UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of **December 2020**

Commission File Number: **001-39034**

BELLUS HEALTH INC.

(*Name of registrant*)

275 Armand-Frappier Blvd.
Laval, Québec
H7V 4A7
Canada

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

☐ Form 20-F ☒ Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BELLUS Health Inc.

Date: December 8, 2020

By: /s/ Ramzi Benamar
Name: Ramzi Benamar
Title: Chief Financial Officer

Form 6-K Exhibit Index

Exhibit Number	Document Description
99.1	News Release dated December 8, 2020. BELLUS Health Announces First Patient Dosed in its Phase 2b SOOTHE Trial of BLU-5937 for the Treatment of Refractory Chronic Cough.

BELLUS Health Inc.
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BELLUS Health Announces First Patient Dosed in its Phase 2b SOOTHE Trial of BLU-5937 for the Treatment of Refractory Chronic Cough

Interim analysis expected in mid-2021, with topline results expected in Q4 2021

LAVAL, Quebec—Dec. 8, 2020— 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 announced that the first patient has been dosed in the Phase 2b SOOTHE trial of BLU-5937, the Company's highly selective P2X3 antagonist, in patients with refractory chronic cough.

"We are thrilled to announce the initiation of our SOOTHE trial, an important milestone for the development of BLU-5937, as well as a promising step forward for the millions of chronic cough patients lacking an approved therapy," said Dr. Cathy Bonuccelli, Chief Medical Officer at BELLUS Health. "BLU-5937's validated mechanism of action, along with the encouraging data generated from our previously completed Phase 2 RELIEF trial, suggest that this candidate has the potential to help meet this large unmet need, with the potential to avoid burdensome class-specific adverse effects. We look forward to conducting the trial and reporting results in 2021."

"Globally, millions of individuals seek therapy for their debilitating refractory chronic cough each year, and without an approved treatment, the condition remains a challenge for both patients and physicians," said Dr. Jaclyn Smith, Professor of Respiratory Medicine at the University of Manchester in the United Kingdom, an Honorary Consultant at the University Hospital of South Manchester NHS Foundation Trust and Chair of BELLUS Health's Clinical Advisory Board. "Building on the results reported from multiple clinical trials, including BELLUS Health's Phase 2 RELIEF trial, the P2X3 class is a promising approach for patients. I look forward to continuing to study BLU-5937's potential in treating chronic cough, in hopes of filling this unmet need."

The SOOTHE trial is a multicenter, randomized, double-blind, four-week, parallel arm, placebo-controlled Phase 2b trial evaluating three doses of BLU-5937 (12.5 mg, 50 mg and 200 mg BID) in 300 participants with refractory chronic cough. 240 participants with a baseline awake cough frequency of ≥25 awake coughs per hour are expected to be randomized across four arms (1:1:1:1) evaluating the three active doses of BLU-5937 and placebo in the main study. Treatment arms will be stratified to balance the number of participants with baseline awake cough frequency ≥45 coughs per hour across trial arms. The primary efficacy endpoint will be the placebo-adjusted change in the 24-hour cough frequency from baseline to day 28 collected with a cough recorder. An exploratory group of an additional 60 participants with a baseline awake cough frequency of ≥10 and <25 coughs per hour are expected to be randomized across 2 arms (1:1) evaluating one active dose (200 mg BID) and placebo to further investigate the effect of BLU-5937 in patients with lower cough frequency.

An interim analysis is expected to be conducted once 50% of patients have completed the main study and is anticipated in mid-2021. Using a predefined probability of efficacy hurdle, results from the interim analysis may be used to initiate planning activities for Phase 3. Topline results are expected in the fourth quarter of 2021.

The trial is expected to enroll participants at approximately 120 sites, including 55 centers in the United States.

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About BLU-5937

BLU-5937, a highly selective P2X3 antagonist - (>1500 fold) - is in development for chronic cough, chronic pruritus and other hypersensitization-related disorders.

The P2X3 receptor in the cough reflex pathway, which is implicated in chronic cough, 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 coughing in patients with refractory chronic cough while limiting taste disturbance adverse events.

In addition to chronic cough and chronic pruritus, BLU-5937 may also have broad applicability across other afferent hypersensitization-related disorders, enabling the Company to consider developing 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, 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 approximately 3 million having refractory chronic cough lasting for more than a year and approximately 6 million having refractory chronic cough lasting more than 8 weeks and under one year. There is no specific therapy approved for refractory chronic cough and current 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 dermatologic disorders, 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, 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 chronic cough, chronic pruritus and other hypersensitization-related disorders, BELLUS Health’s expectations related to its preclinical studies and clinical trials, including the design and timing of its Phase 2b clinical trial of BLU-5937 in refractory chronic cough and its Phase 2 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 refractory chronic cough 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 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, 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 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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