Millendo Therapeutics, Inc. Logo

Millendo Therapeutics Reports Third Quarter 2020 Operating and Financial Results

November 9, 2020

– Phase 1 clinical trial underway for MLE-301, a selective NK3R antagonist being studied for the treatment of vasomotor symptoms (VMS) in menopausal women –

ANN ARBOR, Mich.--(BUSINESS WIRE)--Nov. 9, 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 September 30, 2020.

“We continue to advance MLE-301 as a potential alternative to hormone replacement therapy for the treatment of vasomotor symptoms (VMS) related to menopause, and were pleased to initiate our Phase 1 clinical trial in the 3rd quarter,” said Julia C. Owens, President and Chief Executive Officer of Millendo Therapeutics. “MLE-301 is a priority program for Millendo, given the broader industry excitement around its potential to address a large unmet need, along with a refocusing of our internal pipeline efforts. With over 20 million women in the United States suffering from menopausal VMS, and with symptoms lasting on average over seven years, there is still a critical need for a treatment that has the efficacy of hormone replacement therapy without increased risks of cancer or cardiovascular disease."

Third Quarter 2020 and Recent Highlights

- **MLE-301 Phase 1 clinical trial initiated in 3Q20 as planned**: A selective neurokinin 3 receptor (NK3R) antagonist, MLE-301, is being developed for the treatment of vasomotor symptoms (VMS), commonly known as hot flashes and night sweats, in menopausal women. The single ascending dose portion of the study, being conducted in healthy male volunteers, will determine the pharmacokinetics of MLE-301 and its pharmacodynamic profile as measured by reductions of biomarkers (luteinizing hormone, testosterone). The multiple ascending dose portion will enroll post-menopausal women, with the goal of measuring reductions in VMS frequency and severity and establishing initial clinical proof of concept. The company continues to monitor the COVID-19 pandemic closely and will provide updates pending any potential impact to trial enrollment.
- **Nevanimibe program for patients with congenital adrenal hyperplasia (CAH) winding down**: Further investment in the development of nevanimibe as a potential treatment for CAH has ceased, and out-licensing options are being explored.
- **Comprehensive evaluation of strategic options continues**: SVB Leerink is supporting a strategic review process to build an actionable plan leveraging the company’s assets, capital and capabilities to maximize shareholder value.

Third Quarter 2020 Financial Results

Cash Position: Cash, cash equivalents and restricted cash were $43.8 million at September 30, 2020, compared to $63.5 million at December 31, 2019.

Research and Development (R&D) Expenses: R&D expenses were $2.7 million for the third quarter 2020, as compared to $7.3 million for the same period in 2019. The decrease in R&D expenses was primarily driven by decreased spend due to discontinuing our development of the livoletide program and ceasing investing in the nevanimibe program, offset by increased spend on MLE-301.

General and Administrative (G&A) Expenses: G&A expenses were $3.4 million for the third quarter 2020, as compared to $4.4 million for the same period in 2019. The decrease in G&A expenses was primarily driven by decreased professional fees as a result of lower accounting and consulting fees incurred as compared to the prior period. Compensation and stock-based compensation decreased as a result of a decrease in our general and administrative headcount and changes to compensation arrangements.

Net Loss: The company’s net loss for the quarter ended September 30, 2020 was $6.4 million as compared to $11.6 million for the same period in 2019.

2020 Financial Guidance

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

About MLE-301

MLE-301 is a neurokinin 3 receptor (NK3R) antagonist that is being developed as a potential treatment of vasomotor symptoms (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 has been shown 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 decrease the frequency and severity of vasomotor symptoms.

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 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 Phase 1 clinical trials for and the potential clinical impact of MLE-301 on menopausal vasomotor symptoms and the company's ongoing strategic review of its pipeline, 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 Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 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 September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Operating Expenses				
Research and development	$ 2,676	$ 7,308	$ 16,682	$ 19,493
General and administrative	3,380	4,443	12,113	13,075
Loss from operations	6,056	11,751	28,795	32,568
Other expense (income), net	318	(119)	249	(699)
Net loss	$ (6,374)	$ (11,632)	$ (29,044)	$ (31,869)
Net loss per share of common stock, basic and diluted	$ (0.34)	$ (0.87)	$ (1.54)	$ (2.38)
Weighted-average shares of common stock outstanding, basic and diluted	18,999,701	13,420,614	18,816,481	13,386,381

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

	September 30, 2020	December 31, 2019
Cash, cash equivalents and restricted cash	$ 43,752	$ 63,512
Other assets	5,086	11,458
Total assets	$ 48,838	$ 74,970
Total liabilities	$ 9,024	$ 15,099
Total stockholders' equity	39,814	59,871
Total liabilities and stockholders' equity	$ 48,838	$ 74,970

View source version on businesswire.com: https://www.businesswire.com/news/home/20201109005124/en/

Millendo Investor Contact:
Connie Chang
Millendo Therapeutics
734-864-8006
chang@millendo.com

Millendo Media Contact:
Julie Bane
MacDougall
617-821-1089
jbane@macbiocom.com

Source: Millendo Therapeutics, Inc.