BELLUS Health Reports Year 2022 Financial Results and Business Highlights

March 21, 2023 8:30 PM EDT

- Patient enrollment ongoing in the CALM Phase 3 program with topline data expected for CALM-1 in the second half of 2024 -

- Ended year with US$337.1 million in cash, cash equivalents and short-term investments; cash runway extends to the second half of 2025 and through expected topline results of both CALM-1 and CALM-2 trials -

LAVAL, Quebec--(BUSINESS WIRE)--Mar. 21, 2023-- BELLUS Health Inc. (Nasdaq:BLU; TSX:BLU) ("BELLUS Health" or the "Company"), a clinical-stage biopharmaceutical company working to better the lives of patients suffering from persistent cough, starting with the development of camlipixant (BLU-5937) for the treatment of refractory chronic cough ("RCC"), today reported its financial and operating results for the year ended December 31, 2022.

"In 2022, we laid the groundwork to advance camlipixant, our P2X3 receptor antagonist product candidate with best-in-class potential, into late-stage development in RCC. This included interacting with regulatory officials, solidifying the CALM Phase 3 trial designs and conducting validation work on the VitaloJAK cough monitoring system – all of which allowed us to initiate CALM-1 and CALM-2 in the fourth quarter," commented Roberto Bellini, President and Chief Executive Officer of BELLUS Health. "Looking ahead to 2023, we will remain focused on advancing our CALM Phase 3 clinical program and building out our commercial strategy, while tracking the upcoming key developments in the P2X3 receptor class."

PROGRAM AND CORPORATE HIGHLIGHTS

Actively advancing the CALM Phase 3 clinical program (CALM-1 and CALM-2 trials) for camlipixant (BLU-5937) in RCC, with patient enrollment ongoing.

- The CALM Phase 3 clinical program was initiated in the fourth quarter of 2022, with patient enrollment 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 cough monitoring system 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 systematic error observed. BELLUS Health submitted a validation protocol and statistical analysis plan to the FDA in the fourth quarter of 2022.
- Topline results from CALM-1 are expected in the second half of 2024, and topline results from CALM-2 in 2025.

Completed large U.S. physician survey on the RCC market landscape in 2022.

- Survey included 1,483 U.S. pulmonologists, allergists, ENTs, gastroenterologists and primary care physicians and showed 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 receptor pipeline.

- The Phase 1 clinical trial investigating the pharmacokinetics of a once daily, extended-release formulation of camlipixant is ongoing. The study is expected to be completed in the second quarter of 2023.

Presented SOOTHE clinical data at the American Academy of Allergy, Asthma & Immunology ("AAAAI") Annual Meeting and the CHEST Annual Meeting.

- Clinical data from the Phase 2b SOOTHE trial was presented at the AAAAI Annual Meeting, held in San Antonio, Texas from February 24-27, 2023, and the CHEST Annual Meeting, held in Nashville, Tennessee from October 16-19, 2022. The presentation materials are available in

the “Scientific Publications” section of BELLUS Health's website here.

Presenting on camlipixant’s drug-drug interactions at the American Society of Clinical Pharmacology & Therapeutics (“ASCPT”) 2023 Annual Meeting, being held in Atlanta, GA.

- A poster presentation titled “In Vitro, In Silico, and Clinical Investigations of BLU-5937 as Perpetrator of Drug-Drug Interactions” will be presented at the upcoming ASCPT 2023 Annual Meeting on Thursday, March 23, 2023 from 5:00 – 6:30 p.m. ET. Following the conference, the poster will be available in the “Scientific Publications” section of BELLUS Health's website here.

Ended the year with cash, cash equivalents and short-term investments totaling US$337.1 million.

FINANCIAL RESULTS

Cash Position: As of December 31, 2022, the Company had available cash, cash equivalents and short-term investments totaling US$337.1 million, compared to US$248.8 million as of December 31, 2021. The net increase is primarily attributable to the Company’s offering in July 2022, offset in part by funds used to finance its operating activities, mainly the research and development activities associated with its product candidate camlipixant.

Net Loss: For the year ended December 31, 2022, net loss amounted to US$76.1 million (US$0.66 per share), compared to US$71.2 million (US$0.90 per share) for the previous year.

Research and Development Expenses: Research and development expenses, net of research tax credits, amounted to US$58.4 million for the year ended December 31, 2022, compared to US$59.0 million for the previous year, a US$0.6 million or 1% year over year decrease. The decrease 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 in 2022, offset in part by higher stock-based compensation expense in relation the Company’s stock option plan and higher workforce expenses due to an increase in headcount to support the development of camlipixant.

General and Administrative (“G&A”) Expenses: General and administrative expenses amounted to US$19.5 million for the year ended December 31, 2022, compared to US$14.3 million for the previous year, a US$5.2 million or 37% year over year 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 Income: Net finance income amounted to US$1.9 million for the year ended December 31, 2022, compared to US$1.9 million for the previous year. In 2022, there was higher interest income compared to the previous year due to the increased cash, cash equivalents and short-term investments position following the offerings in 2022 and 2021 and the increase in interest rates, offset in part by 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 year (vs a foreign exchange gain in 2021), due to the weakening of the Canadian dollar versus the U.S. dollar in 2022.

SUMMARY OF FINANCIAL RESULTS

	Unaudited			
	Year ended December 31, 2022		Year ended December 31, 2021	
	(in thousands of dollars, except per share data)			
Revenues	US$	16	US$	16
Research and development expenses, net		(58,403)		(59,037)
General and administrative expenses		(19,496)		(14,263)
Net finance income		1,863		1,861
Income tax (expense) recovery		(60)		199
Net loss for the year	US$	(76,080)	US$	(71,224)
Basic and diluted loss per share	US$	(0.66)	US$	(0.90)

The Company’s full audited consolidated financial statements and accompanying management’s discussion and analysis for the year ended December 31, 2022 will be available shortly on SEDAR at www.sedar.com and on EDGAR at www.sec.gov/edgar.

About Camlipixant (BLU-5937)

Camlipixant, a highly selective P2X3 receptor 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 successfully evaluated in multiple clinical trials with different P2X3 antagonists. The Company believes that camlipixant’s high selectivity as a P2X3 receptor antagonist and the results of its Phase 2b SOOTHE trial position it as a potential best in class P2X3 receptor antagonist to significantly improve the quality of life of patients suffering from RCC.

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

About BELLUS Health (www.bellushealth.com)

BELLUS Health is a clinical-stage biopharmaceutical company working to better the lives of patients suffering from persistent cough, starting with the development of camlipixant (BLU-5937) for the treatment of refractory chronic cough (RCC). Camlipixant, the Company’s lead asset, is an investigational P2X3 receptor antagonist for the treatment of RCC, which is currently being evaluated in the CALM Phase 3 clinical program. With no approved treatments in the U.S., camlipixant has the potential to be a breakthrough in the RCC treatment landscape.

Chronic cough is defined as a cough lasting longer than eight weeks. When the cause of chronic cough cannot be identified or the cough persists despite treatment of any associated condition, the condition is referred to as RCC. RCC is a frequent, yet often under-recognized, medical condition that has significant physical, social, and psychological consequences on one's quality of life. There are currently no approved treatments for this condition in the United States, European Union or the United Kingdom.

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 camlipixant (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 camlipixant 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 cough monitoring system to the satisfaction of relevant regulatory agencies, the potential activity and tolerability profile, selectivity, potency and other characteristics of camlipixant, 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 camlipixant, 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 camlipixant and BELLUS Health's P2X3 receptor platform to treat other disorders. Risk factors that may affect BELLUS Health's future results include but are not limited to: the intended benefits, acceptability to regulatory agencies and impact of its enrichment strategy, continuing feedback and discussions with the FDA and other regulatory authorities regarding the design of the CALM Phase 3 program, estimates and projections regarding the size and opportunity of the addressable RCC market for camlipixant, 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 camlipixant, 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 camlipixant 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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