BELLUS Health Reports Third Quarter 2021 Financial Results and Business Highlights

November 10, 2021

- Announced positive findings from the Phase 2b SOOTHE trial administrative interim analysis, with at least one dose of BLU-5937 meeting the threshold for a high probability of clinical efficacy -

- Phase 2b SOOTHE and Phase 2a BLUEPRINT trials are fully enrolled, with topline results expected in December 2021 -

- Ended third quarter 2021 with US$58.4M cash and cash runway extending to end of 2022 -

LAVAL, Quebec--(BUSINESS WIRE)--Nov. 10, 2021-- 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 hypersensitization-related disorders, today reported its financial and operating results for the third quarter ending September 30, 2021.

"We are pleased with the substantial progress we have made advancing our two ongoing Phase 2 trials this quarter, as the clinical milestones achieved for each of these trials represent important steps forward in our development strategy for our selective P2X3 antagonist, BLU-5937," commented Roberto Bellini, President and Chief Executive Officer of BELLUS Health. "Both SOOTHE and BLUEPRINT trials completed participant enrollment in September, which should enable us to announce topline results from both trials in December 2021. Importantly, we reported positive interim findings from the SOOTHE trial in refractory chronic cough and, while we wait for topline results, we have initiated our planning efforts for the Phase 3 program. We're looking forward to an eventful fourth quarter, with our virtual Analyst Event taking place on November 15th, in addition to the expected topline data from our two randomized, placebo-controlled Phase 2 trials."

PROGRAM AND CORPORATE HIGHLIGHTS

Ongoing Phase 2b SOOTHE clinical trial of BLU-5937 in patients with RCC.

- In September 2021, the Company announced positive findings from a preplanned administrative interim analysis of the SOOTHE trial. A predefined stringent probability threshold for clinical efficacy was met for at least one and up to all three doses of BLU-5937 tested. Limited taste-related adverse events were observed, consistent with previous BLU-5937 trials, and no serious adverse events were reported.
- As of September 2021, the Company completed participant enrollment in the SOOTHE trial with a total of 310 participants with RCC enrolled, including 249 participants in the main trial and 61 in the exploratory group.
- Topline results are expected in December 2021.
- The positive findings from the SOOTHE trial interim analysis enabled the Company to accelerate the planning for its Phase 3 program while awaiting the SOOTHE trial's final results.

Ongoing Phase 2a BLUEPRINT clinical trial of BLU-5937 in patients with chronic pruritus associated with atopic dermatitis ("AD").

- As of September 2021, the Company completed participant enrollment in the BLUEPRINT trial, with a total of 142 participants with moderate to severe chronic pruritus associated with mild to moderate AD enrolled.
- Topline results are expected in December 2021.

Presented additional RELIEF data at the European Respiratory Society International Congress 2021 ("ERS")

- Additional data from the Phase 2a RELIEF trial was presented in an oral presentation at ERS, which was held September 5-8, 2021. The presentation reviewed the observed improvements seen in cough severity and quality of life over a 16-day treatment period that favored BLU-5937.

Hosting a virtual Analyst Event to discuss the chronic cough landscape and the Company's selective P2X3 antagonist BLU-5937.

- On November 15, 2021, the Company is planning to host 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 will be hosted virtually, and a replay of the event will be available on the Events & Presentations page of the Company's website.

Ended the third quarter of 2021 with cash, cash equivalents and short-term investments totaling US$58.4 million.

- Current cash position is expected to be sufficient to fund the Company's operating plan until the end of 2022.

FINANCIAL RESULTS

Cash Position: As of September 30, 2021, the Company had available cash, cash equivalents and short-term investments totaling US$58.4 million,

compared to US$98.3 million as of December 31, 2020. The net decrease is primarily attributable to funds used to finance the Company's operating activities, mainly the research and development activities associated with its product candidate BLU-5937.

Net Loss: For the quarter ended September 30, 2021, net loss amounted to US$22.9 million (US$0.29 per share), compared to US$5.7 million (US$0.09 per share) for the same period in 2020.

Research and Development Expenses: Research and development expenses, net of research tax credits, amounted to US$19.1 million for the quarter ended September 30, 2021, compared to US$5.8 million for the same period in 2020, an increase of US$13.3 million or 229% year over year. The increase is primarily attributable to higher expenses incurred for the development of BLU-5937, mainly activities in relation to the Phase 2b SOOTHE trial in RCC, as well as activities in relation to the Phase 2a BLUEPRINT trial in chronic pruritus associated with AD, preclinical and clinical development activities to support the Company's RCC program and CMC activities.

General and Administrative ("G&A") Expenses: General and administrative expenses amounted to US$3.8 million for the quarter ended September 30, 2021, compared to US$0.5 million for the same period in 2020, an increase of US$3.3 million or 738% year over year. The increase is mainly attributable to a higher stock-based compensation expense related to the Company's deferred share unit plan, due to an increase in the stock price compared to the previous year.

Net Finance (Costs) Income: Net finance costs amounted to US$0.0 million for the quarter ended September 30, 2021, compared to a net finance income of US$0.5 million for the same period in 2020. The increase in net finance costs is mainly attributable to a foreign exchange loss that arose from the translation of the Company's net monetary assets denominated in Canadian dollars during the period, compared to a foreign exchange gain in the corresponding period the previous year, as well as to lower interest income due to lower interest rates on short term investments.

SUMMARY OF FINANCIAL RESULTS

	Three months ended September 30, 2021		Three months ended September 30, 2020	
	(in thousands of dollars, except per share data)			
Revenues	US$	4	US$	3
Research and development expenses, net		(19,054)		(5,796)
General and administrative expenses		(3,821)		(456)
Net finance (costs) income		(10)		540
Net loss for the period	US$	(22,881)	US$	(5,709)
Basic and diluted loss per share	US$	(0.29)	US$	(0.09)

The Company's full unaudited condensed consolidated interim financial statements and accompanying management's discussion and analysis for the three and nine-month periods ended September 30, 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, chronic pruritus and other hypersensitization-related disorders.

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, while limiting taste disturbance adverse events.

In addition to RCC and chronic pruritus, 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 how the P2X3 pathway may contribute to irritation and pain in a variety of afferent hypersensitization-related disorders and whether inhibition of P2X3 receptors can help treat these 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 hypersensitization-related disorders. The Company's product candidate, BLU-5937, is being developed for the treatment of adults with RCC and chronic pruritus associated with AD.

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.

Chronic pruritus associated with AD is an irritating sensation that leads to scratching and persists for longer than 6 weeks in AD patients. It is estimated that up to 10% of adults in the United States suffer from AD – almost all report symptoms of pruritus with over 50% of patients attributing chronic pruritus as their most burdensome symptom. Despite currently available treatments targeting AD, there continues to be a lack of options specifically targeting the burden of pruritus in patients with AD.

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, chronic pruritus associated with AD and other hypersensitization-related disorders, BELLUS Health's expectations related to its preclinical studies and clinical trials, including the design, timing and results of its Phase 2b clinical trial of BLU-5937 in RCC and its Phase 2a clinical trial of BLU-5937 in chronic pruritus associated with AD, including 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, 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, potential payments/outcomes in relation to indemnity agreements and contingent value rights , achievement of forecasted preclinical study and clinical trial milestones, reliance on third parties to conduct preclinical studies and clinical trials for BLU-5937, the ability of the Company's interim analysis of the Phase 2b SOOTHE trial to predict the final results of the trial and the interpretability thereof, and that actual results may vary 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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