



BELLUS Health Reports First Quarter 2022 Financial Results and Business Highlights

May 11, 2022

- End-of-Phase 2 meeting with the U.S. Food and Drug Administration ("FDA") scheduled for June of 2022; Plan to initiate the Phase 3 program in the second half of 2022 -
- Three late-breaking abstracts reviewing clinical data from the Phase 2b SOOTHE trial will be presented at the upcoming American Thoracic Society ("ATS") 2022 International Conference -
- Ended first quarter 2022 with US\$234.0 million in cash, cash equivalents and short-term investments -

LAVAL, Quebec--(BUSINESS WIRE)--May 11, 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 first quarter ending March 31, 2022.

"This quarter, we have focused our efforts on our clinical plans for BLU-5937, our highly selective, second generation P2X3 antagonist product candidate, for the treatment of RCC," commented Roberto Bellini, President and Chief Executive Officer of BELLUS Health. "To that end, we have been granted an End-of-Phase 2 meeting with the FDA in June of this year to discuss and solidify elements of the Phase 3 program, which we plan to begin in the second half of this year. In light of the positive Phase 2b SOOTHE trial and the most recent developments in the P2X3 class, we are confident BLU-5937 has the potential to become a best-in-class treatment for RCC, if approved. The need for chronic cough treatments remains high and we are determined to fill this gap in care with a differentiated treatment option for the patients affected."

PROGRAM AND CORPORATE HIGHLIGHTS

End-of-Phase 2 meeting with the FDA scheduled for June of 2022.

- During the End-of-Phase 2 meeting with the FDA, BELLUS Health intends to discuss its planned Phase 3 program, which the Company expects to initiate in the second half of 2022. The Company will also obtain scientific advice from the European Medicines Agency ("EMA") and the Medicines and Healthcare products Regulatory Agency ("MHRA").

Presenting at the upcoming ATS 2022 International Conference.

- Three late-breaking abstracts reviewing clinical data from the Phase 2b SOOTHE trial, including new responder analysis data, will be presented at the upcoming ATS 2022 International Conference, being held in San Francisco, California from May 13-18, 2022. The abstracts are currently available on the ATS website:
 - "Safety And Efficacy of BLU-5937 In the Treatment of Refractory Chronic Cough from the Phase 2b SOOTHE Trial" ([view abstract](#));
 - "Responders Analyses in Objective 24H Cough Frequency in SOOTHE, a Phase 2b Trial of a Selective P2X3 Antagonist in Refractory Chronic Cough" ([view abstract](#));
 - "Improvements in Cough Severity and Quality of Life in SOOTHE, a Phase 2b, Dose Finding Trial of BLU-5937 in Refractory Chronic Cough" ([view abstract](#)).

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 second half of 2022.

Ended the first quarter of 2022 with cash, cash equivalents and short-term investments totaling US\$234.0 million.

FINANCIAL RESULTS

Cash Position: As of March 31, 2022, the Company had available cash, cash equivalents and short-term investments totaling US\$234.0 million, 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 BLU-5937.

Net Loss: For the quarter ended March 31, 2022, net loss amounted to US\$14.4 million (US\$0.13 per share), compared to US\$15.8 million (US\$0.20 per share) for the same period in 2021. The decrease in net loss is primarily attributable to lower research and development expenses in relation to the development of BLU-5937.

Research and Development Expenses: Research and development expenses, net of research tax credits, amounted to US\$11.3 million for the quarter ended March 31, 2022, compared to US\$12.5 million for the same period in 2021, a US\$1.2 million or 10% 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 trial and is in the planning stage of its Phase 3 program, which is expected to be initiated in the second half of 2022.

General and Administrative (“G&A”) Expenses: General and administrative expenses amounted to US\$4.1 million for the quarter ended March 31, 2022, compared to US\$3.5 million for the same period in 2021, a US\$0.6 million or 17% year over year increase. The increase is mainly attributable to higher expenses related to pre-commercial activities.

Net Finance Income: Net finance income amounted to US\$1.0 million for the quarter ended March 31, 2022, compared to US\$0.2 million for the same period in 2021. The increase in net finance income is mainly attributable to a higher foreign exchange gain 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 March 31, 2022		Three months ended March 31, 2021	
	(in thousands of dollars, except per share data)			
Revenues	US\$	4	US\$	4
Research and development expenses, net		(11,254)		(12,448)
General and administrative expenses		(4,050)		(3,470)
Net finance income		973		163
Income taxes		(25)		—
Net loss for the year	US\$	(14,352)	US\$	(15,751)
Basic and diluted loss per share	US\$	(0.13)	US\$	(0.20)

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

BELLUS Health Announces Election of Directors at Annual Meeting

At the Annual Meeting of Shareholders held by webcast today, the following director nominees listed in the Management Information Circular dated March 23, 2022 were elected as Directors of the Company.

The details of the election are as follows:

Director Nominee	Outcome	Votes For	% For	Votes Withheld	% Withheld
Dr. Francesco Bellini, O.C.	Elected	74,115,825	99.02%	732,126	0.98%
Roberto Bellini	Elected	74,822,654	99.97%	25,297	0.03%
Dr. Youssef L. Bennani	Elected	73,859,442	98.68%	988,509	1.32%
Franklin M. Berger	Elected	67,271,057	89.88%	7,576,894	10.12%
Dr. Clarissa Desjardins	Elected	73,701,642	98.47%	1,146,282	1.53%
Pierre Larochelle	Elected	74,826,580	99.97%	21,371	0.03%
Dr. William Mezzanotte	Elected	74,668,597	99.76%	179,353	0.24%
Joseph Rus	Elected	74,825,707	99.97%	22,244	0.03%

The results of the final votes regarding all matters subject to a vote during the Annual Meeting that took place today will be made available on SEDAR at www.sedar.com and on EDGAR at www.sec.gov/edgar.

Automatic Securities Disposition Plans

The Company also announced that Denis Garceau, Chief Scientific Officer, Tony Matzouranis, Senior Vice President, Business Development and Francois Desjardins, Senior Vice President, Finance (collectively, the “Executives”), have established Automatic Securities Disposition Plans (“ASDPs”) in accordance with applicable United States and Canadian securities legislation, including U.S. Securities and Exchange Commission rule 10b5-1 and the recommended practices set forth in Canadian Securities Administrators’ Staff Notice 55-317 (“Staff Notice 55-317”) and the Company’s internal policies. The ASDPs have also been approved by the Company.

The ASDPs permit trades to be made in accordance with pre-arranged instructions. Up to 188,000 common shares of the Company may be sold under the ASDPs implemented by the Executives in the aggregate. The ASDPs are designed to allow for an orderly disposition of each of the Executives’ shares in the Company at prevailing market prices over the course of the 12 month-period during which the ASDPs will be in place. Sales of the common shares under the ASDPs will commence no earlier than March 1, 2023.

The ASDPs contain meaningful restrictions on the ability of the Executives to amend, suspend or terminate the ASDPs.

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 cough 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 planning a Phase 3 program, which is expected to begin in the second half 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 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 its Phase 3 clinical trials of BLU-5937 in RCC, the timing and outcome of interactions with regulatory agencies, including its planned End-of-Phase 2 meeting with the FDA, 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 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.

Source: BELLUS Health Inc.

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