BELLUS Health Reports Year 2021 Financial Results and Business Highlights

February 23, 2022

- Announced positive topline results from the Phase 2b SOOTHE clinical trial in refractory chronic cough ("RCC"), positioning BLU-5937 as a potentially best-in-class P2X3 antagonist -

- Plans to request an End-of-Phase 2 meeting with the Food and Drug Administration ("FDA") in the second quarter and initiate the Phase 3 program in the second half of 2022 -

- Ended year with US$248.8 million in cash, cash equivalents and short-term investments -

LAVAL, Quebec--(BUSINESS WIRE)--Feb. 23, 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 and other cough hypersensitivity indications, today reported its financial and operating results for the year ending December 31, 2021.

"2021 was a momentous year for BELLUS Health, underscored by positive topline results from the Phase 2b SOOTHE trial and developments within the P2X3 class that positioned BLU-5937 as a differentiated product candidate with the potential to be best-in-class," commented Roberto Bellini, President and Chief Executive Officer of BELLUS Health. "Our optimized Phase 2b design showcased the true promise of our highly selective, second generation P2X3 antagonist in RCC, demonstrating its ability to significantly decrease cough frequency with a favorable tolerability profile. We look forward to another productive year ahead, as we plan to take the necessary steps – including conducting an End-of-Phase 2 meeting with the FDA – to initiate our Phase 3 program in RCC this year."

PROGRAM AND CORPORATE HIGHLIGHTS

Announced positive topline results from the Phase 2b SOOTHE clinical trial of BLU-5937 in patients with RCC.

- In December 2021, BELLUS Health announced that the 50 mg and 200 mg twice-daily ("BID") doses of BLU-5937 in its Phase 2b SOOTHE clinical trial for the treatment of RCC each achieved statistical significance on the primary endpoint, with 34% placebo-adjusted reduction in 24-hour cough frequency observed at day 28. BLU-5937 was generally well-tolerated. Additionally, a dose response was observed between 12.5 mg and 50 mg BID doses.
- The Company intends to request an End-of-Phase 2 meeting with the FDA to discuss its planned Phase 3 program. The meeting is expected to take place in the second quarter of 2022, with plans to initiate the Phase 3 program in the second half of 2022. The Company also intends to obtain scientific advice from the European Medicines Agency.

Completed a $224 million offering in December 2021.

- In December 2021, the Company completed an offering of its common shares (the "2021 Offering") resulting in gross proceeds, including from the underwriters' partial exercise of their over-allotment option, of $224 million.

Announced an update on its P2X3 pipeline.

- The Company believes the success of its Phase 2b SOOTHE clinical trial further validates the role of P2X3 in cough hypersensitivity. BELLUS Health intends to evaluate potential opportunities to study BLU-5937 in additional cough indications where hypersensitivity plays an important role.
- The Company plans to initiate a Phase 1 clinical trial investigating a once-daily ("QD"), extended release formulation of BLU-5937 in the second half of 2022.
- In December 2021, BELLUS Health announced that the Phase 2a BLUEPRINT clinical trial evaluating BLU-5937 in chronic pruritus did not meet the primary endpoint. The Company does not intend to pursue development of BLU-5937 in pruritic conditions.

Hosted a virtual Analyst Event to discuss the chronic cough landscape and its selective P2X3 antagonist BLU-5937.

- On November 15, 2021, the Company hosted an Analyst Event to discuss topics including the RCC landscape, clinical development updates for BLU-5937, RCC market dynamics and P2X3 antagonist platform potential. The event was hosted virtually, and a replay of the event is available on the Events & Presentations page of the Company's website.

Ended the year with cash, cash equivalents and short-term investments totaling US$248.8 million.

FINANCIAL RESULTS

Cash Position: As of December 31, 2021, the Company had available cash, cash equivalents and short-term investments totaling US$248.8 million, compared to US$98.3 million as of December 31, 2020. The net increase is primarily attributable to funds received from the 2021 Offering, offset 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 year ended December 31, 2021, net loss amounted to US$71.2 million (US$0.90 per share), compared to US$31.8 million (US$0.54 per share) for the previous year. The increase in net loss is primarily attributable to higher research and development expenses in relation to the development of BLU-5937, the Company's product candidate for the treatment of RCC.

Research and Development Expenses: Research and development expenses, net of research tax credits, amounted to US$59.0 million for the year ended December 31, 2021, compared to US$23.2 million for the previous year, a US$35.8 million or 154% year over year increase to support the development of BLU-5937. The increase is primarily attributable to higher expenses incurred for the development of BLU-5937.

General and Administrative ("G&A") Expenses: General and administrative expenses amounted to US$14.3 million for the year ended December 31, 2021, compared to US$9.7 million for the previous year, a US$4.6 million or 47% year over year increase. The increase is mainly attributable to higher stock-based compensation expenses related to the Company's stock option and deferred share unit plans.

Net Finance Income: Net finance income amounted to US$1.9 million for the year ended December 31, 2021, compared to US$1.2 million for the previous year. The increase in net finance income is mainly attributable to a higher foreign exchange gain, offset in part by lower interest income.

SUMMARY OF FINANCIAL RESULTS

	Year ended December 31, 2021		Year ended December 31, 2020	
	(in thousands of dollars, except per share data)			
Revenues	US$	16	US$	15
Research and development expenses, net		(59,037)		(23,222)
General and administrative expenses		(14,263)		(9,735)
Net finance income		1,861		1,185
Income taxes		199		—
Net loss for the year	US$	(71,224)	US$	(31,757)
Basic and diluted loss per share	US$	(0.90)	US$	(0.54)

The Company's full audited consolidated financial statements and accompanying management's discussion and analysis for the year ended December 31, 2021 will be available shortly 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 afferent hypersensitization-related disorders, enabling the Company to consider BLU-5937 as a potential treatment for development in a number of other indications. Consequently, BELLUS Health is exploring the potential use of BLU-5937 in other patient populations experiencing cough hypersensitivity as well as other P2X3-related hypersensitization conditions.

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 and is planning a Phase 3 program that is expected to begin in the second half of 2022.

RCC is a cough lasting more than 8 weeks despite appropriate treatment for underlying condition(s). 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 psychosocial 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 trial 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 intention to discontinue development of BLU-5937 in pruritic conditions, 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20220223006178/en/

Ramzi Benamar
Chief Financial Officer
rbenamar@bellushealth.com

Media:
Julia Deutsch
Solebury Trout
jdeutsch@soleburytrout.com

Source: BELLUS Health Inc.