as of the Execution Date are completely and accurately set forth on Exhibit 1.21 hereto. The inventors named in each Arbutus Patent have each assigned to Arbutus or its applicable Affiliate their respective entire right, title and interest in and to such Arbutus Patent. The Arbutus Patents set forth on Exhibit 1.21 are not subject to any liens or encumbrances. Arbutus and its Affiliates have complied with all Appliable Laws in the prosecution and maintenance of the Arbutus Patents;
- (b) Arbutus and its Affiliates exclusively own the Arbutus IP existing as of the Execution Date and there is no agreement, instrument or understanding between Arbutus or its Affiliates and any Third Party pursuant to which Arbutus or its Affiliates have obtained any right or license to the Licensed Compound or the Licensed Products or any intellectual property rights related to the Licensed Compound or the Licensed Products. Arbutus has Control over all Know-How and Patent Rights owned by it or its Affiliates as of the Execution Date that are necessary or reasonably useful for the research, Development, Manufacturing, Commercialization or other Exploitation of the Licensed Compound and Licensed Products as contemplated under this Agreement as of the Execution Date;
- (c) Arbutus has the right to grant all rights and licenses it purports to grant to Qilu with respect to the Arbutus IP under this Agreement;
- (d) there has been no settled, pending or threatened claim made in writing or lawsuit or legal proceeding of a Third Party against Arbutus or its Affiliates alleging that the Arbutus IP or the practice or use thereof misappropriates or infringes, in part or in whole, the intellectual property or intellectual property rights of any Third Party in the Territory;
- (e) to the actual knowledge of Arbutus and its Affiliates, without any independent investigation, the Exploitation of the Licensed Compound and Licensed Products under the Arbutus IP in the Field in the Territory does not infringe the intellectual property or intellectual property rights of any Third Party as of the Execution Date;
- (f) Arbutus and its Affiliates have not granted or agreed, promised or offered to grant, or have been or are under any obligation to grant, any right or license to any Third Party relating to any of the Arbutus IP that would cause a conflict or interfere with any of the rights or licenses granted to Qilu and its Affiliates hereunder;

- (g) Arbutus and its Affiliates have not received any written notice or information concerning the institution of any interference, opposition, reexamination, reissue, revocation, nullification, cancellation, patent protest, or any official proceeding involving any Arbutus Patent anywhere in the Territory. There has been and there is no settled, pending or threatened claim or lawsuit or legal or administrative proceeding of a Third Party alleging that the Arbutus Patents are invalid or unenforceable. To the knowledge of Arbutus and its Affiliates, the Arbutus Patents are, or, upon issuance, will be, valid and enforceable;
- (h) Arbutus has disclosed to Qilu and made available to Qilu for review (i) all safety-related data for the Licensed Compound and Licensed Products and (ii) all material non-clinical and clinical data within the Arbutus IP, in each case of (i) and (ii), in the possession of Arbutus or its Affiliates as of the Execution Date. To the knowledge of Arbutus and its Affiliates, all such data is true and accurate in all material respects as of the time it was disclosed or otherwise made available;
- (i) Arbutus, its Affiliates and its and their respective Relevant Persons have complied with all Applicable Laws in all material respects in connection with the Exploitation of the Licensed Compound and Licensed Products, including cGLP, cGMP, cGCP and cGVP;
- (j) Arbutus and its Affiliates have not used in the research, Development and Manufacture of the Licensed Compound and Licensed Products any employee, consultant or contractor who has been Debarred by any Regulatory Authority, or to the knowledge of Arbutus and its Affiliates, is the subject of a debarment proceeding by any Regulatory Authority;
- (k) neither Arbutus nor any of its Affiliates is a U.S. business that (i) produces, designs, tests, manufactures, fabricates, or develops one or more "critical technologies"; (ii) performs the functions as set forth in column 2 of Appendix A to 31 C.F.R. Part 800 with respect to "covered investment critical infrastructure"; or (iii) maintains or collects, directly or indirectly, "sensitive personal data" of U.S. citizens, in each case as such terms in quotation marks are defined in the Defense Production Act of 1950, as amended, including all implementing regulations thereof; and
- (l) no funding, facilities, or personnel of any Governmental Authority or any public or private educational or research institutions were used to develop or create any Arbutus IP, and neither Arbutus nor any of its Affiliates has entered into a government funding relationship that would result in rights to the Licensed Compound or any Licensed Products residing in any Governmental Authority, including, without limitation, the U.S. Government, the National Institutes of Health, or other government agency, and the licenses granted hereunder are not subject to overriding obligations to any Governmental Authority, including, without limitation, the U.S. Government as set forth in 35 U.S.C. §§ 200 et seq., or any similar obligations under Applicable Laws of any other country or jurisdiction.

Debarment; Exclusion; Disqualification. Each Party hereby certifies to the other as of the License Effective Date and at all times during the Term that neither it, nor any of its Affiliates or, in the case of Qilu, Sublicensees, or, in the case of Arbutus, Third Party Licensees, have been debarred under Section 306(a) or 306(b) of the United States Federal Food, Drug and Cosmetic Act, as may be amended and supplemented from time to time, or any foreign equivalent thereof ("Debarred"), excluded by the Office of Inspector General pursuant to 42 U.S.C. § 1320a-7, et seq. or any state agency from participation in any Federal or state health care program or any foreign equivalent thereof (collectively "Excluded"), or otherwise disqualified or restricted by the USFDA pursuant to 21 C.F.R. 312.70 or any other Regulatory Authority or foreign equivalent thereof ("Disqualified"), and during the Term, neither it, nor any of its Affiliates or, in the case of Qilu, Sublicensees, or, in the case of Arbutus, Third Party Licensees, shall use, in any capacity in connection with the obligations to be performed under this Agreement, any Person who has been Debarred, Excluded or Disqualified. Each Party acknowledges and agrees that this certification imposes a continuing obligation on such Party to notify the other Party promptly if this certification is no longer accurate, and that if, during the Term of this Agreement, it becomes aware that it or any of its or its Affiliates' employees or agents performing under this Agreement is the subject of any investigation or proceeding that could lead to that Party becoming a Debarred, Excluded or Disqualified entity or individual, an Excluded entity or individual or a convicted entity or individual, such Party will promptly notify the other Party.

#### **9.4 Covenants of Arbutus**. Arbutus covenants to Qilu that:

- (a) during the Term, Arbutus and its Affiliates will not make any commitment to any Third Party in conflict with the rights granted by it hereunder;
- (b) neither Arbutus, nor any of its Affiliates, shall assign, transfer, convey or otherwise encumber during the Term, its right, title or interest in or to the Arbutus IP in a manner that would prevent Qilu or its Affiliates, Subcontractors and Sublicensees from researching, Developing, Manufacturing or Commercializing the Licensed Compound or the Licensed Products or from otherwise exploiting its or their rights and licenses granted or assigned by Arbutus hereunder, or that would interfere with or be inconsistent with any of the foregoing activities;
- (c) during the Term, Arbutus will promptly disclose and make available to Qilu for review (i) all safety-related data for the Licensed Compound and Licensed Products, and (ii) all material non-clinical and clinical data within the Arbutus IP, in each case of (i) and (ii), which comes into the possession of Arbutus or its Affiliates and has not been disclosed or otherwise made available to Qilu for review previously. Arbutus shall use Commercially Reasonable Efforts to confirm that all such data is true and accurate in all material respects as of the time it is disclosed or otherwise made available to Qilu, which efforts shall in no event be less than the efforts Arbutus would use if such data were to be used by Arbutus in its own Exploitation of the Licensed Compound and Licensed Products in the Field in the ROW Territory;

- (d) the Licensed Product supplied by Arbutus to Qilu under <u>Section 5.1</u> shall, at the time of delivery, comply with all applicable specifications and have been Manufactured and delivered in accordance with all Applicable Laws, including cGMP; and
- (e) during the Term of this Agreement, Arbutus shall prosecute and maintain all Arbutus Patents in accordance with <u>Section 11.2</u>.
- **9.5 Covenants of Qilu.** Qilu hereby covenants to Arbutus that when performing its activities pursuant to this Agreement:
- (a) it will prepare, maintain and retain all Regulatory Documents in the Territory pursuant to and in accordance in all material respects with all Applicable Laws and will not make any materially false or misleading statement to a Regulatory Authority in connection with such Regulatory Documents;
- (b) it will, and will cause each of its Affiliates and Sublicensees and any of their respective directors, officers, managers, employees, independent contractors, representatives or agents to, at all times, duly obtain and maintain all Approvals from and complete all filings and registrations with the Governmental Authorities as required by Applicable Laws in a timely manner for conducting its business and engaging in the activities as contemplated hereunder in compliance with all Applicable Laws in all material respects;
- (c) during the Term, Qilu will promptly disclose and make available to Arbutus for review (i) all safety-related data for the Licensed Compound and Licensed Products and (ii) all material non-clinical and clinical data for the Licensed Compound and Licensed Products, in each case of (i) and (ii), which comes into the possession of Qilu or its Affiliates or Sublicensees and has not been disclosed or otherwise made available to Arbutus for review previously. Qilu shall use Commercially Reasonable Efforts to confirm that all such data is true and accurate in all material respects as of the time it is disclosed or otherwise made available to Arbutus, which efforts shall in no event be less than the efforts Qilu would use if such data were to be used by Qilu in its own Exploitation of the Licensed Compound and Licensed Products in the Field in the Territory; and
- (d) it will not, and will cause each of its Affiliates and Sublicensees and any of their respective directors, officers, managers, employees, independent contractors, representatives or agents (collectively, "*Relevant Persons*") not to, engage directly or indirectly in transactions connected with any of North Korea, Iraq, Libya, Cuba, Iran, Myanmar or Sudan, or otherwise engage directly or indirectly in transactions connected with any government, country or other entity or Person that is the target of U.S. economic sanctions administered by the Office of Foreign Assets Control of the United States Treasury Department, including those designated on its list of Specially Designated Nationals and Blocked Persons. No Relevant Person will receive unlicensed donations or engaged in any financial transaction while knowing or having reasonable cause to believe that such transaction poses a risk of furthering terrorist attacks anywhere in the world.

## 9.6 Compliance with Anti-Corruption Laws.

- (a) Each Party agrees on behalf of itself, its Affiliates, and its and their shareholders, partners officers, directors, employees, agents and any other persons or entities acting on its behalf in connection with this Agreement (collectively, the "Section 9.6 Representatives") that it and its Section 9.6 Representatives, from and after the Execution Date, when performing its activities pursuant to and in connection with this Agreement:
  - (i) shall not in the performance of this Agreement violate any applicable anti-bribery and anti-corruption laws or regulations, including the US Foreign Corrupt Practices Act, the UK Bribery Act 2010, the PRC Criminal Law, the PRC Anti-Unfair Competition Law or other local law (collectively, the "Anti-Corruption Laws");
  - (ii) shall adhere to its own internal anticorruption policies and shall not, in the performance of this Agreement, directly or indirectly, make any payment, or offer or transfer anything of value, or agree or promise to make any payment or offer or transfer anything of value, to a government official or government employee, to any political party or any candidate for political office or to any other Third Party with the purpose of influencing decisions related to either Party or its business in a manner that would violate Anti-Corruption Laws; and
  - (iii) shall not, directly or indirectly, solicit, receive or agree to accept any payment of money or anything of value in violation of the Anti-Corruption Laws.
- (b) Each Party shall (i) promptly provide written notice to the other Party of any violations of Anti-Corruption Laws by such Party, its Affiliates or its and their respective Section 9.6 Representatives that are performing under this Agreement of which it becomes aware; and (ii) upon the request of the other Party (which such request may be made no more frequently than once a year), verify in writing that to the best of its knowledge, there have been no violations of Anti-Corruption Laws by such Party or its Section 9.6 Representatives that are performing under this Agreement, or shall provide details of any exception to the foregoing.
- (c) Each Party shall maintain records (financial and otherwise) and supporting documentation related to the subject matter of this Agreement as required under applicable Anti-Corruption Laws, including, as applicable, the accounting provisions of the US Foreign Corrupt Practices Act. Should a violation of any applicable Anti-Corruption Laws be suspected by either Party that is related to the Parties' mutual business interests under this Agreement, then upon the suspecting party sharing evidence of such suspected violation with the suspected Party, the suspected Party shall provide the suspecting Party or its representative with access to such records for the limited purpose of verifying compliance with the provisions of this Section 9.6 as related to such specific suspected violation of the Anti-Corruption Laws. Such records shall constitute such suspected Party's Confidential Information.
- (d) Each Party has established and maintains reasonable internal policies and controls intended to ensure compliance with Anti-Corruption Laws to the extent

applicable to it under the laws of the jurisdiction of its incorporation, and to its actual knowledge, neither it nor any of its Section 9.6 Representatives has knowingly violated any Anti-Corruption Laws, including the US Foreign Corrupt Practices Act, that would result in the other Party benefiting from such violation in connection with this Agreement.

- 9.7 Compliance with Law. Each Party hereby covenants to the other Party that, in the course of performing its obligations and exercising its rights under this Agreement, such Party shall, to the extent applicable, perform its activities pursuant to this Agreement in compliance with all Applicable Laws, including cGLP, cGMP, cGCP and cGVP, and with respect to Qilu any Applicable Laws concerning the protection, collection, use, storage, processing or transfer of personal data, important commercial data and human genetic resources materials and information (as such terms are defined under the PRC Human Genetic Resources Administrative Regulations (i.e.中华人民共和国人类遗传资源管理条例) promulgated by the State Council of the PRC effective as of July 1, 2019, as may be amended from time to time), the published standards of any applicable Regulatory Authorities, and the scientific standards applicable to the conduct of such activities, if any. Arbutus represents and warrants that all items, including hardware, materials, software, and technology, to be provided to Qilu under this Agreement will be classified as EAR99 under the U.S. Export Administration Regulations, unless otherwise agreed to in advance in writing by the Parties. Arbutus will provide Qilu with accurate and complete information regarding the Arbutus IP that is reasonably necessary for Qilu to comply with U.S. export laws, including all applicable Export Control Classification Numbers (ECCNs), information regarding eligibility of the Arbutus IP for license exceptions, and any other information reasonably requested by Qilu from time to time for the purposes of export. Arbutus further agrees to promptly inform Qilu of any changes to such information, including as a result of changes to the applicable U.S. export laws or regulations.
- **9.8 Data Protection**. Each Party will comply with Applicable Law relating to data privacy, data protection, and data security, including as they relate to the protection of the personal information of Clinical Trial participants, including the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health (HITECH) Act, and any regulations and official guidance promulgated thereunder or foreign equivalent thereof. The Parties will enter into any additional agreements that are required under Applicable Law with respect to data privacy in order to conduct the activities contemplated by this Agreement.
- **9.9 NO OTHER WARRANTIES**. EXCEPT AS EXPRESSLY STATED IN THIS <u>ARTICLE 9</u>, (A) NO REPRESENTATION, CONDITION OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF ARBUTUS OR QILU; AND (B) ALL OTHER CONDITIONS AND WARRANTIES WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE ARE EXPRESSLY DISCLAIMED, INCLUDING ANY CONDITIONS AND WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT OR MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY WITH RESPECT TO THE LICENSED COMPOUND OR LICENSED PRODUCT.

#### ARTICLE 10 INDEMNIFICATION

- **10.1 By Qilu.** Qilu shall indemnify, defend and hold harmless Arbutus, its Affiliates, and their directors, officers, employees and agents, and their respective successors, heirs and assigns (individually and collectively, the "**Arbutus Indemnitee(s)**") from and against all losses, liabilities, damages, judgments, awards, costs and expenses (including reasonable attorneys' fees) (individually and collectively, "**Losses**") incurred in connection with any claims, demands, actions, suits or other proceedings by any Third Party (individually and collectively, "**Third Party Claims**") to the extent arising from: (a) the Exploitation of the Licensed Products by or on behalf of Qilu or any of its Affiliates, Sublicensees or Subcontractors; (b) the gross negligence or willful misconduct of Qilu or its Affiliates, Sublicensees or Subcontractors, or any Qilu Indemnitees; (c) Qilu's breach of any of its representations, warranties, covenants or obligations made in or pursuant to this Agreement, the Clinical Supply Agreement, the Quality Agreement or the Pharmacovigilance Agreement (the "**Related Agreements**"); (d) the use of the Licensed Compound, Licensed Product or the Arbutus IP outside the scope of this Agreement; or (e) failure of Qilu or its Affiliates, Sublicensees or Subcontractors to abide by any Applicable Laws, in each case of clauses (a) through (e) above, except to the extent such Losses arise out of any matter for which Arbutus has obligations of indemnification pursuant to Section 10.2, with respect to which each Party will indemnify the other in proportion to their respective liability for such Losses.
- **10.2 By Arbutus**. Arbutus shall indemnify, defend and hold harmless Qilu, its Affiliates, and their directors, officers, employees and agents, and their respective successors, heirs and assigns (individually and collectively, the "*Qilu Indemnitee(s)*") from and against all Losses incurred in connection with any Third Party Claims to the extent arising from: (a) the Exploitation of the Licensed Compound or the Licensed Products by or on behalf of Arbutus or any of its Affiliates, Third Party Licensees or Subcontractors; (b) the gross negligence or willful misconduct of Arbutus or its Affiliates, Third Party Licensees or Subcontractors, or any Arbutus Indemnitees; (c) Arbutus' breach of any of its representations, warranties, covenants or obligations made in or pursuant to this Agreement or any of the Related Agreements; or (d) failure of Arbutus or its Affiliates, Third Party Licensees or Subcontractors to abide by any Applicable Laws, in each case of clauses (a) through (d) above, except to the extent such Losses arise out of any matter for which Qilu has obligations of indemnification pursuant to Section 10.1, with respect to which each Party will indemnify the other in proportion to their respective liability for such Losses.
- **10.3 Indemnification Procedure**. In the event that a Party seeks indemnification hereunder with respect to a Third Party Claim, the Party seeking indemnification (the "*Indemnified Party*") shall promptly notify the other Party (the "*Indemnifying Party*") in writing (an "*Indemnification Claim Notice*") of any Third Party Claim in respect of which it intends to claim indemnification under this <u>ARTICLE 10</u> upon actual knowledge of any such claim or proceeding resulting in Losses, <u>provided</u>, <u>however</u>, that any delay to notify shall not excuse any obligation of the Indemnifying Party except to the extent such delay materially prejudices the defense of such Third Party Claim. The Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Losses (to the extent that the nature and amount of such Losses is known at such time). The Indemnifying Party may, at its option, assume exclusive control of the defense and settlement of the Third Party Claim, subject to the limitations on settlement set

forth below. If the Indemnifying Party assumes such defense, then such assumption by the Indemnifying Party will not be construed as an acknowledgement that the Indemnifying Party is liable to indemnify the Indemnified Party of any defenses it may assert against the Indemnified Party's claim for indemnification and the Indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the Indemnifying Party (the Indemnifying Party will consult with the Indemnified Party with respect to a possible conflict of interest of such counsel retained by the Indemnifying Party). The Indemnified Party will have the right to participate in the defense thereof and to employ counsel, at its own expense, separate from the counsel employed by the Indemnifying Party. If the Indemnifying Party does not commence actions to assume control of the defense of a Third Party Claim within [\*\*\*] after the receipt by the Indemnifying Party of the Indemnification Claim Notice required pursuant to this Section 10.3, the Indemnified Party will have the right to defend such claim in such manner as it may deem appropriate at the reasonable cost and expense of the Indemnifying Party. The Indemnified Party shall cooperate as may be reasonably requested by the Indemnifying Party (and at the Indemnifying Party's expense) in order to ensure the proper and adequate defense of any action, claim or liability covered by this indemnification. The Indemnifying Party may not settle or otherwise dispose of any Third Party Claim without the prior written consent of the Indemnified Party unless such settlement includes only the payment of monetary damages (which are fully paid by the Indemnifying Party), does not impose any injunctive or equitable relief upon the Indemnified Party, does not require any admission or acknowledgment of liability or fault of the Indemnified Party and contains an unconditional release of the Indemnified Party in respect of such Third Party Claim. Regardless of whether the Indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnified Party will admit any liability with respect to or settle or otherwise dispose of any Third Party Claim for which the Indemnifying Party may be liable for Losses under this Agreement without the prior written consent of the Indemnifying Party, such consent not to be unreasonably withheld.

- **10.4 Mitigation of Loss**. Each Indemnified Party shall take and shall procure that its Affiliates take all such reasonable steps and actions as are reasonably necessary or as the Indemnifying Party may reasonably require in order to mitigate any claims (or potential losses or damages) under this <u>ARTICLE 10</u>. Nothing in this Agreement shall or shall be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.
- 10.5 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS OR THE PERFORMANCE OF ITS OBLIGATIONS HEREUNDER, INCLUDING ANY LOST PROFITS ARISING OUT OF THIS AGREEMENT, IN EACH CASE, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 10.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY UNDER SECTION 10.1 OR SECTION 10.2, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF ITS OBLIGATIONS UNDER ARTICLE 8.

**10.6 Insurance**. Each Party shall procure and maintain insurance, including Clinical Trial insurance and product liability insurance, with respect to its activities hereunder that is consistent with normal business practices of prudent companies similarly situated at all times during which any Licensed Product is being clinically tested in human subjects or commercially distributed or sold. Each Party shall provide the other Party with evidence of such insurance upon request. Notwithstanding the foregoing, either Party may self-insure in whole or in part the insurance requirements described above, provided such Party continues to be investment grade determined by reputable and accepted financial rating agencies. Such insurance shall not be construed to create a limit of each Party's liability with respect to its indemnification obligations under this <u>ARTICLE 10</u>.

#### ARTICLE 11 INTELLECTUAL PROPERTY

#### 11.1 Ownership.

- (a) Subject to the licenses granted by Arbutus herein, Arbutus is and shall at all times remain the sole and exclusive owner of the Arbutus IP, the Arbutus Materials and all Confidential Information of Arbutus disclosed by or on behalf of Arbutus to Oilu pursuant to this Agreement.
- (b) As between the Parties, Inventions conceived or created by or on behalf of one or both of the Parties in the course of performing activities under this Agreement that (1) constitute an improvement or enhancement of any Arbutus IP, or (2) are derived from or use the Arbutus IP, the Arbutus Materials or Arbutus' Confidential Information, including any such Inventions relating to the Licensed Compound, together with any intellectual property rights relating to such Inventions, shall be owned as follows:
  - (i) Any such Inventions conceived solely by or on behalf of Qilu and all intellectual property rights therein shall be owned solely by Qilu (the "*Qilu New IP*");
  - (ii) Any such Inventions conceived solely by or on behalf of Arbutus and all intellectual property rights therein shall be owned solely by Arbutus (the "*Arbutus New IP*"); and
  - (iii) Any such Inventions conceived jointly by or on behalf of Qilu and Arbutus and all intellectual property rights therein shall be owned jointly by Qilu and Arbutus (the "*Joint New IP*").

Each Party shall assign and hereby assigns to the other Party one-half (1/2) undivided interest it may have in any Joint New IP, and shall cause its Affiliates and Sublicensees or Third Party Licensees, as applicable, to execute and deliver such additional documents, instruments, conveyances and assurances and take any such further actions as may be reasonably required to ensure that one-half (1/2) undivided interest in the Joint New IP is effectively assigned to and held by the other Party. Each Party shall cause its Affiliates and Sublicensees or Third Party Licensees, as applicable, and all of its and its Affiliates' employees, consultants and agents, who in each case conceived of or created any Joint New IP, to assign without additional consideration all ownership rights in such Joint New IP to such Party.

For clarity, to the extent any Arbutus New IP or Joint New IP constitutes any Arbutus IP, such Arbutus New IP or Joint New IP shall be automatically included in the License without additional consideration; <u>provided</u>, that the Parties agree that notwithstanding any terms in this Agreement to the contrary, any Patent Right included within the Joint New IP shall not be royalty-bearing under <u>Section 7.5</u>.

- (c) Qilu shall grant and hereby grants to Arbutus and its Affiliates an exclusive, royalty-free, fully paid-up, perpetual, irrevocable, and sublicensable (through multiple tiers) license under Qilu's rights in the Qilu New IP and the Joint New IP to Exploit the Licensed Compound and Licensed Products in the Field in the ROW Territory.
- (d) Any Product Data relating to the Territory generated by Qilu and its Affiliates and Sublicensees shall be owned solely by Qilu; <u>provided</u>, that Arbutus shall have the right to use the Product Data to Exploit the Licensed Compound and the Licensed Products in the ROW Territory (or to seek any approvals from a Regulatory Authority required for the Development or Manufacturing of the Licensed Product in the Territory in accordance with Arbutus' retained rights) in accordance with <u>Section 4.5</u>.
- (e) Notwithstanding the foregoing, each Party shall own and retain ownership of all Know-How and Patent Rights owned by such Party as of the License Effective Date or that come into the Control of such Party during the Term outside the scope of this Agreement.

53

#### 11.2 Patent Prosecution.

#### (a) **Arbutus Patents**.

- (i) As between the Parties, Arbutus shall have the first right, but not the obligation, to control, at Arbutus' cost and in consultation with Qilu, the Patent Prosecution of all Arbutus Patents in the Territory. Without limiting the foregoing, Arbutus shall file Arbutus Patents in the Territory claiming any Arbutus Know-How identified by Qilu as suitable for patenting purposes, as reasonably requested by Qilu, provided, however, that if prosecuting such Know-How would materially harm Arbutus, Arbutus' Patent Rights strategy or Patents Rights with respect to other products, Arbutus will notify Qilu of such circumstance and shall not be required to prosecute Patent Rights claiming such Know-How (nor shall Qilu have the right under this Section 11.2(a)(i) to file a patent application in the Territory claiming such Arbutus Know-How). If Arbutus intends to abandon the Patent Prosecution of any Arbutus Patent in the Territory, Arbutus shall give Qilu prompt notice thereof (not less than thirty (30) days before any action is required to avoid abandonment or lapse), and Qilu shall have the right to continue such Patent Prosecution of such Arbutus Patent in the Territory at Qilu's cost. To effect Qilu's right to assume Arbutus' prosecution rights and obligations with respect to any Arbutus Patent in the Territory pursuant to this Section 11.2(a)(i), Arbutus shall reasonably cooperate with and assist Qilu in connection with its activities under this Section 11.2(a)(i), upon Qilu's reasonable request, including by making scientists and scientific records reasonably available and the execution of all such documents and instruments and the performance of such acts as may be reasonably necessary in order to permit Qilu to continue any Patent Prosecution of such Arbutus Patent.
- (ii) Arbutus shall have the sole right to control, in its sole discretion, the Patent Prosecution of all Arbutus Patents outside the Territory.
- (iii) The Party conducting Patent Prosecution of any Patent Right under <u>Section 11.2(a)</u> shall consult with the other Party and keep such other Party reasonably informed of the Patent Prosecution of the Patent Rights in the Territory. The prosecuting Party shall provide the other Party with copies of all material correspondence received from any patent authority in the Territory in connection therewith. In addition, the prosecuting Party shall provide the other Party with drafts of all proposed material filings and correspondence to any patent authority in the Territory in connection with the Patent Prosecution of the Patents Right at least thirty (30) days prior (or such shorter period prior if it is not reasonably practicable to provide such copies thirty (30) days prior) to filing to allow for review and comment by such other Party, and shall consider in good faith timely comments from such other Party thereon. The prosecuting Party shall also furnish the other Party with copies of all final filings and responses made to any patent authority in the Territory with respect to the Patent Rights being prosecuted by such Party in a timely manner following submission thereof.

- Qilu's cost, the Patent Prosecution of all Patent Rights included within the Qilu New IP. If Qilu intends to abandon the Patent Prosecution of any such Patent Right in the ROW Territory, Qilu shall give Arbutus prompt notice thereof (not less than thirty (30) days before any action is required to avoid abandonment or lapse), and Arbutus shall have the right to continue such Patent Prosecution of such Qilu New IP in the ROW Territory at Arbutus' cost. To effect Arbutus' right to assume Qilu's prosecution rights and obligations with respect to any such Patent Right in the ROW Territory pursuant to this Section 11.2(b), Qilu shall reasonably cooperate with and assist Arbutus in connection with its activities under this Section 11.2(b), upon Arbutus' reasonable request, including by making scientists and scientific records reasonably available and the execution of all such documents and instruments and the performance of such acts as may be reasonably necessary in order to permit Arbutus to continue any Patent Prosecution of such Patent Right.
- (c) **Other Patents**. Except as expressly set forth in this <u>Section 11.2</u>, each Party shall have the sole right, in its sole discretion, to conduct Patent Prosecution with respect to any and all Patent Rights owned or Controlled by such Party, and the Parties shall negotiate in good faith their respective rights in and responsibilities for Patent Prosecution with respect to any and all Patent Rights within the Joint New IP.
- (d) **Cooperation**. Each Party shall provide the other Party all reasonable assistance and cooperation in the Patent Prosecution efforts under this <u>Section 11.2</u>, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

#### 11.3 Patent Enforcement.

(a) **Notice**. Each Party shall promptly notify the other Party of becoming aware of any alleged or threatened infringement by a Third Party of any of the Arbutus Patents or any related declaratory judgment or equivalent action alleging the invalidity, unenforceability or non-infringement of any Arbutus Patents anywhere in the world.

#### (b) **Enforcement Rights**.

(i) Qilu shall have the first right, but not the obligation, in its sole discretion, to bring and control any legal action to enforce the Arbutus Patents against any Third Party engaged in any potential or actual infringement of the Arbutus Patents related to a compound or product that competes with (or that would compete with if commercialized) a Licensed Compound or a Licensed Product in the Field in the Territory (a "*Product Infringement*"); provided, that Qilu shall not take any position with respect to such proceeding in any way that is reasonably likely to directly and adversely affect the scope, validity or enforceability of the Arbutus Patents, or compromise or settle any such proceeding, without the prior written consent of Arbutus, which consent shall not be unreasonably withheld, conditioned or delayed. For clarity, Product Infringement excludes any adversarial Patent Prosecution proceedings. Qilu shall give Arbutus advance notice of Qilu's intent to file any such suit or take any such action and the reasons therefor, and shall provide Arbutus with an opportunity to make suggestions or comments regarding

such suit or action. Thereafter, Qilu shall keep Arbutus promptly informed, and shall from time to time consult with Arbutus regarding the status of any such suit or action. In the event Qilu does not bring any such legal action within sixty (60) days of receiving notice of such Product Infringement (or settle or otherwise secure the abatement of such Product Infringement action), or ceases to diligently pursue such Product Infringement action, Arbutus may bring and control any legal action to enforce the Arbutus Patents against such Product Infringement at its sole cost.

- (ii) Arbutus shall have the sole right, but not the obligation, in its sole discretion, to bring and control any legal action to enforce Arbutus Patents against any infringement in the ROW Territory; <u>provided</u> that Arbutus notifies Qilu of any such legal action reasonably in advance, and considers in good faith Qilu's comments with respect thereto.
- (c) **Other Patents**. Except as expressly set forth in this <u>Section 11.3</u>, each Party shall have the sole right, in its sole discretion, to enforce against any infringement of any and all Patent Rights owned or Controlled by such Party, and the Parties shall negotiate in good faith their respective rights in and responsibilities for enforcement of any and all Patent Rights within the Joint New IP.
- (d) **Cooperation**. At the request of the Party bringing an action under this <u>Section 11.3(d)</u>, the other Party shall provide reasonable assistance in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery, facilitating registration of licenses and joining as a party to the action if required by Applicable Law to pursue such action.
- (e) **Recoveries**. Any recoveries resulting from any action under  $\underline{Section\ 11.3(b)(i)}$  in the Territory shall be first applied against payment of each Party's costs and expenses in connection therewith (with priority given to the Party bringing such action), and then any remaining recoveries shall be allocated as follows: (i) if Qilu is the Party bringing such action, then such remaining recoveries shall be retained by Qilu and treated as Net Sales subject to the payment of royalties in accordance with  $\underline{Section\ 7.5}$ ; and (ii) if Arbutus is the Party bringing such action, then such remaining recoveries shall be retained in full by Arbutus.

#### 11.4 Infringement of Third Party Rights.

(a) **Notice**. If (i) any Licensed Compound or Licensed Product used or sold by Qilu, its Affiliates or Sublicensees in the Territory becomes the subject of a Third Party's claim or assertion of infringement of a Patent Right or other rights in the Territory that are owned or controlled by such Third Party, or (ii) any Licensed Compound or Licensed Product used or sold by Arbutus, its Affiliates or Third Party Licensees in the Territory or the ROW Territory becomes the subject of a Third Party's claim or assertion of infringement of a Patent Right or other rights in the ROW Territory, then the Party becoming aware of such claim or assertion shall promptly notify the other Party within fifteen (15) days after receipt of such claim or assertion and such notice shall include a copy of any summons or complaint (or the equivalent thereof) received regarding the foregoing. The Parties shall assert and not waive the joint defense privilege with respect to any communications between the Parties in connection with the defense of such claim or assertion.

- Defense by Qilu. As between the Parties, Qilu shall be solely responsible for the defense of any such infringement claims in the Field in the Territory with respect to the activities of Qilu, its Affiliates or Sublicensees; provided, that Qilu shall not agree to any settlement, consent to judgment or other voluntary final disposition in connection with such defense action without Arbutus' consent (such consent not to be unreasonably withheld, conditioned or delayed) if such settlement, consent to judgment or other voluntary final disposition would (i) result in the admission of any liability or fault on behalf of Arbutus, (ii) result in or impose any payment obligations upon Arbutus, or (iii) subject Arbutus to an injunction or otherwise limit Arbutus' ability to take any actions or refrain from taking any actions under this Agreement or with respect to any Licensed Compound or Licensed Product. Qilu shall use Commercially Reasonable Efforts to defend any such infringement claims in the Field in the Territory with respect to the activities of Qilu, its Affiliates or Sublicensees. In the event, despite such Commercially Reasonable Efforts, Qilu does not prevail in such defense action, Qilu shall use Commercially Reasonable Efforts to obtain a license from the applicable Third Party under the asserted Patent Rights or other rights in the Territory so that Qilu or its Affiliates or Sublicensees, as the case may be, may continue the Exploitation of the Licensed Compound and Licensed Products in the Field in the Territory as contemplated hereunder. Qilu shall keep Arbutus informed on the status of such defense action and license negotiation, and Arbutus shall, at its own expense, (A) provide reasonable support to Qilu upon Qilu's reasonable request; and (B) have the right, but not the obligation, to participate or be separately represented in such defense action or license negotiation at its sole option and expense. In the event, despite Qilu's Commercially Reasonable Efforts, Qilu fails to obtain a license from the applicable Third Party under the asserted Patent Rights or other rights in the Territory on commercially reasonable terms so that Oilu or its Affiliates or Sublicensees, as the case may be, are permanently enjoined, prohibited or otherwise prevented from continuing the Exploitation of the Licensed Compound or Licensed Products in the Field in the Territory as contemplated hereunder, Qilu may terminate this Agreement pursuant to Section 12.2(a). For clarity, from and after the date of the notice of termination pursuant to Section 12.2(a) and before the effective date of termination, Qilu shall have no further obligations under Sections 4.1(a), 4.1(b), 4.1(c) or 6.1(a) of this Agreement, and upon written agreement between the Parties, this Agreement may terminate earlier than the effective date of termination set forth in such notice.
- (c) **Defense by Arbutus**. As between the Parties, Arbutus shall be solely responsible for the defense of any such infringement claims with respect to the activities of Arbutus, its Affiliates or Third Party Licensees, including any such infringement claim in the Territory or in the ROW Territory; <u>provided</u>, that Arbutus shall not agree to any settlement, consent to judgment or other voluntary final disposition in connection with such defense action without Qilu's consent (such consent not to be unreasonably withheld, conditioned or delayed) if such settlement, consent to judgment or other voluntary final disposition would (i) result in the admission of any liability or fault on behalf of Qilu, (ii) result in or impose any payment obligations upon Qilu, or (iii) subject Qilu to an injunction or otherwise limit Qilu's ability to take any actions or refrain from taking any actions under this Agreement or with respect to any Licensed Compound or Licensed Product. Arbutus shall keep Qilu informed on the status of such defense action, and Qilu shall, at its own expense, (A) provide reasonable support to Arbutus upon Arbutus' reasonable request; and (B) have the right, but not the obligation, to participate or be separately represented in such defense action at its sole option and expense.

#### 11.5 Qilu Territory Trademarks.

- (a) Ownership and Prosecution of Qilu Territory Trademarks. Qilu shall own all right, title, and interest in and to the Qilu Territory Trademarks (including relevant registrations and applications), and shall have the first right, but not the obligation, for the registration, prosecution, maintenance and renewal thereof. All costs and expenses of registration, prosecuting, maintaining and renewing the Qilu Territory Trademarks shall be borne solely by Qilu. If Qilu intends to abandon the prosecution of (including any decision to not renew) any Qilu Territory Trademark in the Territory, Qilu shall give Arbutus prompt notice thereof (not less than fifteen (15) days before any action is required to avoid abandonment or lapse), and Arbutus shall have the right to continue such prosecution of such Qilu Territory Trademark in the Territory at its sole cost.
- (b) Enforcement of Qilu Territory Trademarks and Licensed Product-Specific Trademarks. Qilu shall have the first right, but not the obligation, for taking such action as Qilu deems necessary against a Third Party based on any alleged, threatened, or actual infringement, dilution, or other violation of, or unfair trade practices or any other like offense relating to, the Qilu Territory Trademarks or the Licensed Product-Specific Trademarks by a Third Party in the Territory. Qilu shall bear the costs and expenses relating to any enforcement action commenced pursuant to this Section 11.5(b) and any settlements and judgments with respect thereto, and shall retain any damages or other amounts collected in connection therewith. Subject to the foregoing, Arbutus may elect at its expense to participate in the enforcement of the Qilu Territory Trademarks or the Licensed Product-Specific Trademarks in the Territory. In the event that Qilu declines to or fails to assume responsibility for such enforcement, and to the extent permitted by Applicable Laws, Arbutus shall have the sole right and responsibility for such action, in which case Arbutus shall bear all costs and expenses and shall retain any damages or other amounts collected in connection therewith.
- (c) **Third Party Claims**. Qilu shall have the sole right and responsibility for defending against any alleged, threatened, or actual claim by a Third Party that the use or registration of the Qilu Territory Trademarks or the Licensed Product-Specific Trademarks by Qilu, its Affiliates or Sublicensees in the Territory infringes, dilutes or otherwise violates any Trademark or other right of that Third Party or constitutes unfair trade practices or any other like offense, or any other claims as may be brought by a Third Party against a Party in connection with the use or registration of the Qilu Territory Trademarks or the Licensed Product-Specific Trademarks by Qilu, its Affiliates or Sublicensees in the Territory. Qilu shall bear the costs and expenses relating to any defense commenced pursuant to this Section 11.5(c) and any settlements and judgments with respect thereto, and shall retain any damages or other amounts collected in connection therewith.

- (d) **Notice and Cooperation**. Each Party shall provide to the other Party prompt written notice of any actual or threatened infringement of the Qilu Territory Trademarks or the Licensed Product-Specific Trademarks in the Territory and of any actual or threatened claim that the use of the Qilu Territory Trademarks or the Licensed Product-Specific Trademarks in the Territory violates the rights of any Third Party. Each Party agrees to cooperate fully with the other Party with respect to any enforcement action or defense commenced pursuant to this <u>Section 11.5(d)</u>, including cooperation required to permit required registration of trademark licenses within the Territory.
- 11.6 Common Interest Agreement. All information exchanged between the Parties regarding the prosecution and maintenance, and enforcement and defense, of Arbutus Patents under this <u>ARTICLE 11</u> will be deemed Confidential Information of the Disclosing Party. In addition, the Parties acknowledge and agree that, with regard to such prosecution and maintenance, and enforcement and defense, the interests of the Parties as collaborators and licensor and licensee are to obtain the strongest patent protection possible, and as such, are aligned and are legal in nature. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning the Patent Rights under this <u>ARTICLE 11</u>, including privilege under the common interest doctrine and similar or related doctrines. Notwithstanding anything to the contrary contained herein, to the extent a Party has a good faith belief that any information required to be disclosed by such Party to the other Party under this <u>ARTICLE 11</u> is protected by attorney-client privilege or any other applicable legal privilege or immunity, such Party will not be required to disclose such information, and the Parties will in good faith cooperate to agree upon a procedure (including entering into a specific common interest agreement, disclosing such information on a "for counsel eyes only" basis or similar procedure) under which such information may be disclosed without waiving or breaching such privilege or immunity.

#### 11.7 Registration Obligations.

- (a) If required by Applicable Law, Qilu shall have the right to register this Agreement with all applicable Regulatory Authorities in the Territory. Arbutus shall reasonably cooperate with Qilu at Qilu's expense in obtaining any such registrations, including providing relevant documents required by the applicable Regulatory Authorities in the Territory.
- (b) Upon the request of Arbutus, Qilu shall promptly provide to Arbutus certified true and complete copies of any registration certificates as well as any other relevant documentation received by Qilu in connection with any registration undertaken by Qilu in accordance with this <u>Section 11.7</u>, including English translations of the same, if appropriate.

#### ARTICLE 12 TERMS AND TERMINATION

**12.1 Term**. This Agreement shall become effective as of the Execution Date (the "*License Effective Date*"), and shall continue, unless terminated earlier in accordance with this <u>ARTICLE 12</u>, until expiration of the last Royalty Term for the last Licensed Product in the Field in the Territory (the "*Term*"). On a Licensed Product-by-Licensed Product and Relevant Region-by-Relevant Region basis, upon the expiration of this Agreement, the License shall become exclusive, transferable, sublicensable (through multiple tiers of Sublicensees), fully paid-up, royalty-free, irrevocable and perpetual. If Qilu has not paid the Upfront Payment in accordance with <u>Section 7.1</u>, this Agreement shall be deemed to be terminated and null and void in its entirety immediately upon written notice by Arbutus to Qilu.

#### 12.2 Termination.

(a) **Termination by Qilu for Convenience**. At any time following the License Effective Date, Qilu may terminate this Agreement in its entirety for convenience by providing written notice of termination to Arbutus, which notice includes an effective date of termination at [\*\*\*] after the date of the notice.

#### (b) **Termination for Material Breach**.

- (i) If either Party believes in good faith that the other Party is in material breach of this Agreement, then the non-breaching Party may deliver written notice of such breach to the other Party. For any such alleged material breach, the allegedly breaching Party shall have [\*\*\*] from the receipt of the initial notice to cure such breach (or in the case of any payment breach other than with respect to the Upfront Payment, [\*\*\*]). If the Party receiving notice of material breach fails to cure the breach within such [\*\*\*] (or other applicable cure period for a payment breach), then the non-breaching Party may terminate this Agreement in its entirety effective on written notice of termination to the other Party. Notwithstanding the foregoing, if such material breach (other than a payment breach), by its nature, is curable, but is not reasonably curable within the [\*\*\*] cure period, then such period shall be extended if the breaching Party provides a written plan for curing such breach to the non-breaching Party and uses commercially reasonable efforts to cure such breach in accordance with such written plan; provided, that no such extension shall exceed an additional [\*\*\*] days without the consent of the non-breaching Party.
- (ii) In case the Party alleged under <u>Section 12.2(b)(i)</u> to have committed a material breach of this Agreement (the "*Defaulting Party*") by the other Party (the "*Non-Defaulting Party*") disputes the existence or materiality of such material breach, then the issue of whether the Non-Defaulting Party may properly terminate this Agreement on expiration of the applicable cure period shall be resolved in accordance with <u>Section 13.6</u> and <u>Section 13.7</u>. If, as a result of such dispute resolution proceeding, it is determined that the Defaulting Party committed a material breach and the Defaulting Party does not cure such material breach within [\*\*\*] after the date of such determination (the "*Additional Cure Period*"), then such termination shall be effective as of the expiration of the Additional Cure

60

Period. If the Parties dispute whether such material breach was so cured, such dispute shall also be determined in accordance with Section 13.6 and Section 13.7. This Agreement shall remain in full force and effect while any such dispute resolution proceeding is pending, such proceeding shall not suspend any obligations of either Party hereunder, and each Party shall use reasonable efforts to mitigate any damage. If, as a result of such dispute resolution proceeding, it is determined that (A) the Defaulting Party did not commit such breach, (B) such breach was not material or (C) such breach was cured in accordance with this Section 12.2(b), then no termination shall be effective, and this Agreement shall continue in full force and effect.

- (c) **Termination by Arbutus for Patent Challenges**. Arbutus has the right, in its sole discretion, to terminate this Agreement in its entirety upon written notice to Qilu, in the event that Qilu or any of its Affiliates or Sublicensees directly or indirectly commences any interference or opposition proceeding, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any Arbutus Patents ("**Patent Challenge**"), provided that, Arbutus will not have the right to terminate this Agreement under this Section 12.2(c) if (i) Qilu causes such Patent Challenge to be terminated or dismissed (or in the case of ex-parte proceedings, multi-party proceedings, or other Patent Challenges in which the challenging party does not have the power to unilaterally cause the Patent Challenge to be withdrawn, withdraws or causes its Affiliate or Sublicensee to withdraw as a party from such Patent Challenge and to cease actively assisting any other party to such Patent Challenge), or (ii) Qilu, with respect to a Sublicensee, terminates such Sublicensee's sublicense to the Patent Rights being challenged by the Sublicensee, in each case (i) and (ii), within [\*\*\*] days of Arbutus' notice to Qilu under this Section 12.2(c).
- (d) **Termination for Insolvency**. Each Party shall have the right to terminate this Agreement upon delivery of written notice to the other Party in the event that (i) such other Party files in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such other Party or its assets, (ii) such other Party is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed within [\*\*\*] days of its filing, or (iii) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors (each of (i) through (iii), an "*Insolvency Event*").

#### 12.3 Effect of Termination.

- (a) In the event of any termination of this Agreement for any reason:
- (i) Except as expressly set forth in this Agreement, all rights and obligations of the Parties shall immediately terminate, including the License; <u>provided</u>, that the license granted by Qilu to Arbutus and its Affiliates under <u>Section 11.1(c)</u> shall survive;

- (ii) The Parties shall have no further obligation to perform any activities under this Agreement other than as provided for or referenced in this <u>ARTICLE 12</u>, and Qilu and its Affiliates and Sublicensees shall cease any and all Development, Manufacture and Commercialization activities relating to the Licensed Products;
- (iii) with respect to any ongoing Clinical Trials of the Licensed Products conducted by Qilu or its Affiliates or Sublicensees, (x) Qilu shall wind down at its sole cost the conduct of such Clinical Trials as soon as reasonably practicable, subject to requirements of Applicable Laws; provided, that Qilu shall not take any action in connection with the winding down of any such Clinical Trials that could reasonably cause material harm to any participants in such Clinical Trials, or, upon the request of Arbutus, transfer to Arbutus or its designee the conduct of such Clinical Trials as soon as reasonably practicable pursuant to the requirements of Applicable Laws, and (y) until such time as the conduct of such Clinical Trials has been successfully terminated or transferred to Arbutus or its designee, Qilu shall continue such Clinical Trials at its sole cost; provided, that the foregoing costs in this subsection (iii) shall be the responsibility of Arbutus if Qilu terminates this Agreement in accordance with Section 12.2(b); and
  - (iv) each Party shall comply with its obligations pursuant to Section 12.5 and Section 12.6.
- (b) Without limiting the generality of <u>Section 12.3(a)</u>, in the event of any termination of this Agreement except a termination of this Agreement by Qilu pursuant to <u>Section 12.2(b)</u>:
  - (i) upon the request of Arbutus, (x) Qilu shall assign and transfer to Arbutus or its designee any and all Regulatory Documents, including regulatory filings made with and all Regulatory Approvals obtained from the Regulatory Authorities in the Territory (to the extent permissible), relating to the Licensed Products in the Field in the Territory pursuant to the requirements of Applicable Laws, and (y) Qilu shall cooperate with Arbutus to facilitate the orderly transition and uninterrupted Development, Manufacturing and Commercialization of the Licensed Products in the Field in the Territory, including by assigning or otherwise transferring (to the extent permissible) to Arbutus or its designee all right, title and interest in all Third Party contracts (or portions thereof) related to such Development, Manufacturing and Commercialization, as reasonably requested by Arbutus; and
  - (ii) upon the request of Arbutus, Qilu shall grant and hereby grants (effective from and after the time when the conditions precedent for such present grant under this Section 12.3(b)(ii) have been satisfied) to Arbutus an exclusive, royalty-free, fully paid-up, sublicensable (through multiple tiers) license under Qilu's right in the Qilu New IP and the Joint New IP Controlled by Qilu or its Affiliates as of the date of notice of termination, for the sole purpose of Exploiting the Licensed Compound and Licensed Products in the Field in the Territory.

- (c) Without limiting the generality of <u>Section 12.3(a)</u>, in the event of any termination of this Agreement by Qilu pursuant to <u>Section 12.2(b)</u>, upon the request of Arbutus, Qilu shall promptly negotiate in good faith to discuss and agree to grant to Arbutus an exclusive, sublicensable (through multiple tiers) license under Qilu's right in the Qilu New IP and the Joint New IP Controlled by Qilu or its Affiliates as of the date of notice of termination, for the purpose of Exploiting the Licensed Compound and Licensed Products in the Field in the Territory, on commercially reasonable terms.
- **12.4 Rights in Insolvency**. All rights and licenses now or hereafter granted by Arbutus to Qilu under or pursuant to this Agreement are, for all purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined in the Bankruptcy Code. Upon an Insolvency Event, Arbutus agrees that Qilu, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code. Arbutus will, during the Term, create and maintain current copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, to the extent feasible, of all intellectual property licensed under this Agreement. Each Party acknowledges and agrees that "embodiments" of intellectual property within the meaning of Section 365(n) include laboratory notebooks, cell lines, product samples and inventory, research studies and data, all Regulatory Approvals (and all applications for Regulatory Approval) and rights of reference therein, the Arbutus IP and all information related to the Arbutus IP.
- **12.5 Accrued Rights**. Expiration or termination of this Agreement for any reason shall be without prejudice to any right which shall have accrued to the benefit of either Party prior to such termination, including damages arising from any breach under this Agreement.
- **12.6 Survival**. The provisions of <u>Section 4.1(e)</u>, the last two sentences of <u>Section 4.5(a)</u>, <u>Section 11.1</u>, <u>Section 11.6</u>, <u>Section 12.3</u>, <u>Section 12.4</u>, <u>Section 12.5</u>, <u>Section 12.6</u>, <u>ARTICLE 1</u> (to the extent relevant to any surviving provisions), <u>ARTICLE 7</u> (to the extent relating to payments that have accrued or been paid prior to the effective date of expiration or termination), <u>ARTICLE 8</u>, <u>ARTICLE 10</u> and <u>ARTICLE 13</u>, together with any other provisions of this Agreement that by their terms are expressly stated to survive, shall survive the expiration or termination of this Agreement.
  - 12.7 Certain Additional Remedies of Qilu in Lieu of Termination. [\*\*\*].

#### ARTICLE 13 MISCELLANEOUS

13.1 Force Majeure. Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement (except for any payment obligation) to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances (except for a strike, lockout or labor disturbance with respect to the non-performing Party's respective employees or agents), fire, floods, pandemic, earthquakes or other acts of God, or any applicable action or inaction by any Governmental Authority, or omissions or delays in acting by the other Party. The affected Party shall

notify the other Party in writing of such force majeure circumstances as soon as reasonably practicable (in any event, within thirty (30) days), and shall promptly undertake and continue diligently all reasonable efforts necessary to cure such force majeure circumstances or to perform its obligations despite the ongoing circumstances.

- **13.2 Assignment**. This Agreement may not be assigned or otherwise transferred by a Party, nor may any right or obligation hereunder be assigned or transferred by a Party (except as expressly permitted under this Agreement), without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, either Party may, without the consent of the other Party, assign this Agreement (a) in whole or in part to any of its Affiliates or (b) in whole, but not in part, to a purchaser of all or substantially all of its assets (whether by merger, stock purchase, consolidation, asset purchase, or otherwise) or to any successor resulting from a Change of Control of such Party, provided that, in the event Arbutus is the assigning Party, such purchaser or successor shall have purchased or otherwise obtained Control of all Arbutus IP in existence as of the date of such assignment. The assigning Party shall provide written notice to the other Party of any assignment permitted under this Section 13.2 within thirty (30) days after effecting such assignment. Any attempted assignment not in accordance with this Section 13.2 shall be null and void and of no legal effect. The terms and conditions of this Agreement shall be binding upon, and shall inure to the benefit of, the Parties and their respected successors and permitted assigns.
- 13.3 Severability. If one (1) or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their commercially reasonable efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) that, insofar as practicable, implement the purposes of this Agreement.
- **13.4 Notices**. All notices that are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by internationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to Arbutus:

Arbutus Biopharma Corporation 701 Veterans Circle Warminster, PA 18974 USA Attention: Arbutus General Counsel

If to Qilu:

Qilu Pharmaceutical Co., Ltd. No. 8888, Lvyou Road Jinan, Shandong, 250014, China Attention: Qilu Legal Director or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered if personally delivered on a Business Day (or if delivered on a non-Business Day, then on the next Business Day); (b) on the second (2<sup>nd</sup>) Business Day after dispatch if sent by internationally-recognized overnight courier; or (c) on the fifth Business Day following the date of mailing if sent by mail.

- 13.5 Governing Law. This Agreement, and all claims or causes of action (whether in contract, tort or statute) that may be based upon, arise out of or relate to this Agreement, or the negotiation, execution or performance of this Agreement or the breach thereof (including any claim or cause of action based upon, arising out of or related to any representation or warranty made in or in connection with this Agreement or as an inducement to enter into this Agreement), shall be governed by, and enforced in accordance with, the internal laws of the State of Delaware, without reference to its conflicts of law principles.
- **13.6 Internal Resolution**. Other than disputes subject to final decision-making authority by a Party pursuant to <u>Section 3.5</u>, in the event of any dispute between the Parties relating to or arising out of this Agreement, the formation, construction, breach or termination hereof, or the rights, duties or liabilities of either Party hereunder, the Parties shall first attempt in good faith to resolve such dispute by negotiation and consultation between themselves, utilizing the Alliance Managers. In the event that such dispute is not resolved on an informal basis within [\*\*\*] days, either Party may, by written notice to the other Party, refer the dispute to the Executive Officers for attempted resolution by good faith negotiation within [\*\*\*] after such notice is received.
- **13.7 Binding Arbitration**. If the Executive Officers are not able to resolve a disputed matter referred to them within [\*\*\*] and any Party wishes to pursue the matter, each such dispute, controversy or claim that is not an Excluded Claim shall be finally resolved by binding arbitration administered by the International Chamber of Commerce ("*ICC*") pursuant to its then prevailing arbitration rules, and judgment on the arbitration award may be entered in any court having jurisdiction thereof. The Parties agree that:
- (a) The arbitration shall be conducted by a single arbitrator appointed by the ICC, who shall (i) be a lawyer of not less than fifteen (15) years' standing who is experienced in the pharmaceutical business in the relevant country, (ii) not be or have been an employee, consultant, officer, director or stockholder of either Party or any Affiliate of either Party, and (iii) not have a conflict of interest under any applicable rules of ethics. The place of arbitration shall be New York, New York, and all proceedings and communications shall be in English, unless otherwise agreed by both Parties involved in such dispute.
- (b) Any Party may apply to the arbitrator for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Any Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award.

(c)	The arbitrator	shall have no	authority to	award p	ounitive or	any	other type	of damages	not me	easurec	d by a
Party's compensatory									equal	share	of the
arbitrator's fees and aı	ny administrati <sup>,</sup>	ve fees of arbi	tration regar	dless of t	he outcom	e of s	such arbitra	ition.			

- (d) Except to the extent necessary to confirm an award or as may be required by law, neither a Party nor the arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding, based on the dispute, controversy or claim, would have been barred by the applicable statute of limitations.
- (e) Each Party hereby irrevocably waives any claim to sovereign immunity in regard to any proceedings to recognise or enforce an arbitral award rendered by an arbitral tribunal constituted pursuant to this Agreement, including, without limitation, immunity from service of process, immunity from jurisdiction of any court, and immunity of any of its property from execution, regardless of the commercial or non-commercial nature of the property in question.
- (f) As used in this <u>Section 13.7</u>, the term "*Excluded Claim*" shall mean a dispute, controversy or claim that concerns the scope, validity, enforceability, inventorship or infringement of a patent, patent application, trademark or copyright. Any Excluded Claim shall be submitted to a court of competent jurisdiction.
- **13.8 Headings**. The captions to the several Articles, Sections, subsections and Exhibits hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles, Sections and Exhibits of this Agreement.
- **13.9 Independent Contractors**. It is expressly agreed that Arbutus and Qilu shall be independent contractors and that the relationship between the two (2) Parties shall not constitute a partnership, joint venture or agency. Neither Arbutus nor Qilu shall have the authority to make any statements, representations or commitments of any kind, or to take any action that is binding on the other Party without the prior written consent of the other Party.
- **13.10 Waiver**. Any waiver of any provision of this Agreement shall be effective only if in writing and signed by Arbutus and Qilu. No express or implied waiver by a Party of any default under this Agreement will be a waiver of a future or subsequent default. The failure or delay of any Party in exercising any rights under this Agreement will not constitute a waiver of any such right, and any single or partial exercise of any particular right by any Party will not exhaust the same or constitute a waiver of any other right provided in this Agreement.
- **13.11 Waiver of Rule of Construction**. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

- **13.12 Cumulative Remedies; Recovery of Damages**. Except as expressly set forth in this Agreement, no remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Applicable Laws. If Qilu seeks direct damages from Arbutus arising from any breach of this Agreement, then Qilu shall be entitled to seek damages including, without limitation, any and all amounts paid by Qilu to Arbutus under this Agreement, including without limitation any payment described as nonrefundable or noncreditable; <u>provided</u> that, nothing in this <u>Section 13.12</u> shall be construed to change any legal obligation under Applicable Law for Qilu to prove its damages for such breach.
- **13.13 Business Day Requirements**. In the event that any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a Business Day then such notice or other action or omission shall be deemed to be required to be taken on the next occurring Business Day.
- 13.14 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as necessary or appropriate in order to carry out the purposes and intent of this Agreement. Without limiting the generality of the foregoing, Arbutus shall reasonably cooperate with Qilu in the preparation, execution and filing of "short-form" agreements in a form reasonably acceptable to Arbutus with relevant Governmental Authorities (including, without limitation, the Ministry of Commerce of the People's Republic of China, the Ministry of Science and Technology of the People's Republic of China, and China National Intellectual Property Administration, and any local office, commission or branch of any of the foregoing) in accordance with Applicable Law, including terms and conditions of this Agreement as required by Applicable Law for purposes of registration or recordation of this Agreement or the licenses granted hereunder with the Governmental Authorities.
- 13.15 Construction. Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation", (c) the word "will" shall be construed to have the same meaning and effect as the word "shall", (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person shall be construed to include the person's successors and assigns, (f) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections, Schedules, or Exhibits shall be construed to refer to Sections, Schedules or Exhibits of this Agreement unless otherwise specified, and references to this Agreement include all Schedules and Exhibits hereto, (h) the word "notice" means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder "agree", "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging),

- (j) references to any specific law, rule or regulation, or Section, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (k) the term "or" shall be interpreted in the inclusive sense commonly associated with the term "and/or." This Agreement is made in English. In the event that this Agreement includes terms in any other language, those terms shall be for reference purposes only and the English language version of this Agreement shall control for any interpretations of the provisions of this Agreement.
- **13.16** Entire Agreement; Amendments. This Agreement, together with the Exhibits hereto, contains the entire understanding of the Parties with respect to the subject matter hereof. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to such subject matter are superseded by the terms of this Agreement. The Exhibits to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representative(s) of both Parties. The Parties agree that, effective as of the Execution Date, that the Existing Confidentiality Agreement shall be subject to the confidentiality and non-use provisions of this Agreement. The foregoing shall not be interpreted as a waiver of any remedies available to either Party or its Affiliates as a result of any breach, prior to the Execution Date, by the other Party or its Affiliates of such other Party's or its Affiliate's obligations pursuant to the Existing Confidentiality Agreement.
- **13.17 Counterparts**. This Agreement may be executed in two (2) counterparts, each of which shall be deemed an original, but both of which together shall constitute one and the same instrument. Each Party shall be entitled to rely on the delivery of executed digital (*e.g.*, PDF) copies of counterpart execution pages of this Agreement and such digital copies shall be legally effective to create a valid and binding agreement between the Parties.

{Signature Page Follows}

68

**In Witness Whereof**, the Parties intending to be bound have caused this Technology Transfer and Exclusive License Agreement to be executed by their duly authorized representatives as of the Execution Date.

#### ARBUTUS BIOPHARMA CORPORATION

By: /s/ William H. Collier

Name: William H. Collier

Title: President & Chief Executive Officer

#### QILU PHARMACEUTICAL CO., LTD.

By: /s/ Haizhong Bao
Name: Haizhong Bao
Title: President and Legal Representative

[Signature Page to Technology Transfer and Exclusive License Agreement]

#### **List of Exhibits**

**Exhibit 1.19: Arbutus Materials** 

**Exhibit 1.20: Arbutus Patents** 

**Exhibit 1.89: Licensed Compound** 

**Exhibit 2.5: Initial Technology Transfer Documents List** 

**Exhibit 4.1: Outline of Development Plan** 

**Exhibit 5.2: Clinical Supply Terms** 

Exhibit 6.3(b): Licensed Product-Specific Trademarks

#### **Arbutus Biopharma Corporation**

#### **List of Subsidiaries**

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

#### **Consent of Independent Registered Public Accounting Firm**

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

- 1. Registration Statement (Form S-3 No. 333-260782) pertaining to the offering, issuance and sale of up to (a) \$250,000,000 of common shares, preferred shares, warrants, debt securities and units of Arbutus Biopharma Corporation and (b) 38,847,462 common shares offered by the selling shareholder named therein,
- 2. Registration Statement (Form S-3 No. 333-248467) pertaining to the offering, issuance and sale of up to \$200,000,000 of common shares, preferred shares, warrants, debt securities and units of Arbutus Biopharma Corporation,
- 3. Registration Statement (Form S-3 No. 333-235674) pertaining to the offering, issuance and sale of up to \$150,000,000 of common shares, preferred shares, warrants, debt securities and units of Arbutus Biopharma Corporation,
- 4. Registration Statement (Form S-8 No. 333-258494) pertaining to the Arbutus Biopharma Corporation 2016 Omnibus Share and Incentive Plan,
- 5. Registration Statement (Form S-8 No. 333-239407) pertaining to the Arbutus Biopharma Corporation 2016 Omnibus Share and Incentive Plan and Arbutus Biopharma Corporation 2020 Employee Stock Purchase Plan,
- 6. Registration Statement (Form S-8 No. 333-233192) pertaining to the Inducement Stock Option Award of Arbutus Biopharma Corporation,
- 7. Registration Statement (Form S-8 No. 333-228919) pertaining to the Arbutus Biopharma Corporation 2011 Omnibus Share Compensation Plan,
- 8. Registration Statement (Form S-8 No. 333-212115) pertaining to the Arbutus Biopharma Corporation 2016 Omnibus Share and Incentive Plan,
- 9. Registration Statement (Form S-8 No. 333-202762) pertaining to the OnCore Biopharma, Inc. 2014 Equity Incentive Plan, and
- 10. Registration Statement (Form S-8 No. 333-186185) pertaining to the Tekmira 2011 Omnibus Share Compensation Plan, the Tekmira Share Option Plan and the Protiva 2000 Incentive Stock Option Plan,

of our report dated March 3, 2022, with respect to the consolidated financial statements of Arbutus Biopharma Corporation included in this Annual Report (Form 10-K) of Arbutus Biopharma Corporation for the year ended December 31, 2021.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania March 3, 2022

# 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(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 3, 2022

/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(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;
    - Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
  - 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting

Date: March 3, 2022

/s/ David Hastings

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

## CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906

OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Arbutus Biopharma Corporation (the "Company") on Form 10-K for the year ended December 31, 2021, 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 3, 2022

/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, 2021, 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 3, 2022

/s/ David Hastings

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