BELLUS Health Reports Third Quarter 2022 Financial Results and Business Highlights

November 14, 2022

- Initiated CALM Phase 3 program with topline data expected for CALM-1 and CALM-2 in the second half of 2024 and 2025, respectively -

- Ended third quarter 2022 with US$364.4 million in cash, cash equivalents and short-term investments; Cash runway extended to the second half of 2025 and through expected topline results of both CALM-1 and CALM-2 trials -

LAVAL, Quebec--(BUSINESS WIRE)--Nov. 14, 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 hypersensitivity indications, today reported its financial and operating results for the third quarter ended September 30, 2022.

"We are pleased to announce the initiation of our CALM Phase 3 program, which we expect to be the final clinical step in potentially bringing BLU-5937, our P2X3 antagonist product candidate, to patients burdened by RCC, if approved. To add, this quarter, we have also made key advancements to ensure successful execution of these pivotal trials, including communicating with regulatory officials, conducting validation work on the VitaloJAK – as well as strengthening our cash position," commented Roberto Bellini, President and Chief Executive Officer of BELLUS Health. "With no approved treatments in the United States, RCC remains a high unmet need and we are encouraged by BLU-5937's potential to be an innovative and best-in-class product in the treatment landscape, if approved. We look forward to advancing the CALM program and expect to share topline data from CALM-1 in the second half of 2024."

PROGRAM AND CORPORATE HIGHLIGHTS

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

- BELLUS Health has 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 its 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.
- BELLUS Health 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. BELLUS Health 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 its 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 US$176.0 million public offering of common shares in Canada and the United States.

- In July 2022, the Company completed a public offering of its common shares resulting in gross proceeds of US$176.0 million (the "2022 Offering"), including the full exercise of the option to purchase additional shares. These proceeds extended the Company's 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.

- The Company entered into an agreement with Jefferies LLC pursuant to which the Company 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.
- The Company has filed a prospectus supplement (the "Supplement") dated the date hereof and a short form base shelf prospectus dated August 26, 2022 (the "Base Prospectus") and in the United States pursuant to a registration statement on Form F-10, which was declared effective by the U.S. Securities and Exchange Commission on August 26, 2022, in accordance with the Multijurisdictional Disclosure System established between Canada and the United States.
- Copies of the Supplement and accompanying Base Prospectus may be obtained by contacting Jefferies LLC, Attention: Equity Syndicate Prospectus Department, 520 Madison Avenue, 2nd Floor, New York, NY 10022, by telephone at 877-821-7388 or by email at prospectus_department@jefferies.com. The Sales Agreement, the Supplement and the accompanying Base Prospectus can also be found on SEDAR at www.sedar.com and on EDGAR at www.sec.gov.
- 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 US$364.4 million.

FINANCIAL RESULTS

Cash Position: As of September 30, 2022, the Company had available cash, cash equivalents and short-term investments totaling US$364.4 million, compared to US$248.8 million as of December 31, 2021. The net increase is primarily attributable to funds obtained through the 2022 Offering, offset in part by funds used to finance its operating activities, mainly the research and development activities associated with its product candidate BLU-5937.

Net Loss: For the quarter ended September 30, 2022, net loss amounted to US$24.7 million (US$0.20 per share), compared to US$22.9 million (US$0.29 per share) for the same period in 2021.

Research and Development Expenses: Research and development expenses, net of research tax credits, amounted to US$17.2 million for the quarter ended September 30, 2022, compared to US$19.1 million for the same period in 2021, a US$1.8 million or 10% quarter over quarter decrease. The decrease in research and development expenses is primarily attributable to a decrease in external R&D spend as the Company has transitioned from its Phase 2b SOOTHE clinical trial to the initiation of its CALM Phase 3 clinical program. The decrease is partially offset by higher expenses due to the Company's increased workforce to support the CALM Phase 3 program as well as higher stock-based compensation expense in relation to the Company's stock option plan.

General and Administrative ("G&A") Expenses: General and administrative expenses amounted to US$5.8 million for the quarter ended September 30, 2022, compared to US$3.8 million for the same period in 2021, a US$2.0 million or 53% quarter over quarter increase. The increase is mainly attributable to higher external G&A expenses, as well as to higher stock-based compensation expense in relation to the Company's stock option plan.

Net Finance Costs: Net finance costs amounted to US$1.7 million for the quarter ended September 30, 2022, compared to US$0.0 million for the same period in 2021. The increase in net finance costs during the current quarter is mainly attributable to an increase in foreign exchange loss resulting from the conversion in U.S. dollars of the Company's net monetary assets denominated in Canadian dollars during the period, due to the weakening of the Canadian dollar versus the U.S. dollar during the period. 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.

SUMMARY OF FINANCIAL RESULTS

	Three months ended September 30, 2022		Three months ended September 30, 2021	
	(in thousands of dollars, except per share data)			
Revenues	US$	4	US$	4
Research and development expenses, net		(17,241)		(19,054)
General and administrative expenses		(5,838)		(3,821)
Net finance income		(1,656)		(10)
Income taxes		25		—
Net loss for the year	US$	(24,706)	US$	(22,881)
Basic and diluted loss per share	US$	(0.20)	US$	(0.29)

The Company's full unaudited consolidated financial statements and accompanying management's discussion and analysis for the three- and nine-month periods ended September 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 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 neuronal hypersensitivity indications. The Company is evaluating potential opportunities to study BLU-5937 in additional 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 hypersensitivity indications. The Company has successfully completed a Phase 2b trial in RCC and has initiated the CALM Phase 3 clinical program (CALM-1 and CALM-2).

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.

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 completion of its Phase 3 clinical trials of BLU-5937 in RCC and the expected timing of topline results from CALM-1 and CALM-2 Phase 3 clinical trials, the timing and outcome of interactions with regulatory agencies, the ability of BELLUS Health to validate its use of the VitaloJAK to the satisfaction of relevant 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 and potential treatment alternatives, BELLUS Health’s financial position and sufficiency of cash resources to bring through topline results of CALM-1 and CALM-2 clinical trials, timely or at all, 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, that final data from studies and clinical trials may differ from reported data from preliminary studies or clinical trials 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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