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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of report (Date of earliest event reported): **February 10, 2020**

Millendo Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-35890**	**45-1472564**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

110 Miller Avenue, Suite 100 **Ann Arbor, Michigan** (Address of principal executive offices)	**48104** (Zip Code)

Registrant's telephone number, including area code: **(734) 845-9000**

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.001 par value per share	**MLND**	**The Nasdaq Capital Market, LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On February 10, 2020, Millendo Therapeutics, Inc. (the "Company") issued a press release announcing that Christophe Arbet-Engels, MD, PhD, has joined the Company as Chief Medical Officer. The Company also announced that it anticipates receiving topline results from the Phase 2b portion of its Phase 2b/3 clinical trial for livoletide in Prader-Willi syndrome patients early in the second quarter of 2020.

A copy of the press release is attached as Exhibit 99.1 hereto and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated February 10, 2020

SIGNATURE

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 hereunto duly authorized.

MILLENDO THERAPEUTICS, INC.

Date: February 10, 2020

By: /s/ Julia C. Owens, Ph.D.
Julia C. Owens, Ph.D.
President and Chief Executive Officer

Exhibit 99.1

Millendo Therapeutics Appoints Christophe Arbet-Engels, MD, PhD, as Chief Medical Officer

– Company also provides update on timeline for pivotal ZEPHYR study –

ANN ARBOR, Mich., February 10, 2020 – Millendo Therapeutics, Inc. (Nasdaq: MLND), a late-stage biopharmaceutical company primarily focused on developing novel treatments for orphan endocrine diseases, announced today that Christophe Arbet-Engels, MD, PhD, has joined the company as Chief Medical Officer. The company also announced that it expects to report topline results from the Phase 2b portion of its pivotal Phase 2b/3 clinical trial for livoletide in patients with Prader-Willi syndrome (PWS), called ZEPHYR, early in the second quarter of 2020.

“We are honored and excited to welcome Christophe to the team,” said Julia C. Owens, PhD, President and Chief Executive Officer of Millendo Therapeutics. “Christophe brings to Millendo broad experience in endocrinology and guiding clinical stage therapies through registration and lifecycle management. We believe this expertise will be a significant asset with the data readout from our pivotal clinical trial for livoletide in PWS anticipated in early second quarter of this year and as we look ahead to potential commercialization of our product candidates, including livoletide for PWS.”

Dr. Arbet-Engels joins Millendo from Poxel Pharmaceuticals where he was Chief Medical Officer, Executive Vice President Late Development and Medical Affairs with responsibility for all medical activities for Poxel’s portfolio, including driving portfolio strategy and execution of registration programs. Previously, he served as Vice President, Worldwide Medical, Collaborative Medical Sciences at Biogen, where Dr. Arbet-Engels built, developed and led global medical research, clinical operations, biostatistics/analytics, communication and expanded access program teams to advance the medical sciences in multiple therapeutic areas. Dr. Arbet-Engels has also held several senior leadership positions, globally and locally, in clinical development and medical affairs at pharmaceutical and biotech companies including Boehringer Ingelheim, Roche, Merck, Aventis (now Sanofi) and Ligand Pharmaceuticals where he led the clinical development and registration, launch and lifecycle management for several new medicines. Dr. Arbet-Engels has a medical degree from University of Paris Sud, a PhD in endocrinology/diabetes and metabolism from University of Paris Descartes, and a master’s degree in business administration from Rutgers University. He will be based in Millendo’s Lexington, Massachusetts office.

“This is a very exciting time to join the talented team at Millendo,” Dr. Arbet-Engels added. “With the data readouts from the Phase 2b portion of the study for livoletide in PWS expected in early second quarter of 2020 and for nevanimibe in classic congenial adrenal hyperplasia (CAH) in the second half of the year, I look forward to working closely with Julia and the rest of the team to guide the company through the critical next steps for advancing Millendo’s pipeline programs through development and into commercialization.”

Inducement Equity Award

On February 10, 2020, the Compensation Committee of Millendo’s Board of Directors approved, effective as of February 10, 2020, the grant of an inducement stock option to purchase 140,000 shares of the Company’s common stock to Dr. Arbet-Engels. The stock option awarded to Dr. Arbet-Engels will have an exercise price equal to the closing price per share of the Company’s common stock on February 10, 2020, and will vest and become exercisable over four years, with 25% of the shares vesting on February 10, 2021, the one-year anniversary of the vesting commencement date, and the remaining shares vesting ratably over the subsequent 36 months, subject to Dr. Arbet-Engels’ continued service with the Company as of each such date. The stock option is subject to acceleration if Dr. Arbet-Engels’ employment terminates in connection with a change in control. The stock option has a ten-year term and is subject to the terms and conditions of the stock option agreement pursuant to which the option was granted.

The stock option was granted as an inducement material to Dr. Arbet-Engels entering into employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4).

About Livoletide

Livoletide is an unacylated ghrelin analogue in late-stage clinical development for the treatment of Prader-Willi syndrome (PWS), a rare genetic disease characterized by hyperphagia, a chronic unrelenting hunger, that leads to obesity, metabolic dysfunction, reduced quality of life and early mortality. In a previous randomized, double-blind, placebo-controlled Phase 2 clinical trial in 47 patients with PWS, administration of livoletide once daily for two weeks was associated with a clinically meaningful improvement in hyperphagia, as well as a reduction in appetite. Millendo has received both Orphan Drug Designation and Fast Track Designation for livoletide for the treatment of PWS from the U.S. Food and Drug Administration (FDA) and Orphan Drug Designation from the European Medicines Agency (EMA). For more information about Millendo’s pivotal study of livoletide (ZEPHYR) please visit www.clinicaltrials.gov (NCT03790865) or the Patients and Families portion of our website.

About Prader-Willi Syndrome

Prader-Willi syndrome (PWS) is a genetic disease caused by the lack of expression of several genes on chromosome 15, which leads to hyperphagia, intellectual disability, short stature and incomplete sexual development, among other symptoms. PWS patients are at risk of premature mortality, mainly from obesity related conditions such as cardiovascular disease, respiratory distress and from accidents. The incidence of PWS is approximately 1 in 15,000 births. The prevalence of PWS is estimated between 8,000-11,000 patients in the United States and 13,000-18,000 in Europe. Currently, there is no effective or approved treatment for hyperphagia and abnormal eating behaviors associated with PWS. Growth hormone is used for improvement in height, cognition and body composition, but has no effect on appetite and over-eating. The only way to effectively manage hyperphagia, obesity and related complications of PWS is strict control over access to food, creating significant burden for families and caregivers.

About the ZEPHYR study

The ZEPHYR study is a two-part, randomized, double-blind, placebo-controlled pivotal Phase 2b/3 study. The first part is a Phase 2b study that includes a three-month double-blind, placebo-controlled core period in which patients receive one of two doses of livoletide or placebo followed by a nine-month extension period in which all patients receive livoletide. The Phase 2b portion of the study, one of the largest global PWS studies ever conducted, has completed recruitment for patients ages 8 to 65 with over 150 patients across 39 clinical sites in the United States, Europe and Australia. Millendo continues to implement a protocol amendment globally adding an additional cohort of PWS patients ages four to seven. Sites that recruit pediatric patients will continue to actively recruit patients for this cohort. The second part is a Phase 3 study that will consist of a six-month double-blind, placebo-controlled core period in which patients will receive livoletide or placebo followed by a six-month extension period in which all patients receive livoletide. The study's primary endpoint measures the change in food-related behaviors using the validated Hyperphagia Questionnaire for Clinical Trials (HQ-CT) during each core period. ZEPHYR is a pivotal study and the results of the Phase 2b portion of the study may be sufficient to support a new drug application (NDA) for livoletide.

About Millendo Therapeutics, Inc.

Millendo Therapeutics is a late-stage biopharmaceutical company primarily focused on developing novel treatments for orphan endocrine diseases where current therapies do not exist or are insufficient. As a leading orphan endocrine company, Millendo seeks to create distinct and transformative treatments where there is a significant unmet medical need. The company is currently advancing livoletide for the treatment of Prader-Willi syndrome, nevanimibe for the treatment of classic congenital adrenal hyperplasia and MLE-301 for the treatment of vasomotor symptoms associated with menopause. For more information, please visit www.millendo.com.

Cautionary Statement Regarding Forward-Looking Statements

Certain statements contained in this press release regarding matters that are not historical facts, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. These include statements regarding our plans to develop and commercialize our product candidates and the progress and timing of our ongoing and planned clinical trials for our product candidates, and, therefore, you are cautioned not to place undue reliance on them. In some cases, you can identify forward-looking statements by the words “may,” “might,” “will,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “objective,” “anticipate,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue” and “ongoing,” or the negative of these terms, or other comparable terminology intended to identify statements about the future. Such forward-looking statements are based on Millendo’s expectations and involve risks and uncertainties; consequently, actual results may differ materially from those expressed or implied in the statements due to a number of factors, including that Millendo has incurred significant losses since inception, Millendo has a limited operating history and has never generated any revenue from product sales, Millendo will require additional capital to finance its operations, Millendo's future success is dependent on the successful clinical development, regulatory approval and subsequent commercialization of livoletide, nevanimibe and any future product candidates, preclinical studies or earlier clinical trials are not necessarily predictive of future results and the results of Millendo's clinical trials may not support Millendo's livoletide or nevanimibe claims, Millendo may encounter substantial delays in its clinical trials or Millendo may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities, enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside Millendo's control, Millendo's product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, or limit their commercial potential and Millendo faces substantial competition. You should refer to the risk factor disclosure set forth in the periodic reports and other documents we file with the Securities and Exchange Commission available at www.sec.gov, including without limitation our including in the section entitled “Risk Factors” in our Quarterly Report on Form 10-Q for our fiscal quarter ended September 30, 2019 and subsequent reports that we file with the Securities and Exchange Commission.

New factors emerge from time to time and it is not possible for Millendo to predict all such factors, nor can Millendo assess the impact of each such factor on the business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Forward-looking statements included in this press release are based on information available to Millendo as of the date of this press release. Millendo disclaims any obligation to update such forward-looking statements to reflect events or circumstances after the date of this press release, except as required by applicable law.

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