BELLUS Health Reports Second Quarter 2022 Financial Results and Business Highlights

August 10, 2022

- Completed positive End-of-Phase 2 meeting with the Food and Drug Administration ("FDA") and received scientific advice from the European Medicines Agency ("EMA") to support design of its CALM Phase 3 program, which is expected to initiate in Q4 2022 -

- Ended second quarter 2022 with approximately US$384.6 million in pro-forma cash, cash equivalents and short-term investments, including net proceeds from the July 2022 financing; Cash runway extended to 2H 2025 and through the topline results of both CALM-1 and CALM-2 trials -

LAVAL, Quebec--(BUSINESS WIRE)--Aug. 10, 2022-- BELLUS Health Inc. (Nasdaq:BLU; TSX:BLU) ("BELLUS Health" or the "Company"), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of refractory chronic cough ("RCC") and other cough hypersensitivity indications, today reported its financial and operating results for the second quarter ending June 30, 2022.

"BELLUS remains committed to bringing BLU-5937, our P2X3 antagonist product candidate, to patients burdened by RCC. This quarter, we have successfully identified a clear regulatory path to a potential approval for this candidate, bringing the Company one step closer to making this goal a reality," commented Roberto Bellini, President and Chief Executive Officer of BELLUS Health. "Following the feedback from our End-of-Phase 2 meeting with the FDA and the scientific advice from the EMA we have solidified the trial design for our CALM Phase 3 program and are looking forward to initiating CALM-1 and CALM-2 later this year. With the proceeds from our recent financing, we have significantly improved our cash position, extending our runway to the second half of 2025, and now have sufficient resources to bring us through topline results of both CALM Phase 3 clinical trials."

PROGRAM AND CORPORATE HIGHLIGHTS

Completed positive End-of-Phase 2 meeting with the FDA and received scientific advice from the EMA to support the design of its CALM Phase 3 clinical program for BLU-5937 in RCC.

- The CALM Phase 3 clinical program consists of two pivotal trials (CALM-1 and CALM-2), with primary efficacy endpoint of 24-hour cough frequency measured at 12- and 24-weeks, respectively. The Company has reached alignment with the FDA on the primary efficacy endpoint of 24H cough frequency reduction being assessed using the VitaloJAK cough monitoring system in a patient population enriched for baseline cough frequency.
- 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 trials will also enroll participants with baseline 24H cough frequency <20 coughs/hour. 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/hour.
- The first patient is expected to be enrolled in both CALM-1 and CALM-2 in the fourth quarter of 2022. Topline results from CALM-1 are expected in the second half of 2024.
- In addition, the Company has obtained scientific advice from the EMA and based on the feedback, it will not be making any modifications to the CALM Phase 3 program design. For additional information on the CALM-1 and CALM-2 trials designs, click here.

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

- In July 2022, the Company completed an offering of its common shares resulting in gross proceeds of US$176.0 million and net proceeds of approximately US$164.5 million (the "2022 Offering"), including the full exercise of the over-allotment option.

Presented at the Twelfth London International Cough Symposium ("LICS") and the American Thoracic Society ("ATS") 2022 International Conference.

- Clinical data from the Phase 2b SOOTHE trial was presented at both the 12th LICS, held in London, England from July 13-14, 2022 and the ATS 2022 International Conference, held in San Francisco, California from May 13-18, 2022. The presentation materials are available in the "Scientific Publications" section of BELLUS Health's website.

Pursuing development of its P2X3 pipeline.

- BELLUS Health expects to initiate a Phase 1 clinical trial investigating a once-daily, extended-release formulation of BLU-5937 in the fourth quarter of 2022.

Ended the second quarter of 2022 with cash, cash equivalents and short-term investments totaling US$220.1 million (approximately US$384.6 million proforma cash that includes the cash at the end of the second quarter and the net proceeds from the July 2022 Offering).

FINANCIAL RESULTS

Cash Position: As of June 30, 2022, the Company had available cash, cash equivalents and short-term investments totaling US$220.1 million (excluding proceeds from the July 2022 Offering), compared to US$248.8 million as of December 31, 2021. The net decrease is primarily attributable to funds used to finance the Company's operating activities, mainly the research and development activities associated with its product candidate BLU-5937.

Net Loss: For the quarter ended June 30, 2022, net loss amounted to US$18.8 million (US$0.18 per share), compared to US$17.8 million (US$0.23 per share) for the same period in 2021.

Research and Development Expenses: Research and development expenses, net of research tax credits, amounted to US$12.5 million for the quarter ended June 30, 2022, compared to US$15.2 million for the same period in 2021, a US$2.7 million or 18% year over year decrease. The decrease in research and development expenses is primarily attributable to the decrease in external R&D spend as the Company is transitioning from its Phase 2b SOOTHE clinical trial and is in the planning stage of its Phase 3 clinical program. The decrease is partially offset by higher expenses due to the Company's increased workforce to support the next steps in its development plans for BLU-5937 as well as higher stock-based compensation expense in relation to its stock option plan.

General and Administrative ("G&A") Expenses: General and administrative expenses amounted to US$5.4 million for the quarter ended June 30, 2022, compared to US$2.8 million for the same period in 2021, a US$2.6 million or 92% year over year increase. The increase is mainly attributable to higher stock-based compensation expense in relation to the Company's deferred share unit plan and its stock option plan, as well as to higher external G&A expenses.

Net Finance (Costs) Income: Net finance costs amounted to US$0.9 million for the quarter ended June 30, 2022, compared to a net finance income of US$0.2 million for the same period in 2021. The increase in net finance costs during the current quarter is mainly attributable to a foreign exchange loss resulting from the conversion in US dollars of the Company's net monetary assets denominated in Canadian dollars during the period.

SUMMARY OF FINANCIAL RESULTS

	Three months ended June 30, 2022		Three months ended June 30, 2021	
	(in thousands of dollars, except per share data)			
Revenues	US$	4	US$	4
Research and development expenses, net		(12,460)		(15,201)
General and administrative expenses		(5,379)		(2,805)
Net finance (costs) income		(900)		174
Income taxes		(41)		—
Net loss for the period	US$	(18,776)	US$	(17,828)
Basic and diluted loss per share	US$	(0.18)	US$	(0.23)

The Company's full unaudited consolidated financial statements and accompanying management's discussion and analysis for the three and six-month periods ended June 30, 2022 will be available on SEDAR at www.sedar.com and on EDGAR at www.sec.gov/edgar.

About BLU-5937

BLU-5937, a highly selective P2X3 antagonist, is in development for RCC and other cough hypersensitivity indications.

The P2X3 receptor, which is implicated in cough reflex hypersensitization, is a rational target for treating chronic cough, and it has been evaluated in multiple clinical trials with different P2X3 antagonists. The Company believes that its highly selective P2X3 antagonist has the potential to reduce cough frequency in patients with RCC and improve quality of life while limiting taste disturbance adverse events.

In addition to RCC, the mechanism of action of BLU-5937 may also have broad therapeutic applicability across other cough hypersensitivity indications. The Company is evaluating potential opportunities to study BLU-5937 in additional cough indications where hypersensitivity plays an important role.

About BELLUS Health (www.bellushealth.com)

BELLUS Health is a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of RCC and other cough hypersensitivity indications. The Company's product candidate, BLU-5937, has successfully completed a Phase 2b trial in RCC. BELLUS Health is preparing to initiate its CALM Phase 3 program in the fourth quarter of 2022.

Chronic cough is a cough lasting longer than eight weeks. When the cause of chronic cough cannot be identified or the cough persists despite treatment of all identified associated causes, the condition is referred to as RCC. It is estimated that there are approximately 9 million patients in the United States suffering from RCC. RCC is associated with significant adverse physical, social, and psychological effects on health and quality of life. Currently, there is no specific therapy approved for RCC outside of Japan and Switzerland and treatment options are limited.

The Company is exploring the potential use of BLU-5937 in other patient populations experiencing cough hypersensitivity as well as other P2X3-related hypersensitization conditions.

Forward-Looking Statements

Certain statements contained in this news release, other than statements of fact that are independently verifiable at the date hereof, may constitute "forward-looking statements" within the meaning of Canadian securities legislation and regulations, the U.S. Private Securities Litigation Reform Act of 1995, as amended, and other applicable securities laws. Forward-looking statements are frequently, but not always, identified by words such as "expects," "anticipates," "believes," "intends," "estimates," "potential," "possible," "projects," "plans," and similar expressions. Such statements, based

as they are on the current expectations of management, inherently involve numerous important risks, uncertainties and assumptions, known and unknown, many of which are beyond BELLUS Health's control. Such statements include, but are not limited to, the potential of BLU-5937 to successfully treat RCC and other hypersensitization-related disorders and benefit such patients, BELLUS Health's expectations related to its preclinical studies and clinical trials, including the timing of initiation of and the design of the Phase 3 clinical trials of BLU-5937 in RCC, the timing and outcome of interactions with regulatory agencies, the potential activity and tolerability profile, selectivity, potency and other characteristics of BLU-5937, including as compared to other competitor candidates, especially where head-to-head studies have not been conducted and cross-trial comparisons may not be directly comparable due to differences in study protocols, conditions and patient populations, the commercial potential of BLU-5937, including with respect to patient population, pricing and labeling, BELLUS Health's financial position and sufficiency of cash resources to bring BELLUS Health through topline results of CALM-1 and CALM-2 clinical trials, and the potential applicability of BLU-5937 and BELLUS Health's P2X3 platform to treat other disorders. Risk factors that may affect BELLUS Health's future results include but are not limited to: the benefits and impact on label of its enrichment strategy, estimates and projections regarding the size and opportunity of the addressable RCC market for BLU-5937, the ability to expand and develop its project pipeline, the ability to obtain adequate financing, the ability of BELLUS Health to maintain its rights to intellectual property and obtain adequate protection of future products through such intellectual property, the impact of general economic conditions, general conditions in the pharmaceutical industry, the impact of the ongoing COVID-19 pandemic on BELLUS Health's operations, plans and prospects, including to the initiation and completion of clinical trials in a timely manner or at all, changes in the regulatory environment in the jurisdictions in which BELLUS Health does business, supply chain impacts, stock market volatility, fluctuations in costs, changes to the competitive environment due to consolidation, achievement of forecasted burn rate, achievement of forecasted preclinical study and clinical trial milestones, reliance on third parties to conduct preclinical studies and clinical trials for BLU-5937 and that actual results may differ from topline results once the final and quality-controlled verification of data and analyses has been completed. In addition, the length of BELLUS Health's product candidate's development process and its market size and commercial value are dependent upon a number of factors. Moreover, BELLUS Health's growth and future prospects are mainly dependent on the successful development, patient tolerability, regulatory approval, commercialization and market acceptance of its product candidate BLU-5937 and other products. Consequently, actual future results and events may differ materially from the anticipated results and events expressed in the forward-looking statements. BELLUS Health believes that expectations represented by forward-looking statements are reasonable, yet there can be no assurance that such expectations will prove to be correct. The reader should not place undue reliance, if any, on any forward-looking statements included in this news release. These forward-looking statements speak only as of the date made, and BELLUS Health is under no obligation and disavows any intention to update publicly or revise such statements as a result of any new information, future event, circumstances or otherwise, unless required by applicable legislation or regulation. Please see BELLUS Health's public filings with the Canadian securities regulatory authorities, including, but not limited to, its Annual Information Form, and the United States Securities and Exchange Commission, including, but not limited to, its Annual Report on Form 40-F, for further risk factors that might affect BELLUS Health and its business.

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