Madrigal Pharmaceuticals Reports 2019 Fourth Quarter and Full Year Financial Results and Highlights

February 26, 2020

CONSHOHOCKEN, Pa., Feb. 26, 2020 (GLOBE NEWSWIRE) -- Madrigal Pharmaceuticals, Inc. (NASDAQ:MDGL) today announced its fourth quarter and full year 2019 financial results and highlights:

“Madrigal made significant progress during 2019 in executing our business strategy and advancing the development of resmetirom. We initiated two Phase 3 studies in NASH: the liver biopsy endpoint study, MAESTRO-NASH, and a non-invasive study in NAFLD patients with presumed NASH, MAESTRO-NAFLD-1,” stated Paul Friedman, M.D., Chief Executive Officer of Madrigal. “We filled vital organizational needs including expansion of our medical operations team and the addition of Jim Daly, who has deep commercial expertise, to our Board. Further, we believe we have sufficient financial resources to fund our two ongoing Phase 3 clinical studies.”

Becky Taub, M.D., CMO and President, Research & Development of Madrigal added, “According to plan, we initiated our Phase 3 MAESTRO-NASH clinical study in the first quarter, and our Phase 3 MAESTRO-NAFLD-1 study in the fourth quarter. Both Phase 3 studies are on track to complete enrollment this year for the 52 week readout by the end of 2021. In addition, MAESTRO-NAFLD-1 includes an open label active treatment arm that will provide data on lipids and non-invasive NASH biomarkers in 2020. We were also pleased with the publication of our successful Phase 2 NASH study in *The Lancet* in 2019. We continue to believe resmetirom has the potential to resolve NASH and reduce liver fibrosis while decreasing cardiovascular risk, through reduction of levels of multiple atherogenic lipids including LDL-C and triglycerides, and through the reduction of inflammatory fat in the liver. Realization of this potential could provide an important new therapy that delivers benefit to patients across the spectrum of early and late-stage NASH.”

Financial Results for the Three Months and Twelve Months Ended December 31, 2019

As of December 31, 2019, Madrigal had cash, cash equivalents and marketable securities of $439.0 million, compared to $483.7 million at December 31, 2018. The decrease in cash and marketable securities resulted primarily from cash used in operations of $41.6 million.

Operating expenses were $30.0 million and $95.0 million, respectively, for the three month and twelve month periods ended December 31, 2019, compared to $14.5 million and $40.7 million in the comparable prior year periods.

Research and development expenses for the three month and twelve month periods ended December 31, 2019 were $24.9 million and $72.3 million, respectively, compared to $8.9 million and $25.4 million in the comparable prior year periods. The increases are primarily attributable to increases in clinical costs resulting from initiation of our Phase 3 studies, and personnel costs, including non-cash stock compensation.

General and administrative expenses for the three month and twelve month periods ended December 31, 2019 were $5.0 million and $22.6 million, respectively, compared to $5.6 million and $15.3 million in the comparable prior year periods. The decrease in general and administrative expenses for the latest three month period was due primarily to lower stock compensation expense, the effect of which was partially offset by higher personnel costs. The increase in general and administrative expenses for the latest twelve month period was due primarily to higher stock compensation, and personnel costs.

Interest income for the three month and twelve month periods ended December 31, 2019 was $2.2 million and $11.0 million, respectively, as compared to $3.0 million and $7.7 million in the comparable prior year periods. The decrease in interest income for the latest three month period was due primarily to lower average principal balances in our investment accounts in 2019, and lower interest rates. The increase in interest income for 2019 was due primarily to higher average principal balances in our investment accounts, the effects of which were partially offset by lower interest rates.

About resmetirom (MGL-3196)
Among its many functions in the human body, thyroid hormone, through activation of its beta receptor, plays a central role in controlling lipid metabolism, impacting a range of health parameters from levels of serum cholesterol and triglycerides to the pathological buildup of fat in the liver. Attempts to exploit this pathway for therapeutic purposes in cardio-metabolic and liver diseases have been hampered by the lack of selectivity of older compounds for the thyroid hormone receptor (THR)-β, chemically-related toxicities and undesirable distribution in the body.

Madrigal recognized that greater selectivity for thyroid hormone receptor (THR)-β and liver targeting might overcome these challenges and deliver the full therapeutic potential of THR-β agonism. Madrigal believes that resmetirom is the first orally administered, small-molecule, liver-directed, truly β-selective THR agonist.

Based on the positive Phase 2 clinical study results in patients with NASH (Phase 2 NASH 36-Week Results Press Release),

Madrigal initiated a Phase 3 multinational, double-blind, randomized, placebo-controlled study of resmetirom in patients with non-alcoholic steatohepatitis (NASH) and fibrosis to resolve NASH and reduce progression to cirrhosis and/or hepatic decompensation (Phase 3 MAESTRO-NASH Initiation Press Release and ClinicalTrials.gov NCT03900429). Additionally, in both the NASH Phase 2 study, and a second positive Phase 2 clinical study in patients with heterozygous familial hypercholesterolemia (Phase 2 HeFH Results Press Release Phase 2 HeFH Results Press Release), significant reductions in multiple atherogenic lipids were observed. Based on the foregoing positive results, Madrigal also initiated MAESTRO-NAFLD-1, a 52-week, double-blind, placebo controlled Phase 3 clinical study in patients with biopsy-confirmed or presumed NASH (Phase 3 MAESTRO-NAFLD-1 Initiation Press Release and ClinicalTrials.gov NCT04197479). Key MAESTRO-NAFLD-1 endpoints are safety, including safety biomarkers, LDL cholesterol, lipid biomarkers, and fibrosis biomarkers. Except for serial liver biopsies, the study protocol is similar to the MAESTRO-NASH study and includes key secondary lipid, MRI-PDFF and NASH biomarker endpoints. In addition, MAESTRO-NAFLD-1 includes an open label arm in which up to 100 patients will be dosed with 100 mg resmetirom. The MAESTRO -NAFLD-1 study will help support the adequacy of the safety database at the time of NDA submission for subpart H approval for treatment of NASH in patients with F2 or F3 fibrosis (MAESTRO-NASH, NASH resolution surrogate endpoint).

About Madrigal Pharmaceuticals
Madrigal Pharmaceuticals, Inc. (Nasdaq: MDGL) is a clinical-stage biopharmaceutical company pursuing novel therapeutics that target a specific thyroid hormone receptor pathway in the liver, which is a key regulatory mechanism common to a spectrum of cardio-metabolic and fatty liver diseases with high unmet medical need. Madrigal's lead candidate, resmetirom, is a first-in- class, orally administered, small-molecule, liver-directed, thyroid hormone receptor (THR)-β selective agonist. For more information, visit www.madrigalpharma.com.

Forward-Looking Statements
This communication contains "forward-looking statements" made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, that are based on our beliefs and assumptions and on information currently available to us. Forward-looking statements include but are not limited to statements or references concerning: our clinical trials, research and development activities, and the timing and results associated with the future development of our lead product candidate, MGL-3196 (resmetirom); our primary and secondary study endpoints for resmetirom and the potential for achieving such endpoints and projections; optimal dosing levels for resmetirom; projections regarding potential future NASH resolution, safety, fibrosis treatment, cardiovascular effects and lipid treatment with resmetirom; the achievement of enrollment objectives concerning patient number, safety database and/or timing for our studies; the risks attendant with conducting trials that are substantially larger than our past trials; potential NASH or NAFLD patient risk profile benefits with resmetirom; our possible or assumed future results of operations and expenses, business strategies and plans, capital needs and financing plans, trends, market sizing, competitive position, industry environment and potential growth opportunities, among other things. Forward-looking statements: reflect management's current knowledge, assumptions, judgment and expectations regarding future performance or events; include all statements that are not historical facts; and can be identified by terms such as "anticipates," "be," "believes," "continue," "could," "estimates," "expects," "forecasts," "future," "goal," "intends," "may," "might," "plans," "potential," "predicts," "projects," "seeks," "should," "will," "would" or similar expressions and the negatives of those terms. Although management presently believes that the expectations reflected in such forward-looking statements are reasonable, it can give no assurance that such expectations will prove to be correct and you should be aware that actual results could differ materially from those contained in the forward-looking statements.

Forward-looking statements are subject to a number of risks and uncertainties including, but not limited to, our clinical development of resmetirom, enrollment uncertainties, outcomes or trends from competitive studies, the risks of achieving potential benefits in a study that includes substantially more patients than our prior study, the timing and outcomes of clinical studies of resmetirom, and the uncertainties inherent in clinical testing. Undue reliance should not be placed on forward- looking statements, which speak only as of the date they are made. Madrigal undertakes no obligation to update any forward-looking statements to reflect new information, events or circumstances after the date they are made, or to reflect the occurrence of unanticipated events. Please refer to Madrigal's filings with the U.S. Securities and Exchange Commission for more detailed information regarding these risks and uncertainties and other factors that may cause actual results to differ materially from those expressed or implied. We specifically discuss these risks and uncertainties in greater detail in the section entitled "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2019, as well as in our other filings with the SEC.

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(**Tables Follow**)

Madrigal Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
Revenues:				
Total revenues	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	24,910	8,871	72,324	25,389
General and administrative	5,044	5,583	22,648	15,293
Total operating expenses	29,954	14,454	94,972	40,682
Loss from operations	(29,954)	(14,454)	(94,972)	(40,682)
Interest income (expense), net	2,214	2,979	11,024	7,671
Other income	-	-	-	200
Net loss	$ (27,740)	$ (11,475)	$ (83,948)	$ (32,811)
Basic and diluted net loss per common share	$ (1.80)	$ (0.75)	$ (5.45)	$ (2.22)
Basic and diluted weighted average number of common shares outstanding	15,429,154	15,348,358	15,394,659	14,796,712

Madrigal Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	December 31, 2019	December 31, 2018
Assets		
Cash, cash equivalents and marketable securities	$ 439,045	$ 483,718
Other current assets	1,152	1,483
Other non-current assets	1,859	227
Total assets	$ 442,056	$ 485,428
Liabilities and Equity		
Current liabilities	$ 25,130	$ 8,444
Long-term liabilities	361	-
Stockholders' equity	416,565	476,984
Total liabilities and stockholders' equity	$ 442,056	$ 485,428

Source: Madrigal Pharmaceuticals, Inc.