



BELLUS Health Reports First Quarter 2023 Financial Results and Business Highlights

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- Announced agreement to be acquired by GSK for US\$14.75 per share of common stock in cash representing an approximate total equity value of US\$2.0 billion and a premium of approximately 103%; transaction expected to close in Q3 2023 –

LAVAL, Quebec--(BUSINESS WIRE)--May 12, 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 quarter ended March 31, 2023.

"Our merger agreement with GSK underscores our corporate and clinical achievements to date and marks the start of a new chapter for our potentially best-in-class P2X3 receptor antagonist, camlipixant," commented Roberto Bellini, President and Chief Executive Officer of BELLUS Health. "We are confident that GSK's resources and focused expertise in the development and commercialization of respiratory therapies will help us to achieve our mission of bettering the lives of patients suffering from persistent cough. As we work to close this transaction with GSK, we remain committed to advancing our CALM Phase 3 program and are on track to report topline data from CALM-1 in the second half of 2024 and CALM-2 in 2025."

PROGRAM AND CORPORATE HIGHLIGHTS

GSK to acquire BELLUS Health.

- On April 18, 2023, GSK plc (LSE/NYSE: GSK) and BELLUS Health Inc. (TSX/NASDAQ: BLU) announced that they have entered into an agreement under which GSK will acquire BELLUS Health for US\$14.75 per share of common stock in cash representing an approximate total equity value of US\$2.0 billion. The per-share price represents a premium of approximately 103% to BELLUS Health's closing stock price on April 17, 2023 and a premium of approximately 101% to BELLUS Health's volume-weighted average price (VWAP) over the prior 30 trading days. The transaction remains subject to shareholder and regulatory approvals and is expected to close in the third quarter of 2023 or earlier.

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 by the Company 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 24-hour 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](#).
- Topline results from CALM-1 are expected in the second half of 2024, and topline results from CALM-2 are expected in 2025.

Pursuing development of its P2X3 receptor pipeline.

- BELLUS Health reported positive results from its Phase 1 clinical trial investigating the safety, tolerability, and pharmacokinetic profile of a once-daily, Extended-Release ("ER") formulation of camlipixant. The ER formulation demonstrated equivalent bioavailability to the twice-daily Immediate Release ("IR") formulation. In addition, the ER formulation was well tolerated, with safety data observed to be consistent with previous camlipixant trials and no taste-related adverse events reported.

Presenting at the upcoming American Thoracic Society ("ATS") 2023 International Conference, being held in Washington, DC from May 19-24, 2023.

- The Company will be presenting an oral abstract entitled "Response in Patient-reported Cough

Severity in SOOTHE, a Phase 2b Trial of Camlipixant in Refractory Chronic Cough” on Sunday, May 21, 2023 at 3:15-3:27 p.m. ET, and a poster presentation entitled “Model-based Dose Selection for Phase 3 Trials of the Selective P2X3 Antagonist Camlipixant in Refractory Chronic Cough” will be presented on Monday, May 22, 2023 at 11:30-1:15 p.m. ET. Following the ATS 2023 International Conference, the presentation materials will be available in the “Scientific Publications” section of BELLUS Health's website [here](#).

- Additionally, conference participants are invited to attend two BELLUS Health-sponsored Guru Bars on Tuesday, May 23, 2023. Booth #1100 entitled “Refractory Chronic Cough: Is it All in Our Head?” will be available at 1:00-1:20 p.m. ET and Booth #1200 entitled “Understanding the Roadmap to Diagnosing Refractory Chronic Cough” will be available at 1:30-1:50 p.m. ET.

Presented at the American Academy of Allergy, Asthma & Immunology (“AAAAI”) Annual Meeting and at the American Society of Clinical Pharmacology & Therapeutics (“ASCPT”) 2023 Annual Meeting.

- The Company presented clinical data from the Phase 2b SOOTHE trial at the AAAAI Annual Meeting, held in San Antonio, Texas from February 24-27, 2023. The Company also presented results from phase 1 drug-drug interactions studies of camlipixant at the ASCPT 2023 Annual Meeting, held in Atlanta, Georgia from March 22-24, 2023. The presentation materials are available in the “Scientific Publications” section of BELLUS Health's website [here](#).

FINANCIAL RESULTS

Cash Position: As of March 31, 2023, the Company had available cash, cash equivalents and short-term investments totaling US\$313.0 million, compared to US\$337.1 million as of December 31, 2022. The net decrease for the three-month period ended March 31, 2023 is primarily attributable to funds used to finance the Company's operating activities, mainly the research and development activities associated with its product candidate camlipixant (BLU-5937).

Net Loss: For the quarter ended March 31, 2023, net loss amounted to US\$25.1 million (US\$0.20 per share), compared to US\$14.4 million (US\$0.13 per share) for the same period in 2022.

Research and Development Expenses: Research and development expenses, net of research tax credits, amounted to US\$22.3 million for the quarter ended March 31, 2023, compared to US\$11.3 million for the same period in 2022, a US\$11.0 million or 98% year over year increase. The increase is primarily attributable to higher external R&D spend incurred for the development of camlipixant, mainly for activities in relation to the Company's CALM Phase 3 clinical program, which was initiated in the fourth quarter of 2022. The increase is also due to higher stock-based compensation expense in relation to 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\$5.4 million for the quarter ended March 31, 2023, compared to US\$4.1 million for the same period in 2022, a US\$1.3 million or 33% 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\$2.7 million for the quarter ended March 31, 2023, compared to US\$1.0 million for the same period in 2022. The increase in net finance income is mainly attributable to higher interest income due to the increased cash, cash equivalents and short-term investments position following the July 2022 Offering and the increase in interest rates, offset in part by a lower foreign exchange gain in the current period resulting from the conversion in U.S. dollars of the Company's net monetary assets denominated in Canadian dollars.

SUMMARY OF FINANCIAL RESULTS

	Unaudited	
	Quarter ended March 31, 2023	Quarter ended March 31, 2022
	(in thousands of dollars, except per share data)	
Revenues	US\$ 3	US\$ 4
Research and development expenses, net	(22,335)	(11,254)
General and administrative expenses	(5,392)	(4,050)
Net finance income	2,683	973
Income tax expense	(19)	(25)
Net loss for the period	US\$ (25,060)	US\$ (14,352)
Basic and diluted loss per share	US\$ (0.20)	US\$ (0.13)

The Company's full unaudited consolidated interim financial statements and accompanying management's discussion and analysis for the quarter ended March 31, 2023 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 refractory chronic cough (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 closing of the acquisition of BELLUS Health by GSK, the timeline thereof and the realization of the anticipated benefits from the transaction, 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, 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: risks associated with the closing of the acquisition of BELLUS Health by GSK on the expected timeline, including as regards regulatory and shareholder approvals, 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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