



BELLUS Health Reports Full Year 2019 Financial Results and Business Highlights on BLU-5937

February 27, 2020

LAVAL, Quebec--(BUSINESS WIRE)-- BELLUS Health Inc. (Nasdaq: BLU; TSX: BLU) ("BELLUS Health" or the "Company"), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of chronic cough and other hypersensitization-related disorders, today reported its financial and operating results for the year ended December 31, 2019.

"The Company closed 2019 on a strong, positive trajectory, and we look at the past year as one of substantial growth and progress in the areas of clinical and corporate development," said Roberto Bellini, President and Chief Executive Officer of BELLUS Health. "Last year was highlighted by the initiation of our Phase 2 RELIEF trial of BLU-5937 in chronic cough, as well as by our US\$79.4 million equity offering and beginning of trading on the Nasdaq exchange. These critical achievements have positioned BELLUS Health to execute on this year's upcoming milestones and development plans, including the data readout for the RELIEF trial in chronic cough and the initiation of the Phase 2 trial in chronic pruritus, a second indication for BLU-5937."

PROGRAM AND CORPORATE HIGHLIGHTS

- **Ongoing Phase 2 RELIEF trial of BLU-5937 for the treatment of refractory chronic cough, with top-line results anticipated in mid-2020.**

In July 2019, the Company enrolled the first patient in the Phase 2 RELIEF trial of BLU-5937 for the treatment of refractory chronic cough. The Company expects to complete patient enrollment by the end of March, with topline results anticipated in mid-2020.

- **Completed a clinical Phase 1 drug-drug interaction ("DDI") trial of BLU-5937 in 28 healthy adult subjects demonstrating no clinically significant interaction with CYP3A4, OATP1B1 and BCRP.**

In December 2019, the Company completed a DDI trial, which indicated that the administration of BLU-5937 should not affect the elimination of other drugs that are substrates of these enzymes/transporters. BLU-5937 was found to be safe and generally well tolerated in the trial (200 mg BID dose administered for 10 days). Two subjects out of 28 (7%) reported a mild taste alteration, which occurred only on the first day of dosing.

- **Closed a US\$79.4 million equity offering and began trading on the Nasdaq.**

In September 2019, the Company issued a total of 11,179,451 common shares from treasury at a price of US\$7.10 per share for aggregate gross proceeds of C\$104.6 million (US\$79.4 million). Concurrently with the pricing of its equity offering, BELLUS Health's common shares began trading on the Nasdaq Global Market ("Nasdaq") on September 5, 2019.

- **Appointed Catherine Bonuccelli, MD as Chief Medical Officer.**

In August 2019, the Company hired Dr. Bonuccelli, who brings over 20 years of pharmaceutical experience at GSK and Astra Zeneca with significant expertise in clinical development of respiratory products.

- **Obtained clearance of U.S. IND for the BLU-5937 Phase 2 trial in chronic pruritus; Phase 2 trial to commence in Q2 2020.**

On February 20, 2020, the U.S. Food and Drug Administration ("FDA") accepted the Company's Investigational New Drug ("IND") application for BLU-5937 for the treatment of chronic pruritus associated with atopic dermatitis ("AD"), also known as eczema. The clinical Phase 2 trial is expected to be initiated in Q2 2020. In July 2019, the Company announced that it was expanding its BLU-5937 P2X3 antagonist platform to include chronic pruritus and in September 2019, presented preclinical data on BLU-5937 in pruritus at the European Society for Dermatological Research Conference.

- **Held a Key Opinion Leader ("KOL") meeting to discuss the state of chronic cough treatment.**

In July 2019, the Company held a KOL event, which was led by Dr. Jacky Smith, Professor at the University of Manchester, United Kingdom, to discuss chronic cough and BLU-5937. A replay of the event is available on the Events & Presentations page of the Company's website.

FINANCIAL RESULTS

- **Cash Position:** As of December 31, 2019, the Company had available cash, cash equivalents and short-term investments totalling C\$116,884,000 (US\$89,980,000), compared to C\$48,906,000 (US\$35,863,000) as at December 31, 2018.
- **Net Loss:** For the year ended December 31, 2019, net loss amounted to C\$34,466,000 (C\$0.73 per share), compared to C\$9,084,000 (C\$0.27 per share) for the previous year.
- **Research and Development Expenses:** Research and development expenses, net of research tax credits, amounted to C\$25,409,000 for the year ended December 31, 2019, compared to C\$6,532,000 for the previous year. The increase is primarily attributable to higher expenses incurred in relation to the development of BLU-5937, mainly for the manufacturing

of the active pharmaceutical ingredient for upcoming studies and activities in relation to the Phase 2 trial in refractory chronic cough, for which the first patient was enrolled in July 2019.

- **General and Administrative Expenses:** General and administrative expenses amounted to C\$8,726,000 for the year ended December 31, 2019, compared to C\$3,409,000 for the previous year. The increase is mainly a result of expenses incurred in relation to the Nasdaq listing in September 2019 as well as a higher stock-based compensation expense due to the Company's deferred share unit plan and its stock option plan.
- **Net Finance (Costs) Income:** Net finance costs amounted to C\$366,000 for the year ended December 31, 2019, compared to net finance income of C\$741,000 for the previous year. The increase in net finance costs is primarily attributable to foreign exchange loss that arose from the translation of the Company's net monetary assets denominated in US dollars, partially offset by higher interest income due to increased cash, cash equivalents and short-term investments position following the 2019 equity offering.

The Company's full audited consolidated financial statements and accompanying management's discussion and analysis for the year ended December 31, 2019 will be available shortly on SEDAR at www.sedar.com and on EDGAR at www.sec.gov/edgar.

About BELLUS Health (www.bellushealth.com)

BELLUS Health is a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of chronic cough and other hypersensitization-related disorders. The Company's product candidate, BLU-5937, is being developed for the treatment of chronic cough and chronic pruritus.

Chronic cough, the lead indication for BLU-5937, is a cough lasting more than eight weeks and is associated with significant adverse physical, social and psychosocial effects on health and quality of life. It is estimated that approximately 26 million adults in the United States suffer from chronic cough with more than 2.6 million having refractory chronic cough lasting for more than a year. There is no specific therapy approved for refractory chronic cough and treatment options are limited.

Chronic pruritus, commonly known as chronic itch, is an irritating sensation that leads to scratching, and persists for longer than six weeks, which can be debilitating and has a significant impact on quality-of-life. It is a hallmark of many conditions, including AD. It is estimated that chronic pruritus associated with AD affects more than 16.9 million adults in the United States.

About BLU-5937

BLU-5937, a highly selective P2X3 antagonist - (>1500 fold) for human P2X3 receptors, which are implicated in chronic cough, versus P2X2/3 receptors, which play a major role in taste - has the potential to be an important treatment option for chronic cough, chronic pruritus and other hypersensitization-related disorders.

The P2X3 receptor in the cough reflex pathway is a rational target for treating chronic cough, and it has been validated in multiple clinical trials with different P2X3 antagonists. With a low-selectivity P2X3 antagonist therapy for chronic cough, an adverse effect on taste perception is a well-known and widely-documented tolerability issue. The Company believes that its highly selective P2X3 antagonist can also reduce coughing in patients with chronic cough, while maintaining taste function, by not inhibiting P2X2/3 receptors. This hypothesis has been validated in a recent clinical trial with a more selective antagonist of P2X3; however, BLU-5937 is the most selective of the P2X3 antagonists currently being studied.

In addition to chronic cough and chronic pruritus, BLU-5937 may also have broad applicability across other afferent hypersensitization-related disorders, potentially enabling the Company to build a pipeline of therapies using its P2X3 platform. BELLUS Health is exploring how P2X3 activation can contribute to irritation and pain, and whether inhibition of P2X3 receptors can help treat these afferent hypersensitization-related disorders.

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 and other applicable securities laws. 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, BELLUS Health's expectations related to its preclinical and clinical studies, including the timing and results for the BLU-5937 Phase 2 RELIEF trial and its chronic pruritus program. Risk factors that may affect BELLUS Health's future results include but are not limited to: the ability to expand and develop its project pipeline, the ability to obtain financing, the impact of general economic conditions, general conditions in the pharmaceutical industry, changes in the regulatory environment in the jurisdictions in which BELLUS Health does business, stock market volatility, heavy dependence on licensed intellectual property, 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 and clinical study milestones, reliance on third parties to conduct preclinical studies and clinical trials for BLU-5937 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, its market size and commercial value, as well as the sharing of proceeds between BELLUS Health and its potential partners from potential future revenues, if any, are dependent upon a number of factors. Moreover, its growth and future prospects are mainly dependent on the successful development, regulatory approval and commercialization of its product candidate BLU-5937. 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 the Annual Information Form, for further risk factors that might affect BELLUS Health and its business.

SUMMARY OF FINANCIAL RESULTS

	Year ended December 31, 2019		Year ended December 31, 2018	
	(in thousands of dollars, except per share data)			
Revenues	C\$	35	C\$	35
Research and development expenses, net		(25,409)		(6,532)
General and administrative expenses		(8,726)		(3,409)
Net finance (costs) income		(366)		741
Change in fair value of contingent consideration receivable		—		81
Net loss for the year	C\$	(34,466)	C\$	(9,084)
Basic and diluted loss per share	C\$	(0.73)	C\$	(0.27)

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