Millendo Therapeutics, Inc. Logo

Millendo Therapeutics Reports First Quarter 2020 Operating and Financial Results

May 8, 2020

ANN ARBOR, Mich.--(BUSINESS WIRE)--May 8, 2020-- Millendo Therapeutics, Inc. (Nasdaq:MLND), a clinical stage biopharmaceutical company primarily focused on developing novel treatments for endocrine diseases with significant unmet needs, today provided a corporate update and reported financial results for the quarter ended March 31, 2020.

“As we wind down activities related to the livoletide program, we have moved quickly to streamline costs and redeploy development efforts to our other portfolio programs, nevanimibe for congenital adrenal hyperplasia and MLE-301 for menopausal vasomotor symptoms,” said Julia C. Owens, President and Chief Executive Officer of Millendo Therapeutics. “We are currently evaluating our business strategy, taking into consideration our existing pipeline assets, assessing the evolving impact of the global COVID-19 pandemic and leveraging the deep development expertise of our leadership team to investigate potential strategic additions to our portfolio.”

First Quarter 2020 and Recent Highlights

- **Discontinuation of the livoletide program in Prader-Willi syndrome (PWS):** Topline data from the Phase 2b ZEPHYR study of livoletide in PWS were announced on April 6, 2020, and showed that treatment with livoletide did not result in a statistically significant improvement in hyperphagia and food-related behaviors compared to placebo, as measured by the Hyperphagia Questionnaire for Clinical Trials. As a result, the company discontinued the program and initiated staffing reductions. Final data tables and listings are currently being reviewed but are not anticipated to alter the topline conclusions of the study.
- **Interim review of data expected by 3Q20 for ongoing Phase 2b study of nevanimibe in patients with classic congenital adrenal hyperplasia (CAH):** Due to the continued global COVID-19 pandemic, new patients are not being actively enrolled in the open-label, Phase 2b nevanimibe study in CAH at this time, as is the case for many clinical studies worldwide. The company expects to conduct an interim review of the current dataset for enrolled patients by 3Q20.
- **MLE-301 expected to initiate Phase 1 clinical trials in 2H20 as planned:** A selective neurokinin 3 receptor (NK3R) antagonist, MLE-301 is intended for the treatment of vasomotor symptoms (VMS), commonly known as hot flashes and night sweats, in menopausal women. Due to the well-established role of NK3R in VMS, MLE-301 may have meaningful potential in an area of high unmet medical need.

First Quarter 2020 Financial Results

Cash Position: Cash, cash equivalents and restricted cash were $58.9 million at March 31, 2020, compared to $63.5 million at December 31, 2019.

Research and Development (R&D) Expenses: R&D expenses were $7.5 million for the first quarter 2020, as compared to $6.2 million for the same period in 2019. The increase in R&D expenses was primarily driven by increased spending on the company’s Phase 2b study of livoletide in PWS, which has since been discontinued.

General and Administrative (G&A) Expenses: G&A expenses were $4.6 million for the first quarter 2020, as compared to $4.5 million for the same period in 2019. The increase in G&A expenses was primarily driven by increased costs related to employee compensation offset by lower professional fees as compared to the prior period.

Net Loss: The company’s net loss for the quarter ended March 31, 2020 was $12.0 million as compared to $10.4 million for the same period in 2019.

2020 Financial Guidance

Millendo expects that its cash, cash equivalents and restricted cash will support the company’s current development and operational plans into 2022.

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 and the European Medicines Agency. 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 clinical stage 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 the impact of the COVID-19 pandemic on Millendo's business, preclinical studies and clinical development programs and timelines, Millendo's financial condition and results of operations, Millendo's future capital needs, the impact of Millendo's discontinuation of the PWS program, Millendo's plans to potentially in-license, acquire and develop additional product candidates and the timelines for 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 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 Millendo's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2020.

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.

Millendo Therapeutics, Inc.
Condensed Statements of Operations
(Unaudited)
(in thousands except share and per share amounts)

	Three Months Ended March 31,	
	2020	**2019**
Operating Expenses		
Research and development	$ 7,540	$ 6,204
General and administrative	4,595	4,453
Loss from operations	12,135	10,657
Other (income) expense, net	(137)	(291)
Net loss	$ (11,998)	$ (10,366)
Net loss per share of common stock, basic and diluted	$ (0.65)	$ (0.78)
Weighted-average shares of common stock outstanding, basic and diluted	18,448,507	13,357,999

Millendo Therapeutics, Inc.
Condensed Balance Sheet Data
(Unaudited)

(in thousands)

	March 31, 2020	December 31, 2019
Cash, cash equivalents and restricted cash	$ 58,877	$ 63,512
Other assets	9,168	11,458
Total assets	$ 68,045	$ 74,970
Total liabilities	$ 13,406	$ 15,099
Total stockholders' equity	54,639	59,871
Total liabilities and stockholders' equity	$ 68,045	$ 74,970

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