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): April 5, 2020

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

Delaware	**001-35890**	**45-1472564**
(State or other jurisdiction of incorporation or organization)	**(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

N/A
(Former name or former address, if changed since last report.)

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

☐ 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, par value $0.001 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 2.05 Costs Associated With Exit or Disposal Activities.

On April 5, 2020, the Board of Directors (the "Board") of Millendo Therapeutics, Inc. (the "Company") approved the decision to discontinue the development of livoletide as a potential treatment for Prader-Willi syndrome ("PWS"), including the 9-month extension study and the initiation of the Phase 3 ZEPHYR trial. In connection with the discontinuation of the PWS clinical development program, the Company is currently evaluating a revised corporate strategic plan that may include a restructuring and that prioritizes and allocates resources towards the advancement of nevanimibe for congenital adrenal hyperplasia, MLE-301 for menopausal vasomotor symptoms and potentially future pipeline assets.

The Company intends to file an amended report on Form 8-K when it is able to estimate the total amount or range of amounts expected to be incurred in connection with the discontinuation of the PWS program, both in the aggregate and for each major type of cost, and an estimate of the amount or range of amounts of the charge that will result in future cash expenditures, if any, and if material.

Item 8.01. Other Events.

Clinical Trial Results

On April 6, 2020, the Company issued a press release announcing topline results from the pivotal Phase 2b ZEPHYR trial of livoletide for the treatment of hyperphagia in patients with PWS. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The Company will host a live conference call and webcast to discuss the results of the pivotal Phase 2b trial and the status of the livoletide program at 8:15 a.m. EDT on April 6, 2020. The conference call may be accessed by phone by dialing (866) 524-3160 (domestic) or +1 (412) 317-6760 (international). A live webcast of the conference call will be available on the Investors & Media section of the Company's website at http://investors.millendo.com. A replay of the webcast will be available for 30 days following the event. The information contained in, or that can be accessed through, the Company's website is not a part of this filing. A copy of the slide presentation to be used by the Company during the conference call is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Risk Factor Supplement

In light of the COVID-19 pandemic, the Company is supplementing the risk factors described in Part I, Item 1A of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as filed with the Securities and Exchange Commission on March 11, 2020.

The Company's business, preclinical studies and clinical development programs and timelines, its financial condition and results of operations could be materially and adversely affected by the current COVID-19 pandemic.

In December 2019, a novel strain of coronavirus, SARS-CoV-2, causing a disease commonly referred to as COVID-19, was initially reported and has since been declared a pandemic. Quarantines, shelter-in-place and similar government orders ("SIP") related to COVID-19 may adversely impact the Company's business operations and the business operations of its contract research organizations conducting its clinical trials and the Company's third-party manufacturing facilities in the United States and other countries. In response to the spread of COVID-19 and SIP orders applicable to the Company's business, the Company has implemented work-from-home policies, which allows employees to work remotely. In addition, the Company may experience significant disruptions to its business, preclinical studies and clinical trials as a result of the COVID-19 pandemic. For example, clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. Some patients may not be able to comply with clinical trial protocols if quarantines or SIP orders impede patient movement or interrupt healthcare services. Similarly, the Company's ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 and may themselves contract COVID-19, may adversely impact its clinical trial operations. As a result, the Company may face delays in meeting its anticipated timelines for its ongoing and planned clinical trials. Further, if the business operations of the Company's third-party manufacturers and suppliers are interrupted, this could disrupt its supply chain and impact on ongoing preclinical studies and clinical trials. In addition, disruptions or delays in chemistry, manufacturing and control activities for the Company's current or future product candidates in general may result in delays and challenges in numerous areas of the drug development lifecycle, including preclinical drug development, clinical stage validation and testing and manufacturing. The extent to which COVID-19 impacts the Company's results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19, its impact on the global supply chain and financial markets, the duration of the outbreak, and various federal, state, local, and foreign governmental responses to the pandemic, among others. The Company's business, preclinical studies and clinical development programs and timelines, its financial condition and results of operations could be materially and adversely affected by the current COVID-19 pandemic.

Special Note Regarding Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of Section 27A of the Securities Act, Section 21E of the Exchange Act and the Private Securities Litigation Reform Act of 1995, which statements involve substantial risks and uncertainties. Forward-looking statements generally relate to future events or our future financial or operating performance. In some cases, forward-looking statements can be identified because they contain words such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “could,” “intends,” “target,” “projects,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these words or other similar terms or expressions that concern the Company’s expectations, strategy, plans or intentions. Forward-looking statements contained in this Current Report on Form 8-K include, but are not limited to, statements about the impact of the COVID-19 pandemic on the Company’s business, preclinical studies and clinical development programs and timelines, its financial condition and results of operations. Such forward-looking statements are based on the Company’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 and other risks and uncertainties described in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2019, this Current Report on Form 8-K, and other filings with the SEC. The Company makes no commitment to revise or update any forward-looking statements in order to reflect events or circumstances occurring or existing after the date of this report, except to the extent required by applicable law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated April 6, 2020.
99.2	Conference Call Presentation, dated April 6, 2020.

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 hereunto duly authorized.

Date: April 6, 2020

Millendo Therapeutics, Inc.

By: /s/ Julia C. Owens
Name: Julia C. Owens
Title: President and Chief Executive Officer

Exhibit 99.1

Millendo Therapeutics Announces Topline Results for Pivotal Phase 2b Study of Livoletide in Patients with Prader-Willi Syndrome (PWS)

– Livoletide did not achieve statistically significant improvement in primary endpoint of change in hyperphagia and food-related behaviors relative to placebo –

– Millendo to discontinue livoletide program in PWS and focus on development of pipeline assets nevanimibe and MLE-301 –

– Company to host a conference call today at 8:15 a.m. EDT –

ANN ARBOR, Mich., April 6, 2020 – Millendo Therapeutics, Inc. (Nasdaq: MLND), a biopharmaceutical company primarily focused on developing novel treatments for endocrine diseases, announced today that it is discontinuing the development of livoletide as a potential treatment for Prader-Willi syndrome (PWS). The decision to discontinue the PWS program was based on topline data from the pivotal Phase 2b ZEPHYR study which showed that treatment with livoletide did not result in a statistically significant improvement in hyperphagia and food-related behaviors as measured by the Hyperphagia Questionnaire for Clinical Trials (HQ-CT) compared to placebo.

“Unfortunately, treatment with livoletide did not significantly improve hyperphagia and food-related behaviors in our ZEPHYR study. While we are disappointed in these results, I want to recognize our team’s hard work and commitment in executing this robust study that informed the difficult decision to discontinue the livoletide PWS program,” said Julia C. Owens, President and Chief Executive Officer of Millendo Therapeutics. “We are deeply grateful to the patients, caregivers and researchers who made the ZEPHYR study possible. We are committed to understanding the totality of the Phase 2b results and we intend to report the data at a future scientific meeting or publication when they are available.”

Owens added, “Moving forward, we will shift our development focus to compelling portfolio programs nevanimibe for congenital adrenal hyperplasia (CAH) and MLE-301 for menopausal vasomotor symptoms. With the rapidly evolving COVID-19 global pandemic and the extraordinary burden it has put on hospitals and healthcare providers, we are monitoring the potential impact of the situation on these programs and will provide an update when we have more clarity on expected timelines.”

The ZEPHYR study was a two-part, randomized, double-blind, placebo-controlled pivotal Phase 2b/3 study. The pivotal Phase 2b study included a three-month double-blind, placebo-controlled period in which patients (N=158) were randomized to either 60 µg/kg or 120 µg/kg of livoletide, or placebo. The Phase 2b data showed improvements from baseline in HQ-CT scores of -4.7 (p = 0.13) and -3.8 (p = 0.45) for the livoletide treated groups (60 µg/kg or 120 µg/kg, respectively) at 12 weeks compared to -2.8 for placebo. The average HQ-CT baseline score was 20.2. No positive trends were observed for any of the secondary endpoints of fat mass, body weight or waist circumference.

Livoletide was well tolerated during the ZEPHYR study, with injection site reaction being the most frequently reported adverse event, as expected with an injectable drug, and mostly mild in severity. A total of 2 patients (1.3%) dropped out of the study during the 12-week core period. There were 4 serious adverse events reported during the 12-week period, with none being related to livoletide treatment.

Millendo has made the decision to stop all livoletide development efforts in PWS, including the 9-month extension study and initiation of the Phase 3 ZEPHYR study.

Conference Call Information

The company will host a live conference call and webcast today at 8:15 a.m. EDT to discuss the topline results. The conference call may be accessed by dialing (866) 524-3160 (domestic) or +1 (412) 317-6760 (international). A live webcast of the conference call will be available on the Investors & Media section of Millendo's website at http://investors.millendo.com. A replay of the webcast will be archived on Millendo's website for 30 days following the presentation.

About Livoletide

Livoletide is an unacylated ghrelin analogue in late-stage clinical development for the treatment of hyperphagia in Prader-Willi syndrome (PWS). This rare genetic disease is characterized by hyperphagia, a chronic unrelenting hunger, that leads to obesity, metabolic dysfunction, reduced quality of life and early mortality. In a randomized, double-blind, placebo-controlled pivotal Phase 2b clinical trial in 158 patients with PWS, administration of livoletide once daily for 12 weeks showed that livoletide did not result in a statistically significant improvement in hyperphagia and food-related behaviors. For more information about Millendo's pivotal study of livoletide (ZEPHYR) please visit www.clinicaltrials.gov (NCT03790865) or the Our Patients portion of our website.

About Nevanimibe

Nevanimibe decreases adrenal steroidogenesis through the inhibition of acyl coenzyme A: cholesterol acyltransferase 1, or ACAT1, and is being studied for the treatment of classic congenital adrenal hyperplasia (CAH). CAH is a rare, monogenic adrenal disease that requires lifelong treatment with exogenous cortisol, often at high doses. These chronic high doses of cortisol can result in side effects that include diabetes, obesity, hypertension and psychological problems. Millendo has received Orphan Drug Designation for nevanimibe for the treatment of CAH from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). In a Phase 2a clinical trial in patients with CAH, Millendo observed nevanimibe to be associated with clear signs of clinical activity in seven of 10 treated patients. A Phase 2b trial of nevanimibe in CAH (NCT03669549) is ongoing.

About MLE-301

MLE-301 is a neurokinin 3 receptor (NK3R) antagonist that is being developed as a potential treatment of VMS, commonly known as hot flashes and night sweats, in menopausal women. NK3R plays a key role in regulating the activity of KNDy (kisspeptin/NKB/dynorphin) neurons, which are believed to participate in the generation of VMS. By inhibiting the NK3R signaling on the KNDy neurons and potentially other NK3R-expressing neurons that propagate heat dissipation signals through the hypothalamus, MLE-301 aims to reduce the effects of hyperactive KNDy neurons and thereby address the excessive heat dissipation signaling associated with VMS. MLE-301 is currently in preclinical studies designed to enable first-in-human clinical studies.

About Millendo Therapeutics, Inc.

Millendo Therapeutics is a biopharmaceutical company primarily focused on developing novel treatments for endocrine diseases where current therapies do not exist or are insufficient. Millendo seeks to create distinct and transformative treatments where there is a significant unmet medical need. The company is currently advancing 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. 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. These include statements with respect to Millendo’s plans to provide a further update on the results of the ZEPHYR study and the timelines for nevanimibe and MLE-301 and the continued development of nevanimibe for congenital adrenal hyperplasia and MLE-301 for menopausal vasomotor symptoms, and, therefore, you are cautioned not to place undue reliance on them. 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 current 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 product candidate 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, Millendo faces substantial competition and Millendo’s business, preclinical studies and clinical development programs and timelines, its financial condition and results of operations could be materially and adversely affected by the current COVID-19 pandemic. You should refer to the risk factor disclosure set forth in the periodic reports and other documents Millendo files with the Securities and Exchange Commission available at www.sec.gov, including without limitation in the section entitled “Risk Factors” in Millendo’s Annual Report on Form 10-K for the fiscal year ended December 31, 2019, Millendo’s Current Report on Form 8-K filed on April 6, 2020 and subsequent current and periodic reports that Millendo files 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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Exhibit 99.2


MILLENDO
THERAPEUTICS
Topline Results for
ZEPHYR Phase 2b
Study of Livoletide
April 6, 2020

Introduction

Connie Chang, Vice President, Corporate Affairs

Cautionary Statement Regarding Forward-Looking Statements

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New factors emerge from time to time and it is not possible for us to predict all such factors, nor can we 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 presentation are based on information available to us as of the date of this presentation. We disclaim any obligation to update such forward-looking statements to reflect events or circumstances after the date of this presentation, except as required by applicable law.

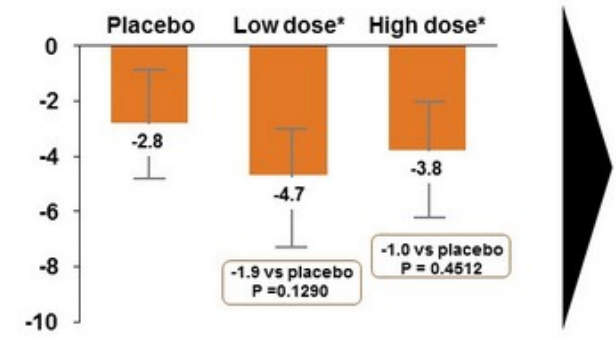
Topline Results for Pivotal Phase 2b Study of Livoletide in Prader-Willi Syndrome

Julia C. Owens, Ph.D., President and Chief Executive Officer

Pivotal Phase 2b ZEPHYR Study in PWS – Topline Data

Livoletide did not meet defined primary endpoint at either dose

Change in HQ-CT from baseline at 12 weeks



Key Findings:

- Larger than expected placebo response
- High variability across most HQ-CT measurements
- No positive trends observed for any secondary endpoints
- Livoletide was well-tolerated in the study, consistent with Phase 2a study results
  - 2 patients (1.3%) dropped out during 12-week period
  - 4 SAEs reported during 12-week period, none being related to livoletide treatment

*Low dose = 60 ug/kg, High dose = 120 ug/kg

** HQ-CT difference reported as Least Square (LS) Mean in Full Analysis Set. Error bars represent 95% CI.

Thank you for making ZEPHYR possible!

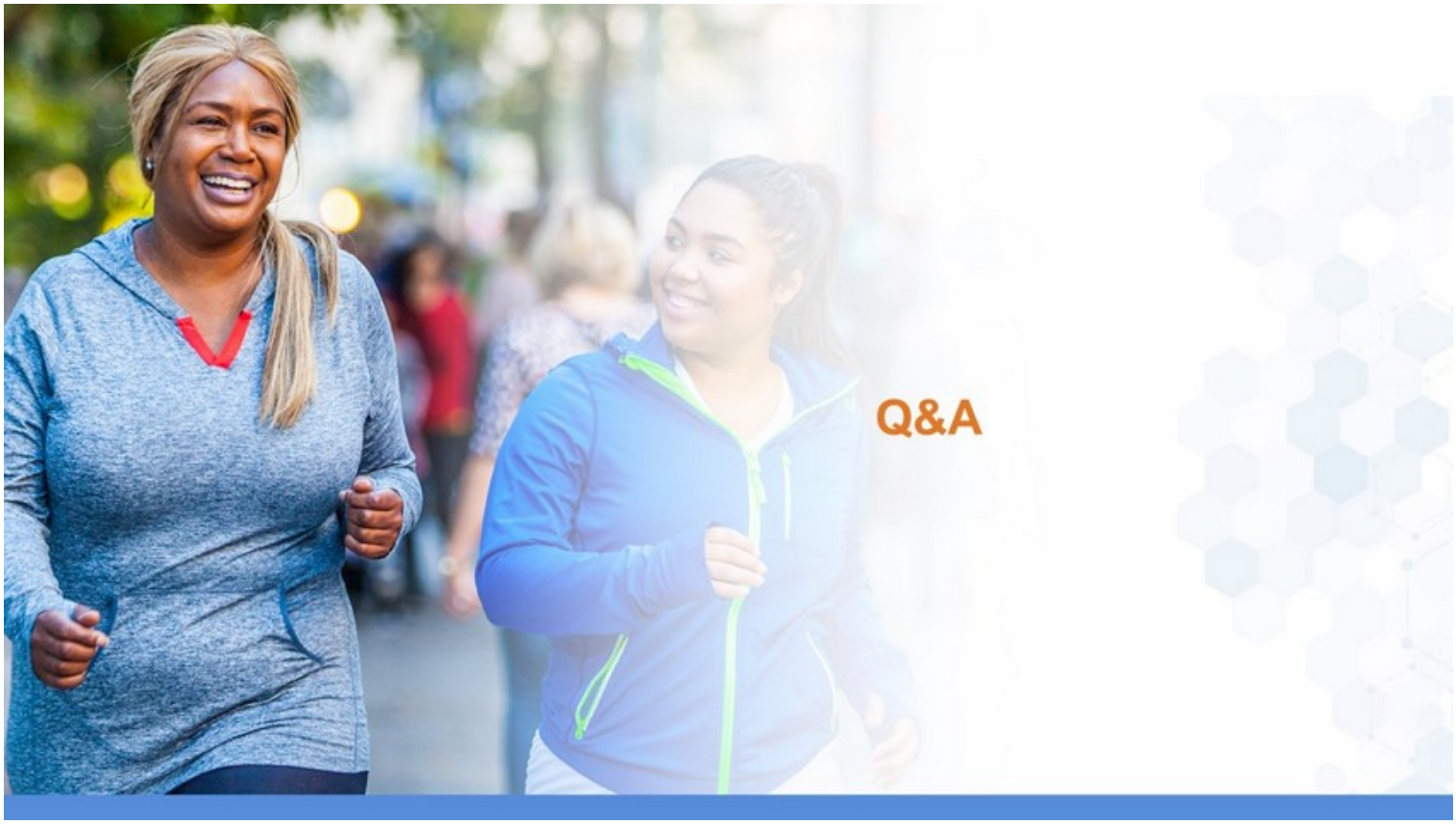
- **Patients**
- **Caregivers**
- **Clinical trial investigators and staff**
- **Millendo team**

Significant Potential Value Creation

Continued focus on novel treatments for endocrine diseases

- **Nevanimibe** for the treatment of patients with congenital adrenal hyperplasia (CAH), with Phase 2b clinical study ongoing
- **MLE-301** for menopausal vasomotor symptoms, currently in preclinical studies designed to enable first-in-human clinical studies
- Potentially **expand our pipeline** by leveraging our expertise in acquiring and in-licensing product candidates
- **Experienced leadership team** to execute on company strategy
- **Financial strength** with cash balance of $63.5M* as of December 31, 2019 *

* Includes cash, cash equivalents, marketable securities and restricted cash


Q&A