



BELLUS Health Reports Financial and Operating Results for the Third Quarter Ended September 30, 2019

November 14, 2019

LAVAL, Quebec--(BUSINESS WIRE)--Nov. 14, 2019-- 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 third quarter ended September 30, 2019.

Key Updates:

- **Completion of a US\$79.4 Million Offering:** In September 2019, BELLUS Health completed an offering of its common shares resulting in gross proceeds to the Company of US\$79.4 million;
- **Listing of Common Shares on Nasdaq:** In September 2019, concurrently with the closing of the equity offering, BELLUS Health's common shares began trading on the Nasdaq Global Market ("Nasdaq");
- **Appointment of a Chief Medical Officer:** In August 2019, BELLUS Health appointed Catherine Bonuccelli, MD to the role of Chief Medical Officer (CMO), bringing to the Company over 20 years of pharmaceutical experience with significant expertise in clinical development and commercialization of respiratory and non-respiratory products;
- **First Patient Enrolled in the Ongoing Phase 2 RELIEF Trial of BLU-5937 for the Treatment of Refractory Chronic Cough:** 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 trial is evaluating the efficacy and safety of BLU-5937 and is expected to build on the Phase 1 evidence showing little to no impact on taste. The Company anticipates top-line results in mid-2020;
- **Second Indication for BLU-5937 in Chronic Pruritus to Start Phase 2 Trial in Q2 2020:** In July 2019, the Company announced that it was expanding its BLU-5937 P2X3 inhibitor platform to include chronic pruritus. In September 2019, BELLUS Health presented preclinical data on BLU-5937 in pruritus at the European Society for Dermatological Research Conference. The Company expects to begin a clinical Phase 2 trial in chronic pruritus associated with atopic dermatitis, also known as eczema, in Q2 2020;
- **Key Opinion Leader ("KOL") Meeting to Discuss the State of Chronic Cough Treatment:** In July 2019, the Company held a KOL event to discuss chronic cough and its P2X3 inhibitor product candidate, BLU-5937. The event was led by Dr. Jacky Smith, Professor at the University of Manchester, United Kingdom. A replay of the event is available on the Company's website; and
- **Cash Position:** BELLUS Health concluded the third quarter with cash, cash equivalents and short-term investments totalling C\$132.2 million (US\$99.9 million).

"We have evolved significantly as an organization in the third quarter, solidifying our business growth strategy, and establishing our path forward from a clinical and regulatory development perspective," said Roberto Bellini, President and Chief Executive Officer of BELLUS Health. "The past quarter was highlighted by our listing on the Nasdaq, and the completion of our US\$79.4 million offering. We also bolstered our executive leadership with the appointment of industry veteran Dr. Cathy Bonuccelli to the position of Chief Medical Officer. Collectively, these achievements have positioned us for continued success, as we look toward the upcoming clinical and regulatory milestones for our product candidate, BLU-5937, in 2020."

BLU-5937 for Chronic Cough

BELLUS Health is developing BLU-5937, a potent, highly selective, small molecule inhibitor of the P2X3 receptor, as an oral therapy to reduce cough frequency in refractory chronic cough patients.

BELLUS Health is currently conducting a Phase 2 clinical trial of BLU-5937 for patients with refractory chronic cough, which is referred to as the RELIEF (A Randomized, Double-blind, Placebo-Controlled, Crossover, Dose Escalation Trial of BLU-5937 in Subjects with Unexplained or Refractory Chronic Cough) trial. The trial was initiated in July 2019 and the Company expects to report topline data in mid-2020.

The RELIEF trial is a randomized, double-blind, placebo-controlled, dose escalation and two-period crossover design trial to assess the efficacy, safety and tolerability of BLU-5937 at four doses: 25, 50, 100 and 200 mg BID. Doses are escalated at four-day intervals. Approximately 65 patients with refractory chronic cough are expected to be enrolled at approximately 15 clinical sites located in the United Kingdom and United States. BELLUS Health enrolled the first patient in the RELIEF trial at the end of July 2019 and is actively recruiting patients.

Phase 1 results showed that no subjects in the BLU-5937 arm receiving anticipated therapeutic doses reported any loss of taste perception, and only one subject out of 24 (<5%) reported transient and sporadic taste alteration only on the first day of dosing. No subject reported total loss of taste at any dose. The RELIEF trial will also collect taste adverse event data to potentially build on this clinical evidence.

Further details on BELLUS Health's Phase 2 RELIEF trial for BLU-5937 can be found at <https://clinicaltrials.gov/ct2/show/NCT03979638>.

Currently, there is no therapy approved specifically for the treatment of refractory chronic cough, and the most advanced therapy in development has substantial tolerability issues, including significant taste alteration or loss. BLU-5937 may be a differentiated option, with little to no effect on taste.

BLU-5937 for Chronic Pruritus

In July 2019, BELLUS Health announced that it is developing BLU-5937 for a second indication, chronic pruritus. The Company believes BLU-5937 may be a viable treatment option for patients with chronic pruritus associated with atopic dermatitis ("AD").

Preclinical studies conducted by BELLUS Health provided evidence that the ATP-induced hypersensitization mediated by P2X3 receptors in cutaneous C-fibers plays a key role in pruritus. In multiple animal models of pruritus, the Company observed that treatment with BLU-5937 resulted in significant anti-pruritic effect. The Company presented preclinical data on BLU-5937 in pruritus at the European Society for Dermatological Research Conference in September 2019.

BELLUS Health plans to initiate a randomized, double-blind, placebo-controlled, parallel group design Phase 2 clinical trial to assess the efficacy, safety, and tolerability of BLU-5937 in approximately 100 patients suffering from moderate to severe chronic pruritus associated with mild to moderate AD. The trial is expected to be a two-arm study comparing BLU-5937 to placebo, each administered orally, twice-daily (BID), for four weeks. The Company expects to initiate the trial in Q2 2020 and report topline data in mid-2021.

Summary of Financial Results

	<i>Three months ended</i>		<i>Three months ended</i>	
	<i>September 30, 2019</i>		<i>September 30, 2018</i>	
	<i>(in thousands of dollars, except per share data)</i>			
Revenues	C\$	9	C\$	9
Research and development expenses, net		(7,395)		(2,138)
General and administrative expenses		(2,200)		(888)
Net finance income		976		60
Change in fair value of contingent consideration receivable		—		(90)
Net loss for the period	C\$	(8,610)	C\$	(3,047)
Basic and diluted loss per share	C\$	(0.18)	C\$	(0.09)

- Research and development expenses, net of research tax credits, amounted to C\$7,395,000 for the three-month period ended September 30, 2019, compared to C\$2,138,000 for the corresponding period the previous year. The increase is primarily attributable to higher expenses incurred in relation to the development of BLU-5937.
- General and administrative expenses amounted to C\$2,200,000 for the three-month period ended September 30, 2019, compared to C\$888,000 for the corresponding period the previous year. The increase is mainly due to expenses incurred in relation to the Nasdaq listing in September 2019.
- Net finance income amounted to C\$976,000 for the three-month period ended September 30, 2019, compared to C\$60,000 for the corresponding period the previous year. The increase is mainly attributable to a foreign exchange gain that arose from the translation of the Company's net monetary assets denominated in US dollars, as well as to higher interest income on its increased cash position following the September 2019 and December 2018 financings.

As at September 30, 2019, the Company had available cash, cash equivalents and short-term investments totalling C\$132,237,000 (US\$99,869,000), compared to C\$48,906,000 (US\$35,863,000) as at December 31, 2018.

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, 2019 will be available shortly on SEDAR at www.sedar.com and on EDGAR at www.sec.gov/edgar.shtml.

About BLU-5937

BLU-5937, a highly selective P2X3 inhibitor (>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 inhibitors. With a low-selectivity P2X3 inhibitor 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 inhibitor can 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 inhibitor of P2X3; however, BLU-5937 is the most selective of the P2X3 inhibitors 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.

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 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.

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 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, 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 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 candidates' development process, their 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. 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.

View source version on businesswire.com: <https://www.businesswire.com/news/home/20191114005162/en/>

Source: BELLUS Health Inc.

Investors:

BELLUS Health
François Desjardins
Vice-President, Finance
450-680-4525
fdesjardins@bellushealth.com

Solebury Trout
Chad Rubin
646-378-2947
crubin@troutgroup.com

Media:

Solebury Trout
Joshua R. Mansbach
646-378-2964
jmansbach@troutgroup.com