

## 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 three-month period ended March 31, 2022. In this MD&A, unless the context otherwise requires, the terms "BELLUS Health", "Company", "we", "us", and "our" refer to BELLUS Health Inc. This document should be read in conjunction with our unaudited condensed consolidated interim financial statements for the three-month period ended March 31, 2022, as well as our audited consolidated financial statements for the year ended December 31, 2021.

We prepare our condensed consolidated interim financial statements in accordance with the International Accounting Standard ("IAS") 34, *Interim Financial Reporting* of International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board ("IASB"). The condensed consolidated interim financial statements and MD&A for the three-month period ended March 31, 2022 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 May 11, 2022. Additional information regarding our business and other matters, including related-party transactions, contractual obligations, financial risk management, disclosure controls and procedures, internal control over financial reporting, and risks and uncertainties, can be found in our Annual Report and Annual Information Form for the year ended December 31, 2021, as well as in our annual report on Form 40-F filed with the U.S. Securities and Exchange Commission and our other public filings, which are available on SEDAR at [www.sedar.com](http://www.sedar.com) and on EDGAR at [www.sec.gov/edgar](http://www.sec.gov/edgar). Please also refer to the "Risks and Uncertainties" section, which can be found below.

This document contains forward-looking statements, which are qualified by reference to, and should be read together with the "Forward-Looking Statements" cautionary notice, which can be found below.

All currency figures reported in the condensed consolidated interim financial statements and in this document are in U.S. dollars, unless otherwise specified

## 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 our actual results, performance or achievements, 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. These statements reflect current expectations of management regarding future events and operating performance and speak only as of the date of this MD&A. 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 refractory chronic cough (“RCC”) and other cough-related conditions;
- our aim to have an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (“FDA”) in June of 2022, to obtain scientific advice from the European Medicines Agency (“EMA”) and the Medicines and Healthcare products Regulatory Agency (“MHRA”), and initiate the Phase 3 program in the second half of 2022;
- our aim to initiate a Phase 1 clinical trial investigating a once-daily (“QD”) dosing, extended-release formulation of BLU-5937 in the second half of 2022;
- our aim to complete preclinical studies supporting Phase 3 trials with BLU-5937, in the second half of 2022;
- our aim to complete additional Phase 1 clinical trials supporting Phase 3 trials with BLU-5937 in the second half of 2022;
- our aim to further explore the potential of BLU-5937 for the treatment of other afferent hypersensitization-related conditions;
- our aim to complete all preclinical and clinical Phase 1 studies with BLU-5937 to support NDA filing;
- our expectations with respect to the timing and cost of the research and development activities of BLU-5937;
- the function, potential benefits, tolerability profile, effectiveness and safety of our product candidates, including BLU-5937, including with respect to the patient population studied, pricing and labeling;
- our expectations with respect to pre-commercialization activities related to the commercial launch of BLU-5937, if approved;
- our expectations regarding the potential development of a once-daily dosing regimen of BLU-5937 utilizing an extended-release formulation;
- our expectations regarding our ability to arrange for and scale up the manufacturing of BLU-5937 to reach commercial scale;
- our estimates and assessment of the potential markets (including size) for our product candidates;

- our expectations regarding coverage, reimbursement and pricing and acceptance of our product candidates by the market, if approved, including pricing comparisons with other P2X3 antagonists;
- our estimates and projections regarding the size of the total addressable global RCC market and associated P2X3 revenue potential;
- the benefits and risks of our product candidates as compared to others;
- our aim to obtain marketing authorizations of our product candidates;
- our expectations with respect to the cost of preclinical studies, clinical trials and potential commercialization of our product candidates, including BLU-5937;
- our expectation of the continued listing of the common shares on the TSX and Nasdaq;
- our current and future capital requirements and anticipated sources of financing or revenue;
- our expectations regarding the ongoing COVID-19 pandemic and its impact on our business;
- our expectations regarding the protection of our intellectual property;
- our business strategy; 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 accuracy of our belief that our selective P2X3 antagonist has an improved tolerability profile compared to the most advanced P2X3 receptor antagonist in development, Merck & Co.'s gefapixant;
- our progress, timing and costs related to the development, completion and potential commercialization of our product candidate;
- our estimates and projections regarding our industry;
- the market acceptance of our product candidate;
- the future success of current research and development activities;
- our achievement of development and commercial milestones, including forecasted preclinical study and clinical trial milestones within the anticipated timeframe;
- our reliance on third parties to conduct preclinical studies and clinical trials for BLU-5937;
- the accuracy of the timelines and cost estimates related to our preclinical and clinical programs;
- the successful development of a QD dosing with extended-release formulation for BLU-5937;
- our ability to achieve intended order of market entry of BLU-5937 relative to other P2X3 antagonists;
- the accuracy of our findings of statistically significant interaction between baseline cough frequency and treatment benefit, and realization of the intended benefits of our enrichment strategy;
- the accuracy of our estimates and projections regarding potential pricing for BLU-5937, including parity to other P2X3 antagonists;
- the accuracy of our estimates and projections regarding the size of the total addressable global RCC market and associated P2X3 revenue potential;
- the capacity of our primary supply chain to produce the required clinical supplies to support a Phase 3 program in RCC within the anticipated timeframe, and the absence of further global supply

chain disruptions with respect to such required clinical supplies, including those that may be caused by the COVID-19 pandemic;

- the absence of interruption or delays in the operations of our suppliers of components or raw materials, contract research organizations or other third parties with whom we engage, whether as a result of disruptions caused by the COVID-19 pandemic or otherwise;
- the accuracy of our expectations regarding labeling indication for BLU-5937 in RCC and the potential to expand the use of P2X3 antagonists to all RCC patients;
- the absence of material deterioration in general business and economic conditions, including the impact on the economy and financial markets of the war in Ukraine, and the COVID-19 pandemic and other health risks;
- the effectiveness of COVID-19 containment efforts, including the roll-out of vaccination programs, the effectiveness of vaccines against variant strains of COVID-19 (including the Omicron and Delta variants) and the gradual recovery of global environment and global economic conditions;
- the impact of COVID-19 on participant enrollment;
- the risks of delays and inability to complete clinical trials due to difficulties enrolling patients, including, but not limited to, as a result of the COVID-19 pandemic;
- the receipt of regulatory and governmental approvals to continue with 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;
- our expectations regarding our status as a passive foreign investment company;
- 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;
- the risk of patent-related litigation;
- the 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 and accuracy of our assumptions and projections regarding profile and market dynamic amongst more selective agents;
- 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 the “Risk Factors” section in our Annual Information Form for the year ended December 31, 2021 as well as our other public filings with the Canadian securities regulatory authorities and the United States Securities and Exchange Commission for further risk factors that might affect us and our business. Please also refer to the “Risks and

Uncertainties” section, which can be found below. Should one or more of the risks, uncertainties or other factors outlined in our Annual Information Form for the year ended December 31, 2021 as well as our other public filings 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 developing novel therapeutics for the treatment of RCC and other cough hypersensitivity indications. Our lead product candidate, BLU-5937, is a highly selective and potentially best-in-class antagonist of the P2X3 receptor, a clinically validated target to treat hypersensitivity. We are currently developing BLU-5937 for the treatment of adults with RCC. We believe RCC represents an area of significant unmet medical need and its treatment represents a potentially large market opportunity. Based on our development work to date, we believe BLU-5937 has the potential to become a differentiated and best-in-class treatment option for patients with RCC. On December 13, 2021, we announced that the 50 mg and 200 mg twice-daily (“BID”) doses of BLU-5937 in our Phase 2b SOOTHE trial for the treatment of RCC achieved statistical significance on the primary endpoint with 34% placebo-adjusted reductions in 24-hour cough frequency observed ( $p \leq 0.005$ ). An End-of-Phase 2 meeting with the FDA is scheduled for June of 2022. We will also obtain scientific advice from the EMA and the MHRA. We plan to initiate our Phase 3 program in the second half of 2022.

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

## **BUSINESS OVERVIEW**

### Key Updates

**Following positive topline results from our Phase 2b SOOTHE clinical trial of BLU-5937 in patients with RCC, an End-of-Phase 2 meeting with the FDA is scheduled for June of 2022.**

- In December 2021, we announced that the 50 mg and 200 mg BID doses of BLU-5937 in our SOOTHE trial for the treatment of RCC achieved statistical significance on the primary endpoint with 34% placebo-adjusted reduction in 24-hour cough frequency observed ( $p \leq 0.005$ ) at day 28. BLU-5937 was generally well-tolerated, with a low rate of class-related taste side effects reported by 6.5% of participants at all doses and similar rates of treatment emergent adverse events (“TEAEs”) reported for placebo and BLU-5937. A dose dependent reduction in cough frequency was observed between the 12.5 mg and 50 mg BID doses. The positive SOOTHE results position BLU-5937 as a potential best-in-class product candidate in the P2X3 class based on activity and tolerability data observed to date.
- During the End-of-Phase 2 meeting with the FDA scheduled for June of 2022, we intend to discuss our planned Phase 3 program, which we expect to initiate in the second half of 2022. We will also obtain scientific advice from the EMA and the MHRA.

### **Presenting at the upcoming ATS 2022 International Conference.**

- Three late-breaking abstracts on clinical data from the Phase 2b SOOTHE trial have been accepted for presentation at the upcoming American Thoracic Society (“ATS”) 2022 International Conference (May 13-18, 2022):
  - “Safety And Efficacy of BLU-5937 In the Treatment of Refractory Chronic Cough from the Phase 2b SOOTHE Trial”;
  - “Responders Analyses in Objective 24H Cough Frequency in SOOTHE, a Phase 2b Trial of a Selective P2X3 Antagonist in Refractory Chronic Cough”;
  - “Improvements in Cough Severity and Quality of Life in SOOTHE, a Phase 2b, Dose Finding Trial of BLU-5937 in Refractory Chronic Cough”.

### **Completed a \$224 million offering in December 2021.**

- In December 2021, we completed an offering of our common shares resulting in gross proceeds, including from the underwriters’ partial exercise of their over-allotment option, of \$224 million, and net proceeds of \$209.7 million.

### **Pursuing development of our P2X3 pipeline.**

- We believe the success of our Phase 2b SOOTHE clinical trial further validates the role of P2X3 in cough hypersensitivity. We are evaluating potential opportunities to study BLU-5937 in additional cough indications where cough hypersensitivity plays an important role.
- We expect to initiate a Phase 1 clinical trial investigating a QD dosing, extended-release formulation of BLU-5937 in the second half of 2022.

**Ended the first quarter of 2022 with cash, cash equivalents and short-term investments totaling \$234.0 million.**

## BUSINESS SECTION

### Our Pipeline

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

RCC is a prevalent condition with a high unmet medical need and a significant market opportunity. We are also developing a QD formulation of our lead asset, BLU-5937.

PROGRAM Indication / Project	DEVELOPMENT				STATUS	
	Preclinical	Phase 1	Phase 2	Phase 3	Worldwide Rights	Next Anticipated Step
<b>BLU-5937</b>						
Refractory Chronic Cough (BID Formulation)						June 2022: FDA End of Phase 2 Meeting 2H 2022: Start of Phase 3 Program
Refractory Chronic Cough (QD Formulation)						2H 2022: Phase 1 Trial Initiation

The SOOTHE trial was initiated at the end of 2020, with the first participant dosed in December 2020. In December 2021, we announced that the 50 mg and 200 mg BID doses of BLU-5937 in our SOOTHE trial for the treatment of RCC achieved statistical significance on the primary endpoint with 34% placebo-adjusted reduction in 24-hour cough frequency observed ( $p \leq 0.005$ ) at day 28. BLU-5937 was generally well-tolerated, with low rates of taste-related adverse events reported ( $\leq 6.5\%$ ) at all doses and TEAEs profile comparable to placebo. A dose dependent reduction in cough frequency was observed between the 12.5 mg and 50 mg BID doses. An End-of-Phase 2 meeting with the FDA is scheduled for June of 2022 to discuss our planned Phase 3 program and we will also obtain scientific advice from the EMA and the MHRA. We expect to initiate the Phase 3 program in the second half of 2022.

In September 2021, we announced the completion of participant enrollment and positive findings from a preplanned administrative interim analysis of the trial in which the predefined stringent probability threshold for clinical efficacy was met for at least one and up to all three doses of BLU-5937 tested. Additionally, we announced that limited taste-related adverse events were observed, consistent with previous BLU-5937 trials, and no serious adverse events were reported.

In July 2020, we announced topline results from our Phase 2 RELIEF clinical trial of BLU-5937 that demonstrated proof-of-concept in RCC patients, and also announced our intention to move forward with BLU-5937 in a Phase 2b trial. In September 2020, we announced the design and details of the SOOTHE Phase 2b trial in RCC patients.

We are also developing a BLU-5937 extended-release formulation for QD dosing. We expect to initiate a Phase 1 clinical trial investigating a QD dosing with the extended-release formulation in the second half of 2022.

RCC, our lead indication for BLU-5937, is a cough lasting more than eight weeks that persists despite treatment of any contributing underlying conditions, and may have a significant adverse impact on patients' quality of life. It is estimated that approximately 26 million adults in the United States suffer from chronic cough of which approximately nine million patients are identified as having RCC. It is also estimated that approximately nine million patients suffer from RCC in EU-5. RCC is also highly prevalent in Asia. 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 RCC. Available treatment options are limited and may have inadequate benefit and/or significant safety and tolerability issues. We believe that BLU-5937, if approved, may be adopted by physicians as an oral cough therapy in patients for whom cough hypersensitivity is the primary etiology.

***Phase 2b SOOTHE Clinical Trial***

On December 8, 2020, we announced that the first participant had been dosed in the Phase 2b SOOTHE trial of BLU-5937. On December 13, 2021, we announced the positive topline data from the SOOTHE trial. The primary efficacy endpoint was statistically significant with a 34% placebo-adjusted reduction in 24-hour cough frequency observed at 50 mg and 200 mg BID doses. An End-of-Phase 2 meeting with the FDA is scheduled for June of 2022 to discuss our planned Phase 3 program and we will also obtain scientific advice from the EMA and the MHRA. We expect to initiate the Phase 3 program in the second half of 2022.

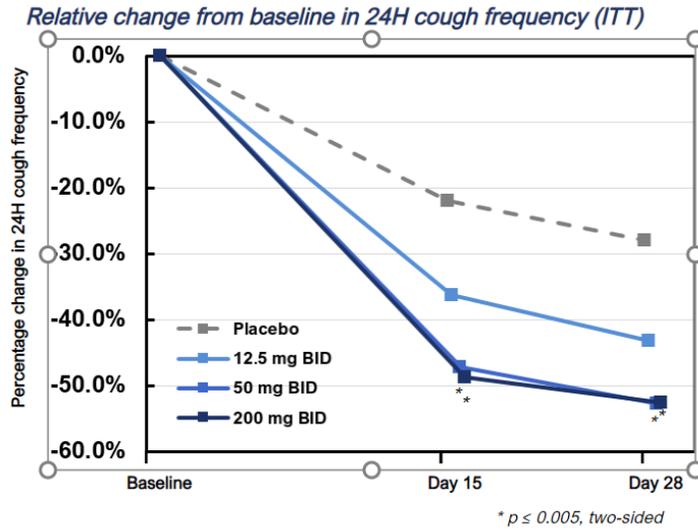
Efficacy Results:

The SOOTHE trial, which enrolled 249 participants with a baseline awake cough frequency of  $\geq 25$  per hour, demonstrated a clinically meaningful and statistically significant placebo-adjusted reduction in 24-hour cough frequency of 34% at the 50 mg and 200 mg BID dose levels of BLU-5937 ( $p \leq 0.005$ ) at day 28. The 12.5 mg BID dose demonstrated a statistical trend with 21% reduction in placebo-adjusted 24-hour cough frequency ( $p = 0.098$ ) with a dose response observed between the 12.5 mg and 50 mg BID doses.

SOOTHE Primary Efficacy Endpoint

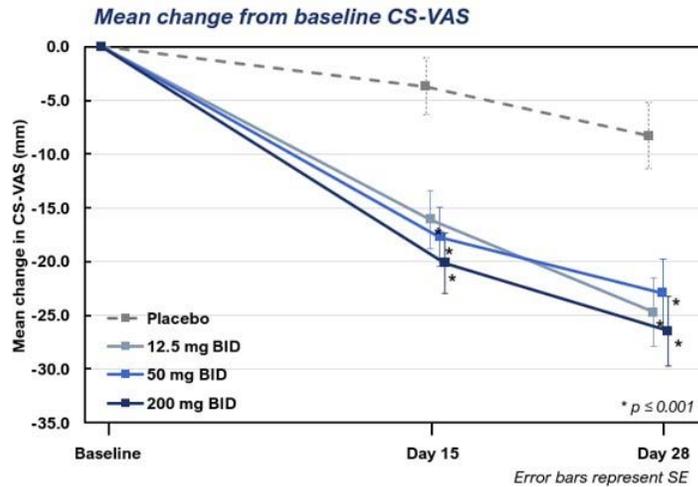
Dose	Placebo-adjusted change in 24-hour cough frequency at day 28	p-value
12.5 mg BID	-21.1%	p=0.098
50 mg BID	-34.4%	p=0.003
200 mg BID	-34.2%	p=0.005

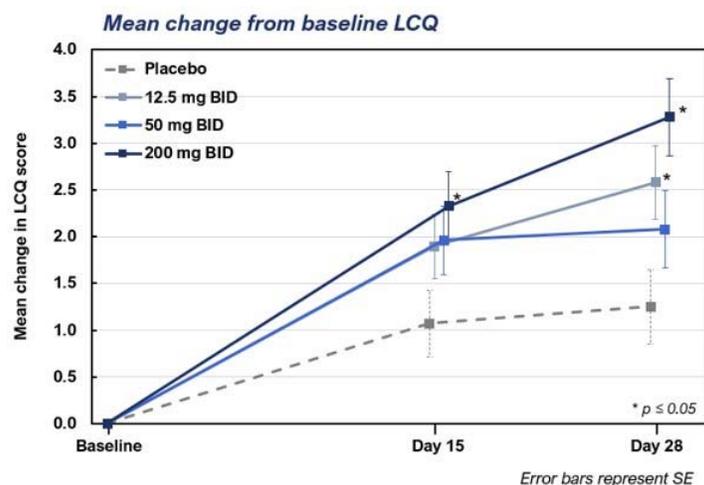
The change from baseline in 24-hour cough frequency was 53% at day 28 with 50 mg and 200 mg BID doses.



Patient Reported Outcomes (“PROs”) constituted secondary endpoints and included Cough Severity Visual Analog Scale (“CS-VAS”) and Leicester Cough Severity Questionnaire (“LCQ”). Even though SOOTHE was not powered to demonstrate statistical significance on the PROs, a clinically meaningful and statistically significant benefit of BLU-5937 was observed at multiple timepoints in the PROs.

SOOTHE Secondary Endpoints: Change from baseline in key patient-reported outcomes





### Safety and Tolerability Results:

BLU-5937's safety and tolerability data were consistent with previous trials, including the Phase 2a RELIEF trial. BLU-5937 was well-tolerated with low impact on taste perception. Taste-related side effects were infrequent at all dose levels with taste alteration observed in 4.8%, 6.5% and 4.8% of participants at 12.5 mg BID, 50 mg BID and 200 mg BID doses, respectively. No participant reported complete or partial taste loss and there were no discontinuations due to taste-related adverse events.

The incidence of TEAEs was comparable to placebo. There were no treatment emergent serious adverse events reported in the trial.

### Treatment Emergent Adverse Events\* \*\*

	Placebo (BID)	BLU-5937 (BID)		
	(n= 63)	12.5 mg (n= 62)	50 mg (n= 62)	200 mg (n= 62)
Subjects with ≥1 TEAE	22 (34.9%)	23 (37.1%)	13 (21.0%)	19 (30.6%)
Subjects with ≥1 TESAE	0	0	0	0
Subjects with TEAE leading to discontinuation, n (%)	1 (1.6%)	0	0	2 (3.2%)
<b>Most Common TEAEs (≥5% at any dose)</b>				
Nausea	0	0	5 (8.1%)	2 (3.2%)
Dysgeusia (taste alteration)	0	3 (4.8%)	4 (6.5%)	3 (4.8%)
UTI	0	3 (4.8%)	0	0
<b>Taste Disturbance Adverse Events (any incidence)</b>				
Dysgeusia (taste alteration)	0	3 (4.8%)	4 (6.5%)	3 (4.8%)
Hypogeusia (partial taste loss)	0	0	0	0
Ageusia (complete taste loss)	0	0	0	0

\* No TEAE reported with an incidence ≥5% in the exploratory population

\*\* TESAE as deemed by investigator. Placebo: worsening of cough; BLU-5937 200 mg BID: worsening of cough, dry mouth. A case of hyperbilirubinemia was reported during the placebo run-in period, prior to randomization of subject to BLU-5937 200 mg BID and resolved after discontinuation of study drug. As it was reported prior to treatment initiation, it was not considered treatment-emergent.

### SOOTHE Trial Design:

The SOOTHE trial was a multicenter, randomized, double-blind, four-week, parallel-arm, placebo-controlled Phase 2b trial evaluating the efficacy and safety of three doses of BLU-5937 (12.5 mg, 50 mg and 200 mg BID) in 310 participants with RCC. Two hundred and forty-nine (249) participants with a baseline awake cough frequency of  $\geq 25$  coughs per hour (“coughs/h”) were randomized across four arms (1:1:1:1) evaluating the three active doses and placebo in the main trial. Treatment arms were stratified to balance the number of participants per treatment group with baseline awake cough frequency  $\geq 45$  coughs/h across trial arms. The primary efficacy endpoint was the change in the 24-hour cough frequency from baseline to day 28 collected with a cough recorder. An exploratory group of an additional 61 participants with a baseline awake cough frequency of  $\geq 10$  and  $< 25$  coughs/h were randomized across two arms (1:1) evaluating one active dose (200 mg BID) and placebo to further investigate the effect of BLU-5937 in patients with lower cough frequency.

A pre-specified, blinded Sample Size Re-Estimation (“SSRE”) analysis was performed in the trial’s main population (participants with  $\geq 25$  coughs/h at baseline). The SSRE analysis was based on the evaluation of the blinded pooled standard deviation for the primary endpoint after approximately 33% of the targeted number of participants were evaluable for the primary endpoint of the trial. Based on the blinded SSRE results, no change was required to the SOOTHE trial size.

On September 13, 2021, we announced positive findings from a preplanned administrative interim analysis of the ongoing Phase 2b SOOTHE trial of BLU-5937 in patients with RCC. Specifically, an independent statistical team reported that the predefined stringent probability threshold for clinical efficacy was met for at least one and up to all three doses of BLU-5937 tested. In addition, the analysis reported that limited taste-related adverse events were observed, consistent with previous trials of BLU-5937, and no serious adverse events were reported. The positive findings from interim analysis of the Phase 2b SOOTHE trial enabled us to accelerate the planning for our Phase 3 program while awaiting the Phase 2b SOOTHE trial final results.

This administrative interim analysis was conducted once approximately 50% of the total planned participants in the main trial completed their 28-day treatment period. Doses were evaluated using predefined efficacy and probability thresholds, with the goal of narrowing down the optimal dose range to confidently prepare for the initiation of the Phase 3 program. The interim analysis was performed for administrative purposes and had no impact on the design or conduct of the SOOTHE trial.

Phase 2b SOOTHE clinical trial enrolled participants in 116 sites of which approximately 50% were in the United States.

On September 23, 2021, we announced that we had completed participant enrollment in the Phase 2b SOOTHE clinical trial of BLU-5937 in RCC.

### **Phase 2a RELIEF Clinical Trial**

In July 2020, we announced topline results from our Phase 2a RELIEF clinical trial of BLU-5937 that demonstrated proof-of-concept in RCC patients. Numerical differences in favor of BLU-5937 were observed in the primary endpoint of reduction in cough frequency. The RELIEF trial did not achieve statistical significance for the primary endpoint of reduction in placebo-adjusted awake cough frequency at any dose tested in the intent to treat population; however, clinically meaningful and statistically significant reductions in cough frequency were observed in two pre-specified sub-group analyses including participants with baseline awake cough frequency of  $\geq 20$  coughs per hour (80% of trial participants) and  $\geq 32$  coughs per hour (50% of trial participants), linking higher baseline cough frequency with improved treatment benefit. In the RELIEF trial, BLU-5937 was well-tolerated and showed an adverse event profile comparable to placebo. The taste disturbance adverse events were limited to 10% or less, confirming the hypothesis that BLU-5937 had a favorable adverse event profile compared to the first generation P2X3 antagonist. Additionally, no complete loss of taste was observed at any dose, no severe taste adverse event was reported and no dropouts due to taste disturbance occurred.

### **Development of a QD Formulation**

We have initiated activities in preparation for the development of a QD formulation for BLU-5937 using an extended-release tablet formulation. We are developing a QD formulation because BLU-5937 has exhibited favorable physico-chemical and pharmacokinetic characteristics, including high solubility and permeability, good absorption in the small and large intestine, linear pharmacokinetic profile, no interaction with food and a low predicted therapeutic dose. A physiological based pharmacokinetic modeling and simulation study has been completed and we have initiated the development of BLU-5937 QD formulation prototypes. We expect to initiate a Phase 1 clinical trial investigating a QD, extended-release formulation of BLU-5937 in the second half of 2022.

### **Competitive Landscape**

In addition to BELLUS Health, other companies are developing P2X3 antagonist product candidates for the treatment of RCC, including Merck & Co. (“Merck”) and Shionogi & Co., Ltd (“Shionogi”). The positive Phase 2b SOOTHE results potentially position BLU-5937 as a best-in-class product candidate in the P2X3 class in terms of activity and tolerability ratio if confirmed in Phase 3 development and approved. Additionally, the greater selectivity for P2X3 over P2X2/3 of our product candidate, BLU-5937, may potentially contribute to supporting a favorable clinical and commercial profile, if approved.

In February 2022, Evotec SE (“Evotec”) announced that its partner, Bayer, had decided to discontinue the development of its P2X3 antagonist program, citing that the overall benefit no longer outweighs the risk in the actively pursued indications. Bayer returned the rights of the entire program to Evotec. Evotec also announced that it plans to evaluate the data and all options.

The table below shows the selectivity, stage of development and dosing regimen of the different P2X3 product candidates currently in the clinic:

	1 <sup>ST</sup> IN CLASS P2X3 ANTAGONIST	2 <sup>ND</sup> GENERATION P2X3 ANTAGONISTS		
<b>Company</b>	 MERCK	 	 SHIONOGI	 Bellus HEALTH
<b>Candidate</b>	Gefapixant	Eliapixant	Sivopixant	BLU-5937
<b>Stage of Development</b>	Approved in Japan	Phase 2b	Phase 2b	Phase 2b
<b>Expected Next Steps</b>	Resubmission in U.S.*; EU decision	Discontinued**	Phase 3 Planning	Phase 3 in 2H 2022
<b>Dosing</b>	BID	BID	QD	BID / QD in development
<b>P2X3 vs. P2X2/3 Selectivity</b>	3-7x <sup>2</sup>	~20x <sup>3</sup>	~ 250x <sup>4</sup>	~ <b>1500x</b>

\* Merck's NDA for gefapixant received a CRL by U.S. FDA in February 2022

\*\* Bayer discontinued eliapixant program and returned rights to Evotec in February 2022

1. Limited head to head studies have been conducted; data presented is derived from company specific disclosures.

2. Ford et al. (2013) FASEB J. 27: 887.5-887.5.

3. Davenport et al. (2021) Sci Rep 6;11(1):19877.

4. Kai et al. 2020 Abstract presented at: ACS Fall 2020 Virtual & Meeting Exposition; August 17-20, 2020.

Merck announced in March of 2020 that the 45 mg BID dose MK-7264 (gefapixant) had reached statistical significance on the primary efficacy endpoint in both the COUGH-1 and COUGH-2 Phase 3 trials and that the 15 mg BID dose had not achieved statistical significance in either trial. Pursuant to this announcement, in September 2020 at the European Respiratory Society (“ERS”) International conference, Merck presented these results in further detail. The 45 mg BID dose of gefapixant achieved a statistically significant result on its primary endpoint of placebo-adjusted reduction in 24-hour cough frequency (18% in the 12-week COUGH-1 trial and 16% in the 24-week COUGH-2 trial) but showed significant rates of taste disturbance adverse events (58% and 69% in the COUGH-1 trial and COUGH-2 trial, respectively). In March 2021, Merck announced that the FDA had accepted their gefapixant New Drug Application (“NDA”) for review. In January 2022, Merck announced that the Japan Ministry of Health, Labor and Welfare granted marketing authorization for gefapixant 45 mg tablets for the treatment of adults with RCC. Additionally, Merck reported that the FDA issued a Complete Response Letter (“CRL”) on which included the need for additional analyses associated with ‘measurement of efficacy’ and that the company planned to meet with the agency to discuss next steps. Merck further clarified in February 2022 that the CRL was not related to the safety of gefapixant, but to an algorithm and underlying methodology used by the audio recording device to assess efficacy. Outside of Japan, gefapixant remains an investigational treatment under review by Health Authorities, such as the EMA.

At the American Thoracic Society International Conference held in August 2020, Bayer announced top-line results from its Phase 2a trial evaluating BAY 1817080 (eliapixant), which demonstrated that higher doses of Bayer's P2X3 antagonist significantly reduced 24-hour cough counts in patients with RCC (ranging from 15% to 25% cough reduction compared to placebo) and cough severity. Taste disturbance adverse events were dose-dependent and reported by 5% to 21% of participants receiving eliapixant. In October 2020, Bayer initiated a Phase 2b trial evaluating three doses of a new formulation of eliapixant in 310 RCC participants. Bayer disclosed on August 3, 2021 that the trial had met its primary endpoint. In August 2021 at the ERS Annual Congress, Bayer presented the efficacy observed in the per-protocol population and the tolerability observed in the safety population. The placebo-adjusted relative changes in 24-hour cough frequency were -12%, -27% and -18% with a 24-hour cough frequency at baseline of 30.3, 31.7 and 21.5 coughs/h for 25 mg, 75 mg and 150 mg BID doses, respectively. Taste disturbances reported for the 25 mg, 75 mg and 150 mg BID doses and placebo groups in the safety analysis population were respectively 4%, 13%, 24% and 4%. Adverse event related discontinuations were 8%. The communication reported that one drug-related serious adverse event was observed in the 150 mg arm during the trial but did not disclose its nature. Bayer also announced that Phase 3 development was warranted. On February 4<sup>th</sup>, 2022, Evotec, Bayer's partner, announced that it had been informed by Bayer about a decision to discontinue the development of eliapixant. Following a review of the available data, Bayer concluded that the overall benefit no longer outweighs the risk in the actively pursued indications. As a consequence of Bayer's decision, Evotec announced that it has regained the rights to all P2X3 assets. The company indicated that it would evaluate the underlying data as soon as they are made available and would assess all options.

Shionogi announced top-line results from its Phase 2a trial of S-600918 (sivopixant) in patients with RCC at the ERS International Congress in October 2019, which included a placebo-adjusted reduction in 24-hour cough frequency of 32% ( $p=0.055$ ) and a rate of 6.5% of taste disturbance adverse events. The mean cough per hour frequency at baseline was 56. At the 2020 ERS International Congress, Shionogi reported that they observed an interaction between baseline cough frequency and treatment effect in its Phase 2a trial; this prompted the utilization of a minimal cough frequency threshold as an inclusion criterion in the Phase 2b trial of sivopixant. On September 29, 2021, Shionogi announced that the primary endpoint of placebo adjusted change in 24-hour cough frequency in its Phase 2b trial of sivopixant was not met at any dose in the full analysis set (+13%, -2% and -12% for 50 mg, 150 mg and 300 mg QD, respectively). Post hoc analysis of patients with a 24-hour cough frequency  $\geq 10$  or more coughs/h at baseline demonstrated 23% reduction in placebo-adjusted cough frequency for 300 mg QD. Taste related adverse events reported for the 50 mg, 150 mg, 300 mg and placebo groups in the safety analysis population were 2%, 14% and 33% and 2.9%, respectively. Shionogi has indicated that it plans to discuss dose selection and Phase 3 design at an upcoming "End-of-Phase 2" meeting with the FDA. On a conference call in January 2022, Shionogi mentioned in its presentation that it is preparing for Phase 3.

### Market Opportunity in Chronic Cough

According to the 2018 National Ambulatory Medical Care Survey, across the U.S. in 2018, cough was the reason for 18.5 million in-office physician consultations and five million emergency visits.

We estimate that 10% of the adult population in developed countries suffer from chronic cough including the United States, nations in the European Union, the United Kingdom and Japan. This represents approximately 26 million patients with chronic cough in the United States alone.

We estimate that approximately 30% of chronic cough patients, or approximately nine million patients in the U.S., are uncontrolled or have RCC, which is the expected addressable patient population for BLU-5937. It is also estimated that approximately nine million patients suffer from RCC in the EU5 countries. RCC is also prevalent in Asia. These RCC patients continue to cough despite treatment for potential underlying causes of their cough or their cough is unexplained.

### **Supporting Preclinical and Clinical Development Activities**

We continue to plan and conduct supporting preclinical, toxicology and clinical development activities for the anticipated Phase 3 RCC program and/or NDA, including: a 9-month chronic toxicity study in dogs, and long-term carcinogenicity studies in mice and rats.

### **Chemistry, Manufacturing, and Controls (“CMC”)**

We have a primary supply chain in place with the capacity to produce the required clinical supplies to support a Phase 3 program in RCC and commercial supplies for a potential launch, if BLU-5937 is approved. We continue to work on activities associated with manufacturing process optimization and upscaling in anticipation of a potential commercial launch.

### **BLU-5937 in Other P2X3 Hypersensitization-Related Disorders**

We believe the success of our Phase 2b SOOTHE trial further validates the role of P2X3 in cough hypersensitivity. We are evaluating potential opportunities to study BLU-5937 in additional cough indications where cough hypersensitivity plays an important role.

### **Intellectual Property**

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, all with an expiration date of 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 avoiding loss of taste response while treating a chronic cough patient through treatment with BLU-5937, expiring in 2038. Patent applications with similarly broad claims are currently pending in other industrialized nations. We own 100% of the BLU-5937 and certain related P2X3 antagonists intellectual property assets.

## RESULTS OF OPERATIONS

For the three-month period ended March 31, 2022, net loss amounted to \$14,352,000 (\$0.13 per share), compared to \$15,751,000 (\$0.20 per share) for the corresponding period the previous year. The decrease in net loss is primarily attributable to lower research and development expenses in relation to the development of BLU-5937.

*Research and development expenses*, net of research tax credits, amounted to \$11,254,000 for the three-month period ended March 31, 2022, compared to \$12,448,000 for the corresponding period the previous year, a decrease of \$1.2 million or 10% year over year. The decrease in research and development expenses is primarily attributable to the decrease in external R&D spend as we are transitioning from our Phase 2b SOOTHE trial and are in the planning stage of our Phase 3 program, which is expected to be initiated in the second half of 2022. The decrease is partially offset by higher expenses due to our increased workforce to support the next steps in our development plans for BLU-5937.

*General and administrative expenses* amounted to \$4,050,000 for the three-month period ended March 31, 2022, compared to \$3,470,000 for the corresponding period the previous year, an increase of \$0.6 million or 17% year over year. The increase is mainly attributable to higher expenses related to pre-commercial activities.

*Net finance income* amounted to \$973,000 for the three-month period ended March 31, 2022, compared to \$163,000 for the corresponding period the previous year. The increase in net finance income is mainly attributable to a higher foreign exchange gain of \$959,000 resulting from the conversion in US dollars of our net monetary assets denominated in Canadian dollars during the period.

### Quarterly Results (Unaudited)

(in thousands of dollars, except per share data)

	2022 Q1	2021 Q4	2021 Q3	2021 Q2	2021 Q1	2020 Q4	2020 Q3	2020 Q2
Revenues	\$4	\$4	\$4	\$4	\$4	\$4	\$3	\$4
Expenses:								
Research and development, net	11,254	12,334	19,054	15,201	12,448	5,017	5,796	5,899
General and administrative	4,050	4,167	3,821	2,805	3,470	3,078	456	3,439
Total operating expenses	15,304	16,501	22,875	18,006	15,918	8,095	6,252	9,338
Operating loss	(15,300)	(16,497)	(22,871)	(18,002)	(15,914)	(8,091)	(6,249)	(9,334)
Net finance income (costs)	973	1,534	(10)	174	163	597	540	912
Loss before income taxes	(14,327)	(14,963)	(22,881)	(17,828)	(15,751)	(7,494)	(5,709)	(8,422)
Income taxes	25	(199)	-	-	-	-	-	-
Net loss	\$( 14,352)	\$( 14,764)	\$( 22,881)	\$( 17,828)	\$( 15,751)	\$( 7,494)	\$( 5,709)	\$( 8,422)
Loss per share	\$( 0.13)	\$( 0.18)	\$( 0.29)	\$( 0.23)	\$( 0.20)	\$( 0.10)	\$( 0.09)	\$( 0.14)

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

The decrease in net loss for the first quarter of 2022 is primarily attributable to lower research and development expenses. The increase in net loss for the fourth and third quarters of 2021 is primarily attributable to higher research and development expenses as well as to a higher stock-based compensation expense related to our deferred share unit plan. The increase in net loss for the second quarter of 2021 is primarily attributable to higher research and development expenses.

### **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 CAD\$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 \$75,000 and \$75,000 (each equivalent to CAD\$95,000) under the consulting and services agreement for the three-month periods ended March 31, 2022 and 2021, respectively.

## **FINANCIAL CONDITION**

### **Liquidity and Capital Resources**

As at March 31, 2022, we had available cash, cash equivalents and short-term investments totaling \$233,968,000, compared to \$248,806,000 as at December 31, 2021. For the three-month period ended March 31, 2022, the net decrease in cash, cash equivalents and short-term investments amounted to \$14,838,000, compared to \$16,237,000 for the corresponding period of the previous year. The net decrease for the three-month period ended March 31, 2022 is primarily attributable to funds used to finance our operating activities, mainly the research and development activities associated with our product candidate BLU-5937.

Based on management's estimate and current level of operations, we believe that our current cash, cash equivalents and short-term investments are projected to be sufficient to fund our operating plan for the foreseeable future. We will need to raise additional capital to fund our operations and to develop BLU-5937.

In December 2021, we raised total gross proceeds of \$224,000,000 from the 2021 Offering by issuing a total of 28,000,000 common shares at a price of \$8 per share including the partial exercise of the underwriters' option to purchase 3,000,000 common shares. Net proceeds from the 2021 Offering amounted to \$209,729,000. We intend to use the net proceeds of the 2021 Offering primarily to fund research and development activities, general and administrative expenses, working capital needs and other general corporate purposes. The use of proceeds presented in our prospectus supplement dated December 14, 2021 did not include funds from the exercise of the underwriters' overallotment option. Taking into consideration these additional funds, we intend to use the net proceeds of the 2021 Offering for the purposes and in the amounts indicated below, with the remaining net proceeds allocated to administrative expenses, working capital and other general corporate purposes.

	As per December 14, 2021 prospectus supplement	As at May 11, 2022, including overallotment option
BLU-5937 clinical trials in chronic cough	\$ 135.9 million	\$ 146.0 million
Manufacturing, formulation and scale-up	\$ 12.4 million	\$ 20.1 million
Other project costs	\$ 18.5 million	\$ 22.8 million

As at March 31, 2022, we have not used any of the 2021 Offering net proceeds.

On December 23, 2020, we entered into an “at-the-market” (“ATM”) sales agreement (the “Sales Agreement”) with Jefferies LLC (“Jefferies”) pursuant to which we may from time to time sell through at-the-market distributions with Jefferies acting as sales agent (the “Agent”), our common shares for aggregate gross proceeds of up to \$50,000,000, including sales made directly on the Nasdaq or on any other existing trading market for the common shares in the United States. No common shares will be offered or sold in Canada. The Common Shares would be issued at market prices prevailing at the time of the sale and, as a result, prices may vary between purchasers and during the period of distribution. The ATM has a 2-year term and requires us to pay to the Agent a commission of up to 3.0% of the gross proceeds of any common shares sold. Subject to the terms and conditions of the Sales Agreement, the Agent will use its commercially reasonable efforts to sell the common shares from time to time, based upon our instructions. We have no obligation to sell any of the common shares and may at any time suspend sales under the Sales Agreement. We and the Agent may terminate the Sales Agreement in accordance with its terms. Under the terms of the Sales Agreement, we have provided the Agent with customary indemnification rights and the Agent will be entitled to compensation, as previously mentioned. During the three-month period ended March 31, 2021, no common shares were sold under the ATM program.

During the three-month period ended March 31, 2022, we purchased short-term investments with initial maturities greater than three months and less than a year for an aggregate amount of \$22,500,000, and redeemed at maturity or sold short-term investments for an aggregate amount of \$35,072,000. We did not sell nor redeem at maturity short-term investments with initial maturities greater than three months and less than a year in 2021.

There has been no significant change to our contractual obligations since December 31, 2021 other than in the ordinary course of business. As at March 31, 2022, we had commitments for expenditures related to contracts for research and development activities of approximately \$20,473,000 (approximately \$15,153,000 as at December 31, 2021), of which \$12,097,000 is expected to be payable in 2022, \$7,087,000 in 2023 and \$1,289,000 in 2024.

On March 16, 2021, a Company stockholder, Carl D. Cachia (“Plaintiff”), filed a complaint against the Company and certain of its executive officers alleging claims under provisions of the Securities Exchange Act of 1934 (“Exchange Act”). On September 17, 2021, Plaintiff filed an amended class action complaint, individually and on behalf of all persons who purchased or otherwise acquired Company securities between September 5, 2019 and July 6, 2020, against the Company, certain of its executive officers, the principal investigator of the Company’s Phase 2a RELIEF trial, and the underwriters of the Company’s initial public offering in September 2019. The amended class action complaint alleges claims under the Exchange Act and the Securities Act of 1933 relating to disclosures concerning the Company’s Phase 2a RELIEF trial, and seeks compensatory damages, pre-judgment and post-judgment interest, as well as attorneys’ fees, expert fees, and any other reasonable costs and expenses. On November 16, 2021, Plaintiff stipulated to dismissal of all claims against the underwriters without prejudice. Also on November 16, the Company and the named executive officers moved to dismiss the amended complaint, which motion is pending. On January 7, 2022, the principal investigator of the Company’s Phase 2a RELIEF trial also moved to dismiss the amended complaint, which motion is pending.

No provision has been made in the financial statements for the resolution of the above matter. Resolution of this matter could have an effect on our financial statements in the period that a determination is made, however, in management’s opinion, given the early stage of this litigation, the final resolution of this matter is not currently projected to have a material adverse effect on our financial position.

During the three-month period ended March 31, 2022, we granted 3,335,000 stock options, 436,388 stock options were exercised and 56,000 stock options were forfeited.

As at May 11, 2022, we had 106,747,804 common shares outstanding and 117,580,249 common shares on a fully diluted basis, including 10,832,445 stock options granted under the stock option plan.

## **CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

The preparation of our condensed consolidated interim financial statements in accordance with IFRS requires management to make judgements, 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.

In preparing these condensed consolidated interim financial statements, the significant judgements made by management in applying our accounting policies and key sources of estimation uncertainty were the same as those applied to the consolidated financial statements for the year ended December 31, 2021.

Refer to the audited consolidated financial statements for the year ended December 31, 2021 for discussions on our accounting policies and estimates that are most important in assessing, understanding and evaluating our consolidated financial statements. Change in these estimates and assumptions could have a significant impact on our consolidated financial statements.

## **CHANGES IN ACCOUNTING POLICIES**

The accounting policies and basis of measurement applied in our condensed consolidated interim financial statements as at March 31, 2022 are the same as those applied in our consolidated financial statements for the year ended December 31, 2021.

## **CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING (ICFR)**

There have been no changes in our ICFR that occurred during the period beginning January 1, 2022 and ended March 31, 2022 that have materially affected, or are reasonably likely to materially affect, our ICFR.

## **RISKS AND UNCERTAINTIES**

We are a clinical-stage biopharmaceutical company that operates in an industry that is dependent on a number of factors that include the capacity to raise additional capital on reasonable terms, obtain positive results of clinical trials, obtain positive results of clinical trials without serious adverse or inappropriate side effects, and obtain market acceptance of its product. An investment in our common shares is subject to a number of risks and uncertainties. An investor should carefully consider the risks described in our AIF and our annual report on Form 40-F filed with the U.S. Securities and Exchange Commission, as well as our other public filings with the securities regulators before investing in our common shares. If any of such described risks occur, or if others occur, our business, operating results and financial condition could be seriously harmed, and investors may lose a significant proportion of their investment. There are important risks which management believes could impact our business. For information on risks and uncertainties, please refer to the "Risk Factors" section of our most recent AIF filed on SEDAR at [www.sedar.com](http://www.sedar.com) and included in the annual report on exhibit 99.3 to Form 40-F filed on EDGAR at [www.sec.gov/edgar](http://www.sec.gov/edgar) and our other public filings.

# BELLUS HEALTH INC.

Condensed Consolidated Interim Statements of Financial Position  
(Unaudited)

March 31, 2022 and December 31, 2021  
(In thousands of United States dollars)

	March 31, 2022	December 31, 2021
<b>Assets</b>		
Current assets:		
Cash and cash equivalents (note 4)	\$ 147,155	\$ 150,078
Short-term investments (note 4)	86,813	98,728
Trade and other receivables	536	369
Research tax credit receivable	1,138	1,000
Prepaid expenses and other assets	9,369	8,029
<b>Total current assets</b>	<b>245,011</b>	<b>258,204</b>
Non-current assets:		
Right-of-use asset	791	853
Other assets	225	218
Deferred tax asset	200	220
In-process research and development asset (note 5)	50,100	50,100
<b>Total non-current assets</b>	<b>51,316</b>	<b>51,391</b>
<b>Total Assets</b>	<b>\$ 296,327</b>	<b>\$ 309,595</b>
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities:		
Trade and other payables	\$ 15,663	\$ 16,674
Current income tax liabilities	26	21
Lease liability	291	254
<b>Total current liabilities</b>	<b>15,980</b>	<b>16,949</b>
Non-current liabilities:		
Lease liability	554	617
<b>Total non-current liabilities</b>	<b>554</b>	<b>617</b>
<b>Total Liabilities</b>	<b>16,534</b>	<b>5,998</b>
Shareholders' equity:		
Share capital (note 6 (a))	800,015	799,391
Other equity (notes 6 (b) (i))	39,156	37,664
Deficit	(568,676)	(554,324)
Accumulated other comprehensive income	9,298	9,298
<b>Total Shareholders' Equity</b>	<b>279,793</b>	<b>292,029</b>
Commitments and contingencies (note 9)		
<b>Total Liabilities and Shareholders' Equity</b>	<b>\$ 296,327</b>	<b>\$ 309,595</b>

See accompanying notes to unaudited condensed consolidated interim financial statements.

# BELLUS HEALTH INC.

Condensed Consolidated Interim Statements of Loss and Other Comprehensive Loss  
(Unaudited)

Periods ended March 31, 2022 and 2021  
(in thousands of United States dollars, except per share data)

	Three-month periods ended	
	March 31,	
	2022	2021
Revenues	\$ 4	\$ 4
Expenses:		
Research and development	11,380	12,586
Research tax credits	(126)	(138)
	11,254	12,448
General and administrative	4,050	3,470
Total operating expenses	15,304	15,918
Loss from operating activities	(15,300)	(15,914)
Finance income	1,255	189
Finance costs	(282)	(26)
Net finance income (note 7)	973	163
Loss before income taxes	(14,327)	(15,751)
Income taxes	25	—
Net loss and total comprehensive loss for the period	\$ (14,352)	\$ (15,751)
Net loss per share (note 8)		
Basic and diluted	\$ (0.13)	\$ (0.20)

See accompanying notes to unaudited condensed consolidated interim financial statements.

# BELLUS HEALTH INC.

## Condensed Consolidated Interim Statements of Changes in Shareholders' Equity (Unaudited)

Periods ended March 31, 2022 and 2021  
(in thousands of United States dollars)

	Share capital (note 6 (a))	Other equity	Deficit	Accumulated other comprehensive income	Total
Balance, December 31, 2021	\$ 799,391	\$ 37,664	\$ (554,324)	\$ 9,298	\$ 292,029
Total comprehensive loss for the period:					
Net loss and comprehensive loss	—	—	(14,352)	—	(14,352)
Total comprehensive loss for the period	—	—	(14,352)	—	(14,352)
Transactions with shareholders, recorded directly in shareholders' equity:					
Issued upon stock option exercises (note 6 (b) (i))	624	(541)	—	—	83
Stock-based compensation (note 6 (b) (i))	—	2,033	—	—	2,033
Balance, March 31, 2022	\$ 800,015	\$ 39,156	\$ (568,676)	\$ 9,298	\$ 279,793

	Share capital (note 6 (a))	Other equity	Deficit	Accumulated other comprehensive income	Total
Balance, December 31, 2020	\$ 575,286	\$ 31,360	\$ (468,829)	\$ 9,298	\$ 147,115
Total comprehensive loss for the period:					
Net loss and comprehensive loss	—	—	(15,751)	—	(15,751)
Total comprehensive loss for the period	—	—	(15,751)	—	(15,751)
Transactions with shareholders, recorded directly in shareholders' equity:					
Stock-based compensation (note 6 (b) (i))	—	1,721	—	—	1,721
Balance, March 31, 2021	\$ 575,286	\$ 33,081	\$ (484,580)	\$ 9,298	\$ 133,085

See accompanying notes to unaudited condensed consolidated interim financial statements.

# BELLUS HEALTH INC.

## Condensed Consolidated Interim Statements of Cash Flows (Unaudited)

Periods ended March 31, 2022 and 2021  
(in thousands of United States dollars)

	Three-month periods ended March 31,	
	2022	2021
<b>Cash flows from operating activities:</b>		
Net loss for the period	\$ (14,352)	\$ (15,751)
Adjustments for:		
Depreciation	72	45
Stock-based compensation	2,033	1,721
Net finance income	(973)	(163)
Other items	11	(21)
Changes in operating assets and liabilities		
Trade and other receivables	(164)	(156)
Research tax credits receivable	(126)	(138)
Prepaid expenses and other assets	(1,415)	(799)
Deferred tax asset	20	—
Trade and other payables	(93)	(806)
Current income tax liabilities	5	—
	(14,982)	(16,068)
<b>Cash flows from financing activities:</b>		
Payment of share issue costs - 2021 Offering	(746)	—
Issuance of common shares upon stock option exercises	83	—
Payment of deferred financing costs	(142)	(420)
Lease liability – principal repayments	(52)	(34)
Interest paid	(5)	(18)
	(862)	(472)
<b>Cash flows from investing activities:</b>		
Purchases of short-term investments	(22,500)	—
Sales of short-term investments	35,072	—
Interest received	72	22
	12,644	22
Net decrease in cash and cash equivalents	(3,200)	(16,518)
Cash and cash equivalents, beginning of period	150,078	48,889
Effect of foreign exchange on cash and cash equivalents	277	86
Cash and cash equivalents, end of period	\$ 147,155	\$ 32,457
<b>Supplemental cashflow disclosure:</b>		
<b>Non-cash transactions:</b>		
Share issue costs related to equity offerings, in Trade and other payables	\$ 25	\$ —
Ascribed value related to issuance of common shares upon stock options exercise (note 6 (b) (i))	541	—
Value of DSUs in Prepaid expenses (note 6 (b) (ii))	34	24

See accompanying notes to unaudited condensed consolidated interim financial statements.

# BELLUS HEALTH INC.

Notes to Condensed Consolidated Interim Financial Statements  
(Unaudited)

Periods ended March 31, 2022 and 2021

(in thousands of United States 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 refractory chronic cough (“RCC”) and other cough hypersensitivity indications. The Company's product candidate, BLU-5937, is a highly selective P2X3 antagonist in development for RCC and other cough hypersensitivity indications. The Company is domiciled in Canada. The address of the Company's registered office is 275 Armand-Frappier Blvd., Laval, Quebec, 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.

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

The annual consolidated financial statements of the Company as at and for the year ended December 31, 2021 are available on our web site at [www.bellushealth.com](http://www.bellushealth.com), on SEDAR at [www.sedar.com](http://www.sedar.com) and on EDGAR at [www.sec.gov/edgar](http://www.sec.gov/edgar).

## 2. Basis of preparation:

### (a) Statement of compliance:

These condensed consolidated interim financial statements have been prepared in accordance with International Accounting Standard (IAS) 34, *Interim Financial Reporting* of International Financial Reporting Standards (“IFRS”). The condensed consolidated interim financial statements do not include all the information required for full annual consolidated financial statements and should be read in conjunction with the annual consolidated financial statements as at and for the year ended December 31, 2021. These condensed consolidated interim financial statements have not been reviewed by the Company's auditors.

These condensed consolidated interim financial statements for the three-month period ended March 31, 2022 were approved by the Board of Directors on May 11, 2022.

### (b) Use of estimates and judgements:

The preparation of the condensed consolidated interim financial statements in accordance with IFRS requires management to make judgements, 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 estimates of the most probable set of economic conditions and planned course of actions. Actual results may differ from these estimates.

# BELLUS HEALTH INC.

Notes to Condensed Consolidated Interim Financial Statements (Continued)  
(Unaudited)

Periods ended March 31, 2022 and 2021  
(in thousands of United States dollars, except per share data, unless otherwise noted)

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## 2. Basis of preparation (continued):

### (b) Use of estimates and judgements (continued):

In preparing these condensed consolidated interim financial statements, the significant judgements made by management in applying the Company's accounting policies and key sources of estimation uncertainty were the same as those applied to the consolidated financial statements for the year ended December 31, 2021.

### (c) Functional and presentation currency:

Items included in the condensed consolidated interim financial statements of the Company are measured using the currency of the primary economic environment in which the Company operates (the functional currency). These condensed consolidated interim financial statements are presented in United State dollars ("USD"), which is the Company's functional and presentation currency for all periods presented.

### (d) COVID-19 pandemic:

The COVID-19 pandemic continues to cause significant financial market and social disruption. The Company cannot presently predict the scope and severity of any potential business shutdowns or disruptions related to COVID-19, the impact of any new variants nor the impact of the vaccines that are now accessible. If the Company or any of the third parties with whom it engages, were to experience shutdowns or other business disruptions due to the pandemic, its ability to conduct its business in the manner and on the timelines presently planned could be materially and negatively impacted. The Company will continue to monitor developments of the pandemic and continuously assess its potential further impact on its operations to prevent any disruptions to the conduct of its business and clinical trials. In the event of a prolonged continuation of the pandemic, it is not clear what the potential impact may be on the Company's business, financial position and financial performance.

## 3. Significant accounting policies and basis of measurement:

The accounting policies and basis of measurement applied in these condensed consolidated interim financial statements are the same as those applied by BELLUS Health in its consolidated financial statements for the year ended December 31, 2021.

# BELLUS HEALTH INC.

Notes to Condensed Consolidated Interim Financial Statements (Continued)  
(Unaudited)

Periods ended March 31, 2022 and 2021

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

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

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

	March 31, 2022	December 31, 2021
Cash balances with banks	\$ 3,248	\$ 31,841
Short-term investments with initial maturities of three months or less or that can be withdrawn on demand: Savings accounts and term deposits, yielding interest at 0.21% to 0.73% as at March 31, 2022 (December 31, 2021 – 0.15% to 0.73%)	143,907	118,237
Cash and cash equivalents	147,155	150,078
Short-term investments with initial maturities greater than three months: Term deposits issued in CAD (CAD \$34,083), yielding interest at 0.45% to 1.10% as at March 31, 2022 (December 31, 2021 – (CAD \$34,007), 0.45% to 1.10%)	27,253	26,906
Bearer deposit notes, yielding interest at 0.40% as at March 31, 2022 (December 31, 2021 – 0.40%)	59,560	37,003
Bearer deposit notes issued in CAD (CAD \$44,008), yielding interest at 0.80% to 0.85% as at December 31, 2021	—	34,819
Short-term investments	86,813	98,728
Cash, cash equivalents and short-term investments	\$ 233,968	\$ 248,806

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

As at March 31, 2022 and December 31, 2021, the aggregate carrying value of the in-process research and development (“IPR&D”) asset related to BLU-5937 amounted to \$50,100. The IPR&D asset related to BLU-5937 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.

# BELLUS HEALTH INC.

Notes to Condensed Consolidated Interim Financial Statements (Continued)  
(Unaudited)

Periods ended March 31, 2022 and 2021  
(in thousands of United States dollars, except per share data, unless otherwise noted)

## 6. Shareholders' equity:

### (a) Share capital:

Changes in issued and outstanding common shares for the three-month periods ended March 31, 2022 and 2021 were as follows:

	Number	Dollars
Balance, December 31, 2021	106,390,361	\$ 799,391
Issued upon stock option exercises (note 6 (b) (i))	354,070	624
Balance, March 31, 2022	106,744,431	\$ 800,015

	Number	Dollars
Balance, March 31, 2021 and December 31, 2020	78,337,361	\$ 575,286

### "At-the-market" sales agreement

On December 23, 2020, the Company entered into an "at-the-market" (ATM) sales agreement (the "Sales Agreement") with Jefferies LLC ("Jefferies") pursuant to which the Company may from time to time sell through at-the-market distributions with Jefferies acting as sales agent (the "Agent") its common shares for aggregate gross proceeds of up to \$50,000, including sales made directly on the Nasdaq or on any other existing trading market for the common shares in the United States. No common shares will be offered or sold in Canada. The common shares would be issued at market prices prevailing at the time of the sale and, as a result, prices may vary between purchasers and during the period of distribution. The ATM has a 2-year term and requires the Company to pay to the Agent a commission of up to 3.0% of the gross proceeds of any common shares sold. Subject to the terms and conditions of the Sales Agreement, the Agent will use its commercially reasonable efforts to sell the common shares from time to time, based upon the Company's instructions. The Company has no obligation to sell any of the common shares and may at any time suspend sales under the Sales Agreement. The Company and the Agent may terminate the Sales Agreement in accordance with its terms. Under the terms of the Sales Agreement, the Company has provided the Agent with customary indemnification rights.

During the three-month period ended March 31, 2022, no common shares were sold under the ATM program. As at March 31, 2022 and December 31, 2021, total costs incurred to register the Sales Agreement, amounting to \$390, are recorded as deferred financing costs and classified as prepaids and other assets in the consolidated statement of financial position. Under an ATM program, proportional costs for commission, legal and costs related to common shares sold are reclassified from deferred financing costs to deficit upon share issuance.

# BELLUS HEALTH INC.

Notes to Condensed Consolidated Interim Financial Statements (Continued)  
(Unaudited)

Periods ended March 31, 2022 and 2021  
(in thousands of United States dollars, except per share data, unless otherwise noted)

## 6. Shareholders' equity (continued):

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

#### (i) Stock option plan:

Changes in outstanding stock options issued under the stock option plan for the three-month periods ended March 31, 2022 and 2021 were as follows:

	Number	Weighted average exercise price <sup>(1)</sup>
Balance, December 31, 2021	7,774,833	\$3.97
Granted <sup>(2),(3)</sup>	3,335,000	\$6.94
Exercised <sup>(4)</sup>	436,388	\$1.46
Forfeited	(56,000)	\$4.34
Balance, March 31, 2022	10,617,445	\$5.01

	Number	Weighted average exercise price <sup>(1)</sup>
Balance, December 31, 2020	6,288,166	\$3.83
Granted <sup>(5),(6)</sup>	1,458,000	\$4.34
Forfeited	(39,000)	\$3.28
Balance, March 31, 2021	7,707,166	\$3.93

<sup>(1)</sup> USD equivalent of stock options granted in CAD is presented at the closing rate of the corresponding period.

<sup>(2)</sup> 2,945,000 stock options were granted on February 23, 2022, having an exercise price of \$7.01; 2,320,000 stock options were granted to key management personnel and 625,000 were granted to other employees.

<sup>(3)</sup> 390,000 stock options were granted to key management personnel on March 23, 2022, having an exercise price of \$6.38.

<sup>(4)</sup> Of these stock options exercised, 354,070 common shares were issued, and 82,318 stock options were returned to the Company and cancelled as a result of the cashless exercise feature provided in the Company's stock option plan.

<sup>(5)</sup> 1,408,000 stock options were granted on February 25, 2021, having an exercise price of \$4.36; 1,171,000 stock options granted to key management personnel and 237,000 granted to other employees.

<sup>(6)</sup> 50,000 stock options were granted to key management personnel on March 30, 2021, having an exercise price of \$3.83.

# BELLUS HEALTH INC.

Notes to Condensed Consolidated Interim Financial Statements (Continued)  
(Unaudited)

Periods ended March 31, 2022 and 2021  
(in thousands of United States dollars, except per share data, unless otherwise noted)

## 6. 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 March 31, 2022:

Exercise price/share	Options outstanding		Options exercisable
	Number	Weighted average years To expiration	Number
Stock options granted in USD			
\$3.83	50,000	9.0	10,000
\$3.92	50,000	9.1	—
\$4.36	1,388,000	8.9	273,400
\$6.38	390,000	10.0	—
\$7.01	2,945,000	9.9	—
\$7.04	160,000	8.9	—
Stock options granted in CAD <sup>(1)</sup>			
\$0.86 (CAD \$1.08)	667,222	5.1	523,611
\$1.01 (CAD \$1.26)	1,111,113	5.9	882,224
\$1.21 (CAD \$1.51)	41,667	5.6	33,333
\$1.44 (CAD \$1.80)	666,945	0.4	666,945
\$1.64 (CAD \$2.05)	41,667	6.3	25,000
\$2.51 (CAD \$3.14)	165,000	8.6	33,000
\$2.86 (CAD \$3.58)	30,000	8.4	6,000
\$3.22 (CAD \$4.03)	28,611	3.9	28,611
\$3.29 (CAD \$4.12)	420,000	8.7	84,000
\$3.48 (CAD \$4.36)	974,998	6.9	582,777
\$6.71 (CAD \$8.39)	512,222	7.6	204,889
\$11.12 (CAD \$13.91)	910,000	8.0	182,000
\$11.77 (CAD \$14.72)	65,000	8.1	13,000
	10,617,445	7.8	3,548,790

<sup>(1)</sup> USD equivalent of stock options granted in CAD is presented at the closing rate.

# BELLUS HEALTH INC.

Notes to Condensed Consolidated Interim Financial Statements (Continued)  
(Unaudited)

Periods ended March 31, 2022 and 2021  
(in thousands of United States dollars, except per share data, unless otherwise noted)

## 6. Shareholders' equity (continued):

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

#### (i) Stock option plan (continued):

##### Stock-based compensation

For the three-month period ended March 31, 2022, the Company recorded a stock-based compensation expense related to the stock option plan (excluding compensation under the DSU plans) in the amount of \$2,033 in the condensed consolidated interim statement of loss and other comprehensive loss; of this amount, \$699 is presented in Research and development expenses and \$1,334 is presented in General and administrative expenses (\$1,721 for the corresponding period of the previous year, \$574 and \$1,147 respectively presented in Research and development and 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. The weighted average assumptions for stock options granted during the three-month periods ended March 31, 2022 and 2021 were as follows:

	2022	2021
Weighted average fair value of stock options at grant date	\$5.13	\$3.36
Weighted average share price	\$6.94	\$4.34
Weighted average exercise price	\$6.94	\$4.34
Risk-free interest rate	1.96%	0.94%
Expected volatility	100%	112%
Expected life in years	7	7
Expected dividend yield	Nil	Nil

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.

# BELLUS HEALTH INC.

Notes to Condensed Consolidated Interim Financial Statements (Continued)  
(Unaudited)

Periods ended March 31, 2022 and 2021  
(in thousands of United States dollars, except per share data, unless otherwise noted)

## 6. Shareholders' equity (continued):

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

(ii) Deferred share unit ("DSU") plan:

Changes in the number of units outstanding for the three-month periods ended March 31, 2022 and 2021 were as follows:

Number of units	2022	2021
Balance, beginning and end of period	311,065	253,028
Balance of DSU liability, included in Trade and other payables <sup>(1)</sup>	\$ 2,149	\$ 967

<sup>(1)</sup> Balance of DSU liability as at December 31, 2021 amounted to \$2,503.

The stock-based compensation net (recovery) expense related to DSU plan recorded in the condensed consolidated interim statement of loss and other comprehensive loss for the three-month period ended March 31, 2022 amounted to \$(310), presented in General and administrative expenses (\$242 for the corresponding period of the previous year).

## 7. Net finance income:

Finance income and Finance costs for three-month periods ended March 31, 2022 and 2021 were attributed as follows:

	Three-month periods ended March 31,	
	2022	2021
Interest income	\$ 296	\$ 71
Foreign exchange gain	959	118
Finance income	1,255	189
Interest expense on lease liability	(9)	(8)
Interest and bank charges	(5)	(18)
Realized loss on sale of bearer deposit notes prior to maturity	(268)	—
Finance costs	(282)	(26)
Net finance income	\$ 973	\$ 163

# BELLUS HEALTH INC.

Notes to Condensed Consolidated Interim Financial Statements (Continued)  
(Unaudited)

Periods ended March 31, 2022 and 2021  
(in thousands of United States dollars, except per share data, unless otherwise noted)

## 8. Loss per share:

	Three-month periods ended March 31,	
	2022	2021
Basic weighted average number of common shares outstanding	106,489,413	78,337,361
Basic and diluted loss per share	\$ (0.13)	\$ (0.20)

Excluded from the calculation of the diluted loss per share for the three-month periods ended March 31, 2022 and 2021 is the impact of all stock options granted under the stock option plan, as they would be anti-dilutive.

Stock options granted under the stock option plan could potentially be dilutive in the future.

## 9. 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 March 31, 2022, the Company has commitments for expenditures related to contracts for research and development activities of approximately \$20,473 (approximately \$15,153 as at December 31, 2021), of which \$12,097 is expected to be payable in 2022, \$7,087 in 2023 and \$1,289 in 2024.

# BELLUS HEALTH INC.

Notes to Condensed Consolidated Interim Financial Statements (Continued)  
(Unaudited)

Periods ended March 31, 2022 and 2021  
(in thousands of United States dollars, except per share data, unless otherwise noted)

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## 9. Commitments and contingencies (continued):

### (b) Contingencies:

On March 16, 2021, a Company stockholder, Carl D. Cachia (“Plaintiff”), filed a complaint against the Company and certain of its executive officers alleging claims under provisions of the Securities Exchange Act of 1934 (“Exchange Act”). On September 17, 2021, Plaintiff filed an amended class action complaint, individually and on behalf of all persons who purchased or otherwise acquired Company securities between September 5, 2019 and July 6, 2020, against the Company, certain of its executive officers, the principal investigator of the Company’s Phase 2a RELIEF trial, and the underwriters of the Company’s initial public offering in September 2019. The amended class action complaint alleges claims under the Exchange Act and the Securities Act of 1933 relating to disclosures concerning the Company’s Phase 2a RELIEF trial, and seeks compensatory damages, pre-judgment and post-judgment interest, as well as attorneys’ fees, expert fees, and any other reasonable costs and expenses. On November 16, 2021, Plaintiff stipulated to dismissal of all claims against the underwriters without prejudice. Also on November 16, the Company and the named executive officers moved to dismiss the amended complaint, which motion is pending. On January 7, 2022, the principal investigator of the Company’s Phase 2a RELIEF trial also moved to dismiss the amended complaint, which motion is pending.

No provision has been made in the financial statements for the resolution of the above matter. Resolution of this matter could have an effect on the Company’s financial statements in the period that a determination is made, however, in management’s opinion, given the early stage of this litigation, the final resolution of this matter is not currently projected to have a material adverse effect on the Company’s financial position.

## 10. 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 \$75 and \$75 (CAD\$95) under the consulting and services agreement for the three-month periods ended March 31, 2022 and 2021, respectively.

# BELLUS HEALTH INC.

Notes to Condensed Consolidated Interim Financial Statements (Continued)  
(Unaudited)

Periods ended March 31, 2022 and 2021  
(in thousands of United States dollars, except per share data, unless otherwise noted)

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## 10. Related party transactions (continued):

(c) Key management personnel:

The Chief Executive Officer, the Chief Financial Officer, the Chief Medical Officer, the Chief Scientific Officer, Senior Vice Presidents and Directors of BELLUS Health are considered key management personnel of the Company.

The aggregate compensation for the three-month periods ended March 31, 2022 and 2021 to key management personnel of the Company is set out below:

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	Three-month periods ended March 31,	
	2022	2021
Short-term benefits	\$ 966	\$ 736
DSU plan (recovery) expense	(310)	242
Stock option plan expense	1,597	1,308
	<hr/>	<hr/>
	\$ 2,253	\$ 2,286

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## 11. 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. A three-tier fair value hierarchy prioritizes the inputs used in measuring fair value.

There was no financial asset or liability fair valued on a recurring basis as at March 31, 2022 and December 31, 2021.

For its financial assets and liabilities measured at amortized cost as at March 31, 2022, the Company has determined that the carrying value of its short-term financial assets and liabilities approximates their fair value because of the relatively short periods to maturity of these instruments.