Madrigal Pharmaceuticals Reports 2019 Third Quarter Financial Results and Highlights

November 6, 2019

CONSHOHOCKEN, Pa., Nov. 06, 2019 (GLOBE NEWSWIRE) -- Madrigal Pharmaceuticals, Inc. (NASDAQ:MDGL) today announced its third quarter 2019 financial results and highlights:

“Madrigal continued to execute its clinical development strategy in non-alcoholic steatohepatitis (NASH) and non-alcoholic fatty liver disease (NAFLD) during the third quarter. We opened clinical sites and enrolled subjects in accordance with the plan for our Phase 3 study of MGL-3196 (resmetirom) in patients with biopsy-proven NASH and liver fibrosis (MAESTRO-NASH),” stated Paul Friedman, M.D., Chief Executive Officer of Madrigal. “We also made progress toward initiating a second Phase 3 clinical study in a broader segment of NASH patients, many of whom also have hyperlipidemia, MAESTRO-NAFLD-1. These patients, like the later stage NASH patients, are at high risk of cardiovascular disease. In this regard, we are pleased that Seth Baum, M.D., Immediate Past President, American Society for Preventive Cardiology, will present 'Managing Cardiovascular Risk in NAFLD/NASH' from 1:30 – 2:00 PM ET on Monday, November 11, 2019, during the AASLD Annual Meeting.”

Becky Taub, M.D.,CMO, President, Research & Development of Madrigal, added, “We are pleased to announce that The Lancet has accepted for publication Madrigal’s Phase 2 study results in patients with NASH. We are also pleased to announce that FDA has granted Madrigal’s request for Fast Track designation of resmetirom for NASH. We look forward to the upcoming Liver Meeting® AASLD 2019 in Boston this month, where our abstract 'Effects of Resmetirom (MGL-3196) on Hepatic Fat, Lipids, Liver Enzymes and Markers of Liver Fibrosis in an Open-Label 36-Week Extension Study in NASH Patients' has been selected for oral presentation, and our poster, 'Steatosis and Fibrosis Measured as Continuous Variables on Paired, Serial Liver Biopsies in the Resmetirom (MGL-3196) 36-Week Phase 2 NASH Study' will also be presented.”

Details of the presentations mentioned above are as follows:

- Seth Baum, M.D., Immediate Past President, American Society for Preventive Cardiology, will present “Managing Cardiovascular Risk in NAFLD/NASH,“ Monday November 11, 1:30 – 2:00 PM, Product Theater, Exhibition Floor.
- Stephen Harrison, M.D. TITLE: "Effects of Resmetirom (MGL-3196) on Hepatic Fat, Lipids, Liver Enzymes and Markers of Liver Fibrosis in an Open-Label 36-Week Extension Study in NASH Patients" Parallel Session 39 (oral) (4:30-6:00 PM) Hynes Convention Center Ballroom BC, Monday November 11, 5:30 PM.
- Poster 2133 "Steatosis and Fibrosis Measured as Continuous Variables on Paired, Serial Liver Biopsies in the Resmetirom (MGL-3196) 36-Week Phase 2 NASH Study," Monday November 11, 8:00 AM, Poster Hall. NAFLD and NASH Therapeutics: Pharmacologic and Other.
- Madrigal will also have a medical information booth - #513 on the exhibition floor.

Additional information about Madrigal’s Phase 3 study in patients with NASH [NCT03900429] can be obtained at www.clinicaltrials.gov.

Financial Results for the Three and Nine Months Ended September 30, 2019

As of September 30, 2019, Madrigal had cash, cash equivalents and marketable securities of $453.6 million, compared to $483.7 million at December 31, 2018. The decrease of $30.1 million was largely the result of $29.3 million cash used in operating activities during the first nine months of 2019.

Operating expenses were $24.2 million and $65.0 million for the three and nine month periods ended September 30, 2019, compared to $11.3 million and $26.2 million in the comparable prior year periods.

Research and development expenses for the three and nine month periods ended September 30, 2019 were $19.4 million and $47.4 million compared to $6.2 million and $16.5 million in the comparable prior year periods. The increases are primarily attributable to additional activities related to initiation of our Phase 3 clinical trial in NASH, including a payment due related to a milestone achieved under our agreement with Roche, an increase in headcount and increased non-cash stock compensation from stock option awards.

General and administrative expenses for the three and nine month periods ended September 30, 2019 were $4.7 million and $17.6 million compared to $5.1 million and $9.7 million in the comparable prior year periods. The decrease for the three month period is due primarily to lower non-cash stock compensation expense from stock option awards. The increase for the nine month period is due primarily to increased non-cash stock compensation from stock option awards.

Interest income for the three and nine month periods ended September 30, 2019 was $2.8 million and $8.8 million compared to

$2.8 million and $4.7 million in the comparable prior year periods. The change in interest income for the nine month period was due primarily to a higher average principal balance in our investment portfolio in 2019, and increased 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 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 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), significant reductions in multiple atherogenic lipids were observed. Madrigal is planning a Phase 3 study in NASH and NAFLD patients to further assess effects on LDL-cholesterol, other atherogenic lipids, biomarkers of fibrosis, MRI-PDFF and fibroscans to better characterize potential clinical benefits of resmetirom on cardiovascular and liver related endpoints using noninvasive measures.

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, 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; optimal dosing levels for resmetirom; projections regarding potential future NASH resolution, fibrosis treatment, cardiovascular effects and lipid treatment; the achievement of enrollment objectives concerning patient number and/or timing for our studies; potential NASH or NAFLD patient risk profile benefits; 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," "future," "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, the company's 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, 2018, 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 September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Revenues:				
Total revenues	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	19,447	6,211	47,414	16,518
General and administrative	4,748	5,122	17,604	9,710
Total operating expenses	24,195	11,333	65,018	26,228
Loss from operations	(24,195)	(11,333)	(65,018)	(26,228)
Interest income (expense), net	2,766	2,821	8,810	4,692
Other income	-	-	-	200
Net loss	$ (21,429)	$ (8,512)	$ (56,208)	$ (21,336)
Basic and diluted net loss per common share	$ (1.39)	$ (0.56)	$ (3.65)	$ (1.46)
Basic and diluted weighted average number of common shares outstanding	15,415,096	15,307,872	15,383,034	14,610,809

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

	September 30, 2019	December 31, 2018
Assets		
Cash, cash equivalents and marketable securities	$ 453,610	$ 483,718
Other current assets	1,712	1,483
Other non-current assets	932	227
Total assets	$ 456,254	$ 485,428
Liabilities and Equity		
Current liabilities	$ 15,464	$ 8,444
Long-term liabilities	441	-
Stockholders' equity	440,349	476,984
Total liabilities and stockholders' equity	$ 456,254	$ 485,428

Source: Madrigal Pharmaceuticals, Inc.