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- and nine-month periods ended September 30, 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- and nine-month periods ended September 30, 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- and nine-month periods ended September 30, 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 November 14, 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 and on EDGAR at 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 complete our CALM Phase 3 clinical trials, including our expectations to release topline results from CALM-1 and CALM-2 in the second half of 2024 and 2025, respectively;
- our expectations regarding the timing of our Phase 1 clinical trial investigating a once-daily ("QD") dosing, extended-release formulation of BLU-5937, which was initiated in the fourth quarter of 2022 and is expected to be completed in the first half of 2023;
- our aim to complete preclinical studies supporting Phase 3 clinical program with BLU-5937;
- our aim to complete additional Phase 1 clinical trials supporting Phase 3 clinical program with BLU-5937;
- our aim to further explore the potential of BLU-5937 for the treatment of other afferent hypersensitization-related conditions;
- our aim to complete all non-clinical and clinical pharmacology activities with BLU-5937 necessary to support a New Drug Application ("NDA") filing;
- our expectations with respect to the timing and cost of the research and development activities of BLU-5937;
- our aim to complete the validation of the VitaloJAK for cough frequency measurement in our studied patient population to the satisfaction of relevant regulatory agencies;
- the function, potential benefits, tolerability profile and clinical activity 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 QD 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 regulatory approval to market 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 and our ability to secure patent term extensions for 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 may have 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, if approved;
- 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 clinical 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 ongoing 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 ongoing 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 ongoing COVID-19 pandemic and other health risks;
- the effect of macroeconomic conditions, including rising interest rates and inflation, on our business operations;
- 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 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 participants, including, but not limited to, as a result of the ongoing 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 refractory chronic cough ("RCC") and other hypersensitization disorders. Our lead product candidate, BLU-5937, is a highly selective second generation antagonist of the P2X3 receptor, a clinically validated target to treat cough hypersensitivity. We are currently developing BLU-5937 for the treatment of adults with RCC. We believe this hypersensitization-related disorder, which includes a pathophysiology that is mediated through the P2X3 receptor, represents an area of significant unmet medical need and its treatment represents a potentially large market opportunity. We believe BLU-5937's characteristics observed in our preclinical studies, Phase 1 and Phase 2 clinical trials support the development of BLU-5937 and, if approved, position it as a potentially best-in-class agent in the P2X3 antagonist class for the treatment of RCC. On December 13, 2021, we announced positive topline results from SOOTHE, a Phase 2b trial evaluating the tolerability and clinical activity of BLU-5937 in participants diagnosed with RCC. On July 12, 2022, we announced a positive End-of-Phase 2 ("EOP2") meeting with the U.S. Food and Drug Administration ("FDA") and the details of the CALM Phase 3 clinical program for BLU-5937 for the treatment of RCC. In addition, we have received scientific advice on the CALM program from the European Medicines Agency's ("EMA") Committee for Medicinal Products for Human Use ("CHMP") and from the UK's Medicines and Healthcare products Regulatory Agency ("MHRA"). We have initiated the CALM Phase 3 program. We expect to report topline data from CALM-1 in the second half of 2024 and from CALM-2 in 2025.

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

BUSINESS OVERVIEW

Key Updates

Initiated the CALM Phase 3 clinical program (CALM-1 and CALM-2).

- We have completed a positive End-Of-Phase 2 meeting with the U.S. Food and Drug Administration ("FDA"), and received scientific advice on the design of our CALM Phase 3 clinical program from both the European Medicines Agency ("EMA") and the Medicines and Healthcare products Regulatory Agency ("MHRA").
- The CALM Phase 3 clinical program has been initiated with patient screening ongoing.The CALM program consists of two pivotal trials, CALM-1 and CALM-2, with the primary endpoint of 24H cough frequency measured at 12- and 24-weeks, respectively, using the VitaloJAK cough monitoring system. For additional information on the CALM-1 and CALM-2 trials designs, click here.
- We conducted validation work on the VitaloJAK comparing compressed vs. non-compressed recordings in a cohort of 45 SOOTHE Phase 2b trial participants. The results showed a sensitivity of 98.7%, with no systemic error and no bias observed. We will submit a validation protocol and statistical analysis plan to the FDA before year-end.
- Topline results from CALM-1 are expected in the second half of 2024, with topline results from CALM-2 expected in 2025.

Completed large U.S. physician survey on the RCC market landscape.

- Survey included 1,483 U.S. pulmonologists, allergists, ENTs, gastroenterologists and primary care physicians showing that there are about 8.6 million RCC patients in the United States and 1.8 million RCC patients currently being seen by specialists.

Pursuing development of our P2X3 pipeline.

- The Phase 1 clinical trial investigating the pharmacokinetics of a once daily, extended-release formulation of BLU-5937 has been initiated with enrollment ongoing. The study is expected to be completed in the first half of 2023.

Presented at the CHEST Annual Meeting, the European Respiratory Society ("ERS") International Congress 2022 and the Twelfth London International Cough Symposium ("LICS").

- Clinical data from the Phase 2b SOOTHE trial was presented at the CHEST Annual Meeting, held in Nashville, Tennessee from October 16-19, 2022, the ERS International Congress 2022, held in Barcelona, Spain from September 4-6, 2022, and the 12th LICS, held from July 13-14, 2022. The presentation materials are available in the "Scientific Publications" section of BELLUS Health's website here.

Completed a $176.0 million public offering of common shares in Canada and the United States.

- In July 2022, we completed a public offering of our common shares resulting in gross proceeds of $176.0 million, including the full exercise of the option to purchase additional shares. These proceeds extended our cash runway to the second half of 2025 and through the topline results of both CALM-1 and CALM-2.

Established At-the-Market ("ATM") Facility.

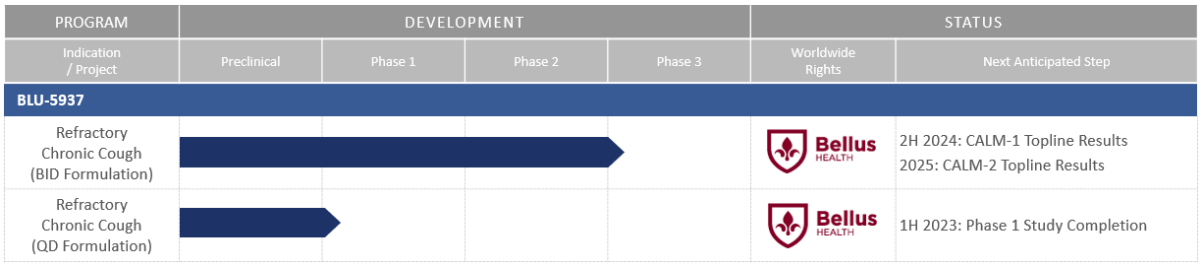
- We entered into an agreement with Jefferies LLC pursuant to which we may from time to time sell, through ATM distributions with Jefferies acting as sales agent, common shares with an aggregate offer price of up to US$80.0 million, including sales made directly on The Nasdaq Global Market ("Nasdaq") 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. BELLUS Health's common shares are dual-listed on Nasdaq and the Toronto Stock Exchange ("TSX") under the trading symbol "BLU." For the purposes of the TSX approval, the Company relied on the exemption set forth in Section 602.1 of the TSX Company Manual, which provides that the TSX will not apply its standards to certain transactions involving eligible interlisted issuers on a recognized exchange, such as Nasdaq. This news release shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any province, state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such province, state or jurisdiction.

Ended the third quarter of 2022 with cash, cash equivalents and short-term investments totaling $364.4 million.

BUSINESS SECTION

Our Pipeline

We are developing BLU-5937, an investigational, potent, highly selective, small molecule antagonist of the P2X3 receptor, as an oral therapy for RCC patients.



On November 14, 2022, we announced that we had initiated enrollment in both CALM-1 and CALM-2 Phase 3 studies after receiving feedback from the FDA, EMA, and MHRA. CALM-1 and CALM-2 topline results are expected respectively in the second half of 2024 and in 2025. Additionally we conducted validation work on the VitaloJAK cough monitoring system comparing compressed vs. non-compressed recordings in a cohort of 45 SOOTHE Phase 2b trial participants. The results demonstrated a sensitivity of 98.7%, with no systemic error and no bias observed. We will submit a validation protocol and statistical analysis plan to the FDA before year-end. Furthermore, the Phase 1 clinical trial investigating a once daily, extended-release formulation of BLU-5937 has been initiated and is expected to be completed in the first half of 2023.

On July 12, 2022, we announced a positive EOP-2 meeting with the FDA and the details of the CALM Phase 3 clinical program for BLU-5937. Additionally, we received scientific advice on the design of the CALM Phase 3 clinical program from the EMA's CHMP and MHRA in the third quarter of 2022. The CALM Phase 3 clinical program consists of two pivotal trials, CALM-1 and CALM-2 with three expected arms: 25 mg, 50 mg and placebo twice daily ("BID") dosing. Primary efficacy endpoint is 24H cough frequency at 12 weeks in CALM-1 and 24 weeks in CALM-2. We have reached alignment with the FDA

on using primary efficacy endpoint in population enriched for baseline cough frequency, similar to the successful SOOTHE Phase 2b clinical trial. The safety database will be supported by randomized extension and an additional open label extension of CALM-1 and open label extension of CALM-2. The VitaloJAK cough monitoring system, which was used in SOOTHE and most recent cough trials, will be used in the CALM Phase 3 clinical program.

The Phase 2b trial 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, at all doses and the treatment-emergent adverse events ("TEAEs") profile was comparable to placebo. A dose response was observed between the 12.5 mg and 50 mg BID doses.

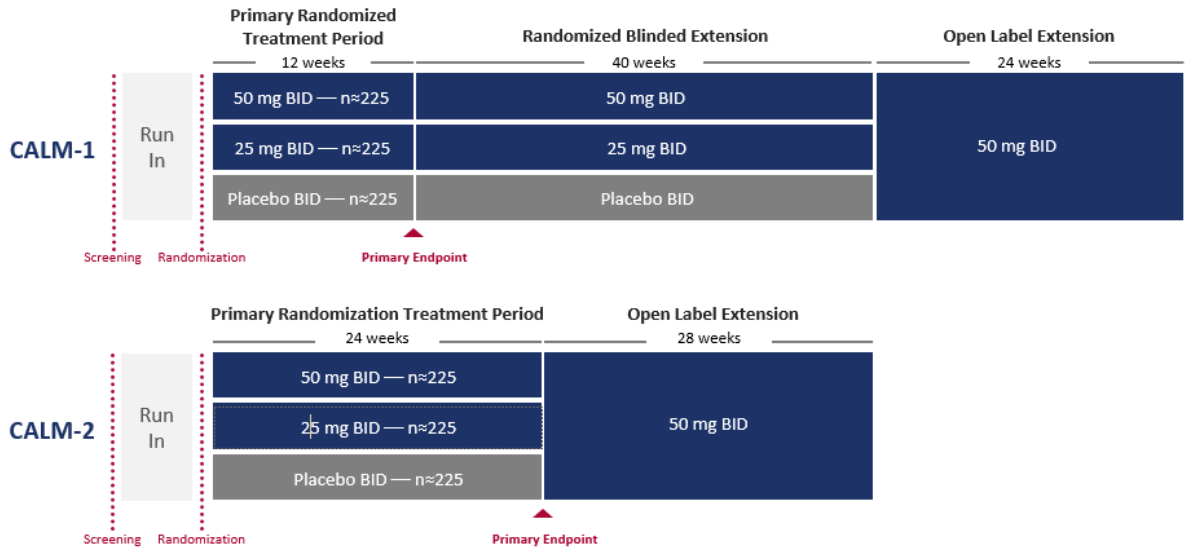
In July 2020, we announced topline results from our Phase 2a RELIEF clinical trial of BLU-5937 that demonstrated proof-of-concept in RCC participants. Numerical differences in favor of BLU-5937 were observed in the primary endpoint of reduction in cough frequency. Clinically meaningful and statistically significant reductions in cough frequency were observed in two pre-specified sub-group analyses in participants with baseline awake cough frequency of ≥ 20 coughs/h (80% of trial participants) and ≥ 32 coughs/h (50% of trial participants). We also announced our intention to move forward with BLU-5937 in a Phase 2b trial.

Our lead indication for BLU-5937 is RCC, defined as 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 9 million patients are identified as having RCC. It is also estimated that approximately 9 million patients suffer from RCC in the United Kingdom, Germany, France, Spain and Italy. Additionally, RCC is highly prevalent in Asia. Many patients report that their condition has a marked effect on their quality of life including sleep disruption, fatigue, urinary incontinence, and disruption of social interactions. Currently, there is no pharmacologic therapy approved specifically for the treatment of RCC outside of Japan and Switzerland. 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.

CALM Phase 3 Clinical Program

On July 12, 2022, we announced a positive EOP-2 meeting with the FDA and the details of the CALM Phase 3 clinical program for BLU-5937 for the treatment of RCC. Subsequently, we received scientific advice from the EMA's CHMP and MHRA in the third quarter of 2022.

The CALM Phase 3 clinical program will evaluate the efficacy, safety and tolerability of BLU-5937 in approximately 675 adults with RCC for each of CALM-1 and CALM-2 trials. CALM-1 and CALM-2 will be placebo-controlled, parallel-arm trials randomized 1:1:1 with expected treatment arms of 25 mg BID, 50 mg BID and placebo. The primary endpoint of 24H cough frequency will be measured at 12-weeks for CALM-1 and 24-weeks for CALM-2. We have reached alignment with the FDA that the CALM Phase 3 clinical trials' primary endpoint, similar to the successful SOOTHE Phase 2b clinical trial, can be assessed using the VitaloJAK cough monitoring system in a patient population enriched for baseline 24H cough frequency of ≥ 20 coughs/hour ("coughs/h") (comparable to awake cough frequency of ≥ 25 coughs/h used in SOOTHE Phase 2b clinical trial). Secondary efficacy endpoints include Cough Severity using Visual Analogue Scale ("CS-VAS"), the Leicester Cough Questionnaire ("LCQ") and Chronic Cough Diary ("CCD"). The CALM Phase 3 clinical program will also enroll participants with baseline 24H cough frequency < 20 coughs/h. A secondary efficacy endpoint will assess reduction in cough frequency in a broader population including the enriched population and additional participants with baseline 24H cough frequency below 20 coughs/h. CALM-1 will have a 40-week randomized extension period and an additional 24-week open label extension. CALM-2 will have a 28-week open label extension. CALM-1 and CALM-2 will run in parallel, and both trials have been initiated in the fourth quarter of 2022. Topline data from CALM-1 and CALM-2 are respectively expected in the second half of 2024 and in 2025.



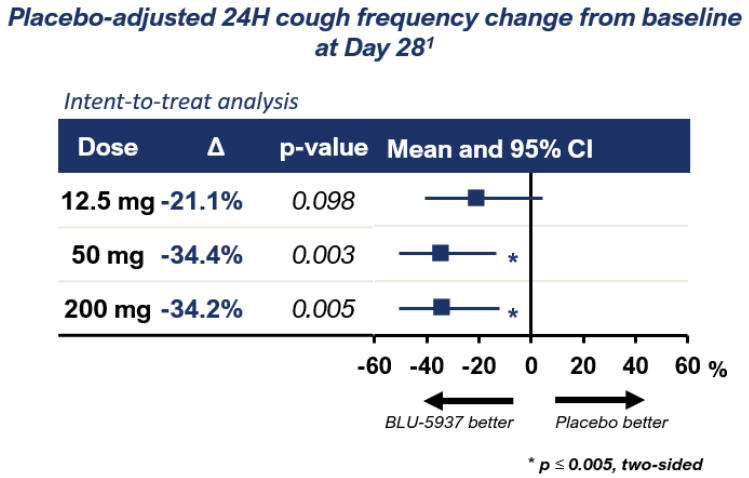
SOOTHE Phase 2b Clinical Trial

On December 8, 2020, we announced that the first participant had been dosed in the Phase 2b SOOTHE clinical 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.

Efficacy Results:

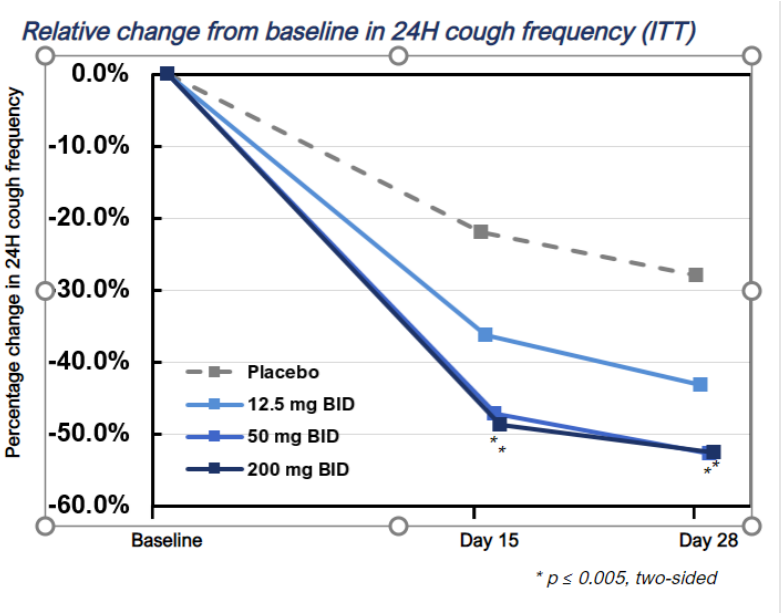
The SOOTHE clinical trial, which enrolled 249 participants with a baseline awake cough frequency of ≥ 25 per hour, demonstrated a clinically meaningful and statistically significant placebo-adjusted reduction in 24-hour cough frequency of 34% at the 50 mg and 200 mg BID dose levels of BLU-5937 ($p \leq 0.005$) 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



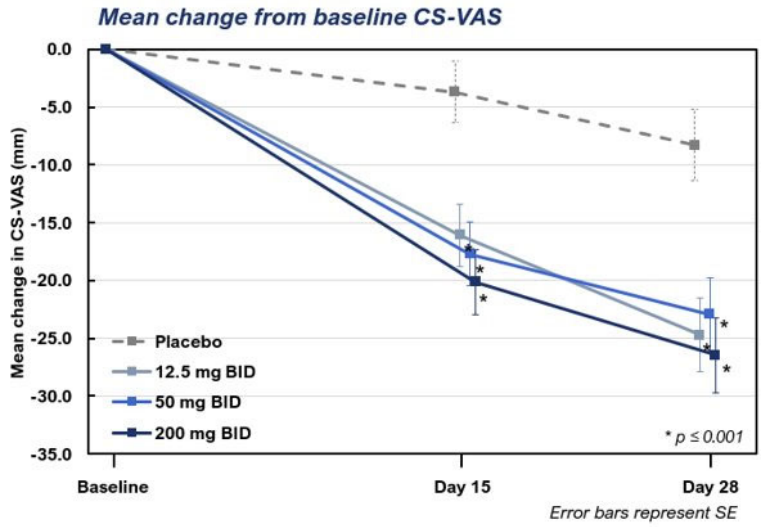
1. Geometric mean ratio of difference from baseline between BLU-5937 doses and placebo is estimated by back transformation of the LS mean difference. Percent treatment benefit over placebo in mean cough frequency is defined as 100x ((geom. LS mean Ratio)-1).

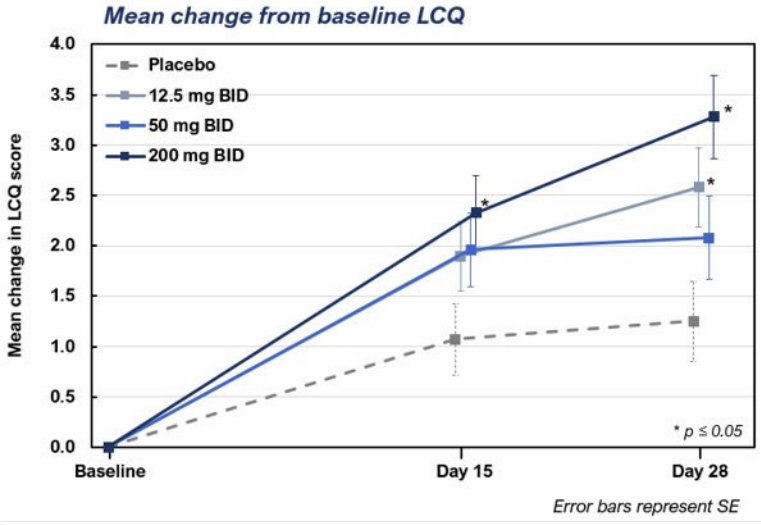
The change from baseline in 24-hour cough frequency was 53% at day 28 with 50 mg and 200 mg BID doses.



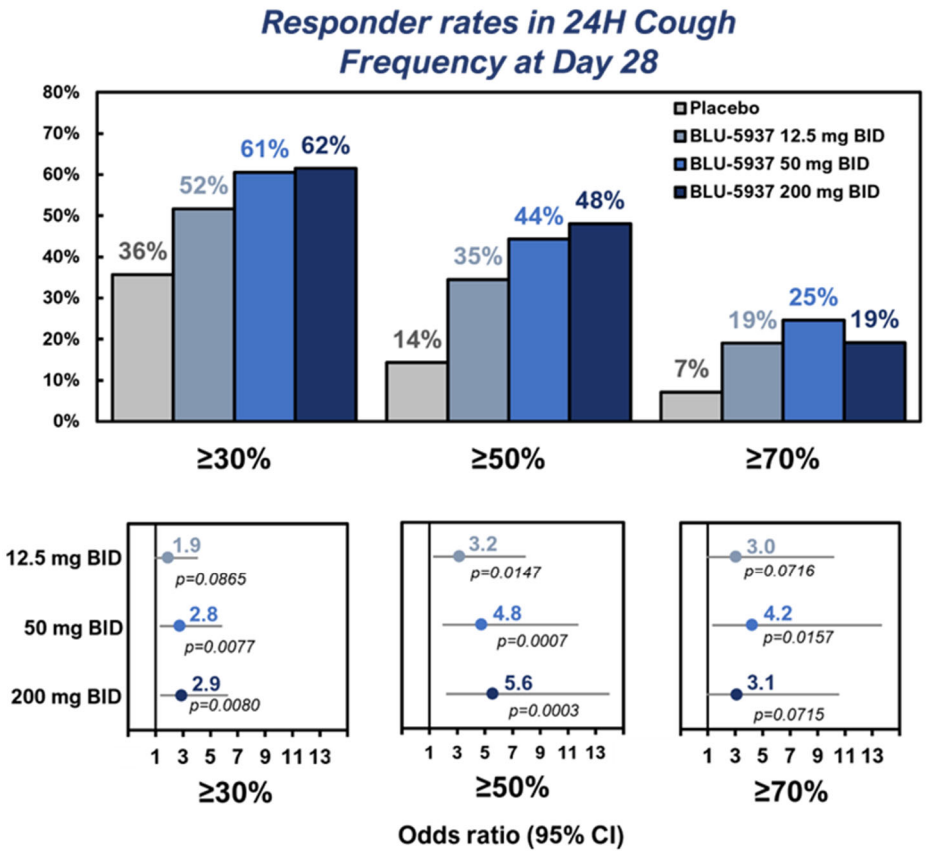
SOOTHE Secondary Endpoints: Change from Baseline in Key Patient-Reported Outcomes

Patient Reported Outcomes ("PROs") constituted secondary endpoints and included CS-VAS and LCQ. Even though SOOTHE was not powered to demonstrate statistical significance on the PROs, a clinically meaningful and nominally significant benefit of BLU-5937 was observed at multiple timepoints in the PROs.





Responder analyses showed that, after 28 days of treatment, ≥ 60% of participants achieved a clinically meaningful ≥ 30% reduction in 24H cough frequency at the two higher doses, with ≥ 44% and ≥ 19% achieving responses of ≥ 50% and ≥ 70% reductions, respectively. Odds ratios numerically favored treatment over placebo for every dose of BLU-5937. The 50 and 200 mg treatment groups demonstrated a nominally significant likelihood ($p < 0.01$) to achieve a clinically meaningful response (≥ 30%) over placebo.



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 reported in 4.8%, 6.5% and 4.8% of participants at 12.5 mg, 50 mg and 200 mg doses, respectively. No participant reported complete or partial taste loss and there were no discontinuations due to taste-related adverse events.

The TEAE profile was comparable to placebo. There were no treatment emergent serious adverse events reported in the trial.

Treatment Emergent Adverse Events [1]

n (%)	Placebo (n= 63)	BLU-5937 12.5 mg BID (n= 62)	BLU-5937 50 mg BID (n= 62)	BLU-5937 200 mg BID (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%)**
Most Common TEAEs (≥5% at any dose)†				
Nausea	0	0	5 (8.1%)	2 (3.2%)
Dysgeusia	0	3 (4.8%)	4 (6.5%)	3 (4.8%)
UTI	0	3 (4.8%)	0	0

Notes

† TEAE reported with an incidence ≥5% in the exploratory population

(1) TEAEs leading to discontinuation, as deemed by investigator. Placebo: worsening of cough; BLU-5937 200 mg BID: worsening of cough and dry mouth

Incidence of Taste Disturbance Events

	Main population			
	Placebo (n= 63)	BLU-5937 12.5 mg BID (n= 62)	BLU-5937 50 mg BID (n= 62)	BLU-5937 200 mg BID (n= 62)
Taste alteration (dysgeusia)	0	3 (4.8%)	4 (6.5%)	3 (4.8%)
Partial taste loss (hypogeusia)	0	0	0	0
Complete taste loss (ageusia)	0	0	0	0
Total taste disturbances	0	3 (4.8%)	4 (6.5%)	3 (4.8%)

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 tolerability 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 ≥ 25 coughs per hour were randomized across four treatment 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 ≥ 45 coughs per hour across trial arms. The primary efficacy endpoint was the placebo-adjusted 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 ≥ 10 and < 25 coughs per hour 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 participants with lower cough frequency. Phase 2b clinical trial enrolled participants at 116 sites, of which approximately 50% were in the United States. The SOOTHE trial was initiated in December 2020.

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 participants 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 the interim analysis of the Phase 2b SOOTHE trial enabled us to accelerate the planning of our Phase 3 clinical program while awaiting the Phase 2b SOOTHE clinical trial final results. This administrative interim analysis was conducted when 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.

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

On December 13, 2021, we announced the positive topline results of the Phase 2b SOOTHE clinical trial.

RELIEF Phase 2a 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 participants. 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 ≥ 20 coughs per hour (representing 80% of total trial participants) and ≥ 32 coughs per hour (representing 50% of total trial participants), linking higher baseline cough frequency with improved treatment benefit. In the RELIEF trial, BLU-5937 was generally well-tolerated and showed an adverse event profile comparable to placebo. The taste disturbance adverse events were reported in 10% or less of the participants. 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

BLU-5937 has exhibited favorable physicochemical 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 Phase 1 clinical trial investigating the pharmacokinetics of a once daily, extended-release formulation of BLU-5937 has been initiated. The study is expected to be completed in the first half of 2023.

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 position BLU-5937 as a potential best-in-class product candidate in the P2X3 class in terms of its clinical activity and tolerability profile, if confirmed in Phase 3 development and approved. Additionally, the greater selectivity for P2X3 over P2X2/3 observed for our product candidate, BLU-5937, may contribute to supporting a favorable clinical and commercial profile.

The table below shows the selectivity, stage of development and dosing regimen of the different P2X3 product candidates currently in development [1]:

	1ST IN CLASS P2X3 ANTAGONIST	2ND GENERATION P2X3 ANTAGONISTS	
Company	MERCK	SHIONOGI	Bellus HEALTH
Candidate	Gefapixant	Sivopixant	BLU-5937
Stage of Development	Approved in Japan, Switzerland	Phase 2b	Phase 3
Expected Next Steps	Resubmission in U.S.*; EU under review	Evaluating Next Steps	CALM-1 topline results expected in 2H 2024
Dosing	BID	QD	BID / QD in development
P2X3 vs. P2X2/3 Selectivity	3-7x[2]	~ 250x[3]	**~ 1500x**

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

1. Active programs. 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. 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 Phase 3 trials, COUGH-1 and COUGH-2 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 and COUGH-2, respectively). In March 2021, Merck announced that the FDA had accepted gefapixant NDA for review. In January 2022, Merck announced that the Japan Ministry of Health, Labor and Welfare granted regulatory approval for gefapixant 45 mg tablets for the treatment of adults with RCC. Additionally, Merck reported that the FDA issued a Complete Response Letter ("CRL"), which included the need for additional analyses associated with "measurement of efficacy". 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. In May 2022, Gefapixant was approved in Switzerland. In August 2022, Merck announced that it is performing additional analyses and anticipates submitting this information to the FDA in the first half of 2023 in response to the CRL. Merck also reported that the review period in the EU had been extended pending the receipt of additional information and it plans to submit the information to the EMA in the first half of 2023. Outside of Japan and Switzerland, gefapixant remains an investigational treatment under review by regulatory authorities, such as the EMA.

At the American Thoracic Society International Conference held in August 2020, Bayer announced topline results from its Phase 2a clinical trial evaluating BAY 1817080 (eliapixant), which demonstrated that higher doses of Bayer's P2X3 antagonist significantly reduced 24-hour cough counts in participants 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 clinical 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 Bayer did not disclose its nature. Bayer also announced that Phase 3 development was warranted. On February 4, 2022, Evotec, Bayer's partner, announced that it had been informed by Bayer about the decision to discontinue the development of eliapixant. Following a review of the available data, Bayer concluded that the overall benefit no longer outweighed 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. Subsequently, it was announced in May 2022 at the American Thoracic Society International Conference that the program had been discontinued by Bayer due to a report of drug-induced liver injury.

Shionogi announced topline results of its Phase 2a clinical trial of S-600918 (sivopixant) in participants 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 it observed an interaction between baseline cough frequency and treatment effect in its Phase 2a clinical trial; this prompted the utilization of a minimal cough frequency threshold as an inclusion criterion in the Phase 2b clinical 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 clinical 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 participants with a 24-hour cough frequency ≥ 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 indicated then that it was planning to discuss dose selection and Phase 3 clinical trial design at an upcoming EOP-2 meeting with the FDA. In a conference call in January 2022, Shionogi mentioned in its presentation that it was preparing for a Phase 3 clinical trial. On October 12, 2022, Shionogi mentioned in a presentation that "competitor landscape and regulators' comments on endpoint" will determine whether to conduct Phase 3.

Market Opportunity in RCC

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 5 million emergency visits.

We estimate that up to 10% of the adult population in developed countries suffer from chronic cough, including the United States, nations in the European Union and the United Kingdom. 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 9 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 9 million patients suffer from RCC in the EU5 countries. RCC is also prevalent in Asia. RCC patients continue to cough despite treatment for potential underlying causes of their cough or have a cough that is unexplained. We estimate that approximately one-third, or approximately 3 million, of these RCC patients in the U.S. have been coughing for over a year, a key inclusion criteria in current RCC clinical trials, including our Phase 2a RELIEF clinical trial and Phase 2b SOOTHE clinical trial of BLU-5937. Many patients report that their condition has a marked effect on their quality of life including sleep disruption, fatigue, urinary incontinence, and disruption of social interactions. Currently, there is no pharmacological therapy approved specifically for the treatment of RCC outside of Japan and Switzerland. Available treatment options outside of Japan and Switzerland 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.

In October 2022, we completed large quantitative surveys of 1,483 U.S. pulmonologists, allergists, ENTs, gastroenterologists, and primary care physicians showing that there are about 8.6 million RCC patients in the United States and 1.8 million RCC patients are currently being seen by specialists

Supporting Non-Clinical and Clinical Pharmacology Activities

Non-clinical toxicology studies and clinical pharmacology studies to support an anticipated NDA filing and inform labeling for RCC are ongoing or planned**.**

Chemistry, Manufacturing, and Controls

We have a primary supply chain in place with the capacity to produce the required clinical supplies to support a Phase 3 clinical 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 to support a potential commercial launch.

BLU-5937 in Other P2X3 Hypersensitization-Related Disorders

We believe the results of our Phase 2b SOOTHE clinical trial further validate the role of P2X3 in cough hypersensitivity. We intend to evaluate potential opportunities to study BLU-5937 in additional cough indications where hypersensitivity plays an important role.

In addition to RCC, the mechanism of action of BLU-5937 may also have broad therapeutic applicability across other neuronal hypersensitivity indications, enabling us to consider BLU-5937 as a potential treatment for development in a number of other indications. Consequently, 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.

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 intellectual property estate covering BLU-5937 and its use for the treatment of chronic cough.

July 2022 Equity Offering

In July 2022, we raised total gross proceeds of $176.0 million by issuing a total of 19,021,622 common shares in the United States and in Canada (the “2022 Offering”).

More specifically, on July 18, 2022, we closed an equity offering, issuing 16,540,541 common shares from treasury at a price of $9.25 per share for gross proceeds of $153.0 million. On July 28, 2022, the underwriters of the equity offering exercised their option to purchase additional common shares, resulting in the issuance of an additional 2,481,081 common shares from treasury at a price of $9.25 per share, for additional gross proceeds of $23.0 million. We intend to use the net proceeds of the 2022 Offering, amounting to approximately $164.5 million, primarily to fund BLU-5937 research and development activities, working capital needs and other general corporate purposes.

2022 ATM Sales Agreement

On November 14, 2022, we entered into an “at-the-market” (“ATM”) sales agreement (the “2022 ATM Sales Agreement”) with Jefferies LLC (“Jefferies”) pursuant to which we may from time to time sell through ATM distributions with Jefferies acting as sales agent our common shares for aggregate gross proceeds of up to $80 million, including sales made directly on 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 Company intends to use the ATM program in the ordinary course of business, notably to address reverse inquiries it may receive from investors from time to time. 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.

RESULTS OF OPERATIONS

For the three-month period ended September 30, 2022, net loss amounted to $24,706,000 ($0.20 per share), compared to $22,881,000 ($0.29 per share) for the corresponding period the previous year. For the nine-month period ended September 30, 2022, net loss amounted to $57,834,000 ($0.52 per share), compared to $56,460,000 ($0.72 per share) for the corresponding period the previous year. The increase in net loss during the periods is primarily attributable to an increase in foreign exchange loss resulting from the conversion in US dollars of our net monetary assets denominated in Canadian dollars, as well as to an increase in external G&A expense, partially offset by a decrease in external R&D spend.

Research and development expenses, net of research tax credits, amounted to $17,241,000 for the three-month period ended September 30, 2022 ($40,955,000 for the nine-month period), compared to $19,054,000 for the corresponding period of the previous year ($46,703,000 for the nine-month period), a decrease of $1.8 million or 10% quarter over quarter (decrease of $5.7 million or 12% year over year for the nine-month period). The decrease in research and development expenses is primarily attributable to a decrease in external R&D spend as we have transitioned from our Phase 2b SOOTHE clinical trial to the initiation of our CALM Phase 3 clinical program. 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 as well as higher stock-based compensation expense in relation to our stock option plan.

General and administrative expenses amounted to $5,838,000 for the three-month period ended September 30, 2022 ($15,267,000 for the nine-month period), compared to $3,821,000 for the corresponding period of the previous year ($10,096,000 for the nine-month period), an increase of $2.0 million or 53% year over year (increase of $5.1 million or 51% year over year for the nine-month period). The increase is mainly attributable to higher external G&A expenses, as well as to higher stock-based compensation expense in relation to our stock option plan.

Net finance costs amounted to $1,656,000 for the three-month period ended September 30, 2022 ($1,583,000 for the nine-month period), compared to $10,000 for the corresponding period of the previous year (net finance income of $327,000 for the nine-month period). The increase in net finance costs is mainly attributable to an increase in foreign exchange loss resulting from the conversion in U.S. dollars of our net monetary assets denominated in Canadian dollars during the periods, due to the weakening of the Canadian dollar versus the US dollar. The increase is partially offset by higher interest income due to the increased cash, cash equivalents and short-term investments position following the 2022 and 2021 Offerings and the increase in interest rates.

Quarterly Results (Unaudited)

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

Quarterly Results (*in thousands of dollars,*	2022 Q3	2022 Q2	2022 Q1	2021 Q4	2021 Q3	2021 Q2	2021 Q1	2020 Q4
Revenues	$4	$4	$4	$4	$4	$4	$4	$4
Expenses:								
Research and development, net	17,241	12,460	11,254	12,334	19,054	15,201	12,448	5,017
General and administrative	5,838	5,379	4,050	4,167	3,821	2,805	3,470	3,078
Total operating expenses	23,079	17,839	15,304	16,501	22,875	18,006	15,918	8,095
Operating loss	(23,075)	(17,835)	(15,300)	(16,497)	(22,871)	(18,002)	(15,914)	(8,091)
Net finance (costs) income	(1,656)	(900)	973	1,534	(10)	174	163	597
Loss before income taxes	(24,731)	(18,735)	(14,327)	(14,963)	(22,881)	(17,828)	(15,751)	(7,494)
Income taxes	(25)	41	25	(199)	-	-	-	-
Net loss	$(24,706)	$(18,776)	$(14,352)	$(14,764)	$(22,881)	$(17,828)	$(15,751)	$(7,494)

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 increase in net loss for the third quarter of 2022 is primarily attributable to an increase in foreign exchange loss resulting from the conversion in US dollars of our net monetary assets denominated in Canadian dollars. The increase in net loss for the second quarter of 2022 is primarily attributable to higher general and administrative expenses. 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 quarter 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.

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 $69,000 and $207,000 (CAD$96,000 and CAD$286,000) and $76,000 and $228,000 (CAD$96,000 and CAD$286,000) under the consulting and services agreement for the three and nine-month periods ended September 30, 2022 and 2021, respectively.

FINANCIAL CONDITION

Liquidity and Capital Resources

As at September 30, 2022, we had available cash, cash equivalents and short-term investments totaling $364,366,000 compared to $248,806,000 as at December 31, 2021. For the nine-month period ended September 30, 2022, the net increase in cash, cash equivalents and short-term investments amounted to $115,560,000, compared to a net decrease of $39,910,000 for the corresponding period of the previous year. The net increase for the nine-month period ended September 30, 2022 is primarily attributable to funds obtained through the 2022 Offering, offset in part by 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, will be sufficient to extend our runway to the second half of 2025 and through expected topline results of both CALM-1 and CALM-2 trials. We may need to raise additional capital to fund our operations, develop BLU-5937 and prepare for commercialization.

In July 2022, we raised total gross proceeds of $175,950,000 from the 2022 Offering by issuing a total of 19,021,622 common shares at a price of $9.25 per share including the exercise of the underwriters' option to purchase 2,481,081 common shares. Net proceeds from the 2022 Offering amount to approximately $164,453,000. We intend to use the net proceeds from the 2022 Offering primarily to fund BLU-5937 research and development activities, working capital needs and other general corporate purposes.

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 supplements dated December 14, 2021 ("2021 Prospectus Supplement") and July 13, 2022 ("2022 Prospectus Supplement") did not include funds from the exercise of the underwriters' option to purchase additional common shares. Taking into consideration these additional funds, we intend to use the net proceeds of the 2021 Offering and 2022 Offering for the purposes and in the amounts indicated below.

	As per 2021 and 2022 Prospectus Supplements without options to purchase additional common shares	As at November 14, 2022 including options to purchase additional common shares
BLU-5937 clinical trials in chronic cough	$ 217.9 million	$ 238.4 million
Manufacturing, formulation and scale-up	$ 42.1 million	$ 51.8 million
Other BLU-5937 project costs	$ 36.5 million	$ 42.4 million
Working capital and other general administration costs	$ 34.4 million	$ 41.5 million

As at September 30, 2022, we have used $9.8 million of the 2021 and 2022 Offering net proceeds. For additional details regarding the development of BLU-5937, see “Business Section” – “Our Pipeline” in this MD&A.

On July 13, 2022, prior to the 2022 Offering, we terminated the ATM Sales Agreement entered into with Jefferies on December 23, 2020 (the “2020 ATM Sales Agreement”). Under the 2020 ATM Sales Agreement, we could from time to time sell through ATM distributions with Jefferies acting as sales agent, our common shares for aggregate gross proceeds of up to $50 million, including sales made directly on Nasdaq or on any other existing trading market for the common shares in the United States. We did not make any sales of common shares under the Sale Agreement.

On November 14, 2022, we entered into the 2022 ATM Sales Agreement with Jefferies pursuant to which we may from time to time sell through ATM distributions with Jefferies acting as sales agent (the “Agent”), our common shares for aggregate gross proceeds of up to $80 million, including sales made directly on 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. We have no obligation to sell any of the common shares and may at any time suspend sales under the 2022 ATM Sales Agreement. We and the Agent may terminate the 2022 ATM Sales Agreement in accordance with its terms.

During the nine-month period ended September 30, 2022, we purchased short-term investments with initial maturities greater than three months and less than a year for an aggregate amount of $236,930,000 and redeemed at maturity or sold short-term investments for an aggregate amount of $42,812,000. For the nine-month period ended September 30, 2021, we sold short-term investments with initial maturities greater than three months and less than a year for an aggregate amount of $16,358,000. We did not purchase any short-term investments with initial maturities greater than three months and less than a year during that period in 2021.

As at September 30, 2022, we had commitments for expenditures related to contracts for research and development activities of approximately $52,708 (approximately $15,153,000 as at December 31, 2021), of which $4,718 is expected to be payable in 2022, $15,968 in 2023, $14,755 in 2024, $10,569 in 2025 and $6,698 in 2026.

We are an “emerging growth company” as defined in the JOBS Act. As of June 30, 2022, the market value of our common shares held by non-affiliates exceeded US$700 million, and as a result, as of January 1, 2023, we will no longer qualify as an emerging growth company. 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. Pursuant to Section 404 of the Sarbanes-Oxley Act (2002), as amended, we are 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. We will require an attestation report on ICFR for the year ended December 31, 2022.

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, 2021, the Company and the named executive officers moved to dismiss the amended complaint. On January 7, 2022, the principal investigator of the Company's Phase 2a RELIEF trial also moved to dismiss the amended complaint. On June 17, 2022, Plaintiff filed a motion for leave to amend his complaint, which all remaining defendants opposed. On September 21, 2022, the court granted all defendants' motions to dismiss in full, dismissing all counts, denied Plaintiff's motion for leave to amend his complaint, and ordered the case to be closed. On September 22, 2022, all of Plaintiff's claims were dismissed and the case was closed. Plaintiff did not file a notice of appeal within the 30-day deadline for appeal.

On July 6, 2022, a Company stockholder, Jason Gallanti (the "Canadian Plaintiff"), filed a statement of claim before the Ontario Superior Court of Justice against the Company alleging negligent misrepresentation and claims under the Ontario *Securities Act* ("OSA") and equivalent provincial securities legislation relating to disclosures concerning the Company's Phase 2a RELIEF trial. The Canadian Plaintiff seeks certification of the action as a class proceeding on behalf of those who purchased the Company's stock on the TSX, leave to pursue statutory claims under the OSA, compensatory damages, prejudgment and post-judgment interest, and costs of the action.

No provision has been made in the financial statements for the resolution of the above matters. Resolution of these matters 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 these matters, the final resolution is not currently projected to have a material adverse effect on our financial position.

During the nine-month period ended September 30, 2022, we granted 3,755,000 stock options, 468,054 stock options were exercised, and 76,000 stock options were forfeited.

As at November 14, 2022, we had 125,792,916 common shares outstanding and 136,997,195 common shares on a fully diluted basis, including 11,204,279 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 our 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 September 30, 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 September 30, 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 Canadian securities regulatory authorities and the United States Securities and Exchange Commission for further risk factors that might affect us and our business 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 and included in the annual report on exhibit 99.3 to Form 40-F filed on EDGAR at www.sec.gov/edgar and our other public filings.