

**Bellus**  
HEALTH

# **2019** ANNUAL REPORT



Certain statements contained in this document, other than statements of fact that are independently verifiable at the date hereof, may constitute "forward-looking statements" within the meaning of Canadian securities legislation and regulations and other applicable securities laws. Such statements, based as they are on the current expectations of management, inherently involve numerous important risks, uncertainties and assumptions, known and unknown, many of which are beyond BELLUS Health's control. Such statements include, but are not limited to, the potential of BLU-5937 to successfully treat chronic cough, chronic pruritus and other hypersensitization-related disorders, BELLUS Health's expectations related to its preclinical studies and clinical trials, including the timing and results for the BLU-5937 Phase 2 RELIEF trial and its chronic pruritus program, the potential patient tolerance of BLU-5937 as compared to other competitor candidates and the potential applicability of BLU-5937 and BELLUS Health's P2X3 platform to treat other disorders. Risk factors that may affect BELLUS Health's future results include but are not limited to: the ability to expand and develop its project pipeline, the ability to obtain adequate financing, the impact of general economic conditions, general conditions in the pharmaceutical industry, the impact of the COVID-19 pandemic on its operations, changes in the regulatory environment in the jurisdictions in which BELLUS Health does business, stock market volatility, heavy dependence on licensed intellectual property, fluctuations in costs, changes to the competitive environment due to consolidation, achievement of forecasted burn rate, potential payments/outcomes in relation to indemnity agreements and contingent value rights, achievement of forecasted preclinical study and clinical trial milestones, reliance on third parties to conduct preclinical studies and clinical trials for BLU-5937 and that actual results may vary once the final and quality-controlled verification of data and analyses has been completed. In addition, the length of BELLUS Health's product candidate's development process, its market size and commercial value, as well as the sharing of proceeds between BELLUS Health and its potential partners from potential future revenues, if any, are dependent upon a number of factors. Moreover, its growth and future prospects are mainly dependent on the successful development, patient tolerability, regulatory approval, commercialization and market acceptance of its product candidate BLU-5937 and other products. Consequently, actual future results and events may differ materially from the anticipated results and events expressed in the forward-looking statements. BELLUS Health believes that expectations represented by forward-looking statements are reasonable, yet there can be no assurance that such expectations will prove to be correct. The reader should not place undue reliance, if any, on any forward-looking statements included in this document. These forward-looking statements speak only as of the date made, and BELLUS Health is under no obligation and disavows any intention to update publicly or revise such statements as a result of any new information, future event, circumstances or otherwise, unless required by applicable legislation or regulation. Please see BELLUS Health's public filings with the Canadian securities regulatory authorities, including, but not limited to, its Annual Information Form, and the United States Securities and Exchange Commission for further risk factors that might affect BELLUS Health and its business.

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## MANAGEMENT'S DISCUSSION AND ANALYSIS

This Management's Discussion and Analysis ("MD&A") provides a review of BELLUS Health Inc.'s operations and financial performance for the years ended December 31, 2019 and 2018. In this MD&A, unless the context otherwise requires, the terms "BELLUS Health", "we", "us", and "our" refer to BELLUS Health Inc. This document should be read in conjunction with the our audited consolidated financial statements for the year ended December 31, 2019, which have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB"). Additional information relating to us, including our Annual Report and Annual Information Form, as well as other public filings, is available on SEDAR at [www.sedar.com](http://www.sedar.com) and on EDGAR at [www.sec.gov/edgar](http://www.sec.gov/edgar).

The consolidated financial statements and MD&A have been reviewed by our Audit Committee and approved by our Board of Directors. This MD&A was prepared by management with information available as at February 26, 2020.

Information in relation to common shares, stock options, broker warrants and per share amounts included in the audited consolidated financial statements and MD&A for the year ended December 31, 2019 reflect the 3.6 for 1 share consolidation effective on August 19, 2019.

All currency figures reported in the consolidated financial statements and in this document are in Canadian dollars, unless otherwise specified. The Canadian dollar was the Company's functional and presentation currency for all years presented.

### FORWARD-LOOKING STATEMENTS

Certain statements contained in this MD&A may constitute "forward-looking information" within the meaning of applicable securities laws in Canada and "forward-looking statements" within the meaning of the United States Private Securities Litigation Reform Act of 1995, as amended (collectively, "forward-looking statements"), which involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. These forward-looking statements include information about possible or assumed future results of our business, financial condition, results of operations, liquidity, objectives and strategies to achieve those objectives, as well as statements with respect to our beliefs, targets, expectations, anticipations, estimates or intentions. In some cases, you can identify forward-looking statements by terminology such as "believe", "may", "estimate", "continue", "anticipate", "intend", "should", "plan", "expect", "predict", "potential", "could", "assume", "project", "guidance" or the negative of these terms or other similar expressions, although not all forward-looking statements include such words. The statements we make regarding the following matters are forward-looking by their nature and are based on certain of the assumptions noted below:

- our aim to develop and commercialize BLU-5937 for the treatment of hypersensitization disorders, including chronic cough and chronic pruritus;
- our aim to complete additional preclinical studies on BLU-5937;
- our aim to pursue the Phase 2 clinical trial on BLU-5937 for the treatment of patients with refractory chronic cough with topline data in mid-2020, and initiate later stage clinical studies thereafter;
- our aim to initiate a Phase 2 clinical trial on BLU-5937 for the treatment of patients with chronic pruritus associated with atopic dermatitis, in Q2 2020, with topline data expected in mid-2021;

- our aim to further explore the potential of BLU-5937 for the treatment of other afferent hypersensitization-related conditions;
- our expectations relating to the timing and cost of significant preclinical study and clinical trial milestones;
- our expectations with respect to the timing and cost of the research and development activities of BLU-5937;
- the function, potential benefits, effectiveness and safety of our product candidates, including BLU-5937;
- our expectations with respect to pre-commercialization activities related to the commercial launch of BLU-5937;
- our estimates and assessment of the potential markets for our product candidates;
- our expectations regarding pricing and acceptance of our product candidates by the market;
- the benefits and risks of our product candidates as compared to others;
- our aim to obtain regulatory approvals to market our product candidates;
- our expectations with respect to the cost of preclinical studies and clinical trials and commercialization of our product candidates, including BLU-5937;
- our current and future capital requirements and anticipated sources of financing or revenue;
- our expectations regarding the protection of our intellectual property;
- our business strategy;
- potential milestone payments and royalties pursuant to license agreements and other partnerships; and
- our development and partnership plans and objectives.

The preceding list is not intended to be an exhaustive list of all of our forward-looking statements.

Conclusions, forecasts and projections set out in forward-looking information are based on our current objectives and strategies and on expectations and estimates and other factors and assumptions that we believe to be reasonable at the time applied but may prove to be incorrect. These include, but are not limited to:

- the function, potential benefits, effectiveness and safety of BLU-5937;
- the benefits and risks of our product candidates as compared to others;
- progress, timing and costs related to the development, completion and potential commercialization of our product candidate;
- estimates and projections regarding our industry;
- market acceptance of our product candidate;
- future success of current research and development activities;
- achievement of development and commercial milestones, including forecasted preclinical study and clinical trial milestones;
- our reliance on third parties to conduct preclinical studies and clinical trials for BLU-5937;
- that the timeline and costs for our preclinical and clinical programs are not incorrectly estimated or affected by unforeseen circumstances;
- absence of material deterioration in general business and economic conditions;
- the receipt of regulatory and governmental approvals for research and development projects and timing thereof;
- the availability of tax credits and financing for research and development projects, and the availability of financing on favorable terms;
- the accuracy of our estimates regarding future financing and capital requirements and expenditures;
- the achievement of our forecasted cash burn rate;

- the sufficiency and validity of our intellectual property rights;
- our ability to secure, maintain and protect our intellectual property rights, and to operate without infringing on the proprietary rights of others or having third parties circumvent the rights owned or licensed by us;
- our ability to source and maintain licenses from third-party owners on acceptable terms and conditions;
- absence of significant changes in Canadian dollar-U.S. dollar and other foreign exchange rates or significant variability in interest rates;
- the absence of material changes in market competition;
- our ability to attract and retain skilled staff;
- our ability to maintain ongoing relations with employees and business partners, suppliers and other third parties;
- the accuracy of the market research, third-party industry data and forecasts relied upon by us; and
- the absence of adverse changes in relevant laws or regulations.

There are important factors that could cause our actual results, levels of activity, performance or achievements to differ materially from the results, levels of activity, performance or achievements expressed or implied by the forward-looking statements. See “Risk Factors” in this MD&A. Should one or more of the risks, uncertainties or other factors outlined in this MD&A materialize, our objectives, strategies or intentions change, or any of the factors or assumptions underlying the forward-looking information prove incorrect, our actual results and our plans and targets could vary significantly from what we currently foresee. Accordingly, we warn investors to exercise caution when considering statements containing forward-looking information and that it would be unreasonable to rely on such statements as creating legal rights regarding our future results or plans or targets. All of the forward-looking information in this MD&A is qualified by the cautionary statements herein.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this MD&A, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that future results, levels of activity, performance and events and circumstances reflected in the forward-looking statements will be achieved or will occur. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this MD&A, to conform these statements to actual results or to changes in our expectations.

## CORPORATE PROFILE

We are a clinical stage biopharmaceutical company focused on the development of novel therapeutics for the treatment of chronic cough and other hypersensitization disorders. Our product candidate, BLU-5937, is a twice daily oral small molecule specifically designed to be a highly selective antagonist of the P2X3 receptor, a clinically validated target linked to hypersensitivity. We are developing BLU-5937 for the treatment of chronic cough and chronic pruritus, or chronic itch. These hypersensitization-related disorders, which share a common pathophysiology that is mediated through the P2X3 receptor, represent areas of significant unmet medical need and potentially large market opportunities. We believe BLU-5937's characteristics shown in our preclinical studies and Phase 1 trial position it as a differentiated treatment option in the P2X3 antagonists class.

Our shares trade on the Nasdaq Global Market ("Nasdaq") and on the Toronto Stock Exchange ("TSX") both under the symbol "BLU".

## BUSINESS OVERVIEW

### 2020 Corporate Plan

Our priorities for 2020 will be focused on achieving the following:

- Completing recruitment for the Company's Phase 2 RELIEF trial for BLU-5937 in refractory chronic cough, anticipated by the end of March 2020.
- Releasing top-line data for our Phase 2 RELIEF trial for BLU-5937 in refractory chronic cough patients, anticipated in mid-2020.
- Initiating a Phase 2 trial of BLU-5937 in patients with chronic pruritus associated with atopic dermatitis ("AD") in Q2 2020, with top-line results anticipated in mid-2021.
- Pursuing activities that will further enable late-stage clinical development of BLU-5937.
- Presenting detailed BLU-5937 Phase 2 RELIEF trial data at a medical conference.

### 2019 Highlights and Recent 2020 Developments

- **Ongoing Phase 2 RELIEF trial of BLU-5937 for the treatment of refractory chronic cough, with top-line results anticipated in mid-2020.**

In July 2019, we enrolled the first patient in the Phase 2 RELIEF trial of BLU-5937 for the treatment of refractory chronic cough. We expect to complete patient enrollment by the end of March, with topline results anticipated in mid-2020.

- **Completed a clinical Phase 1 drug-drug interaction ("DDI") trial of BLU-5937 in 28 healthy adult subjects demonstrating no clinically significant interaction with CYP3A4, OATP1B1 and BCRP.**

In December 2019, we completed a DDI trial, which indicated that the administration of BLU-5937 should not affect the elimination of other drugs that are substrates of these enzymes/transporters. BLU-5937 was found to be safe and generally well tolerated in the trial (200 mg BID dose administered for 10 days). Two subjects out of 28 (7%) reported a mild taste alteration, which occurred only on the first day of dosing.

- **Closed a US\$79.4 million equity offering and began trading on the Nasdaq.**  
In September 2019, we completed an offering of our common shares resulting in gross proceeds to BELLUS Health of US\$79.4 million. Concurrently with the pricing of our equity offering, our common shares began trading on the Nasdaq on September 5, 2019.
- **Appointed Catherine Bonuccelli, MD as Chief Medical Officer.**  
In August 2019, we hired Dr. Bonuccelli, who brings over 20 years of pharmaceutical experience at GSK and Astra Zeneca with significant expertise in clinical development of respiratory products.
- **Obtained clearance of U.S. IND for the BLU-5937 Phase 2 trial in chronic pruritus; Phase 2 trial to commence in Q2 2020.**  
On February 20, 2020, the U.S. Food and Drug Administration ("FDA") accepted our Investigational New Drug ("IND") application for BLU-5937 for the treatment of chronic pruritus associated with AD, also known as eczema. The clinical Phase 2 trial is expected to be initiated in Q2 2020. In July 2019, we announced that we were expanding our BLU-5937 P2X3 antagonist platform to include chronic pruritus and in September 2019, presented preclinical data on BLU-5937 in pruritus at the European Society for Dermatological Research Conference.
- **Held a Key Opinion Leader ("KOL") meeting to discuss the state of chronic cough treatment.**  
In July 2019, we held a KOL event, which was led by Dr. Jacky Smith, Professor at the University of Manchester, United Kingdom, to discuss chronic cough and BLU-5937. A replay of the event is available on the Events & Presentations page of our website.
- **Ended the year with cash, cash equivalents and short-term investments totalling \$116.9 million (US\$90.0 million).**

#### **September 2019 Equity Offering, Nasdaq Listing and Share Consolidation**

In September 2019, we raised total gross proceeds of \$104.6 million (US\$79.4 million) by issuing a total of 11,179,451 common shares in the United States and in Canada (the "2019 Offering"). Concurrently with the pricing of our equity offering, our common shares began trading on the Nasdaq on September 5, 2019. Our common shares are now dual-listed on the Nasdaq and the TSX.

On September 9, 2019, we closed an equity offering, issuing 9,859,155 common shares from treasury at a price of \$9.35 (US\$7.10) per share for gross proceeds of \$92.2 million (US\$70.0 million). On September 17, 2019, the underwriters of the equity offering partially exercised their option to purchase additional common shares (over-allotment option), resulting in the issuance of an additional 1,320,296 common shares from treasury at a price of \$9.40 (US\$7.10) per share, for additional gross proceeds of \$12.4 million (US\$9.4 million). We intend to use the net proceeds of the 2019 Offering, together with the cash, cash equivalents and short-term investments on hand at the time of closing, primarily to fund research and development activities, general and administrative expenses, working capital needs and other general corporate purposes.

Prior to the financing, we completed a share consolidation on the basis of one new common share for every 3.6 outstanding shares, effective on August 19, 2019, in order to increase our share price to allow listing on the Nasdaq. With the share consolidation, our number of outstanding common shares was reduced from approximately 159.1 million outstanding common shares to approximately 44.2 million outstanding common shares at August 19, 2019.



## Our Pipeline

The following table sets forth the status of our BLU-5937 pipeline.

PROGRAM	DEVELOPMENT				STATUS	
Indication	Preclinical	Phase 1	Phase 2	Phase 3	Worldwide Rights	Next Anticipated Milestone
<b>BLU-5937</b>						
Refractory Chronic Cough					Bellus HEALTH	Mid-2020: Topline data
Chronic Pruritus Associated with Atopic Dermatitis					Bellus HEALTH	Q2 2020: Phase 2 initiation

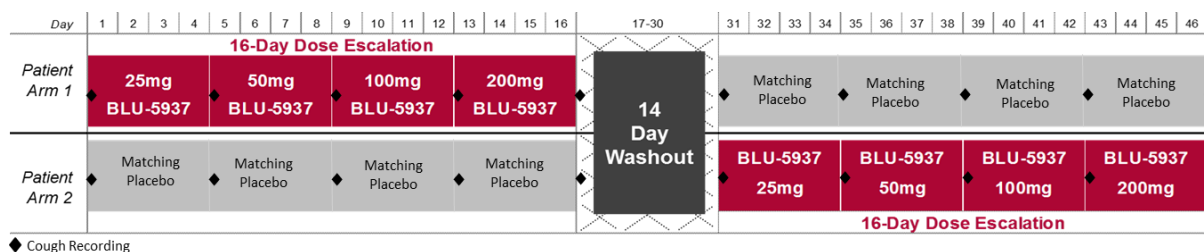
### BLU-5937 for Chronic Cough

We are developing BLU-5937, a potent, highly selective, small molecule antagonist of the P2X3 receptor, as an oral therapy to reduce cough frequency in refractory chronic cough patients.

We are currently conducting a Phase 2 clinical trial of BLU-5937 for patients with refractory chronic cough, which we refer to as the RELIEF (A Randomized, Double-blind, Placebo-Controlled, Crossover, Dose Escalation Trial of BLU-5937 in Subjects with Unexplained or Refractory Chronic Cough) trial. The trial was initiated in July 2019 and we expect to report topline data in mid-2020.

The RELIEF trial is a randomized, double-blind, placebo-controlled, dose escalation and two-period crossover design trial to assess the efficacy, safety and tolerability of BLU-5937 at four doses: 25, 50, 100 and 200 mg BID. Doses are escalated at four-day intervals. Approximately 65 patients with refractory chronic cough are expected to be enrolled at 16 clinical sites located in the United Kingdom and United States. We enrolled the first patient in the RELIEF trial at the end of July 2019. The end of patient enrollment is expected by the end of March 2020.

The four doses selected for the RELIEF trial were based on pharmacokinetic/pharmacodynamic modeling using data gathered from preclinical cough studies, data from a Phase 2 clinical trial with a class competitor and the BLU-5937 Phase 1 trial. Based on that modeling, it is anticipated that the optimal therapeutic doses will be 50 mg to 100 mg BID; however, to allow a better characterization of the dose response range and proper dose selection for future clinical trials, the 25 mg BID and 200 mg BID doses are also being evaluated.



The primary efficacy endpoint of the RELIEF trial is the change from baseline in awake cough frequency as measured by a cough recorder at the end of each dose level. Secondary efficacy endpoints include the change in 24-hour cough frequency and the change in the Leicester Cough Questionnaire, Cough Severity Visual Analogue Scale (VAS) and the Global Rating of Change Scale.

Phase 1 results showed that no subjects in the BLU-5937 arm receiving anticipated therapeutic doses reported any loss of taste perception, and only one subject out of 24 (<5%) reported transient and sporadic taste alteration only on the first day of dosing. No subject reported total loss of taste at any dose. The RELIEF trial will also collect taste adverse event data to potentially build on this clinical evidence. To fully characterize any potential taste disturbance effects seen in the RELIEF trial, a questionnaire will be provided to patients who report taste side effects in the trial.

The key inclusion criteria in the RELIEF trial are that patients must have unexplained or refractory chronic cough for at least one year, an awake cough count of  $\geq 10$  per hour (Awake Cough Count at Screening) and a score of  $\geq 40$ mm on the Cough Severity VAS at Screening. Current or past smoking (within the past six months) or a diagnosis of chronic obstructive pulmonary disease, bronchiectasis, or idiopathic pulmonary fibrosis are key exclusion criteria.

The RELIEF trial is being conducted with Illingworth Research Group, a clinical research organization which has conducted multiple clinical trials in chronic cough. Each of the trial sites are experienced in conducting chronic cough trials. Many of the sites are Centers of Excellence for the treatment of chronic cough and have access to a significant pool of patients.

In our Phase 1 trial conducted with healthy volunteers given BLU-5937, at the anticipated therapeutic doses of 50 mg to 100 mg, no subjects reported loss of taste perception and only one subject out of 24 (<5%) reported a transient and sporadic taste alteration, which occurred only on the first day of dosing.

Our preclinical studies demonstrated that BLU-5937 is a highly selective P2X3 antagonist exhibiting a potent anti-tussive effect without affecting taste perception. In a guinea pig cough model, BLU-5937 showed comparable anti-tussive efficacy to the current leading P2X3 antagonist in development, Merck & Co's gefapixant. In a rat taste model, BLU-5937 was not associated with taste loss whereas, consistent with clinical trial data previously presented by Merck & Co, gefapixant led to significant taste loss.

Chronic cough, the lead indication for BLU-5937, is a cough lasting more than eight weeks, and may have a significant adverse impact on patients' quality of life. It is estimated that more than 26 million adults in the United States suffer from chronic cough, with more than 2.6 million of those people having refractory chronic cough lasting more than one year. Many patients report that their condition has a marked effect on their quality of life including sleep disruption, tiredness, incontinence, and disruption of social interactions. Currently, there is no therapy approved specifically for the treatment of refractory chronic cough, and the most advanced P2X3 antagonist therapy in development has substantial tolerability issues, including significant taste alteration or loss. BLU-5937 may be a differentiated option, with little to no effect on taste.

#### BLU-5937 Drug-Drug Interaction Trial

We are pursuing BLU-5937 enabling activities to prepare our program for later stage clinical development. We completed in December 2019 a clinical Phase 1 drug-drug interaction (DDI) trial in 28 healthy adult subjects to study potential interactions of BLU-5937 (200 mg BID for 10 days) with CYP3A4, OATP1B1 and BCRP. This trial revealed that BLU-5937 is not a CYP3A4 inducer. BLU-5937 was shown to be a weak inhibitor of OATP1B1 and a very weak inhibitor of BCRP, which is not considered clinically meaningful at the predicted therapeutic doses studied in the Phase 2 RELIEF trial. These results indicate that the administration of BLU-5937 should not affect the elimination of other drugs that are substrates of these enzymes/transporters. Furthermore, the weak inhibition of OATP1B1 is consistent with the hypothesis that BLU-5937 is affecting bilirubin disposition at predicted supra-

therapeutic doses. BLU-5937 was found to be safe and generally well tolerated in the trial. Only two subjects out of 28 (7%) reported a mild taste alteration, only on the first day of dosing.

#### KOL Meeting to Discuss the State of Chronic Cough Treatment

In July 2019, we held a KOL meeting led by Dr. Jacky Smith to discuss chronic cough. The event included discussions on the unmet medical need, a review of current therapies in development, including P2X3 antagonists, as well as a clinical and regulatory update on our P2X3 antagonist product candidate for the treatment of chronic cough, BLU-5937.

Dr. Jacky Smith, MB, ChB, FRCP, PhD, is a Professor of Respiratory Medicine at the University of Manchester, United Kingdom and an Honorary Consultant at University Hospital of South Manchester NHS Foundation Trust. Dr. Smith runs a multi-disciplinary research team whose focus is on understanding mechanisms underlying pathological cough, and a regional clinical service seeing patients with refractory chronic cough. Her main research interests lie in developing new endpoints in cough monitoring, understanding the mechanisms underlying cough in respiratory diseases and the testing of novel anti-tussive therapies. Dr. Smith is the Principal Investigator of our Phase 2 RELIEF trial of BLU-5937 in refractory chronic cough.

#### BLU-5937 for Chronic Pruritus

On February 20, 2020, the FDA accepted our IND application for the clinical Phase 2 trial of BLU-5937 in chronic pruritus associated with AD, thus clearing the start of the trial in the United States. We expect to initiate the Phase 2 trial in Q2 2020 and report topline data in mid-2021. In July 2019, we announced that we were developing BLU-5937 for a second indication, chronic pruritus. We believe BLU-5937 may be a viable treatment option for patients with chronic pruritus associated with AD.

Preclinical studies conducted by us provided evidence that the ATP-induced hypersensitization mediated by P2X3 receptors in cutaneous C-fibers plays a key role in pruritus. In multiple animal models of pruritus, we observed that treatment with BLU-5937 resulted in significant anti-pruritic effect. We presented preclinical data on BLU-5937 in pruritus at the European Society for Dermatological Research Conference in September 2019.

The clinical Phase 2 trial will be a randomized, double-blind, placebo-controlled, parallel group design trial to assess the efficacy, safety, and tolerability of BLU-5937 in approximately 100 patients suffering from moderate to severe chronic pruritus associated with mild to moderate AD. The trial is expected to be a two-arm study comparing BLU-5937 to placebo, each administered orally, twice-daily (BID), for four weeks.

Chronic pruritus, commonly known as chronic itch, is an irritating sensation that leads to scratching, and persists for longer than six weeks, which can be debilitating and significantly impacts quality of life. It is a hallmark of many conditions, including AD. It is estimated that AD affects more than 16.9 million adults in the United States. Despite currently available treatments, an estimated 40-50% of AD patients have inadequate relief of their pruritus and are in need of new, efficacious pruritus therapies.

#### BLU-5937 P2X3 Antagonist Platform

BLU-5937, a highly selective P2X3 antagonist – (>1500 fold) for human P2X3 receptors, which are implicated in chronic cough, versus P2X2/3 receptors, which play a major role in taste - has the potential to be an important treatment option for chronic cough, chronic pruritus patients and other hypersensitization-related disorders.

The P2X3 receptor in the cough reflex pathway is a rational target for treating chronic cough, and it has been validated in multiple clinical trials with different P2X3 antagonists. With a low-selectivity P2X3 antagonist therapy for chronic cough, an adverse effect on taste perception is a well-known and widely-documented tolerability issue. We believe that our highly selective P2X3 antagonist can also reduce coughing in patients with chronic cough, while maintaining taste function, by not inhibiting P2X2/3 receptors. This hypothesis has been validated in a recent clinical trial with a more selective antagonist of P2X3; however, BLU-5937 is the most selective of the P2X3 antagonists currently being studied.

There are important similarities between chronic cough and chronic pruritus with respect to the P2X3 signaling pathway. Both conditions present inflammatory underlying conditions that trigger ATP release. Extracellular ATP activates P2X3 receptors in the upper airways or in the skin, which transmit an irritation signal to the brain that is interpreted as an urge to cough or urge to scratch, respectively.

In addition to chronic cough and chronic pruritus, BLU-5937 may also have broad applicability across other afferent hypersensitization-related disorders, potentially enabling us to build a pipeline of therapies using our P2X3 platform. We are exploring how P2X3 activation can contribute to irritation and pain, and whether inhibition of P2X3 receptors can help treat these afferent hypersensitization-related disorders.

#### Other

We have exclusive worldwide development and commercialization rights to BLU-5937 in all indications. Our BLU-5937 program is protected by a comprehensive patent estate comprised of issued and allowed patents, as well as pending patent applications. We have secured composition of matter patent protection for BLU-5937 in all major pharmaceutical markets, including the United States of America, Europe, Japan and China until 2034. Under certain circumstances, such patent term may be extended for up to five years in certain jurisdictions such as the United States, Europe and Japan. In addition, we have secured methods of use patent protection in the United States for the treatment of chronic cough using BLU-5937 expiring in 2034 and for avoiding loss of taste response while treating a chronic cough patient with BLU-5937, expiring in 2038. Patent applications with similarly broad claims are currently pending in other industrialized nations.

#### **Appointment of a Chief Medical Officer**

In August 2019, we appointed Catherine Bonuccelli, MD to the role of CMO. Dr. Bonuccelli is a pediatric pulmonologist that brings to BELLUS Health over 20 years of pharmaceutical experience with significant expertise in clinical development of respiratory products. Prior to joining BELLUS Health, Dr. Bonuccelli held a number of leadership positions focusing on the late-stage clinical development of large and small molecule programs in the respiratory and inflammation therapeutic areas. During her more than 20-year tenure with AstraZeneca, she played a number of roles, including Global Medicines Clinical Vice President for the Inflammation, Neuroscience, & Respiratory Therapeutic Area, and Therapy Area Clinical Vice President, Respiratory and Inflammation. Dr. Bonuccelli subsequently spent more than four years serving as US Medical Affairs Respiratory Therapeutic Area Head for GSK.

#### **2018 Equity Offering**

On December 18, 2018, we closed an equity offering, issuing a total of 10,233,918 common shares from treasury at a price of \$3.42 per share for aggregate gross proceeds of \$35 million (the “2018 Offering”). The 2018 Offering was subscribed in vast majority by U.S. institutional healthcare investors led by OrbiMed. In addition, we issued to the agents of the 2018 Offering 402,851 broker warrants to buy one common share at a price of \$3.42 per share, exercisable until June 18, 2020.

## Selected Financial Information

(In thousands of dollars, except per share data)

	Years ended December 31		
	2019	2018	2017
Revenues	\$ 35	\$ 35	\$ 165
Expenses:			
Research and development	26,119	7,185	3,610
Research tax credits	(710)	(653)	(289)
	25,409	6,532	3,321
General and administrative	8,726	3,409	2,529
Total operating expenses	34,135	9,941	5,850
Results from operating activities	(34,100)	(9,906)	(5,685)
Finance income	1,520	746	80
Finance costs	(1,886)	(5)	(61)
Net finance (costs) income	(366)	741	19
Change in fair value of contingent consideration receivable	-	81	-
Realized gain on sale of investment in FB Health	-	-	1,909
Gain on sale of subsidiary	-	-	1,944
Loss before income taxes	(34,466)	(9,084)	(1,813)
Deferred tax expense	-	-	61
Net loss for the year	\$ (34,466)	\$ (9,084)	\$ (1,874)
Loss per share – Basic and diluted	\$ (0.73)	\$ (0.27)	\$ (0.10)

### Financial Position:

	At December 31, 2019	At December 31, 2018	At December 31, 2017
Total assets	\$ 125,188	\$ 53,300	\$ 28,498
Total non-current financial liabilities	\$ 27	\$ Nil	\$ Nil

## RESULTS OF OPERATIONS

### Year Ended December 31, 2019 Compared to Year Ended December 31, 2018

For the year ended December 31, 2019, *net loss* amounted to \$34,466,000 (\$0.73 per share), compared to \$9,084,000 (\$0.27 per share) for the previous year. The increase in net loss is primarily attributable to higher research and development expenses in relation to the development of BLU-5937, our product candidate for the treatment of chronic cough and chronic pruritus, and to higher general and administration expenses.

*Research and development expenses*, net of research tax credits, amounted to \$25,409,000 for the year ended December 31, 2019, compared to \$6,532,000 for the previous year. The increase is primarily attributable to higher expenses incurred in relation to the development of BLU-5937, mainly for the manufacturing of active pharmaceutical ingredient for upcoming studies and activities in relation to the Phase 2 trial in refractory chronic cough, for which the first patient was enrolled in July 2019. We expect these expenses to continue to increase in subsequent years as we pursue the Phase 2 trial in refractory chronic cough, the development of BLU-5937 into a second indication, chronic pruritus, for which we expect a Phase 2 trial will be initiated in Q2 2020, and BLU-5937 enabling activities to prepare the program for later stage clinical development.

*General and administrative expenses* amounted to \$8,726,000 for the year ended December 31, 2019, compared to \$3,409,000 for the previous year. The increase is mainly due to increased general and administrative costs incurred since our Nasdaq listing in September 2019 as well as to higher stock-based compensation expense in relation to our deferred share unit plan and our stock option plan.

*Net finance costs* amounted to \$366,000 for the year ended December 31, 2019, compared to net finance income of \$741,000 for the previous year. The increase in net finance costs is primarily attributable to foreign exchange loss that arose from the translation of our net monetary assets denominated in US dollars, partially offset by higher interest income due to increased cash, cash equivalents and short-term investments position following the 2019 Offering.

*Change in fair value of contingent consideration receivable* for the year ended December 31, 2019 amounted to nil compared to an increase of \$81,000 for the previous year. The contingent consideration receivable is related to the sale of our equity interest in FB Health S.p.A. ("FB Health") in June 2017.

As at December 31, 2019, total assets amounted to \$125,188,000, compared to \$53,300,000 as at December 31, 2017. The increase is primarily due to the funds received from the 2019 Offering, offset by funds used to finance our operating activities. Total non-current financial liabilities amounted to 27,000 as at December 31, 2019, compared to nil as at December 31, 2018.

### Year Ended December 31, 2018 Compared to Year Ended December 31, 2017

For the year ended December 31, 2018, *net loss* amounted to \$9,084,000 (\$0.27 per share), compared to \$1,874,000 (\$0.10 per share) for the previous year. Net loss for 2017 included a gain on the sale of our wholly-owned subsidiary, Thallion Pharmaceuticals Inc. ("Thallion"), to Taro Pharmaceuticals Inc. ("Taro") in March 2017 in the amount of \$1.9 million and a realized gain on the sale of our equity interest in FB Health in the amount of \$1.9 million. Excluding these gains, the increase in net loss is primarily attributable to higher research and development expenses.

*Revenues* amounted to \$35,000 for the year ended December 31, 2018, compared to \$165,000 for the previous year. Revenues in 2017 are mainly attributable to a service agreement with Taro following the sale of Thallion to Taro in March 2017.

*Research and development expenses*, net of research tax credits, amounted to \$6,532,000 for the year ended December 31, 2018, compared to \$3,321,000 for the previous year. The increase is primarily attributable to higher expenses incurred in relation to the development of BLU-5937, including the clinical Phase 1 trial completed in 2018.

*General and administrative expenses* amounted to \$3,409,000 for the year ended December 31, 2018, compared to \$2,529,000 for the previous year. The increase is mainly due to higher stock-based compensation expense in relation to our stock option plan and deferred share unit plan.

*Net finance income* amounted to \$741,000 for the year ended December 31, 2018, compared to \$19,000 for the previous year. The increase is primarily attributable to higher interest income due to the increased cash, cash equivalents and short-term investments position following the 2017 Offering as well as to the foreign exchange gain that arose from the translation of the net monetary assets denominated in US dollars.

*Change in fair value of contingent consideration receivable* amounted to an increase of \$81,000 for the year ended December 31, 2018, compared to nil for the previous year. The contingent consideration receivable is related to the sale of our equity interest in FB Health in June 2017.

*Realized gain on sale of investment in FB Health* amounted to \$1,909,000 for the year ended December 31, 2017 and is related to the sale of our equity interest in FB Health in June 2017, as discussed previously.

*Gain on sale of subsidiary* amounted to \$1,944,000 for the year ended December 31, 2017 and is related to the sale of our wholly-owned subsidiary Thallion in March 2017, as discussed previously.

As at December 31, 2018, total assets amounted to \$53,300,000, compared to \$28,498,000 as at December 31, 2017. The increase is primarily due to the funds received from the 2018 Offering, offset by funds used to finance operating activities. Total non-current financial liabilities amounted to nil as at December 31, 2018 and December 31, 2017.

#### **Quarter Ended December 31, 2019 Compared to Quarter Ended December 31, 2018**

For the three-month period ended December 31, 2019, *net loss* amounted to \$13,163,000 (\$0.24 per share), compared to \$2,630,000 (\$0.08 per share) for the corresponding period the previous year. The increase in net loss is primarily attributable to higher research and development expenses, higher general and administration expenses as well as a higher foreign exchange loss.

*Research and development expenses*, net of research tax credits, amounted to \$9,302,000 for the three-month period ended December 31, 2019, compared to \$2,268,000 for the corresponding period the previous year. The increase is attributable to expenses incurred in relation to the development of BLU-5937, including for the manufacturing of active pharmaceutical ingredient for upcoming studies and activities in relation to the Phase 2 trial in refractory chronic cough.

*General and administrative expenses* amounted to \$2,756,000 for the three-month period ended December 31, 2019, compared to \$871,000 for the corresponding period the previous year. The increase is mainly due to increased general and administrative costs incurred since our Nasdaq listing in September 2019 as well as to higher stock-based compensation expense in relation to our deferred share unit plan and our stock option plan.

*Net finance costs* amounted to \$1,114,000 for the three-month period ended December 31, 2019, compared to net finance income of \$500,000 for the corresponding period the previous year. The increase in net finance costs is primarily attributable to foreign exchange loss that arose from the translation of our net monetary assets denominated in US dollars, partially offset by higher interest income due to increased cash, cash equivalents and short-term investments position following the 2019 Offering.

### **Quarterly Results**

*(in thousands of dollars, except per share data)*

Quarter	Revenues	Net loss	Basic and diluted loss per share
<i>Year ended December 31, 2019</i>			
Fourth	\$ 9	\$ (13,163)	\$ (0.24)
Third	9	(8,610)	(0.18)
Second	8	(7,902)	(0.18)
First	9	(4,791)	(0.11)
<i>Year ended December 31, 2018</i>			
Fourth	\$ 9	\$ (2,630)	\$ (0.08)
Third	9	(3,047)	(0.09)
Second	8	(1,564)	(0.05)
First	9	(1,843)	(0.05)

The variation of the net loss of a quarter compared to the corresponding quarter of the previous year are explained by the following elements.

The increase in net loss for the fourth quarter of 2019 is primarily attributable to higher research and development expenses, higher general and administration expenses as well as to a higher foreign exchange loss. The increases in net loss for the third quarter of 2019, the second quarter of 2019 and the first quarter of 2019 are primarily attributable to higher research and development expenses in relation to the BLU-5937 program.

### **Related Party Transactions**

Dr. Francesco Bellini is the Chairman of our Board of Directors and provides ongoing advisory services under the terms of a consulting and services agreement between us and Picchio International Inc. ("Picchio International"), wholly-owned by Dr. Francesco Bellini and his spouse. Picchio International receives a monthly fee of \$20,833, plus the reimbursement of applicable expenses for services rendered under the agreement. The agreement has a one-year term renewable for successive one-year terms. We have recorded fees and expenses of \$381,000 under the consulting and services agreement for both the years ended December 31, 2019 and 2018.



## FINANCIAL CONDITION

### Liquidity and Capital Resources

As at December 31, 2019, we had available cash, cash equivalents and short-term investments totaling \$116,884,000 (US\$89,980,000), compared to \$48,906,000 (US\$35,863,000) as at December 31, 2018. For the year ended December 31, 2019, the net increase in cash, cash equivalents and short-term investments amounted to \$67,978,000, compared to a net increase of \$25,018,000 for the corresponding period the previous year. Working capital amounted to \$112,537,000 as at December 31, 2019, compared to \$48,148,000 as at December 31, 2018. The net increase in cash and working capital for the year ended December 31, 2019 is primarily attributable to funds received from the 2019 Offering, offset by funds used to finance our operating activities, mainly the research and development of our product candidate BLU-5937.

The other significant changes in our financial position as at December 31, 2019, compared to the financial position as at December 31, 2018, are as follows:

- The increase in Trade and other payables reflects the Company's increased operations in 2019.
- The increase in Prepaid and other assets is mainly due to payments made in relation to the BLU-5937 Phase 2 trial and general and administrative costs.

Based on management's estimate and current level of operations, we believe that our current liquidity position is sufficient to finance our operations in the foreseeable future.

We do not have any long-term debt nor do we have pre-arranged credit facilities or other sources of financing cash flows.

We are subject to a number of risks, including risks associated with the conduct of our product candidate's development programs and their results, the establishment of strategic alliances and the successful development of new product candidates and their marketing. We have incurred significant operating losses and negative cash flows from operations since inception. To date, we have financed our operations primarily through public offerings of common shares, private placements, the issuance of convertible notes, assets sales and the proceeds from research tax credits. Our ability to ultimately achieve future profitable operations is dependent upon the successful expansion and development of our project pipeline, obtaining regulatory approval in various jurisdictions and successful sale or commercialization of our products and technologies, which is dependent on a number of factors outside of our control. Refer to the Risk Factors section below.

Also refer to Financial Condition – Contractual Obligations and Financial Risk Management – Liquidity Risk sections for further details on our liquidity and capital resources.

### Financing and Investing Activities

In September 2019, we raised total gross proceeds of \$104.6 million (US\$79.4 million) from the 2019 Offering by issuing a total of 11,179,451 common shares at a price of US\$7.10 per share, including an overallotment option for 1,320,296 common shares exercised on September 17, 2019 at a price of \$9.40 (US\$7.10). Net proceeds from the 2019 Offering amounted to \$95.7 million (US\$72.7 million).

The use of proceeds presented in our prospectus supplement dated September 4, 2019 did not include funds from the exercise of the overallotment option. Taking into consideration these additional funds, we intend to use the net proceeds of the 2019 Offering, together with our cash, cash equivalents and short-term investments on hand at the time of closing for the purposes and in the amounts indicated below.

	As per September 4, 2019 prospectus supplement		As at February 26, 2020, including overallotment option	
BLU-5937 clinical trials in chronic cough and chronic pruritus	US\$	46 million	US\$	55 million
Preclinical studies	US\$	10 million	US\$	9 million
Manufacturing, formulation and scale-up	US\$	13 million	US\$	14 million
Other project costs	US\$	4 million	US\$	4 million

with the remaining net proceeds allocated to administrative expenses, working capital and other general corporate purposes.

As at December 31, 2019, we have used US\$9.1 million of the net financing (\$14.5 million including a foreign exchange loss of \$2.4 million).

During 2019, we purchased short-term investments with initial maturities greater than three months and less than a year for an aggregate amount of \$93,367,000, and redeemed at maturity or sold short-term investments for an aggregate amount of \$33,482,000 (purchased for \$33,751,000 and redeemed at maturity or sold for \$16,100,000 in 2018).

In December 2018, we completed the 2018 Offering by issuing 10,233,918 common shares from treasury at a price of \$3.42 per share for aggregate gross proceeds of \$35 million. In addition, 402,851 broker warrants exercisable for common shares were issued to the agents. Each warrant entitles the holders to buy one common share at a price of \$3.42 per share for a period of 18 months from the closing of the 2018 Offering.

#### Other

As at February 26, 2020, we had 55,378,660 common shares outstanding and 60,277,193 common shares on a fully diluted basis, including 4,726,943 stock options granted under the stock option plan and 171,590 broker warrants issued in relation to the 2018 Offering.

During 2019, we granted 1,548,330 stock options (1,194,446 in 2018), and 41,667 stock options were exercised (nil in 2018). We received an aggregate amount \$75,000 and issued 41,667 common shares from treasury in 2019 upon the exercise of stock options.

During 2019, we received an aggregate amount of \$1,208,000 and issued 535,406 common shares from treasury upon the exercise of broker warrants issued in connection with our 2017 and 2018 equity offering. Also, during the year, 3,282 broker warrants expired. During 2018, we received an amount of \$266,000 and issued 194,444 common shares from treasury upon the exercise of broker warrants issued in connection with our 2017 equity offering.

#### **Contractual Obligations**

As at December 31, 2019, our minimum future contractual obligations are principally for payments in relation to property leases, consulting fees for Picchio International, trade and other payables and contracts for research and development activities. Future contractual obligations by year of maturity are presented below.

Contractual obligations (in thousands of dollars)	Total	2020	2021 and after
Lease liabilities	\$ 259	\$ 230	\$ 29
Consulting fees	250	250	—
Trade and other accrued liabilities	9,671	9,671	—
Contracts for research and development activities	11,332	11,216	116

We are potentially liable in relation to the following indemnity agreement:

In March 2017, we entered into a share purchase agreement with Taro for the sale of our wholly-owned subsidiary Thallion, including all the rights to the drug candidate Shigamab™. We agreed to indemnify Taro, subject to certain conditions and limitations, for losses which it may suffer or incur, arising out of any debts, liabilities, commitments or obligations of any nature resulting from any matters, actions, events, facts or circumstances related to the activities or affairs of Thallion, which occurred prior to the effective time of the share purchase agreement. No indemnity provision has been recorded as at December 31, 2019 and 2018 for this matter as we do not expect to make any payments under this indemnity agreement.

We have a letter of credit issued in connection with a lease agreement in the amount of \$50,000. Cash is pledged under the letter of credit and is presented as restricted cash under non-current Other assets in the consolidated statement of financial position as at December 31, 2019.

We have entered into other agreements which involve future commitments, including an agreement with NEOMED. Refer to note 16 (c) to the consolidated financial statements for the year ended December 31, 2019 for details.

We have not engaged in commodity contract trading or off-balance sheet financing.

## FINANCIAL RISK MANAGEMENT

This section provides disclosures relating to the nature and extent of our exposure to risks arising from financial instruments, including credit risk, liquidity risk, foreign currency risk and interest rate risk, and how we manages those risks.

### Credit Risk

Credit risk results from the possibility that a loss may occur from the failure of another party to perform according to the terms of the contract. Financial instruments that potentially subject us to significant concentrations of credit risk consist principally of cash and cash equivalents, short-term investments and trade and other receivables. We invest our cash mainly with major North American financial institutions. Cash equivalents and short-term investments are comprised of fixed income instruments with a high credit ranking (not less than A-1) as rated by Standard and Poor's. We have investment policies that are designed to provide for the safety and preservation of principal, liquidity needs and yields that are appropriate.

As at December 31, 2019, our maximum credit exposure corresponded to the carrying amount of these financial assets.

### Liquidity Risk

Liquidity risk is the risk that we will not be able to meet our financial obligations as they fall due. We require continued access to capital markets to support our operations, as well as to achieve our strategic plans. Any impediments to our ability to access capital markets, including the lack of financing capability or an adverse perception in capital markets of our financial condition or prospects, could have a materially adverse effect on us. In addition, our access to financing is influenced by the economic and credit market environment.

We manage liquidity risk through the management of our capital structure, as outlined in note 19 to the consolidated financial statements for the year ended December 31, 2019 (Capital Disclosures). In addition, we manage liquidity risk by continuously monitoring actual and projected cash flows. The Board of Directors reviews, approves and monitors our annual operating and capital budgets, as well as any material transactions.

### Foreign Currency Risk

Foreign currency risk is the risk that the fair value of future cash flows of a financial instrument will fluctuate because of changes in foreign exchange rates. Foreign currency risk is limited to the portion of our business transactions denominated in currencies other than Canadian dollars. Our exposure relate primarily to changes in the Canadian dollar versus the US dollar exchange rate. For foreign currency transactions, fluctuations in the respective exchange rates relative to the Canadian dollar will create volatility in our cash flows and the reported amounts for revenue and expenses in income. Additional variability arises from the translation of monetary assets and liabilities denominated in currencies other than the Canadian dollar at the rates of exchange at each reporting date, the impact of which is reported as a foreign exchange gain or loss in income.

Our objective in managing our foreign currency risk is to minimize our net exposures to foreign currency cash flows, by transacting with third parties in our functional currency to the maximum extent possible and practical and holding cash, cash equivalents and short-term investments as well as incurring borrowings in our functional currency. We hold a portion of our cash, cash equivalents and short-term investments in US dollars to meet our liquidity needs in US dollars, but do not use derivative financial instruments to reduce our foreign exchange exposure. Note 20 (d) to the consolidated financial statements for the year ended December 31, 2019 provides indication of our significant foreign exchange currency exposures as at that date.

### Interest Rate Risk

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market rates. Our financial instruments exposed to interest rate risk are cash and cash equivalents, short-term investments and restricted cash. We believe that the risk that we will realize a loss as a result of the decline in the fair value of our cash equivalents and short-term investments is limited because these investments have short-term maturities and are generally held to maturity. Our capacity to reinvest the short-term amounts with equivalent returns will be impacted by variations in short-term fixed interest rates available in the market.

We have had no interest rate hedging activities during the current year.

## **DISCLOSURE CONTROLS AND PROCEDURES**

Disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in our reports filed with securities regulatory authorities is recorded, processed, summarized and reported within prescribed time periods and is accumulated and communicated to management, including the Chief Executive Officer and the Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

The Chief Executive Officer and the Chief Financial Officer are responsible for establishing and maintaining disclosure controls and procedures designed to ensure that information required to be disclosed in the reports filed or submitted under securities legislation is recorded, processed, summarized and reported within the time periods specified by applicable securities legislation. The design of any system of controls and procedures is based in part upon certain assumptions about the likelihood of certain events. There can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote. The Chief Executive Officer and the Chief Financial Officer are assisted in this responsibility by our disclosure committee, which is composed of members of senior management. Based on an evaluation of our disclosure controls and procedures, the Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2019.

## **INTERNAL CONTROL OVER FINANCIAL REPORTING**

### **Management's Annual Report on Internal Control Over Financial Reporting**

Internal control over financial reporting ("ICFR") is designed to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with IFRS. Management, including the Chief Executive Officer and the Chief Financial Officer, is responsible for establishing and maintaining adequate ICFR. The design of any system of controls and procedures is based in part upon certain assumptions about the likelihood of certain events. There can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote. Management assessed the effectiveness of the Company's ICFR as of December 31, 2019 based on the framework established in Internal Control – Integrated Framework (2013) by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on this assessment, the Chief Executive Officer and the Chief Financial Officer concluded that our ICFR were effective as of December 31, 2019. The assessment is not subject to an attestation report of our auditors regarding ICFR.

### **Changes in Internal Controls Over Financial Reporting**

In accordance with the Canadian Securities Administrators' Multilateral Instrument 52-109, we have filed certificates signed by the Chief Executive Officer and the Chief Financial Officer, that, among other things, report on the design of disclosure controls and procedures and the design of internal control over financial reporting.

There have been no changes in our ICFR during the quarter ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect our ICFR.

## **CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

The preparation of the consolidated financial statements in conformity with IFRS requires management to adopt accounting policies and to make certain judgments, estimates and assumptions that we believe are reasonable based upon the information available at the time these decisions are made. These accounting policies, judgments, estimates and assumptions affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the date of the financial statements, and the reported amounts of revenues, expenses and cash flows during the reporting periods. By their nature, these judgments are subject to an inherent degree of uncertainty and are based upon historical experience, trends in the industry and information available from outside sources. On an ongoing basis, management reviews its estimates and actual results could differ from estimates.

Our significant accounting policies are described in note 3 to the consolidated financial statements for the year ended December 31, 2019. Management considers that the following accounting policies and estimates are more important in assessing, understanding and evaluating our consolidated financial statements.

*Accrued expenses:* As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with personnel and service providers to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. For research and development activities, the majority of service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. There may be instances in which payments to the service providers will exceed the level of services provided and result in a prepayment of the expense.

*In-process research and development asset:* The in-process research and development (“IPR&D”) asset is accounted for as an indefinite-lived intangible asset until the project is completed or abandoned, at which point it will be amortized or impaired, respectively. We account for subsequent research and development costs associated with the acquired IPR&D asset consistent with the research and development policy in note 3 (d) to the consolidated financial statements. We assess at each reporting date whether there is an indication that the asset may be impaired. Irrespective of whether there is any indication of impairment, the IPR&D asset is tested for impairment annually by comparing its carrying amount with its recoverable amount.

Note 2 (d) to the consolidated financial statements provides additional information regarding the use of estimates and judgements in the application of accounting policies.

## **CHANGES IN ACCOUNTING POLICIES**

### **Changes in significant accounting policies in 2019**

On January 1, 2019, we adopted the new accounting standard IFRS 16, Leases issued by the IASB. As a result, we, as a lessee, recognize a right-of-use asset representing our rights to use the underlying asset and a lease liability representing our obligation to make lease payments in our statement of financial position, in relation to our property leases.

Further information on this accounting change can be found in notes 4 and 6 to the consolidated financial statements for the year ended December 31, 2019.

### Change in functional and presentation currency in 2020

As a result of the advancement of our development programs, we anticipate higher research and development costs in future periods which will be denominated mainly in US dollars. In addition, these will be financed from proceeds received from our new financing in US dollars in September 2019. As a result of these changes, we have determined that the US dollar will better reflect the primary economic environment in which we will operate in the future, as a result of these changes, a significant portion of our expenses and net assets are and will continue to be denominated in US dollars. Therefore, effective January 1, 2020, we adopted the US dollar as our functional and presentation currency. On January 1, 2020, the change in functional currency will result in the assets, liabilities and equity transactions as of January 1, 2020 being translated in US dollars using the exchange rate in effect on that date and the change in functional currency will then be applied prospectively. The change in presentation currency will be applied retrospectively resulting in the comparative financial information being recasted into US dollars.

### **RISK FACTORS**

*Investing in our common shares involves a significant amount of risk. You should carefully consider the risks described below. If any of these risks actually occurs, our business, financial condition, results of operations or prospects could be materially adversely affected. These are not the only risks and uncertainties that we face. Additional risks and uncertainties not presently known to us, or that we currently consider immaterial, may also materially and adversely affect us. In such an event, the trading price of our common shares could decline and you may lose part or all of your investment in our securities. Any reference in this section to the Company's "products" or "product candidates" includes a reference to BELLUS Health's product candidate and future products or product candidates that may be developed.*

#### **Risks related to our business**

***We may not be able to maintain our operations and research and development without additional funding, and we may not have access to sufficient capital.***

To date, we have financed our operations primarily through public offerings of common shares, private placements, the issuance of convertible notes and research tax credits. We have incurred significant operating losses and negative cash flows from operations since inception. As at December 31, 2019, we had available cash, cash equivalents and short-term investments totaling \$116.9 million (US\$90.0 million). Based on management's estimate and current level of operations, we believe that our current liquidity position is sufficient to finance our operations into the foreseeable future. We will need to raise additional capital to fund our operations and to develop BLU-5937. Our future capital requirements will be substantial and may increase beyond current expectations depending on many factors, such as the duration, scope, rate of progress, results and costs of any preclinical studies and clinical trials for our current or any future product candidates; unexpected delays or developments in seeking regulatory approvals and the outcome thereof; the time and cost in preparing, filing, prosecuting, maintaining, and enforcing patent claims; other unexpected developments encountered in implementing our business development and commercialization strategies; the outcome of any litigation; and arrangements with collaborators. Further, changing circumstances may cause us to consume capital significantly faster than we currently anticipate. We have based the foregoing estimates on assumptions that may prove to be wrong, and we could utilize our available financial resources sooner than we currently expect.

We may seek to raise additional funds through public or private equity or debt financing, collaborations agreements with other companies and/or from other sources. We have no committed source of additional capital and additional funding may not be available on terms that are acceptable to us, or at all. If adequate funding is not available on reasonable terms, we may need to obtain funds on terms less favorable than we would otherwise accept. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of those securities could result in dilution to our shareholders. Moreover, the incurrence of debt financing could result in a substantial portion of our future operating cash flow, if any, being dedicated to the payment of principal and interest on such indebtedness and could impose restrictions on operations. This could render us more vulnerable to competitive pressures and economic downturns. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of BLU-5937 or other future product candidates or other research and development initiatives. We could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

No assurance can be given that any such additional funding will be available or that, if available, it can be obtained on terms favorable to us. The failure to obtain additional financing on favorable terms, or at all, could have a material adverse effect on our business, financial condition, results of operations and prospects.

***We have a history of losses and have not generated any product sales revenue to date. We may never achieve or maintain profitability.***

Our product candidate, BLU-5937, is still only in development, and as a result, we have not generated any revenues from product sales to date. We have incurred substantial expenses in our efforts to develop BLU-5937, and consequently, have generated operating losses each year since our inception. For the years ended December 31, 2018 and 2019, we incurred net losses of \$9.1 million and \$34.5 million, respectively. As of December 31, 2019, we had an accumulated deficit of \$522.5 million. Our losses have adversely affected, and will continue to adversely impact, working capital, total assets, and shareholders' equity. We do not expect to generate any revenues from product sales in the immediate future. We may never successfully commercialize any products. Even if we succeed in developing commercial products, we expect to incur additional operating losses for at least the next several years. If we do not ultimately commercialize products and achieve or maintain profitability, an investment in our shares could result in a significant or total loss.

***Our prospects currently depend heavily on the success and market acceptance of BLU-5937, which is still in clinical development.***

We currently have no products for sale and may never be able to successfully develop products for sale. We currently believe that our growth and future prospects are mainly dependent on the successful development, regulatory approval and commercialization of our product candidate BLU-5937, which may never occur. We are focusing our efforts and resources into the development of BLU-5937. Our business thus depends on the successful preclinical and clinical development, regulatory approval and commercialization of BLU-5937, for which we must conduct additional preclinical studies and clinical trials, undergo further development activities and seek and receive regulatory approval prior to commercial launch. Further development of BLU-5937 will require substantial investment, access to



sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales, if approved.

We anticipate that our ability to generate revenues will depend on the commercial success of BLU-5937, which will depend upon its market acceptance by purchasers in the pharmaceutical market and the future market demand and medical need for products and research utilizing BLU-5937. Most prescription drug candidates never reach the clinical development stage and even those that do reach clinical development have only a small chance of successfully completing clinical development and gaining regulatory approval. If we are unable to successfully commercialize BLU-5937, we may never generate revenues. There is also the risk that the actual market size or opportunity for BLU-5937 is not certain. If BLU-5937 reaches commercialization and there is low market demand for BLU-5937 or the market for BLU-5937 develops less rapidly than we anticipate, we may not have the ability to shift our resources to the development of alternative products. Failure to gain market acceptance of BLU-5937 or an incorrect estimate in the nature and size of our market could have a material adverse effect on us.

***We rely on third parties to conduct preclinical studies and clinical trials for BLU-5937, and if they do not properly and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for BLU-5937.***

We have designed the clinical trials for BLU-5937. However, we rely on contract research organizations and other third parties to assist in managing, monitoring and otherwise carrying out these trials. We compete with many other companies for the resources of these third parties. The third parties on whom we rely generally may terminate their engagements at any time, and having to enter into alternative arrangements would delay development and commercialization of our product candidate. The U.S. Food and Drug Administration, or the “FDA”, and comparable foreign regulatory authorities require compliance with regulations and standards for designing, conducting, monitoring, recording, analyzing, and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Although we rely on third parties to conduct our clinical trials, they are not our employees, and we are responsible for ensuring that each of these clinical trials is conducted in accordance with our general investigational plan, protocol and other requirements. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities.

If these third parties do not successfully carry out their duties under their agreements, if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to clinical trial protocols or to regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, the clinical trials of BLU-5937 may not meet regulatory requirements. If clinical trials do not meet regulatory requirements or if these third parties need to be replaced, preclinical development activities or clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of BLU-5937 on a timely basis or at all.

***We rely completely on one third-party contract manufacturer to manufacture the active pharmaceutical ingredient, or “API”, for BLU-5937 and another third-party contract manufacturer to manufacture the final drug product, and we intend to rely on third parties to produce non-clinical, clinical and commercial supplies of BLU-5937 and any other future product candidates.***

We do not currently have, nor do we plan to acquire, the infrastructure or capability to internally manufacture our clinical drug supply of BLU-5937, or any other product candidates we may develop in

the future, for use in the conduct of our research and development activities, preclinical studies and clinical trials, and we lack the internal resources and the capability to manufacture any product candidates on a clinical or commercial scale. We currently have the API for BLU-5937 manufactured by one third-party contract manufacturer and final drug product supplied by another contract manufacturer, and do not currently have backup manufacturing capacity.

We plan to continue to rely on contract manufacturers for the foreseeable future to produce quantities of products and substances necessary for research and development, preclinical studies, human clinical trials and product commercialization, and to perform their obligations in a timely manner and in accordance with applicable government regulations. While we intend to contract for the commercial manufacture of our product candidates, we may not be able to identify and qualify contractors or obtain favorable contracting terms.

Our third-party contract manufacturer for the API for BLU-5937 is located in China. The COVID-19 (coronavirus) outbreak could potentially disrupt the operations of such third-party contract manufacturer if any of its employees are suspected or have been infected by the virus, and identified as a possible source of spreading the infection. Our contract manufacturer may also be required to disinfect its production plant and therefore suffer a temporary suspension of business operations.

If our current or future third-party manufacturers do not perform as agreed, experience business disruptions as previously described, or breach or terminate their agreements with us, significant additional time and costs would be required to effect a transition to a new contract manufacturer. If we are unable to retain our current contractors, or are unable to secure arrangements with new contractors to provide manufacturing services in a timely manner and on acceptable terms as needed, it will delay or prevent the development, promotion, marketing, or sale of BLU-5937, if approved, or any other future product candidates we may develop, and have a negative effect on our operations and financial condition. Moreover, if a replacement to our current or future contract manufacturers is required, the ability to establish second-sourcing or find a replacement manufacturer may be difficult due to the lead times generally required to manufacture drug products and the need for regulatory compliance inspections and approvals of any replacement manufacturer, all of which factors could result in production delays and additional costs.

Manufacturing of API and final drug products is complex and requires significant expertise. Difficulties could be encountered in production, particularly in scaling up and validating production. There can be no assurance that contract manufacturers will be successful at scaling up and producing BLU-5937 with the required quality and in the quantities and timelines that will be needed for clinical and/or commercial purposes. So far, we have only produced small quantities of BLU-5937 at kilogram scale for use in preclinical studies and clinical trials.

Our reliance on these contract manufacturers also exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may appropriate our trade secrets or other proprietary information.

We rely on third-party contract manufacturers that are located outside of Canada. As a result, our operations are subject to customary risks related to the import of goods, including fluctuations in the value of currencies, changes in import duties, exchange controls, trade restrictions, work stoppages and general political and economic conditions in foreign countries. The countries from which we import pharmaceutical ingredients may, from time to time, impose new duties, tariffs or other restrictions or adjust presently prevailing duties or tariffs, which could adversely impact our ability to purchase such pharmaceutical ingredients or significantly increase the cost of doing so. The occurrence of any of these risks could delay or prevent the development, promotion, marketing, or sale of BLU-5937, if approved,

or of any other future product candidates we may develop, and have a negative effect on our operations and financial condition.

***The clinical effectiveness of BLU-5937 is not yet supported by clinical data.***

The preclinical toxicology studies and the Phase 1 topline data announced in November 2018 showed that BLU- 5937 has a favorable safety and tolerability profile. However, the clinical safety of BLU-5937 has to be demonstrated through further clinical studies. The clinical effectiveness of BLU-5937 is not yet supported by clinical data and the medical community has not yet developed a large body of peer reviewed literature that supports the safety and efficacy of BLU-5937. If future studies call into question the safety or efficacy of BLU-5937 or any other product candidates we may develop in the future, our business, financial condition, results of operations or prospects could be adversely affected.

Even if BLU-5937 or any other product candidates we may develop in the future successfully complete the clinical trials and receive the regulatory approval necessary to market the product candidates to the public, there is also the risk of unknown side effects, which may not appear until the product candidates are on the market and may result in delay or denial of regulatory approval or withdrawal of previous approvals, product recalls or other adverse events, which could materially adversely affect us.

***Our clinical trials may not yield results that will enable us to obtain regulatory approval for our current or future product candidates.***

We will only receive regulatory approval for a product candidate if we can demonstrate in carefully designed and conducted clinical trials that the product candidate is safe and effective. We do not know whether our current or any future clinical trials will demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals or if they will result in marketable products.

Clinical trials are lengthy, complex, costly, and uncertain processes. It takes several years to complete testing, and failure can occur at any stage of testing. The early stage of our product candidate involves risks related to safety, efficacy, drug metabolism, pharmacokinetic profile, tolerability, manufacturing, formulation and distribution, among others. Results attained in preclinical testing and early clinical studies or trials may not be indicative of results that are obtained in later studies. We have suffered, and may suffer further, significant setbacks in advanced clinical trials, even after promising results in earlier studies. For instance, in June 2016, we announced that KICTA (eprodiate) did not meet the primary efficacy endpoint in a Phase 3 clinical trial. Based on results at any stage of clinical trials, we may decide to repeat or redesign a trial or discontinue the development of a product candidate. Furthermore, actual results may vary once the final and quality-controlled verification of data and analyses has been completed. If we fail to adequately demonstrate the safety and efficacy of BLU-5937, we will not be able to obtain the required regulatory approvals to commercialize that product candidate.

Clinical trials are subject to continuing oversight by governmental regulatory authorities and institutional review boards, and must meet the requirements of these authorities; must meet requirements for informed consent; and must meet requirements for good clinical practices.

We may not be able to comply with these requirements. We rely on third parties, including contract research organizations and outside consultants, to assist in managing and monitoring clinical trials. Our reliance on these third parties may result in delays in completing, or in failing to complete, these trials if one or more third parties fail to perform with the speed and level of competence expected. If clinical trials for a product candidate are unsuccessful, we will be unable to commercialize such product candidate. If one or more of the clinical trials is delayed, we will be unable to meet our anticipated

development or commercialization timelines. Either circumstance could have a material adverse effect on our business, financial condition, results of operations and prospects.

***If we encounter difficulties enrolling patients in clinical trials, the trials could be delayed or otherwise adversely affected.***

Clinical trials for product candidates require us or third parties we contract with to identify and enroll a large number of patients with the disorder under investigation. We or the third parties we contract with may not be able to enroll a sufficient number of patients to complete clinical trials in a timely manner. Patient enrollment is a function of many factors, including the following: design of the protocol, size of the patient population, eligibility criteria for the trial in question, perceived risks and benefits of the drug under study, availability of competing therapies, efforts to facilitate timely enrollment in clinical trials, patient referral practices of physicians, and availability of clinical trial sites. If we or the third parties we contract with have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay or terminate ongoing clinical trials.

***The outcome of preclinical studies and earlier-stage clinical trials may not be predictive of the success of later-stage clinical trials.***

The outcome of preclinical testing and earlier-stage clinical trials may not be predictive of the success of later-stage clinical trials. BLU-5937 and any other product candidates we may develop may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials. Numerous companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Furthermore, the failure of any product candidate to demonstrate safety and efficacy in any clinical trial could negatively impact the perception of any other product candidates then under development and/or cause applicable regulatory authorities to require additional testing before approving any other product candidates.

***Interim topline and preliminary results from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures, which could result in material changes in the final data.***

From time to time, we may publish interim topline or preliminary results from our clinical trials. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or topline results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common shares to fluctuate significantly.

***Even if we or any future partners obtain regulatory approvals for our product candidates, we will be subject to ongoing government regulation.***

Even if regulatory authorities approve BLU-5937 or any future product candidate we may develop, the manufacturing, marketing, and sale of such products will be subject to strict and ongoing regulation. Compliance with such regulation may be costly and consume substantial financial and management

resources. For example, an approval for a product may be conditioned on conducting costly post-marketing follow-up studies. In addition, if, based on these studies, a regulatory authority does not believe that the drug demonstrates a benefit to patients, such authority could limit the indications for which the product may be sold or revoke the product's regulatory approval.

We and our contract manufacturers are required to comply with applicable current Good Manufacturing Practice regulations for the manufacture of product candidates. These regulations include requirements relating to quality assurance, as well as the corresponding maintenance of records and documentation. Manufacturing facilities must be approved before they can be used in the commercial manufacturing of products and are subject to subsequent periodic inspection by regulatory authorities. In addition, material changes in the methods of manufacturing or changes in the suppliers of raw materials are subject to further regulatory review and approval.

If we or any future marketing collaborators or contract manufacturers fail to comply with applicable regulatory requirements, we may be subject to sanctions, including fines, drug recalls or seizures, injunctions, total or partial suspension of production, civil penalties, withdrawals of previously granted regulatory approvals, and criminal prosecution. Any of these penalties could delay or prevent the promotion, marketing, or sale of our products.

In addition, we are currently or will in the future be subject to healthcare regulation and enforcement by the federal government and the states in which we will conduct our business once our product candidates are approved by the FDA and commercialized in the United States. In addition to the FDA's restrictions on marketing of pharmaceutical products, the healthcare laws and regulations that may affect our ability to operate include: the federal fraud and abuse laws, including the federal anti-kickback and false claims laws; federal data privacy and security laws; and federal transparency laws related to payments and/or other transfers of value made to physicians and other healthcare professionals and teaching hospitals. Many states have similar laws and regulations that may differ from each other and federal law in significant ways, thus complicating compliance efforts. These laws may adversely affect our sales, marketing and other activities with respect to any product candidate for which we receive approval to market in the United States by imposing administrative and compliance burdens on us.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities, particularly any sales and marketing activities after a product candidate has been approved for marketing in the United States, could be subject to legal challenge and enforcement actions. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to significant civil, criminal, and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

***We may not achieve our projected development goals in the announced and expected time frames.***

From time to time, we set goals for and make public statements regarding the expectations for and timing of the accomplishment of objectives material to our success, such as the commencement and completion of clinical trials, expected results, anticipated regulatory submission and approval dates, and timing of product launch. The actual timing of these events can vary dramatically due to factors such as delays or failures in clinical trials, the uncertainties inherent in the regulatory approval process,

and delays in achieving manufacturing or marketing arrangements sufficient to commercialize products. There can be no assurance that our clinical trials will be completed, that we will make regulatory submissions or receive regulatory approvals as planned, or that we will be able to adhere to our current schedule for the launch of BLU-5937 or any other future product candidates we may develop. If we fail to achieve one or more of these milestones as planned, the price of our common shares would likely be adversely affected.

***If we or our partners fail to obtain acceptable prices, coverage or adequate reimbursement for our products, our ability to generate revenues will be diminished.***

Patients in the United States and elsewhere generally rely on third-party payors to reimburse part or all of the costs associated with their prescription drugs. Accordingly, our ability to successfully commercialize our products would depend significantly on the ability to obtain acceptable prices and the availability of coverage and adequate reimbursement from third-party payors, such as government and private insurance plans. Coverage and reimbursement policies for drug products can differ significantly among payors as there is no uniform policy of coverage and reimbursement for drug products among U.S. third-party payors. There may be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time-consuming and costly which will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage or adequate reimbursement will be obtained. While we have not commenced discussions with any such parties, these third-party payors frequently require companies to provide predetermined discounts from list prices, and they are increasingly challenging the prices charged for pharmaceuticals and other medical products. Our products may not be considered cost-effective, and reimbursement to the patient may not be available or sufficient to allow us to sell our products on a competitive basis. Even if we obtain coverage for a given product candidate, the associated reimbursement rate may not be adequate to cover our costs, including research, development, intellectual property, manufacture, sale and distribution expenses, or may require co-payments that patients find unacceptably high.

In addition, the continuing efforts of third-party payors to contain or reduce the costs of healthcare through various means may limit our commercial opportunity and reduce any associated revenue and profits. We expect proposals to implement similar government controls to continue. In addition, increasing emphasis on managed care will continue to put pressure on the pricing of pharmaceutical and biopharmaceutical products. Cost-control initiatives could decrease the price that we or any current or potential collaborators could receive for any of the products and could adversely affect profitability. In addition, in Canada and in many other countries, where significant healthcare reforms are currently under discussion, pricing and/or profitability of some or all prescription pharmaceuticals and biopharmaceuticals are subject to government control. In the United States, there have been and continue to be a number of healthcare-related legislative initiatives that have significantly affected the pharmaceutical industry. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, was passed in March 2010, and substantially changed the way healthcare is financed by both governmental and private insurers, and continues to significantly impact the pharmaceutical industry. There also has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. If we fail to obtain acceptable prices, coverages or an adequate level of reimbursement for

our products, the sales of the products would be adversely affected or there may be no commercially viable market for our products.

***Competition in the biopharmaceutical industry is intense, and development by other companies could render our product candidate or any future product candidates or technologies non-competitive.***

The biopharmaceutical industry is intensely competitive and is subject to rapid and significant change. We face potential competition from many sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies. We consider our primary competitors to be those companies that are developing products specifically to treat chronic cough and those companies that develop products that, when approved, could be used off-label to treat cough. We are aware of other companies targeting chronic cough as the primary outcome measure in clinical studies of products. There are multiple companies developing products at varying stages of development specifically intended to treat chronic cough including Merck & Co., Bayer AG, Shionogi Inc. and NeRRe Therapeutics Ltd, some of which have substantially greater product development capabilities and financial, scientific, marketing, and human resources than us. Of these companies, Merck, Bayer and Shionogi are developing P2X3 antagonists for chronic cough that could compete directly with BLU-5937. Moreover, there are multiple companies developing therapeutic treatments for atopic dermatitis specifically, or various other forms of pruritus which could also have a therapeutic effect on atopic dermatitis itch including Sanofi S.A., Bayer AG, Pfizer Inc., Novartis International AG, LEO Pharma Inc., Menlo Therapeutics Inc., Vanda Pharmaceuticals Inc., Trevi Therapeutics Inc., Galderma S.A., Sienna Biopharmaceuticals, Inc., Tioga Pharmaceuticals, Inc. and Cara Therapeutics Inc.

***We are heavily dependent on licensed intellectual property. If we were to lose our rights to licensed intellectual property, we would not be able to continue developing or commercializing BLU-5937. If we breach any of the agreements under which we license the use, development and commercialization rights to BLU-5937 or any other future product candidate or technology from third parties or if certain insolvency events were to occur, we could lose license rights that are critical to our business.***

We have an exclusive worldwide license to develop and commercialize BLU-5937 pursuant to a license agreement with the NEOMED Institute, now adMare Bionnovations ("NEOMED"), that is critical to our business, which is subject to termination for breach of our terms and, therefore, our rights may only be available to us for as long as our development and commercialization activities are sufficient to meet the terms of the license. In addition, we may need to enter into additional license agreements in the future. Our existing license agreements impose, and any future license agreements may impose on us, various developments, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license, which would have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, our current or future licenses may provide for a reversion to the licensor of our rights in regulatory filings or other intellectual property or data that we regard as our own in the event the license terminates under certain circumstances, such as due to breach.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including with respect to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the rights of our licensors under the license agreements; and
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of BLU-5937 and any future product candidates, and what activities satisfy those diligence obligations.

Any disputes with our licensors over intellectual property that we have licensed from them may prevent or impair our ability to maintain our current licensing arrangements on acceptable terms. Termination or expiry of our license agreements could result in the loss of significant rights and could materially harm our ability to further develop and commercialize BLU-5937 or other future product candidates.

We depend on our licensors to protect a significant portion of our proprietary rights that derive from license agreements, including our exclusive worldwide license with NEOMED to develop and commercialize BLU-5937. BLU-5937 is covered by a patent that is not owned by us but is instead licensed to us by NEOMED. Moreover, our licensors under current licenses retain and our licensors under future licenses may retain certain rights and obligations.

Our business could suffer, for example, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

***We may not obtain adequate protection for our products through our intellectual property.***

Our success depends, in large part, on our ability to protect our competitive position through patents, trade secrets, trademarks, and other intellectual property rights. Our success, competitive position and future revenues with respect to these product candidates will depend, in part, on our ability to protect our intellectual property. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. We attempt to protect our proprietary position by maintaining trade secrets and by filing U.S. and foreign patent applications related to our in-licensed technology, inventions and improvements that are important to the development of our business. Our failure to do so may adversely affect our business and competitive position.

The patent positions of pharmaceutical and biopharmaceutical firms, including ours, are uncertain and involve complex questions of law and fact for which important legal issues remain unresolved. The patents issued or to be issued to us may not provide us with any competitive advantage. We may not be able to protect our intellectual property rights throughout the world. Our patents may be challenged by third parties in patent litigation. In addition, it is possible that third parties with drugs that are very similar to ours will circumvent our patents by means of alternate designs or processes. We may have to rely on method of use protection for our compounds in development and any resulting drugs, which



may not confer the same level of protection as protection of our compounds per se. We may be required to disclaim part of the term of certain patents. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that our patents would, if challenged, be held by a court to be valid or enforceable or that a competitor's technology or drug would be found by a court to infringe our patents.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Patent applications relating to or affecting our business may have been filed by a number of pharmaceutical and biopharmaceutical companies and academic institutions. A number of the technologies in these applications or patents may conflict with our technologies, patents, or patent applications, and such conflict could reduce the scope of patent protection that we could otherwise obtain. We could become involved in interference proceedings in the United States in connection with one or more of our patents or patent applications to determine priority of invention. Our granted patents could also be challenged and revoked in opposition proceedings in certain countries outside of the United States. In addition to patents, we rely on trade secrets and proprietary know-how to protect our intellectual property. We generally require employees, consultants, outside scientific collaborators, and sponsored researchers and other advisors to enter into confidentiality agreements. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all of the technology that is conceived by the individual during the course of employment is our exclusive property. These agreements may not provide meaningful protection or adequate remedies in the event of unauthorized use or disclosure of proprietary information. In addition, it is possible that third parties could independently develop proprietary information and techniques substantially similar to ours or otherwise gain access to our trade secrets.

We may obtain the right to use certain technology under license agreements with third parties. Our failure to comply with the requirements of material license agreements could result in the termination of such agreements, which could cause us to terminate the related development program and cause a complete loss of investment in that program. As a result of the foregoing factors, we may not be able to rely on our intellectual property to protect our products in the marketplace.

***If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.***

We seek to protect our confidential proprietary information, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and collaborators. These agreements are designed to protect our proprietary information. However, we

cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

***We may infringe the intellectual property rights of others.***

Our commercial success depends significantly on our ability to operate without infringing on the patents and other intellectual property rights of third parties. There could be issued patents of which we are not aware that our products infringe or patents that we believe we do not infringe, but that we may ultimately be found to infringe. Moreover, patent applications are, in some cases, maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications were filed. Because patents can take many years to issue, there may be currently pending applications of which we are unaware that may later result in issued patents that our products infringe. For example, pending applications may exist that provide support or can be amended to provide support for a claim that results in an issued patent that our drug infringes.

The biopharmaceutical industry has produced a proliferation of patents, and it is not always clear to industry participants which patents cover various types of products. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. We believe that BLU-5937 does not infringe any valid claim of these patents, although there can be no assurances of this. In the event of an infringement or violation of another party's patent, we may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost. Any inability to secure licenses or alternative technology could result in delays in the introduction of drugs or lead to prohibition of the manufacture or sale of drugs by us.

***Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could harm our business.***

Third parties may assert patent or other intellectual property infringement claims against us or our other licensors arising from the manufacture, use, or sale of our current or future product candidates. An unfavorable outcome could result in loss of patent rights and require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

***We may become involved in lawsuits or other proceedings to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.***

Competitors may infringe our patents or other intellectual property. If we were to initiate legal proceedings against a third party to enforce a patent covering our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the United States Patent and Trademark Office, or “USPTO”, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. The validity of our current or future patents or patent applications or those of our licensors may also be challenged in interference or derivation proceedings, opposition, post grant review, inter partes review, or other similar enforcement and revocation proceedings, provoked by third parties or brought by us. Our patents could be found invalid, unenforceable, or their scope significantly reduced.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market.

***Patent litigation is costly and time consuming and may subject us to liabilities.***

Our involvement in any patent litigation, interference, post-grant proceedings such as inter partes review or opposition, or other administrative proceedings will likely cause us to incur substantial expenses, and the efforts of technical and management personnel will be significantly diverted. In addition, an adverse determination in litigation could subject us to significant liabilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common shares.

***We may be subject to claims challenging the inventorship of our patents and other intellectual property.***

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors’ ownership of our owned or in-licensed patents, trade secrets or

other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

***We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.***

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employees' former employers or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

***The market price of our common shares experiences a high level of volatility due to factors such as the volatility in the market for biotechnology stocks generally and the short-term effect of a number of possible events.***

We are a public growth company in the biotechnology sector. As frequently occurs among these companies, the market price for our common shares may experience a high level of volatility. During the 12-month period ended on December 31, 2019, giving effect to the one-for-3.6 consolidation of our common shares effective on August 19, 2019, our common shares traded between \$3.49 and \$11.20

per share on the TSX. Since their initial Nasdaq listing on September 5, 2019, up to December 31, 2019, our common shares traded between US\$5.55 and US\$7.88 per share on Nasdaq.

Numerous factors, including many over which we have no control, may have a significant impact on the market price of our common shares, including, among other things, the following: (1) clinical and regulatory developments regarding our product candidate and those of our competitors; (2) arrangements or strategic partnerships by our competitors; (3) other announcements by us or our competitors regarding technological, drug development, sales, or other matters; (4) patent or other intellectual property achievements or adverse developments; (5) arrivals or departures of key personnel; (6) changes in financial estimates and recommendations by securities analysts; (7) government regulatory action affecting our product candidate and our competitors' products in the United States, Canada, and foreign countries; (8) actual or anticipated fluctuations in revenues or expenses; (9) general market conditions and fluctuations for the emerging growth and biopharmaceutical market sectors; (10) failure to enter into favorable third-party manufacturing agreements; (11) events related to threatened, new, or existing litigation; (12) economic conditions in the United States, Canada, or abroad; (13) purchases or sales of blocks of our securities; and (14) difficulties in our ability to obtain additional financing.

The recent listing of our common shares on Nasdaq may increase share price volatility due to various factors, including that the stock market in recent years has experienced extreme price and trading volume fluctuations that often have been unrelated or disproportionate to the operating performance of individual companies. These broad market fluctuations may adversely affect the price of our common shares, regardless of our operating performance. In addition, sales of substantial amounts of our common shares in the public market after any offering, or the perception that those sales may occur, could cause the market price of our common shares to be adversely affected.

As at December 31, 2019, OrbiMed Advisors LLC ("OrbiMed"), Power Sustainable Capital Investments Inc. ("PSCI"), a subsidiary of Power Corporation of Canada, and Rocabe Investments Inc., a company in which Mr. Roberto Bellini, our President and Chief Executive Officer, has a 50% equity interest ("Rocabe" and, collectively with OrbiMed and PSCI, the "Major Shareholders"), together own, directly or indirectly, an aggregate of approximately 29.8% of our outstanding common shares. A decision by one or more of our Major Shareholders or any other significant shareholder to sell a substantial amount of our common shares could cause the trading price of our common shares to be adversely affected. Furthermore, shareholders may initiate securities class action lawsuits if the market price of our common shares drops significantly, which may cause us to incur substantial costs and could divert the time and attention of our management.

These factors, among others, could depress the trading price of our securities. Because we may experience high volatility in our common shares, individuals or entities should not invest in our common shares unless prepared to absorb a significant loss of capital. At any given time, investors may not be able to sell their shares at a price that is acceptable or at all. The market liquidity for our stock is low. While a more active trading market may develop in the future, the limited market liquidity for our common shares may affect an investor's ability to sell at a price that is satisfactory to them or at all.

***We do not expect to pay any cash dividends for the foreseeable future.***

Investors should not rely on an investment in our common shares to provide dividend income. We do not anticipate that we will pay any cash dividends to holders of our common shares in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our operations. In addition, any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common shares. Accordingly, investors must rely on sales of their

common shares after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common shares.

***If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.***

The trading market for our common shares will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover our company downgrade our common shares or publish inaccurate or unfavorable research about our business, our share price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our common shares could decrease, which might cause our share price and trading volume to decline.

***We would not be able to successfully commercialize product candidates if we are unable to create sales, marketing, and distribution capabilities or make adequate arrangements with third parties, including entering into collaborations with partners, for such purposes.***

In order to commercialize our product candidates successfully, we could, on a product-by-product basis, either develop internal sales, marketing, and distribution capabilities or make arrangements with third parties, including entering into collaborations with partners, to perform some or all of these services. We currently have no marketing capabilities and sales force. To the extent that we internally develop a sales force, the cost of establishing and maintaining a sales force would be substantial and may exceed our cost effectiveness. In addition, in marketing our drugs, we would likely compete with many companies that currently have extensive and well-funded marketing and sales operations. Despite marketing and sales efforts, we may be unable to compete successfully against these companies. We may not be able to do so on favorable terms. We could rely on third parties to market and sell our products in certain territories, rather than establishing an internal sales force. When we contract with third parties, including entering into collaborations with partners, for the sale and marketing of our products, revenues depend upon the efforts of these third parties, which may not be successful. If we fail to establish successful marketing and sales capabilities or to make arrangements with third parties for such purposes, our business, financial condition, results of operations and prospects will be materially adversely affected.

***We are subject to intense competition for skilled personnel. The loss of key personnel or the inability to attract additional personnel could impair our ability to conduct operations.***

We are highly dependent on our management and staff; the loss of whose services might adversely impact our ability to achieve our objectives. Recruiting and retaining qualified management and other personnel is critical to our success. Competition for skilled personnel is intense, and the ability to attract and retain qualified personnel may be affected by such competition. We do not maintain “key person” insurance for any of our key personnel.

***We are subject to the risk of product liability claims, for which we may not have, or may not be able to obtain, adequate insurance coverage.***

Human therapeutic products involve the risk of product liability claims and associated adverse publicity. Currently, our principal risks relate to participants in the clinical trials who may suffer unintended consequences. Claims might be made directly by consumers, patients, healthcare providers, or pharmaceutical companies or others selling or consuming any of our products, if approved. We may not have or be able to obtain or maintain sufficient and affordable insurance coverage, including

coverage for potentially very significant legal expenses. Without sufficient coverage, any claim brought against us could have a materially adverse effect on our business, financial condition, results of operations or prospects.

***Legislative actions, potential new accounting pronouncements, and higher insurance costs are likely to impact our future financial position or results of operations.***

Future changes in financial accounting standards may cause adverse, unexpected revenue or expense fluctuations and affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with greater frequency and are expected to occur in the future, and we may make, or may be required to make, changes in our accounting policies in the future. Compliance with changing regulations of corporate governance and public disclosure, notably with respect to internal controls over financial reporting, may result in additional expenses. Changing laws, regulations, and standards relating to corporate governance and public disclosure are creating uncertainty for companies like us, and insurance costs are increasing as a result of this uncertainty.

***We may incur losses associated with foreign currency fluctuations.***

Our operations are, in some instances, conducted in currencies other than our functional currency and a portion of our net monetary assets is denominated currencies other than our functional currency. Fluctuations in the value of foreign currencies relative to our functional currency could cause us to incur currency exchange losses.

***We may incur losses due to adverse decisions by tax authorities.***

Our income tax reporting is subject to audit by tax authorities. The effective tax rate may change from year to year based on the mix of income; non-deductible expenses; changes in tax law; and changes in the estimated values of future income tax assets and liabilities.

We may enter into transactions and arrangements in the ordinary course of business in which the tax treatment is not entirely certain. We must therefore make estimates and judgments in determining our consolidated tax provision. In addition, we apply for numerous tax credits that play an important role in our financial planning and we are not certain that the tax authorities will grant them. The final outcome of any audits by taxation authorities may differ from estimates and assumptions used in determining the consolidated tax provisions and accruals. This could result in a material effect on our consolidated research tax credits, income tax provision, financial position and the net income/loss for the period in which such determinations are made.

We are subject to taxation in Canada and were subject to taxation in certain foreign jurisdictions prior to the corporate reorganization. Our effective tax rate and tax liability are determined by a number of factors, including the amount of taxable income in particular jurisdictions, the tax rates in these jurisdictions, tax treaties between jurisdictions, the extent to which we transfer funds to and repatriate funds from our subsidiaries and future changes in laws. An adverse interpretation or ruling by one of the taxing authorities in a jurisdiction in which we operate or a change in law could increase our tax liability or result in the imposition of penalty payments, which could adversely impact our operating results.

***Our Major Shareholders have influence over our business and corporate matters, including those requiring shareholder approval. This could delay or prevent a change in control. Sales of common shares by our largest shareholders could have an impact on the market price of our common shares.***

Our Major Shareholders together own, directly or indirectly, an aggregate of approximately 29.8% of our outstanding common shares as at December 31, 2019. Pursuant to a board representation agreement dated December 18, 2018 between us and Orbimed, Orbimed is entitled to cause one nominee to be included in the list of management nominees to be proposed for election to our Board at each shareholders' meeting occurring following that date. Orbimed's nomination right terminates on the date Orbimed ceases to beneficially hold at least 10% of our issued and outstanding common shares. OrbiMed's nominated candidate is Mr. Khuong. In addition, pursuant to board representation agreements dated April 16, 2009, between us and each of PSCI and a predecessor to Rocabe (the **"2009 Board Representation Agreements"**), each of PSCI and Rocabe is entitled to cause two nominees to be included in the list of management nominees to be proposed for election to the Board at each shareholders meeting occurring following that date. Despite their rights, each of PSCI and Rocabe has only nominated one candidate. PSCI's and Rocabe's right to two nominees each shall terminate on the date each of PSCI, on the one hand, and Rocabe, the FMRC Family Trust (**"FMRC"**) and 1324286 Alberta Limited, a wholly-owned subsidiary of FMRC, collectively, on the other hand, ceases to beneficially hold at least 7.5% of our issued and outstanding common shares. Therefore, OrbiMed, PSCI, FMRC, Rocabe and certain persons related to such entities have the ability to exercise a significant degree of influence over our business and the outcome of various corporate matters, including those requiring shareholder approval. In particular, this concentration of ownership may have the effect of delaying or deferring a change in control of the Company and may adversely affect the price of our common shares.

***We may be required to make a payment under an indemnity agreement.***

In March 2017, we entered into a share purchase agreement with Taro for the sale of our wholly-owned subsidiary Thallion, including all the rights to the product candidate Shigamab™. We agreed to indemnify Taro, subject to certain conditions and limitations, for losses which it may suffer or incur, arising out of any debts, liabilities, commitments or obligations of any nature resulting from any matters, actions, events, facts or circumstances related to the activities or affairs of Thallion, which occurred prior to the effective time of the share purchase agreement. We have no indemnity provision recorded as at December 31, 2019.

***If we are a passive foreign investment company, or PFIC, for U.S. federal income tax purposes, the consequences to U.S. holders of our common shares may be adverse.***

Under the U.S. Internal Revenue Code of 1986, as amended, or the **"Code"**, we will be classified as a PFIC in respect of any taxable year in which either (i) 75% or more of our gross income consists of certain types of "passive income" or (ii) 50% or more of the average quarterly value of our assets is attributable to "passive assets" (assets that produce or are held for the production of passive income). For purposes of these tests, passive income includes dividends, interest, gains from the sale or exchange of investment property and certain rents and royalties. In addition, for purposes of the above calculations, if we directly or indirectly own at least 25% by value of the shares of another corporation, we will be treated as if it held our proportionate share of the assets and received directly our proportionate share of the income of such other corporation. PFIC status is a factual determination that needs to be made annually after the close of each taxable year, on the basis of the composition of our income, the relative value of our active and passive assets, and our market capitalization. For this



purpose, our PFIC status depends in part on the application of complex rules, which may be subject to differing interpretations, relating to the classification of our income and assets. Based on our interpretation of the law, our recent financial statements, and taking into account expectations about our income, assets and activities, we believe that we were a PFIC for the taxable year ended December 31, 2018 and expect that we will be a PFIC for the current taxable year.

If we are a PFIC for any taxable year during which a U.S. holder holds our common shares, we will continue to be treated as a PFIC with respect to such U.S. holder in all succeeding years during which the U.S. holder owns the common shares, regardless of whether we continue to meet the PFIC test described above, unless the U.S. Holder makes a specified election once we cease to be a PFIC. If we are classified as a PFIC for any taxable year during which a U.S. holder holds our common shares, the U.S. holder may be subject to adverse tax consequences regardless of whether we continue to qualify as a PFIC, including ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements. In certain circumstances, a U.S. holder may alleviate some of the adverse tax consequences attributable to PFIC status by making either a “qualified electing fund,” or “QEF”, election or a mark-to-market election (if our common shares constitute “marketable” securities under the Code).

***We are an emerging growth company and intend to take advantage of reduced disclosure requirements applicable to emerging growth companies, which could make our common shares less attractive to investors.***

We are an “emerging growth company” as defined in the JOBS Act. We will remain an emerging growth company until the earliest to occur of (i) the last day of the fiscal year in which we have total annual gross revenue of US\$1.07 billion or more; (ii) December 31, 2024 (the last day of the fiscal year ending after the fifth anniversary of the date of the completion of the first sales of its common equity pursuant to an effective registration statement under the U.S. Securities Act; (iii) the date on which we have issued more than US\$1 billion in non-convertible debt securities during the prior three-year period; or (iv) the date we qualify as a “large accelerated filer” under the rules of the SEC, which means the market value of our common shares held by non-affiliates exceeds US\$700 million as of the last business day of its most recently completed second fiscal quarter after we have been a reporting company in the United States for at least 12 months. For so long as we remain an emerging growth company, we are permitted to and intend to rely upon exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 (“**Section 404**”) of the Sarbanes-Oxley Act Sarbanes-Oxley Act (2002), as amended (the “**Sarbanes-Oxley Act**”).

We may take advantage of some, but not all, of the available exemptions available to emerging growth companies. We cannot predict whether investors will find our common shares less attractive if we rely on these exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and our share price may be more volatile.

***Brexit may create volatility in markets and uncertainty regarding future laws and regulations in the United Kingdom and the rest of Europe.***

Our Phase 2 clinical trial for the treatment of refractory chronic cough is being conducted at clinical sites located in the United Kingdom. In June 2016, a majority of voters in the United Kingdom elected to withdraw from the European Union in a national referendum. On January 31, 2020, under the terms of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, the United Kingdom withdrew from

the European Union, beginning a transition period ending on December 31, 2020, unless extended. While the terms of this withdrawal are still subject to negotiation between the United Kingdom and the European Union, the referendum has led to volatility in the financial markets of the United Kingdom and more broadly across Europe and may lead to a weakening in consumer, corporate and financial confidence in such markets. The referendum has also created significant uncertainty about the future relationship between the United Kingdom and the European Union, including with respect to the laws and regulations that will apply as the United Kingdom determines which European Union laws to replace or replicate in the event of a withdrawal, and has also given rise to calls for the governments of other European Union member states to consider withdrawal. The risks of changing laws and regulations in the United Kingdom are creating uncertainty for companies like us. Compliance with any such changing laws and regulations may be costly and consume substantial financial and management resources, as well as delay or prevent the development, promotion, marketing, or sale of our product candidates. The extent and process by which the United Kingdom may exit the European Union, and the longer term economic, legal, political and social framework to be put in place between the United Kingdom and the European Union are likely to lead to ongoing political and economic uncertainty and periods of exacerbated volatility in both the United Kingdom and in wider European markets for some time. This mid-to-long-term uncertainty may have an adverse effect on global economic conditions and on our ability to carry out our plans with respect to the development of BLU-5937, which in turn could have a material adverse effect on our business and financial condition.

***Our internal computer systems, or those used by our contractors or consultants, may fail or suffer security breaches.***

Despite the implementation of security measures, our internal computer systems, and those of our third parties on which we rely, are vulnerable to damage from computer viruses and unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication, electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. While we have not experienced any such material system failure or security breach to our knowledge to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our future product candidates could be delayed.

***The biopharmaceutical industry is subject to rapid technological change, which could affect the commercial viability of our products.***

The biopharmaceutical industry is subject to rapid and significant technological change. Research, discoveries or inventions by others may result in medical insights or breakthroughs which render our products less competitive or even obsolete. Furthermore, there may be breakthroughs of new biopharmaceutical technologies which may become superior to ours that may result in the loss of our commercial advantage. Our future success will, in part, depend on our ability to, among others:

- develop or license new technologies that address the changing needs of the medical community; and
- respond to technological advances and changing industry standards and practices in a cost-effective and timely manner.

Developing technology entails significant technical and business risks and substantial costs. We cannot assure you that we will be able to utilize new technologies effectively or that we will be able to adapt our existing technologies to changing industry standards in a timely or cost-effective manner, or at all. If we are unable to keep up with advancements in technology, our business, financial conditions and results of operations could be materially adversely affected.

***An investor may be unable to bring actions or enforce judgments against us and certain of our directors and officers.***

We are incorporated under the laws of Canada, and our principal executive offices are located in Canada. Most of our directors and officers reside outside of the United States and all or a substantial portion of our assets and the assets of such persons are located outside the United States. Consequently, it may not be possible for an investor to effect service of process within the United States on us or those persons. Furthermore, it may not be possible for an investor to enforce judgments obtained in United States courts based upon the civil liability provisions of United States federal securities laws or other laws of the United States against those persons or us.

There is doubt as to the enforceability, in original actions in Canadian courts, of liabilities based upon United States federal 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 the United States federal securities laws. Therefore, it may not be possible for U.S. holders of common shares to enforce those actions against us, certain of our directors and officers. Additionally, some of our directors and officers reside outside of Canada. Some or all of the assets of such persons may be located outside of Canada. Therefore, it may not be possible for U.S. holders of common shares to collect or to enforce judgments obtained in Canadian courts predicated upon the civil liability provisions of applicable Canadian securities laws against such persons.

***The market price for our common shares may be volatile and subject to wide fluctuations in response to numerous factors, many of which are beyond our control.***

The factors which may contribute to market price fluctuations of our common shares include, but are not limited to, the following:

- actual or anticipated fluctuations in our quarterly results of operations;
- recommendations by securities research analysts;
- changes in the economic performance or market valuations of companies in the industry in which we operate;
- addition or departure of our executive officers and other key personnel;
- release or expiration of transfer restrictions on outstanding common shares;
- sales or perceived sales of additional common shares;
- operating and financial performance that vary from the expectations of management, securities analysts and investors;
- regulatory changes affecting our industry generally and its business and operations;
- announcements of developments and other material events by us or our competitors;
- fluctuations to the costs of vital production materials and services;
- changes in global financial markets and global economies and general market conditions, such as interest rates and pharmaceutical product price volatility;

- significant acquisitions or business combinations, strategic partnerships, joint ventures or capital commitments by or involving us or our competitors;
- operating and share price performance of other companies that investors deem comparable to us or from a lack of market comparable companies; and
- news reports relating to trends, concerns, technological or competitive developments, regulatory changes and other related issues in our industry or target markets.

***We will incur increased costs as a result of operating as a public company in the United States and our management will be required to devote substantial time to new compliance initiatives.***

As a public company, particularly after we are no longer an “emerging growth company” as defined under the JOBS Act, we will incur significant legal, accounting and other expenses that we did not incur prior to being listed in the United States. In addition, the Sarbanes-Oxley Act, and rules implemented by the SEC, and Nasdaq, impose various other requirements on public companies, and we will need to spend time and resources to ensure compliance with our reporting obligations under Canadian securities laws, as well as our obligations in the United States.

***Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting (“ICFR”), which, after we are no longer an emerging growth company, must be accompanied by an attestation report on ICFR issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will document and evaluate our ICFR, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our ICFR, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for ICFR. Despite our efforts, there is a risk that neither us nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our ICFR is effective as required by Section 404. This could result in a determination that there are one or more material weaknesses in our ICFR, which could cause an adverse reaction in the financial markets due to a loss of confidence in the reliability of our consolidated financial statements.***

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities required for public company more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as regulatory and governing bodies provide new guidance. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and divert management’s time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Being a public company in the United States and complying with applicable rules and regulations will make it more expensive for us to obtain director and officer liability insurance. These factors could also make it more difficult for us to attract and retain qualified executive officers and members of our Board.

***As a foreign private issuer, we are subject to different U.S. securities laws and rules than a domestic U.S. issuer, which may limit the information publicly available to our U.S. shareholders.***

As a foreign private issuer under applicable U.S. federal securities laws, we are not required to comply with all of the periodic disclosure and current reporting requirements of the U.S. Exchange Act and related rules and regulations. As a result, we do not file the same reports that a U.S. domestic issuer would file with the SEC, although we will be required to file with or furnish to the SEC the continuous disclosure documents that we are required to file in Canada under Canadian securities laws. In addition, our officers, directors and principal shareholders are exempt from the reporting and “short swing” profit recovery provisions of Section 16 of the U.S. Exchange Act. Therefore, our shareholders may not know on as timely a basis when our officers, directors and principal shareholders purchase or sell securities of the Company as the reporting periods under the corresponding Canadian insider reporting requirements are longer. In addition, as a foreign private issuer, we are exempt from the proxy rules under the U.S. Exchange Act.

***The Company may lose its foreign private issuer status in the future, which could result in significant additional costs and expenses to the Company.***

In order to maintain our current status as a foreign private issuer, a majority of our common shares must be either directly or indirectly owned of record by non-residents of the United States unless we also satisfy one of the additional requirements necessary to preserve this status. We may in the future lose our foreign private issuer status if a majority of the common shares are owned of record in the United States and we fail to meet the additional requirements necessary to avoid loss of foreign private issuer status. The regulatory and compliance costs to us under U.S. federal securities laws as a U.S. domestic issuer may be significantly more than the costs we incur as a Canadian foreign private issuer eligible to use MJDS. If we are not a foreign private issuer, we would not be eligible to use the MJDS or other foreign issuer forms and would be required to file periodic and current reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive than the forms available to a foreign private issuer. In addition, we may lose the ability to rely upon exemptions from Nasdaq corporate governance requirements that are available to foreign private issuers.

## MANAGEMENT'S RESPONSIBILITY FOR FINANCIAL REPORTING

The accompanying consolidated financial statements have been prepared by management and approved by the Board of Directors of the Company. The consolidated financial statements were prepared in accordance with International Financial Reporting Standards and, where appropriate, reflect management's best estimates and judgments. When it was possible to apply diverse accounting methods, management has chosen those it deemed to be most appropriate in the circumstances. Management is responsible for the accuracy, integrity and objectivity of the consolidated financial statements within reasonable limits of materiality, and for the consistency of financial data included in the text of the Management's Discussion and Analysis with the data contained in the consolidated financial statements.

To assist management in the discharge of these responsibilities, the Company maintains a system of internal control over financial reporting as described in the Management's Discussion and Analysis.

The Company's Audit Committee is appointed by the Board of Directors annually and is comprised exclusively of outside, independent directors. The Audit Committee meets with management as well as with the external auditors to satisfy itself that management is properly discharging its financial reporting responsibilities and to review the consolidated financial statements. The Audit Committee reports its findings to the Board of Directors for consideration in approving the consolidated financial statements to be issued to shareholders. The Audit Committee also considers, for review by the Board of Directors and approval by the shareholders, the engagement or reappointment of the external auditors. The external auditors, KPMG LLP, have direct access to the Audit Committee of the Board of Directors.

The consolidated financial statements have been independently audited by KPMG LLP on behalf of the shareholders, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB") for the year ended December 31, 2019, and in accordance with Canadian generally accepted auditing standards for the year ended December 31, 2018. Their reports outline the nature of their audits and expresses their opinion on the consolidated financial statements of the Company.



Roberto Bellini  
President and Chief Executive Officer



François Desjardins, CPA, CA  
Vice President, Finance

Laval, Quebec, Canada  
February 26, 2020



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## **REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Shareholders and Board of Directors of BELLUS Health Inc.

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

We have audited the accompanying consolidated statement of financial position of BELLUS Health Inc. (the "Company") as of December 31, 2019, the related consolidated statements of loss and other comprehensive loss, changes in shareholders' equity, and cash flows for the year ended December 31, 2019, and the related notes (collectively, the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2019, and its consolidated financial performance and its consolidated cash flows for the year ended December 31, 2019, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

### ***Basis for Opinion***

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We are a public accounting firm registered with the 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.



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We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

A handwritten signature in black ink that reads 'KPMG LLP'. The signature is written in a cursive, stylized font. Below the signature is a horizontal line that starts under the 'K' and ends under the 'P'.

We have served as the Company's auditor since 1995.

Montréal, Canada

February 26, 2020





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## INDEPENDENT AUDITORS' REPORT

To the Shareholders of BELLUS Health Inc.

### ***Opinion***

We have audited the consolidated financial statements of BELLUS Health Inc. (the "Entity"), which comprise:

- the consolidated statement of financial position as at December 31, 2018
- the consolidated statement of loss and other comprehensive loss for the year then ended
- the consolidated statement of changes in shareholders' equity for the year then ended
- the consolidated statement of cash flows for the year then ended
- and notes to the consolidated financial statements, including a summary of significant accounting policies

(Hereinafter referred to as the "financial statements").

In our opinion, the accompanying financial statements present fairly, in all material respects, the consolidated financial position of the Entity as at December 31, 2018, and its consolidated financial performance and its consolidated cash flows for the year then ended in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board.

### ***Basis for Opinion***

We conducted our audit in accordance with Canadian generally accepted auditing standards. Our responsibilities under those standards are further described in the "***Auditors' Responsibilities for the Audit of the Financial Statements***" section of our auditors' report.

We are independent of the Entity in accordance with the ethical requirements that are relevant to our audit of the financial statements in Canada and we have fulfilled our other responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

### ***Other information***

Management is responsible for the other information. Other information comprises:

- The information included in 2018 Management's Discussion and Analysis filed with the relevant Canadian Securities Commissions.
- The information, other than the financial statements and the auditors' report thereon, included in a document entitled "2018 Annual Report".

Our opinion on the financial statements does not cover the other information and we do not and will not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information identified above and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit and remain alert for indications that the other information appears to be materially misstated.

We obtained the information included in 2018 Management's Discussion and Analysis filed with the relevant Canadian Securities Commissions as at the date of this auditors' report. If, based on the work we have performed on this other information, we conclude that there is a material misstatement of this other information, we are required to report that fact in the auditors' report.

We have nothing to report in this regard.

The information, other than the financial statements and the auditors' report thereon, included in a document entitled "2018 Annual Report" is expected to be made available to us after the date of this auditors' report. If, based on the work we will perform on this other information, we conclude that there is a material misstatement of this other information, we are required to report that fact to those charged with governance.

### ***Responsibilities of Management and Those Charged with Governance for the Financial Statements***

Management is responsible for the preparation and fair presentation of the financial statements in accordance with International Financial Reporting Standards (IFRS), and for such internal control as management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is responsible for assessing the Entity's ability to continue as a going concern, disclosing as applicable, matters related to going concern and using the going concern basis of accounting unless management either intends to liquidate the Entity or to cease operations, or has no realistic alternative but to do so.

Those charged with governance are responsible for overseeing the Entity's financial reporting process.

### ***Auditors' Responsibilities for the Audit of the Financial Statements***

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditors' report that includes our opinion.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with Canadian generally accepted auditing standards will always detect a material misstatement when it exists.

Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the financial statements.

As part of an audit in accordance with Canadian generally accepted auditing standards, we exercise professional judgment and maintain professional skepticism throughout the audit.

We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion.

The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Entity's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- Conclude on the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Entity's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditors' report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditors' report. However, future events or conditions may cause the Entity to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.



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- Communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.
- Provide those charged with governance with a statement that we have complied with relevant ethical requirements regarding independence, and communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the group Entity to express an opinion on the financial statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.

A handwritten signature in black ink that reads 'KPMG LLP' with a horizontal line underneath.

Montréal, Canada

February 20, 2019

# BELLUS HEALTH INC.

## Consolidated Statements of Financial Position

December 31, 2019 and 2018  
(in thousands of Canadian dollars)

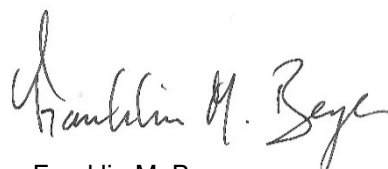
	December 31, 2019	December 31, 2018
<b>Assets</b>		
Current assets:		
Cash and cash equivalents (note 5)	\$ 24,276	\$ 14,933
Short-term investments (note 5)	92,608	33,973
Trade and other receivables	313	154
Research tax credits receivable	1,346	655
Prepaid expenses and other assets	3,882	1,149
Total current assets	122,425	50,864
Non-current assets:		
Right-of-use asset (notes 4 and 6)	265	—
Other assets	139	77
In-process research and development asset (note 7)	2,359	2,359
Total non-current assets	2,763	2,436
<b>Total Assets</b>	<b>\$ 125,188</b>	<b>\$ 53,300</b>
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities:		
Trade and other payables (note 8)	\$ 9,671	\$ 2,716
Lease liability (notes 4 and 6)	217	—
Total current liabilities	9,888	2,716
Non-current liabilities:		
Lease liability (notes 4 and 6)	27	—
Total non-current liabilities	27	—
<b>Total Liabilities</b>	<b>9,915</b>	<b>2,716</b>
Shareholders' equity:		
Share capital (note 9 (a))	609,156	502,706
Other equity (notes 9 (b) (i) and (ii))	28,659	27,101
Deficit	(522,542)	(479,223)
<b>Total Shareholders' Equity</b>	<b>115,273</b>	<b>50,584</b>
Commitments and contingencies (note 16)		
<b>Total Liabilities and Shareholders' Equity</b>	<b>\$ 125,188</b>	<b>\$ 53,300</b>

See accompanying notes to consolidated financial statements.

On behalf of the Board of Directors by:



Pierre Larochelle  
Director



Franklin M. Berger  
Director

# BELLUS HEALTH INC.

## Consolidated Statements of Loss and Other Comprehensive Loss

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data)

	Year ended December 31, 2019	Year ended December 31, 2018
Revenues	\$ 35	\$ 35
Expenses:		
Research and development	26,119	7,185
Research tax credits	(710)	(653)
	25,409	6,532
General and administrative	8,726	3,409
Total operating expenses	34,135	9,941
Loss from operating activities	(34,100)	(9,906)
Finance income	1,520	746
Finance costs	(1,886)	(5)
Net finance (costs) income (note 11)	(366)	741
Change in fair value of contingent consideration receivable (note 14)	—	81
Net loss and total comprehensive loss for the year	\$ (34,466)	\$ (9,084)
Loss per share (note 13)		
Basic and diluted	\$ (0.73)	\$ (0.27)

See accompanying notes to consolidated financial statements.

# BELLUS HEALTH INC.

## Consolidated Statements of Changes in Shareholders' Equity

Years ended December 31, 2019 and 2018  
(in thousands of Canadian dollars)

	Share capital (note 9 (a))	Other equity	Deficit	Total
Balance, December 31, 2018	\$ 502,706	\$ 27,101	\$ (479,223)	\$ 50,584
Total comprehensive loss for the year:				
Net loss and comprehensive loss	—	—	(34,466)	(34,466)
Total comprehensive loss for the year	—	—	(34,466)	(34,466)
Transactions with shareholders, recorded directly in shareholders' equity:				
Issued in connection with the 2019 Offering (note 9 (a) (i))	104,591	—	(8,853)	95,738
Issued upon stock options exercise (note 9 (b) (i))	137	(62)	—	75
Issued upon broker warrants exercise (note 9 (b) (ii))	1,722	(514)	—	1,208
Stock-based compensation (note 9 (b) (i))	—	2,134	—	2,134
Balance, December 31, 2019	\$ 609,156	\$ 28,659	\$ (522,542)	\$ 115,273

	Share capital (note 9 (a))	Other equity	Deficit	Total
Balance, December 31, 2017	\$ 467,253	\$ 26,202	\$ (467,167)	\$ 26,288
Total comprehensive loss for the year:				
Net loss and comprehensive loss	—	—	(9,084)	(9,084)
Total comprehensive loss for the year	—	—	(9,084)	(9,084)
Transactions with shareholders, recorded directly in shareholders' equity:				
Issued in connection with the 2018 Offering (note 9 (a) (ii))	35,000	387	(2,972)	32,415
Issued upon broker warrants exercise (note 9 (b) (ii))	453	(187)	—	266
Stock-based compensation (note 9 (b) (i))	—	699	—	699
Balance, December 31, 2018	\$ 502,706	\$ 27,101	\$ (479,223)	\$ 50,584

See accompanying notes to consolidated financial statements.

# BELLUS HEALTH INC.

## Consolidated Statements of Cash Flows

Years ended December 31, 2019 and 2018  
(in thousands of Canadian dollars)

	Year ended December 31, 2019	Year ended December 31, 2018
Cash flows from (used in) operating activities:		
Net loss for the year	\$ (34,466)	\$ (9,084)
Adjustments for:		
Depreciation (note 6)	158	—
Stock-based compensation	2,134	699
Net finance costs (income)	366	(741)
Change in fair value of contingent consideration	—	(81)
Other items	112	42
Changes in operating assets and liabilities		
Trade and other receivables	(159)	279
Research tax credits receivable	(691)	(249)
Prepaid expenses and other assets	(2,564)	(999)
Trade and other payables	7,245	(20)
Financial liabilities – CVRs	—	(20)
	(27,865)	(10,174)
Cash flows from (used in) financing activities:		
Issuance of common shares through 2019 Offering, net of share issue costs	95,738	—
Issuance of common shares through 2018 Offering, net of share issue costs	(406)	32,888
Issuance of common shares upon stock options exercise	75	—
Issuance of common shares upon broker warrants exercise	1,208	266
Deferred financing costs	(56)	—
Lease liability – principal repayments	(195)	—
Interest paid	(14)	(5)
	96,350	33,149
Cash flows from (used in) investing activities:		
Purchases of short-term investments	(93,367)	(33,751)
Sales of short-term investments	33,482	16,100
Interest received	1,077	340
Interest accrued	17	—
Acquisition of in-process research and development asset, net of costs and deferred development support payments (note 7)	—	475
Proceeds on sale of investment in FB Health (note 14)	—	465
Proceeds from sale of subsidiary, net of costs (note 15)	—	400
	(58,791)	(15,971)
Net increase in cash and cash equivalents	9,694	7,004
Cash and cash equivalents, beginning of year	14,933	7,749
Effect of foreign exchange on cash and cash equivalents	(351)	180
Cash and cash equivalents, end of year	\$ 24,276	\$ 14,933
Supplemental cash flow disclosure:		
Non-cash transactions:		
Initial recognition of right-of-use asset and lease liability (note 4)	\$ 156	\$ —
Additions to right-of-use asset and lease liability (note 6)	267	—
Share issue costs - 2018 Offering, in Trade and other payables (note 9(a) (ii))	67	473
Deferred financing costs, in Trade and other payables	152	—
Issuance of broker warrants in connection with 2018 Offering (note 9 (b) (ii))	—	387
Ascribed value related to issuance of common shares upon stock options exercise (note 9 (b) (i))	62	—
Ascribed value related to issuance of common shares upon broker warrants exercise (note 9 (b) (ii))	514	187
Value of DSUs in Prepaid expenses and other assets (note 9 (b) (iii))	96	73

See accompanying notes to consolidated financial statements.



# BELLUS HEALTH INC.

## Notes to Consolidated Financial Statements

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

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### 1. Reporting entity:

BELLUS Health Inc. ("BELLUS Health" or the "Company") is a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of chronic cough and other hypersensitization-related disorders. The Company's product candidate, BLU-5937, is being developed for the treatment of chronic cough and chronic pruritus. The Company is domiciled in Canada. The address of the Company's registered office is 275 Armand-Frappier Blvd., Laval, Quebec, Canada H7V 4A7. BELLUS Health's common shares trade on the Nasdaq Capital Market ("Nasdaq") and on the Toronto Stock Exchange ("TSX") both under the symbol BLU. The Company's common shares began trading on the Nasdaq on September 9, 2019, concurrently with the closing of the equity offering at that date (refer to note 9 (a) (i)).

The Company completed a share consolidation on the basis of one new common share for every 3.6 outstanding shares effective on August 19, 2019. As a result, all issued and outstanding common shares, stock options, deferred share units, broker warrants and per share amounts contained in these consolidated financial statements have been retrospectively adjusted to reflect the share consolidation for all years presented.

The Company is subject to a number of risks, including risks associated with the conduct of its product candidate's development programs and results, the establishment of strategic alliances and the successful development of new product candidates and their marketing. The Company has incurred significant operating losses and negative cash flows from operations since inception. To date, the Company has financed its operations primarily through public offerings of common shares, private placements, the issuance of convertible notes, asset sales and the proceeds from research tax credits. The ability of the Company to ultimately achieve future profitable operations is dependent upon the successful development of its product candidates obtaining regulatory approval in various jurisdictions and successful sale or commercialization of the Company's products and technologies, which is dependent on a number of factors outside of the Company's control.

### 2. Basis of preparation:

#### (a) Statement of compliance:

These consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

These consolidated financial statements for the year ended December 31, 2019, were approved by the Board of Directors on February 26, 2020.

# BELLUS HEALTH INC.

## Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

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### 2. Basis of preparation (continued):

#### (b) Basis of measurement (continued):

The financial statements have been prepared on the historical cost basis, except certain of the Company's accounting policies and disclosures that require the determination of fair value, namely:

- Liabilities related to cash-settled share-based arrangements and stock-based compensation, which is measured at fair value on grant date pursuant to IFRS 2, *Share-based payments*.
- Financial and non-financial assets and liabilities.

In establishing the fair value, the Company uses a fair value hierarchy based on levels as defined below:

- Level 1: defined as observable inputs such as quoted prices in active markets.
- Level 2: defined as inputs other than quoted prices in active markets that are either directly or indirectly observable.
- Level 3: defined as inputs that are based on little or no little observable market data, therefore requiring entities to develop their own assumptions.

#### (c) Functional and presentation currency:

Items included in the consolidated financial statements of the Company are measured using the currency of the primary economic environment in which the Company operates (the functional currency). These consolidated financial statements are presented in Canadian dollars, which is the Company's functional and presentation currency for all years presented.

Change in functional and presentation currency in 2020:

As a result of the advancement of the Company's development programs, the Company anticipates higher research and development costs in future periods which will be denominated mainly in US dollars. In addition, these will be financed from proceeds received from the new financing in US dollars in September 2019 (refer to note 9 (a) (i)). As a result of these changes the Company has determined that the US dollar will better reflect the primary economic environment in which the Company will operate in the future. As a result of these changes, a significant portion of the Company's expenses and net assets are and will continue to be denominated in US dollars. Therefore, effective January 1, 2020, the Company adopted the US dollar as its functional and presentation currency. On January 1, 2020, the change in functional currency will result in the assets, liabilities and equity transactions as of January 1, 2020 being translated in US dollars using the exchange rate in effect on that date and the change in functional currency will then be applied prospectively. The change in presentation currency will be applied retrospectively resulting in the comparative financial information being recasted into US dollars.

# BELLUS HEALTH INC.

## Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

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### 2. Basis of preparation (continued):

#### (d) Use of estimates and judgments:

The preparation of the consolidated financial statements in accordance with IFRS requires management to make judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income and expenses. The reported amounts and note disclosures reflect management's best estimate of the most probable set of economic conditions and planned course of actions. Actual results may differ from these estimates.

A critical judgment in applying accounting policies that has the most significant effect on the amounts recognized in the consolidated financial statements relates to the use of the going concern basis of preparation of the financial statements. At the end of each reporting period, management assesses the basis of preparation of the financial statements. These financial statements have been prepared on a going concern basis in accordance with IFRS. The going concern basis of presentation assumes that the Company will continue its operations for the foreseeable future and be able to realize its assets and discharge its liabilities and commitments in the normal course of business.

Information about assumptions and estimation uncertainties that have a significant risk of resulting in a material adjustment is included within the following notes and is described below:

#### (i) Estimation of accrued expenses:

As part of the process of preparing its financial statements, the Company is required to estimate its accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with personnel and service providers to identify services that have been performed on the Company's behalf and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of the actual cost.

For research and development activities, the majority of service providers invoice the Company in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. There may also be instances in which payments to the service providers will exceed the level of services provided and result in a prepayment of the expense.

The Company estimates its accrued expenses and prepaid expenses as of each statement of financial position date in its financial statements based on facts and circumstances known at that time.

#### (ii) Estimating the recoverable amount of the in-process research and development asset related to BLU-5937 for the purpose of the annual impairment test (note 7).

# BELLUS HEALTH INC.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

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## 2. Basis of preparation (continued):

### (d) Use of estimates and judgments (continued):

Other areas requiring the use of management estimates and judgements include assessing the recoverability of research tax credits as well as estimating the initial fair value of equity-classified stock-based compensation. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which they are made and in future periods affected.

## 3. Significant accounting policies:

The accounting policies set out below have been applied consistently to all years presented in these consolidated financial statements.

### (a) Basis of consolidation:

These consolidated financial statements include the accounts of BELLUS Health Inc. and its subsidiaries.

Subsidiaries are entities controlled by BELLUS Health Inc. The financial statements of subsidiaries are included in the consolidated financial statements from the date that control commences until the date that control ceases. Intercompany balances and transactions have been eliminated on consolidation.

### (b) Cash, cash equivalents and short-term investments:

The Company considers all investments with maturities of three months or less at inception, that are highly liquid and readily convertible into cash, to be cash equivalents. Investments with maturities greater than three months and less than one year are presented as short-term investments in the consolidated statement of financial position.

### (c) Revenue recognition:

Revenue from contracts with customers is measured based on the consideration specified in a contract with a customer and excludes amounts collected on behalf of third parties. A company recognizes revenue when it transfers control of a product or service to a customer. The Company does not have any revenue from contracts with customers.

Revenue from other contracts may be derived from development and other services provided by the Company. Revenue from contracted services is recognized over time as the contracted services are performed.

Consideration received from other contracts may also include amounts received as licensing fees, costs reimbursements, sales-based royalty payments, upfront payments and regulatory and sales-based milestone payments for specific achievements. Revenue is recognized in income only when conditions and events under the contract have been met or occurred and it is probable that the Company will collect the consideration to which it is entitled.

# BELLUS HEALTH INC.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

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## 3. Significant accounting policies (continued):

### (d) Research and development:

Research and development costs consist of direct and indirect expenditures, including a reasonable allocation of overhead expenses, associated with the Company's development programs. Overhead expenses comprise general and administrative support provided to the development programs and involve costs associated with support activities.

Research expenditures undertaken with the prospect of gaining new scientific or technical knowledge are expensed as incurred. Development expenditures are deferred when they meet the criteria for capitalization in accordance with IFRS, and the future benefits could be regarded as being reasonably certain. The criteria to be fulfilled in order to capitalize development costs are if such costs can be measured reliably, if the product or process is technically and commercially feasible, if future economic benefits are probable and if the Company intends to and has sufficient resources to complete the development and to use or sell the asset. As at December 31, 2019 and 2018, no development costs were deferred.

### (e) In-process research and development asset:

The in-process research and development ("IPR&D") asset acquired by the Company in 2017 is accounted for as an indefinite-lived intangible asset until the project is completed or abandoned, at which point it will be amortized or impaired, respectively. Subsequent research and development costs associated with the IPR&D asset are accounted for consistent with the research and development policy in note 3 (d).

The Company assesses at each reporting date whether there is an indication that the asset may be impaired. Irrespective of whether there is any indication of impairment, the IPR&D asset is tested for impairment annually by comparing its carrying amount with its recoverable amount.

The asset's recoverable amount is the greater of its fair value less costs to sell and its value in use. If the carrying amount of the asset exceeds its recoverable amount, the asset is considered impaired and is written down to its recoverable amount immediately. Impairment losses are recognized in income. A previously recognized impairment loss is reversed only if there has been a change in the assumptions used to determine the asset's recoverable amount since the last impairment loss was recognized. The reversal is limited so that the carrying amount of the asset does not exceed its recoverable amount, nor exceed the carrying amount that would have been determined, had no impairment loss been recognized for the asset in prior years.

# BELLUS HEALTH INC.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

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## 3. Significant accounting policies (continued):

### (f) Government assistance:

Government assistance, consisting of research tax credits, is recorded as a reduction of the related expense. Research tax credits are recognized when management determines that there is reasonable assurance that the tax credits will be received. Research tax credits claimed for the current and prior years are subject to government review and approval which could result in adjustments to amounts recognized by the Company. Adjustments from tax authorities, if any, would be recognized in the period of revision.

### (g) Foreign exchange:

Transactions in foreign currencies are translated to the functional currency of the Company at exchange rates at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated to the functional currency at the exchange rate at the reporting date. Non-monetary assets and liabilities denominated in foreign currencies that are measured at historical cost are translated using the exchange rate at the date of the transaction. Income and expenses denominated in foreign currencies are translated at exchange rates in effect at the transaction date. Translation gains and losses are recognized in income.

### (h) Income taxes:

Deferred tax is recognized for temporary differences between the financial reporting bases and the income tax bases of the Company's assets and liabilities and is recorded using the substantively enacted tax rates anticipated to be in effect when the tax differences are expected to reverse. Deferred tax assets and liabilities are offset if there is a legally enforceable right to offset current tax liabilities and assets, and they relate to income taxes levied by the same tax authority on the same taxable entity, or on different tax entities, but they intend to settle current tax liabilities and assets on a net basis or their tax assets and liabilities will be realized simultaneously. A deferred tax asset is recognized for unused tax losses, tax credits and deductible temporary differences, to the extent that it is probable that future taxable profits will be available against which they can be utilized. Deferred tax assets are reviewed at each reporting date and are reduced to the extent that it is no longer probable that the related tax benefit will be realized.

### (j) Provisions:

A provision is recognized if, as a result of a past event, the Company has a present, legal or constructive obligation that can be estimated reliably, and it is probable that an outflow of economic benefits will be required to settle the obligation. Provisions are determined by discounting the expected future cash flows at a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the liability. The unwinding of the discount is recognized as finance cost.

# BELLUS HEALTH INC.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

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## 3. Significant accounting policies (continued):

### (j) Earnings per share:

Basic earnings per share are determined using the weighted average number of common shares outstanding during the period. Diluted earnings per share are computed in a manner consistent with basic earnings per share, except that the weighted average number of shares outstanding is increased to include additional shares from the assumed exercise of dilutive stock options and broker warrants. The number of additional shares is calculated by assuming that outstanding stock options and broker warrants were exercised, and that the proceeds from such exercises were used to acquire common shares at the average market price during the reporting period.

### (k) Employee benefits:

#### (i) Short-term employee benefits:

Short-term employee benefit obligations are measured on an undiscounted basis and are expensed as the related service is provided. A liability is recognized for the amount expected to be paid if the Company has a present legal or constructive obligation to pay this amount as a result of past service provided by the employee, and the obligation can be estimated reliably.

#### (ii) Share-based payment arrangements:

The Company follows the fair value-based method to account for stock options granted to employees, whereby compensation cost is measured at fair value at the date of grant and is expensed over the award's vesting period with a corresponding increase to equity. For the stock options with graded vesting, the fair value of each tranche is recognized over its respective vesting period. The amount recognized as an expense is adjusted to reflect the number of awards for which the related service vesting conditions are expected to be met, such that the amount ultimately recognized as an expense is based on the number of awards that meet the related service conditions at the vesting date.

When stock options are exercised, the Company issues new shares. The proceeds received, together with the related portion previously recorded in other equity, are credited to share capital.

# BELLUS HEALTH INC.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

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## 3. Significant accounting policies (continued):

### (k) Employee benefits (continued):

#### (ii) Share-based payment arrangements (continued):

The Company also grants Deferred Share Units ("DSU") as compensation for directors and designated employees. Upon termination of service, DSU participants are entitled to receive for each DSU credited to their account the payment in cash on the date of settlement based on the value of a BELLUS Health common share. For DSUs, compensation cost is measured based on the market price of the Company's common shares from the date of grant through to the settlement date. Any changes in the market value of the Company's common shares through to the settlement date result in a change to the measure of compensation cost for those awards and are recorded in income in the same line item as stock-based compensation expense.

### (l) Financial instruments:

The Company measures its financial instruments as follows:

#### *Financial assets and Financial liabilities*

#### (i) Recognition and initial measurement:

Trade receivables are initially recognized when they are originated. All other financial assets and financial liabilities are initially recognized when the Company becomes a party to the contractual provisions of the instrument.

A financial asset (unless it is a trade receivable without a significant financing component) or financial liability is initially measured at fair value plus, for an item not at fair value through profit or loss ("FVTPL"), transaction costs that are directly attributable to its acquisition or issue. A trade receivable without a significant financing component is initially measured at the transaction price.

#### (ii) Classification and subsequent measurement:

##### Financial assets - Classification:

On initial recognition, a financial asset is classified as measured at amortized cost, fair value through other comprehensive income ("FVOCI") – debt investment, FVOCI – equity investment or FVTPL.

Financial assets are not reclassified subsequent to their initial recognition unless the Company changes its business model for managing financial assets, in which case all affected financial assets are reclassified on the first day of the first reporting period following the change in the business model.



# BELLUS HEALTH INC.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

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## 3. Significant accounting policies (continued):

### (i) Financial instruments (continued):

#### *Financial assets and Financial liabilities (continued)*

### (ii) Classification and subsequent measurement (continued):

#### Financial assets - Classification (continued):

A financial asset is measured at amortized cost if it meets both the following conditions and is not designated as at FVTPL: it is held within a business model whose objective is to hold assets to collect contractual cash flows; and its contractual terms give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

A debt investment is measured at FVOCI if it meets both of the following conditions and is not designated as FVTPL: it is held within a business model whose objective is achieved by both collecting contractual cash flows and selling financial assets; and its contractual terms give rise on specified dates to cash flows that are solely payments of principal and interest in the principal amount outstanding.

On initial recognition of an equity investment that is not held for trading, the Company may irrevocably elect to present subsequent changes in the investment's fair value in other comprehensive income ("OCI"). This election is made on an investment by investment basis.

All financial assets not classified as measured at amortized cost or FVOCI as described above are measured at FVTPL. On initial recognition, the Company may irrevocably designate a financial asset that otherwise meets the requirements to be measured at amortized cost or FVOCI as at FVTPL if doing so eliminates or significantly reduces an accounting mismatch that would otherwise arise.

#### Financial assets - Subsequent measurement and gains and losses:

Financial assets at amortized cost are subsequently measured at amortized cost using the effective interest method. The amortized cost is reduced by impairment losses. Interest income, foreign exchange gains and losses and impairment are recognized in income. Any gain or loss on derecognition is recognized in income.

Debt investments at FVOCI are subsequently measured at fair value. Interest income calculated using the effective interest method, foreign exchange gains and losses and impairment are recognized in income. Other net gains and losses are recognized in OCI. On derecognition, gains and losses accumulated in OCI are reclassified to income.

Equity investments at FVOCI are subsequently measured at fair value. Dividends are recognized as income in income unless the dividend clearly represents a recovery of part of the cost of the investment. Other net gains and losses are recognized in OCI and are never reclassified to income.

# BELLUS HEALTH INC.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

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## 3. Significant accounting policies (continued):

### (i) Financial instruments (continued):

#### *Financial assets and Financial liabilities (continued)*

### (ii) Classification and subsequent measurement (continued):

#### Financial assets - Subsequent measurement and gains and losses (continued):

Financial assets at FVTPL are subsequently measured at fair value. Net gains and losses are recognized in income.

#### Financial liabilities - Classification:

Financial liabilities are classified as measured at amortized cost or FVTPL. A financial liability is classified as at FVTPL if it is classified as held-for-trading, it is a derivative or it is designated as such on initial recognition.

#### Financial liabilities - Subsequent measurement and gains and losses:

Financial liabilities at FVTPL are subsequently measured at fair value and net gains and losses, including any interest expense, are recognized in income. Other financial liabilities are subsequently measured at amortized cost using the effective interest method. Interest expense and foreign exchange gains and losses are recognized in income. Any gain or loss on derecognition is also recognized in income.

Cash, cash equivalents and short-term investments, trade receivables, amounts receivable under license agreements and other receivables are measured at amortized cost.

Trade and other payables are measured at amortized cost.

#### *Share capital*

Common shares and preferred shares that are not redeemable or are redeemable only at the Company's option are classified as equity. Incremental costs directly attributable to the issue of equity-classified shares are recognized as a deduction from the deficit, net of any tax effects.

## 4. Changes in significant accounting policies

The Company has initially adopted IFRS 16, *Leases* effective on January 1, 2019.

IFRS 16 introduced a single, on-balance sheet accounting model for lessees. As a result, BELLUS Health, as a lessee, has recognized a right-of-use asset representing its rights to use the underlying asset and a lease liability representing its obligation to make lease payments in its statement of financial position, in relation to its property lease.

# BELLUS HEALTH INC.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

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## 4. Changes in significant accounting policies (continued)

The Company has applied IFRS 16 using the modified retrospective approach, under which the cumulative effect of initial application is recognized in retained earnings as at January 1, 2019. Accordingly, the comparative information presented for 2018 has not been restated. It is presented under IAS 17, *Leases* and related interpretations. There was no impact to the deficit at January 1, 2019 upon the adoption of IFRS 16.

The details of the changes in accounting policies are disclosed below.

### (a) Definition of a lease:

The Company now assesses whether a contract is or contains a lease based on the new definition of a lease. Under IFRS 16, a contract is, or contains, a lease if the contract conveys a right to control the use of an identified asset for a period of time in exchange for consideration. On transition to IFRS 16, the Company elected to apply the practical expedient to grandfather the assessment of which transactions are leases. It applied IFRS 16 only to contracts that were previously identified as leases. Contracts that were not identified as leases under IAS 17 and IFRIC 4 were not reassessed. Therefore, the definition of a lease under IFRS 16 has been applied only to contracts entered into or modified on or after January 1, 2019.

At inception or on reassessment of a contract that contains a lease component, BELLUS Health allocates the consideration in the contract to each lease and non-lease component on the basis of their relative stand-alone prices. However, for its lease of property in which it is a lessee, the Company has elected not to separate non-lease components and will instead account for the lease and non-lease components as a single lease component.

### (b) As a lessee:

#### (i) Significant accounting policies:

BELLUS Health recognizes a right-of-use asset and a lease liability at the lease commencement date. The right-of-use asset is initially measured at cost, and subsequently at cost less any accumulated depreciation and impairment losses, and adjusted for certain remeasurements of the lease liability. The right-of-use asset is depreciated using the straight-line method from the commencement date to the earlier of the end of the useful life of the asset or the end of the lease term.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, the Company's incremental borrowing rate. Generally, the Company uses its incremental borrowing rate as the discount rate.

# BELLUS HEALTH INC.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

## 4. Changes in significant accounting policies (continued)

### (b) As a lessee (continued):

The lease liability is subsequently increased by the interest cost on the lease liability and decreased by lease payment made. It is remeasured when there is a change in future lease payments arising from a change in an index or rate, a change in the estimate of the amount expected to be payable under a residual value guarantee, or as appropriate, changes in the assessment of whether a purchase or extension option is reasonably certain to be exercised or a termination option is reasonably certain not to be exercised.

### (ii) Transition:

Prior to January 1, 2019, the Company classified its property lease as an operating lease under IAS 17.

### (c) Impacts on consolidated financial statements:

#### (i) Impacts on transition:

On transition to IFRS 16, the Company recognized a right-of-use asset and a corresponding lease liability. The impact on transition is summarised below:

	January 1, 2019
Right-of-use asset	\$ 156
Lease liability	(156)

When measuring the lease liability for the property lease that was previously classified as an operating lease, the Company discounted the remaining lease payments using its incremental borrowing rate as at January 1, 2019. The rate applied was 5%.

	January 1, 2019
Operating lease commitment as at December 31, 2018 as disclosed in the Company's consolidated financial statements	\$ 164
Discounting of lease payments	(8)
Lease liability recognized as at January 1, 2019	\$ 156

# BELLUS HEALTH INC.

## Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

### 4. Changes in significant accounting policies (continued)

(c) Impacts on consolidated financial statements:

(ii) Impacts for the year:

Under IFRS 16, the Company has recognized depreciation and interest expense on its right-of-use asset and lease liability, respectively, instead of an operating lease expense. During the year ended December 31, 2019, the Company recognized in its consolidated statement of loss and other comprehensive loss \$158 of depreciation expense (of which \$111 is presented in Research and development expenses and \$47 is presented in General and administrative expenses) and \$16 of interest, presented in Finance costs. For the year ended December 31, 2018, the Company recognized \$147 of operating lease expense.

### 5. Cash, cash equivalents and short-term investments:

Cash, cash equivalents and short-term investments consist of cash balances with banks and short-term investments:

	December 31, 2019	December 31, 2018
Cash balances with banks	\$ 7,137	\$ 1,464
Short-term investments with initial maturities of less than three months:		
High interest savings accounts, yielding interest at 1.28% to 1.85% at December 31, 2019 (December 31, 2018 – 1.70% to 1.95%)	17,139	13,469
Cash and cash equivalents	24,276	14,933
Short-term investments with initial maturities greater than three months and less than one year:		
Term deposits issued in US currency (US\$36,701), yielding interest at 1.80% to 2.15% at December 31, 2019 (December 31, 2018 – US\$10,510, 2.96% to 3.10%)	47,675	14,333
Term deposit issued in CDN currency, yielding interest at 1.92% to 2.60% at December 31, 2019 (December 31, 2018 – 1.90% to 3.10%)	15,555	19,640
Bearer deposit notes issued in US currency (US\$22,616), yielding interest at 1.76% to 1.83% at December 31, 2019	29,378	—
Short-term investments	92,608	33,973
Cash, cash equivalents and short-term investments	\$ 116,884	\$ 48,906

# BELLUS HEALTH INC.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

## 6. Right-of-use asset and lease liability:

BELLUS Health Inc. leases office space in Laval, Quebec, Canada. An amendment to the Company's property lease was signed on June 25, 2019, extending the property lease by an additional one-year term beyond the initial expiry on January 31, 2020, to January 31, 2021. In addition, the Company entered into a property lease on November 1, 2019 for additional office space at the same location, which expires on January 31, 2021.

Right of use asset:

		Net book value
Cost:		
Balance as at January 1, 2019	\$	156
Additions to right-of-use asset		267
Balance as at December 31, 2019	\$	423
Accumulated amortization:		
Balance as at January 1, 2019	\$	—
Depreciation expense for the year		(158)
Balance as at December 31, 2019	\$	(158)
Net book value:		
Balance as at January 1, 2019	\$	156
Balance as at December 31, 2019	\$	265

Lease liability:

		Carrying value
Balance as at January 1, 2019	\$	156
Additions to lease liability		267
Interest expense		16
Principal repayment		(195)
Balance as at December 31, 2019	\$	244
Current portion of lease liability		217
Non-current portion of lease liability	\$	27

The remaining life of the Company's property leases as of December 31, 2019 is 1.1 year.

Lease payments were discounted using an incremental borrowing rate of 5%.

# BELLUS HEALTH INC.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

## 6. Right-of-use asset and lease liability (continued):

Lease liability (continued):

Minimum annual payments under the non-cancelable leases, undiscounted, are as follows:

Years ending December 31,		
2020	\$	230
2021 and after		29
	\$	259

## 7. In-process research and development asset:

BELLUS Health acquired the IPR&D asset related to BLU-5937 in February 2017 through the obtention from the NEOMED Institute ("NEOMED") of an exclusive worldwide license to develop and commercialize BLU-5937, a potent, highly selective, orally bioavailable small molecule antagonist of the P2X3 receptor, a clinically validated target for chronic cough. The IPR&D asset is accounted for as an indefinite-lived intangible asset until the project, currently in its clinical phase, is completed or abandoned, at which point it will be amortized or impaired, respectively. The carrying value of the IPR&D asset related to BLU-5937 amounted to \$2,359 as at December 31, 2019 and 2018.

Under the terms of the agreement, NEOMED provided development support to the BLU-5937 program, of which an amount of \$475 was received by the Company in May 2018.

As at December 31, 2019 and 2018, the carrying amount of the IPR&D asset related to BLU-5937 did not exceed its estimated recoverable amount. The recoverability of this asset is dependent on successfully developing this project and achieving the expected future revenues from commercialization.

## 8. Trade and other payables:

Trade and other payables consist of:

	December 31, 2019	December 31, 2018
Trade payables	\$ 5,164	\$ 555
Other accrued liabilities	2,205	1,495
DSU liability (note 9 (b) (iii))	2,302	666
	\$ 9,671	\$ 2,716

# BELLUS HEALTH INC.

## Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

### 9. Shareholders' equity:

#### (a) Share capital:

The authorized share capital of the Company consists of:

- an unlimited number of voting common shares with no par value; and
- an unlimited number of non-voting preferred shares, issuable in one or more series, with no par value.

Issued and outstanding common shares are as follows:

	Number	Dollars
Balance, December 31, 2018	43,622,136	\$ 502,706
Issued in connection with the 2019 Offering (note 9 (a) (i))	11,179,451	104,591
Issued upon stock options exercise (note 9 (b) (i))	41,667	137
Issued upon broker warrants exercise (note 9 (b) (ii))	535,406	1,722
Balance, December 31, 2019	55,378,660	\$ 609,156

	Number	Dollars
Balance, December 31, 2017	33,193,774	\$ 467,253
Issued in connection with the 2018 Offering (note 9 (a) (ii))	10,233,918	35,000
Issued upon broker warrants exercise (note 9 (b) (ii))	194,444	453
Balance, December 31, 2018	43,622,136	\$ 502,706

- (i) On September 9, 2019, the Company closed an equity offering, issuing 9,859,155 common shares from treasury at a price of \$9.35 (US\$7.10) per share for gross proceeds of \$92,176 (US\$70,000), and on September 17, 2019, the underwriters of the equity offering partially exercised their option to purchase additional common shares (over-allotment option) to purchase common shares of the Company, resulting in the issuance of an additional 1,320,296 common shares from treasury at a price of \$9.40 (US\$7.10) per share, for additional gross proceeds of \$12,415 (US\$9,374) (together, the "2019 Offering"). Share issue costs of \$8,853, comprised mainly of agents' commission, legal, professional and filing fees, have been charged to the deficit.



# BELLUS HEALTH INC.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

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## 9. Shareholders' equity (continued):

### (a) Share capital (continued):

- (ii) On December 18, 2018, the Company closed an equity offering, issuing a total of 10,233,918 common shares from treasury at a price of \$3.42 per share for aggregate gross proceeds of \$35,000 (the "2018 Offering"). Share issue costs of \$2,972, comprised mainly of agent commission, legal, professional and filing fees of \$2,585, as well as broker warrants having a fair value of \$387 (refer to note 9 (b) (ii)), have been charged to the deficit.

### (b) Share-based payment arrangements:

#### (i) Stock Option Plan:

Under its stock option plan, the Company may grant options to purchase common shares to directors, officers, employees and consultants of the Company (the "Stock Option Plan"). The number of common shares subject to each stock option, the vesting period, the expiration date and other terms and conditions related to each stock option are determined and approved by the Board of Directors. In general, stock options vest over a period of up to five years and are exercisable over a period of 10 years from the grant date. The aggregate number of common shares reserved for issuance under this plan shall not exceed 12.5% of the total issued and outstanding common shares of the Company from time to time. The aggregate number of common shares reserved for issuance at any time to any optionee shall not exceed 5% of the issued and outstanding common shares of the Company. The aggregate number of common shares issuable or reserved for issuance to insiders of the Company under this plan and any other share compensation arrangement of the Company cannot at any time exceed 10% of the issued and outstanding common shares of the Company. The option price per share is equal to the weighted average trading price of common shares for the five days preceding the date of grant during which the common shares were traded on the TSX.

# BELLUS HEALTH INC.

Notes to Consolidated Financial Statements (Continued)

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(in thousands of Canadian dollars, except per share data, unless otherwise noted)

## 9. Shareholders' equity (continued):

(b) Share-based payment arrangements (continued):

(i) Stock Option Plan (continued):

Changes in outstanding stock options issued under the Stock Option Plan for the years ended December 31, 2019 and 2018 were as follows:

	Number	Weighted average exercise price
Balance, December 31, 2018	3,220,280	\$ 1.47
Granted <sup>(1)</sup> <sup>(2)</sup> <sup>(3)</sup>	1,548,330	5.79
Exercised	(41,667)	1.80
Balance, December 31, 2019	4,726,943	\$ 2.88
	Number	Weighted average exercise price
Balance, December 31, 2017	2,025,834	\$ 1.58
Granted <sup>(4)</sup> <sup>(5)</sup>	1,194,446	1.29
Balance, December 31, 2018	3,220,280	\$ 1.47

<sup>(1)</sup> 1,015,275 stock options were granted on February 20, 2019, having an exercise price of \$4.36; 895,830 stock options granted to key management personnel and 119,445 granted to other employees.

<sup>(2)</sup> 20,833 stock options were granted to other employees on August 7, 2019, having an exercise price of \$11.41.

<sup>(3)</sup> 512,222 stock options were granted on November 13, 2019, having an exercise price of \$8.39; 472,222 stock options granted to key management personnel and 40,000 granted to other employees.

<sup>(4)</sup> 1,152,779 stock options were granted on February 20, 2018, having an exercise price of \$1.26; 1,055,558 granted to key management personnel and 97,221 granted to other employees.

<sup>(5)</sup> 41,667 stock options were granted on July 10, 2018 to other employees, having an exercise price of \$2.05.

# BELLUS HEALTH INC.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

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## 9. Shareholders' equity (continued):

(b) Share-based payment arrangements (continued):

(i) Stock Option Plan (continued):

The following table summarizes information about stock options outstanding and exercisable as at December 31, 2019:

Exercise price/share	Options outstanding		Options exercisable
	Number	Weighted average years to expiration	Number
\$1.08	730,556	7.3	299,722
\$1.26	1,152,779	8.1	230,556
\$1.51	55,556	7.9	22,222
\$1.80	1,152,777	2.6	1,152,777
\$2.05	41,667	8.5	8,333
\$3.78	16,667	2.6	16,667
\$4.03	28,611	6.2	17,167
\$4.36	1,015,275	9.1	—
\$8.39	512,222	9.9	—
\$11.41	20,833	9.6	—
	4,726,943	7.1	1,747,444

Stock-based compensation:

For the year ended December 31, 2019, the Company recorded a stock-based compensation expense related to stock options granted under the stock option plan in the amount of \$2,134 in the consolidated statement of loss and other comprehensive loss; from this amount, \$540 is presented in Research and development expenses and \$1,594 is presented in General and administrative expenses (2018 – \$699, \$109 presented in Research and development expenses and \$590 presented in General and administrative expenses).

The fair value of each stock option granted is estimated on the date of grant using the Black-Scholes pricing model. Expected volatility is estimated by considering historic average share price volatility for a period commensurate with the expected life.

# BELLUS HEALTH INC.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

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## 9. Shareholders' equity (continued):

(b) Share-based payment arrangements (continued):

(i) Stock Option Plan (continued):

Stock-based compensation (continued):

The weighted average assumptions for stock options granted during the years ended December 31, 2019 and 2018 were as follows:

	2019 <sup>(1)</sup>	2018 <sup>(2)</sup>
Weighted average fair value of stock options at grant date	\$ 4.72	\$ 1.04
Weighted average share price	\$ 5.79	\$ 1.29
Weighted average exercise price	\$ 5.79	\$ 1.29
Risk-free interest rate	1.73%	2.19%
Expected volatility	100%	100%
Expected life in years	7	7
Expected dividend yield	Nil	Nil

<sup>(1)</sup> Stock options were granted on February 20, 2019, August 7, 2019 and November 13, 2019.

<sup>(2)</sup> Stock options were granted on February 20, 2018 and July 10, 2018.

Dividend yield was excluded from the calculation, since it is the present policy of the Company to retain all earnings to finance operations and future growth.

(ii) Broker warrants:

In connection with the 2018 Offering on December 18, 2018 (refer to note 9 (a) (ii)), the Company issued 402,851 broker warrants exercisable for common shares. Each broker warrant entitles the holders to buy one common share at a price of \$3.42 per share for a period of 18 months from the closing of the 2018 Offering. The fair value of brokers warrants of \$387 was allocated to Other Equity upon issuance.

Changes in outstanding broker warrants for the years ended December 31, 2019 and 2018 were as follows:

	Number	Dollars
Balance, December 31, 2018	710,278	\$ 683
Exercised – from the 2018 Offering <sup>(1)</sup>	(231,261)	(222)
Exercised – from the 2017 Offering <sup>(2)</sup>	(304,145)	(292)
Expired – from the 2017 Offering	(3,282)	(3)
Balance, December 31, 2019	171,590	\$ 166

# BELLUS HEALTH INC.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

## 9. Shareholders' equity (continued):

(b) Share-based payment arrangements (continued):

(ii) Broker warrants (continued):

	Number	Dollars
Balance, December 31, 2017	501,871	\$ 483
Issued in connection with the 2018 Offering	402,851	387
Exercised – from the 2017 Offering <sup>(3)</sup>	(194,444)	(187)
Balance, December 31, 2018	710,278	\$ 683

(1) In 2019, the Company issued a total of 231,261 common shares from treasury upon the exercise of a total of 231,261 broker warrants issued in connection with the 2018 Offering. As a result of their exercise, the aggregate carrying value of the broker warrants of \$222, initially allocated to Other equity pending the issuance of common shares, was reclassified to Share capital.

(2) In 2019, the Company issued a total of 304,145 common shares from treasury upon the exercise of a total of 304,145 broker warrants issued in connection with the Company's equity offering on December 12, 2017 (the "2017 Offering"). Each broker warrant issued entitled the holders to buy one common share at a price of \$1.37 per share for a period of 18 months from the closing of 2017 Offering. As a result of their exercise, the aggregate carrying value of the broker warrants of \$292, initially allocated to Other equity pending the issuance of common shares, was reclassified to Share capital.

(3) On September 12, 2018, the Company issued 194,444 common shares from treasury upon the exercise of 194,444 broker warrants issued in connection with the 2017 Offering. As a result of their exercise, the carrying value of the broker warrants of \$187, initially allocated to Other equity pending the issuance of common shares, was reclassified to Share capital.

The fair value of broker warrants issued was estimated on the date of issuance using the Black-Scholes pricing model. Expected volatility is estimated by considering historic average share price volatility for a period commensurate with the expected life.

# BELLUS HEALTH INC.

## Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

### 9. Shareholders' equity (continued):

#### (b) Share-based payment arrangements (continued):

##### (ii) Broker warrants (continued):

The assumptions for broker warrants issued during the year ended December 31, 2018 were as follows:

	2018 <sup>(1)</sup>
Fair value of broker warrants at grant date	\$ 0.96
Share price	\$ 3.42
Exercise price	\$ 3.42
Risk-free interest rate	1.95%
Expected volatility	56%
Expected life in years	1.5
Expected dividend yield	Nil

<sup>(1)</sup> Broker warrants issued on December 18, 2018 in connection with the 2018 Offering.

Dividend yield was excluded from the calculation, since it is the present policy of the Company to retain all earnings to finance operations and future growth.

##### (iii) Deferred share unit (DSU) plan:

The Company has a deferred share unit ("DSU") plan for employees and members of the Board of Directors created to afford the Company the flexibility to offer DSUs as an alternative to cash compensation.

The price of DSUs is determined by the five-day volume weighted average trading price of the Company's common shares at the time the DSUs are issued, as provided for under the plan. The DSUs are redeemable only upon the participant's resignation, termination, retirement or death, in cash, at a value equal to the number of DSUs credited, multiplied by the 5-day market value weighted average price of common shares prior to the date on which a notice of redemption is filed.

For DSUs, compensation cost is measured based on the market price of the Company's common shares from the date of grant through to the settlement date. Any changes in the market value of the Company's common shares through to the settlement date result in a change to the measure of compensation cost for those awards and are recorded in income.

# BELLUS HEALTH INC.

## Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

### 9. Shareholders' equity (continued):

#### (b) Share-based payment arrangements (continued):

##### (iii) Deferred share unit (DSU) plan (continued):

Changes in the number of units for the years ended December 31, 2019 and 2018 were as follows:

Number of units	2019	2018
Balance, beginning of year	181,352	60,543
Units granted <sup>(1)</sup>	53,281	120,863
Units redeemed	—	(54)
Balance, end of year	234,633	181,352
Balance of DSU liability, included in Trade and other payables	\$ 2,302	\$ 666

<sup>(1)</sup> All DSUs were granted to key management personnel.

During the year ended December 31, 2019, the Company granted 53,281 DSUs having a weighted average fair value per unit of \$5.12. During the year ended December 31, 2018, the Company granted 120,863 DSUs having a weighted average fair value per unit of \$1.98, and 54 units were redeemed at a fair value per unit of \$3.84.

As at December 31, 2019, the Company estimated the fair value of the DSU liability at \$2,302, based on the market price of the Company's common shares at that date (\$666 as at December 31, 2018). The stock-based compensation expense related to the DSU plan recorded in the consolidated statement of loss for the year ended December 31, 2019 amounted to \$1,613; from this amount, \$3 is presented in Research and development expenses and \$1,610 is presented in General and administrative expenses (2018 – \$512; \$1 presented in Research and development expenses and \$511 presented in General and administrative expenses). The value of DSUs granted in 2019 for which services have not been rendered as at December 31, 2019 amounted to \$96 and is presented in Prepaid expenses and other assets in the consolidated statement of financial position (the value of DSUs granted in 2018 for which services have not been rendered as at December 31, 2018 amounted to \$73).

# BELLUS HEALTH INC.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

## 10. Personnel expenses:

The aggregate compensation to personnel of the Company for the years ended December 31, 2019 and 2018 is set out below:

	2019	2018
Short-term benefits	\$ 3,467	\$ 2,412
DSU plan expense	1,613	512
Stock option plan expense	2,134	699
	<u>\$ 7,214</u>	<u>\$ 3,623</u>

## 11. Net finance (costs) income:

Finance income and Finance costs for the years ended December 31, 2019 and 2018 were attributed as follows:

	2019	2018
Interest income	\$ 1,520	\$ 362
Foreign exchange gain	—	384
Finance income	<u>1,520</u>	<u>746</u>
Interest expense on lease liability (note 6)	(16)	—
Interest and bank charges	(14)	(5)
Foreign exchange loss	(1,856)	—
Finance costs	<u>(1,886)</u>	<u>(5)</u>
Net finance (costs) income	<u>\$ (366)</u>	<u>\$ 741</u>

## 12. Income taxes:

Deferred tax expense

	December 31, 2019	December 31, 2018
Origination and reversal of temporary differences	\$ (8,564)	\$ (2,111)
Change in unrecognized deductible temporary differences including effect of change in tax rate of \$32 in 2019 (2018 – \$26)	<u>8,564</u>	<u>2,111</u>
Deferred tax expense	<u>\$ —</u>	<u>\$ —</u>



# BELLUS HEALTH INC.

## Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

### 12. Income taxes (continued):

Deferred tax expense (continued)

Reconciliation of effective tax rate:

	Year ended December 31, 2019	Year ended December 31, 2018
Loss before income taxes:		
Canadian operations	\$ (34,140)	\$ (9,084)
US operations	(326)	—
	(34,466)	(9,084)
Tax using the Company's domestic tax rate	(9,168)	(2,425)
Change in unrecognized deductible temporary differences	8,564	2,111
Difference in tax rate of a foreign subsidiary	18	—
Non-taxable accounting gain on sale of investment in FB Heath and sale of subsidiary	—	(22)
Effect of change in tax rate	32	26
Non-deductible stock option expense	568	186
Permanent differences and other items	(14)	124
Total deferred tax expense	\$ —	\$ —

The applicable statutory tax rates are 26.6% in 2019 and 26.7% in 2018. The Company's applicable tax rate is the Canadian combined rates applicable in the jurisdiction in which the Company operates. The decrease is due to the reduction of the Quebec income tax rate in 2019 from 11.7% to 11.6%.

Deferred tax assets and liabilities

Recognized deferred tax assets and liabilities:

As at December 31, 2019 and 2018, recognized deferred tax assets and liabilities are attributable to the following:

	Assets		Liabilities		Net	
	2019	2018	2019	2018	2019	2018
Taxes losses carried forward	\$ 79	\$ 25	\$ —	\$ —	\$ 79	\$ 25
Right-of-use assets	—	—	(70)	—	(70)	—
Equipment	—	—	—	(16)	—	(16)
Trade and other receivables	—	—	(9)	(9)	(9)	(9)
Tax assets (liabilities)	79	25	(79)	(25)	—	—
Set off of tax	(79)	(25)	79	25	—	—
Net tax assets (liabilities)	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —

# BELLUS HEALTH INC.

## Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

### 12. Income taxes (continued):

Deferred tax assets and liabilities (continued)

Unrecognized deferred tax assets and investment tax credits:

As at December 31, 2019 and 2018, the amounts and expiry dates of tax attributes and temporary differences for which no deferred tax assets was recognized were as follows:

	December 31, 2019		December 31, 2018	
	Federal	Provincial	Federal	Provincial
Research and development expenses, without time limitation	\$ 9,874	\$ 10,084	\$ 6,300	\$ 6,496
Federal research and development investment tax credits				
2037	309	—	309	—
2038	464	—	462	—
2039	519	—	—	—
	1,292	—	771	—
Tax losses carried forward				
2032	338	211	338	211
2033	894	1,148	894	894
2034	822	822	822	822
2035	1,116	1,116	1,116	1,051
2036	1,143	1,143	1,143	1,143
2037	2,251	2,476	2,311	2,476
2038	5,025	4,886	5,131	4,947
2039	29,488	29,318	—	—
	41,077	41,120	11,755	11,544
Capital losses	14,199	14,199	14,120	14,120
Other deductible temporary differences, without time limitation	\$ 11,655	\$ 11,655	\$ 3,808	\$ 3,808

Deferred tax assets and investments tax credits have not been recognized in respect to these items because it is not probable that future taxable profit will be available against which the Company can utilize the benefits therefrom. The generation of future taxable profit is dependent on the successful commercialization of the Company's products and technologies.

# BELLUS HEALTH INC.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

## 13. Loss per share:

	Year ended December 31, 2019	Year ended December 31, 2018
Basic weighted average number of common shares outstanding	47,430,219	33,616,869
Basic and diluted loss per share	\$ (0.73)	\$ (0.27)

Excluded from the calculation of the diluted loss per share for the years ended December 31, 2019 and 2018 is the impact of all stock options granted under the Stock Option Plan and broker warrants, as they would be anti-dilutive.

Stock options granted under the Stock Option Plan and broker warrants could potentially be dilutive in the future.

## 14. Sale of investment in FB Health:

The Company received an amount of \$465 in November 2018 as payment of the contingent consideration receivable in relation to the sale of its equity interest in FB Health S.p.A in June 2017.

Prior to payment, the Company adjusted the estimated fair value of the contingent consideration receivable to \$465 in the consolidated statement of financial position, based on available information representing management's revised best estimate of the amount to be received (\$384 as at December 31, 2017). The change in fair value for the year ended December 31, 2018 amounted to \$81, presented in the consolidated statement of loss and other comprehensive loss.

## 15. Sale of subsidiary:

The Company received an amount of \$400 in January 2018 as deferred payment on the sale of its wholly-owned subsidiary, Thallion Pharmaceuticals Inc. ("Thallion"), to Taro Pharmaceuticals Inc. ("Taro") in March 2017.

## 16. Commitments and contingencies:

### (a) Contracts in the normal course of business:

The Company enters into contracts in the normal course of business, including for research and development activities, consulting and other services.

As at December 31, 2019, the Company has commitments for expenditures related to contracts for research and development activities of approximately \$11,332 (approximately \$6,785 as at December 31, 2018), of which \$11,216 is due in 2020 and \$116 is due in 2021.

# BELLUS HEALTH INC.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

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## 16. Commitments and contingencies (continued):

### (b) Indemnity agreement:

The Company is potentially liable in relation to the following indemnity agreement:

In March 2017, the Company entered into a share purchase agreement with Taro for the sale of the Company's wholly-owned subsidiary Thallion, including all the rights to the drug candidate Shigamab™. The Company agreed to indemnify Taro, subject to certain conditions and limitations, for losses which it may suffer or incur, arising out of any debts, liabilities, commitments or obligations of any nature resulting from any matters, actions, events, facts or circumstances related to the activities or affairs of Thallion, which occurred prior to the effective time of the share purchase agreement. No indemnity provision has been recorded by the Company as at December 31, 2019 and 2018 for this matter as the Company does not expect to make any payments under this indemnity agreement.

### (c) License agreements and research collaborations:

(i) In February 2017, BELLUS Health announced that it had obtained from NEOMED an exclusive worldwide license to develop and commercialize BLU-5937 (refer to note 7). Under the terms of the agreement, the Company is committed to pay NEOMED a royalty on potential net sales-based future revenues from BLU-5937, and in lieu of milestone payments, a certain portion of all other revenues received from BLU-5937 in accordance with a pre-established schedule whereby the shared revenue portion decreases as the program progresses in development. No amount is payable as at December 31, 2019 and 2018 under this agreement.

(ii) In the past the Company has entered into various agreements whereby future cash payments may be made based on criteria such as sales for certain legacy products. The Company has not recorded any provision on such agreements as the possibility for a payment is remote.

### (d) Consulting and services agreement:

The payments under the consulting and services agreement with Picchio International Inc. (Picchio International) (refer to note 17 (b)) will amount to \$250 in 2020, plus the reimbursement of applicable expenses for services rendered under the agreement.

# BELLUS HEALTH INC.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

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## 16. Commitments and contingencies (continued):

(e) Letter of credit:

As at December 31, 2019, the Company is contingently liable for a letter of credit in the amount of \$50 (2018 - \$50). Cash is pledged under the letter of credit and is presented as non-current Other assets in the consolidated statement of financial position as at December 31, 2019.

## 17. Related party transactions:

(a) There is no single ultimate controlling party.

(b) Dr. Francesco Bellini, Chairman of the Board of Directors, provides ongoing advisory services to the Company under the terms of a consulting and services agreement between the Company and Picchio International, wholly-owned by Dr. Francesco Bellini and his spouse. The agreement has a one-year term and shall renew for successive one-year terms. The Company recorded fees and expenses of \$381 for both of the years ended December 31, 2019 and 2018.

(c) Key management personnel:

The Chief Executive Officer, Chief Medical Officer, Vice-Presidents and Directors of BELLUS Health are considered key management personnel.

The aggregate compensation to key management personnel of the Company for the years ended December 31, 2019 and 2018 is set out below:

	2019	2018
Short-term benefits	\$ 2,384	\$ 1,810
DSU plan expense	1,613	512
Stock option plan expense	1,868	626
	\$ 5,865	\$ 2,948

## 18. Segment disclosures:

Business segment:

The Company operates in one business segment, which is the development of therapeutic candidates for the treatment of health disorders. As at December 31, 2019, the Company's operations were conducted in Canada and the United States. All of the Company's non-current assets are located in Canada.

# BELLUS HEALTH INC.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

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## 19. Capital management:

The Company's objective in managing capital is to ensure a sufficient liquidity position to finance its research and development activities, including pipeline expansion, general and administrative expenses, working capital and overall capital expenditures.

Since inception, the Company has financed its liquidity needs primarily through public offerings of common shares, private placements, the issuance of convertible notes, asset sales and the proceeds from research tax credits. When possible, the Company tries to optimize its liquidity needs by non-dilutive sources, including research tax credits, grants, interest income, as well as with proceeds from collaboration and research agreements, asset sales or product licensing agreements.

Historically, when the Company had the option, it has settled its obligations through the issuance of common shares instead of in cash to preserve its liquidities to finance its operations and future growth.

The Company defines capital to include total shareholders' equity.

The capital management objectives remain the same as previous fiscal year.

As at December 31, 2019, cash, cash equivalents and short-term investments amounted to \$116,884. The Company's general policy on dividends is to retain cash to keep funds available to finance the Company's growth.

The Company is not subject to any capital requirements that are externally imposed.

## 20. Financial instruments:

### (a) Financial instruments - carrying values and fair values:

Fair value estimates are made as of a specific point in time, using available information about the financial instrument. These estimates are subjective in nature and may not be determined with precision.

For its financial assets and liabilities measured at amortized cost as at December 31, 2019, the Company has determined that the carrying value of its short-term financial assets and liabilities (consisting of cash, cash equivalents and short-term investments, trade receivables, amounts receivable under license agreements and other receivables, and trade and other payables) approximates their fair value because of the relatively short periods to maturity of these instruments.

# BELLUS HEALTH INC.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

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## 20. Financial instruments (continued):

### (b) Credit risk management:

Credit risk results from the possibility that a loss may occur from the failure of another party to perform according to the terms of the contract.

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist principally of cash and cash equivalents, short-term investments and trade and other receivables. The Company invests cash mainly with major North American financial institutions. Cash equivalents and short-term investments are comprised of fixed income instruments with a high credit ranking (not less than A-1) as rated by Standard and Poor's. The Company has investment policies that are designed to provide for the safety and preservation of principal, the Company's liquidity needs and yields that are appropriate.

As at December 31, 2019, the Company's maximum credit exposure corresponded to the carrying amount of these financial assets.

### (c) Liquidity risk management:

Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they fall due. The Company requires continued access to capital markets to support its operations, as well as to achieve its strategic plans. Any impediments to the Company's ability to access capital markets, including the lack of financing capability or an adverse perception in capital markets of the Company's financial condition or prospects, could have a materially adverse effect on the Company. In addition, the Company's access to financing is influenced by the economic and credit market environment.

The Company manages liquidity risk through the management of its capital structure, as outlined in note 19. It also manages liquidity risk by continuously monitoring actual and projected cash flows. The Board of Directors reviews, approves and monitors the Company's operating and capital budgets, as well as any material transactions.

The balance of accounts payable and accrued liabilities is due within one year. For information on the maturity of commitments and contingencies, see note 16.

# BELLUS HEALTH INC.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

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## 20. Financial instruments (continued):

### (d) Foreign currency risk management:

Foreign currency risk is the risk that the fair value of future cash flows of a financial instrument will fluctuate because of changes in foreign exchange rates. Foreign currency risk is limited to the portion of the Company's business transactions denominated in currencies other than Canadian dollars. The Company's exposure relates primarily to changes in the Canadian dollar versus the US dollar exchange rate. For the Company's foreign currency transactions, fluctuations in the respective exchange rates relative to the Canadian dollar will create volatility in the Company's cash flows and the reported amounts for revenue and expenses in income. Additional variability arises from the translation of monetary assets and liabilities denominated in currencies other than the Canadian dollar at the rates of exchange at each statement of financial position date, the impact of which is reported as a foreign exchange gain or loss in income. The Company holds a portion of its cash, cash equivalents and short-term investments in US dollars to meet its liquidity needs in US dollars, but does not use derivative financial instruments to reduce its foreign exchange exposure.

The following table provides an indication of the Company's significant foreign currency exposures as at December 31, 2019:

(in CDN dollars)	December 31, 2019
Net assets denominated in US dollars:	
Cash and cash equivalents	\$ 16,317
Short-term investments	77,053
Other assets	45
Trade and other payables	(5,670)
	<hr/>
	\$ 87,745

Based on the Company's net foreign currency exposure noted above, and assuming that all other variables remain constant, a hypothetical 10% depreciation or appreciation of the Canadian dollar against the US dollar would result in an increase/decrease of \$8,775 in income.

The \$US to \$CDN exchange rate applied as at December 31, 2019 was 1.2990.



# BELLUS HEALTH INC.

Notes to Consolidated Financial Statements (Continued)

Years ended December 31, 2019 and 2018

(in thousands of Canadian dollars, except per share data, unless otherwise noted)

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## 20. Financial instruments (continued):

### (e) Interest rate risk:

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates.

The Company's exposure to interest rate risk is as follows:

---

Cash and cash equivalents	Short-term fixed and variable interest rate
Short-term investments	Short-term fixed interest rate
Restricted cash	Short-term fixed interest rate

---

Based on the carrying amount of the Company's variable interest-bearing financial instruments as at December 31, 2019, an assumed 1% increase or 1% decrease in interest rates during such period would have resulted in an increase/decrease of \$171 in income.

Management believes that the risk that the Company will realize a loss as a result of the decline in the fair value of its cash equivalents and short-term investments is limited because these investments have short-term maturities and are generally held to maturity.

The capacity of the Company to reinvest the short-term amounts with equivalent returns will be impacted by variations in short-term fixed interest rates available in the market.

Interest income presented in the consolidated statement of loss represents interest income on financial assets classified as loans and receivables.

## CORPORATE GOVERNANCE

BELLUS Health Inc. is committed to sound corporate governance practices, which ensure that its affairs are managed in the best interest of all stakeholders. The Board of Directors undertakes a periodic review to verify that BELLUS Health Inc.'s governance practices have kept pace with changing regulatory environments in the United States and in Canada, to which BELLUS Health Inc. is subject as a company listed on Nasdaq and TSX. Please refer to the management information circular for more information on the overall structure of the Board and its Committees and for details of BELLUS Health Inc.'s corporate governance practices.

## EXECUTIVE MANAGEMENT

**Mr. Roberto Bellini**  
President & Chief Executive Officer

**Dr. Catherine M. Bonuccelli**  
Chief Medical Officer

**Dr. Denis Garceau**  
Senior Vice President, Drug Development

**Mr. François Desjardins, CPA, CA**  
Vice President, Finance

**Mr. Tony Matzouranis**  
Vice President, Business Development

## BOARD OF DIRECTORS

**Dr. Francesco Bellini, O.C.**  
Chairman of the Board of BELLUS Health  
Chairman of the Board of Picchio International Inc.

**Mr. Roberto Bellini**  
President & Chief Executive Officer of  
BELLUS Health

**Dr. Youssef L. Bennani**  
Chairman of the Board of Domain Therapeutics

**Mr. Franklin M. Berger, CFA**  
Consultant

**Dr. Clarissa Desjardins**  
Corporate Director

**Mr. Chau Q. Khuong**  
Private Equity Partner of OrbiMed  
Advisors LLC

**Mr. Pierre Larochelle**  
President & Chief Executive Officer  
of Power Energy Corporation

**Mr. Joseph Rus**  
Consultant

## AUDITORS

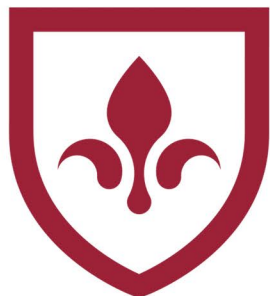
**KPMG LLP**  
600 de Maisonneuve Blvd. West  
Suite 1500  
Montreal, Quebec H3A 0A3

## TRANSFER AGENTS

**Computershare Investor  
Services Inc.**  
100 University Avenue  
9th Floor, North Tower  
Toronto, Ontario M5J 2Y1

## STOCK LISTING

Nasdaq Global Market  
("Nasdaq")  
Toronto Stock Exchange ("TSX")  
Symbol: **BLU**



# Bellus

HEALTH

**BELLUS Health is a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of chronic cough and other hypersensitization-related disorders. The Company's product candidate, BLU-5937, is a highly selective P2X3 antagonist being developed for the treatment of chronic cough and chronic pruritus. The Company's shares trade on the Nasdaq Global Market ("Nasdaq") and the Toronto Stock Exchange ("TSX") under the symbol BLU.**

**BELLUS HEALTH INC.**

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