Madrigal Pharmaceuticals Reports 2019 First Quarter Financial Results and Highlights

May 8, 2019

CONSHOHOCKEN, Pa., May 08, 2019 (GLOBE NEWSWIRE) -- Madrigal Pharmaceuticals, Inc. (NASDAQ:MDGL) today announced its first quarter 2019 financial results and highlights:

“Madrigal continued to make significant progress in the first quarter of 2019, initiating a Phase 3 study of MGL-3196 (resmetirom) in patients with biopsy-proven non-alcoholic steatohepatitis (NASH) and liver fibrosis (MAESTRO-NASH),” stated Paul Friedman, M.D., Chief Executive Officer of Madrigal. “We also look forward to advancing our planned Phase 3 clinical trial in patients with NAFLD/NASH and dyslipidemia in the latter half of this year.”

Becky Taub, M.D., CMO and Executive VP, Research & Development of Madrigal added, “An experienced group of NASH investigators and clinical sites around the world are participating in MAESTRO-NASH, and we are encouraged regarding timely enrollment. We believe the pleiotropic effects of resmetirom provide the potential to resolve NASH and improve liver fibrosis, and in addition, by reducing the levels of multiple atherogenic lipids and liver fat, also reduce cardiovascular risk.”

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 Months Ended March 31, 2019

As of March 31, 2019, Madrigal had cash, cash equivalents and marketable securities of $477.8 million, compared to $483.7 million at December 31, 2018. Cash used in operating activities during the first quarter of 2019 was $6.5 million.

Operating expenses were $18.1 million for the three month period ended March 31, 2019, compared to $7.1 million in the comparable prior year period.

Research and development expenses for the three month period ended March 31, 2019 were $12.4 million compared to $5.2 million in the comparable prior year period. The increase is primarily attributable to additional activities related to initiation of our Phase 3 clinical trial in NASH, including an increase in headcount and increased non-cash stock compensation from stock option awards.

General and administrative expenses for the three month period ended March 31, 2019 were $5.7 million compared to $1.9 million in the comparable prior year period. The increase is due primarily to higher non-cash stock compensation expense from stock option awards.

Interest income for the three month period ended March 31, 2019 was $3.0 million compared to $705 thousand in the comparable prior year period. The change in interest income 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 recently announced the initiation of 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. As a result, Madrigal is designing a Phase 3 study intended to treat the prevalent dyslipidemias in NAFLD and NASH patients and improve the fatty liver phenotype in this population.

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. Such statements contain words such as "expect," "could," "may," "might," "will," "be, "predict," "project," "intend," "believe," "estimate," "continue," "future," or the negative thereof or comparable terminology and the use of future dates. Forward-looking statements reflect management's current knowledge, assumptions, judgment and expectations regarding future performance or events. Such forward-looking statements include but are not limited to statements or references concerning: our primary and secondary study endpoints and their achievement potential; 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; and potential NASH or NAFLD patient risk profile benefits. Although management believes that the expectations reflected in such statements are reasonable, they 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 March 31,	
	2019	**2018**
Revenues:		
Total revenues	$ -	$ -
Operating expenses:		
Research and development	12,373	5,198
General and administrative	5,746	1,871
Total operating expenses	18,119	7,069
Loss from operations	(18,119)	(7,069)
Interest income (expense), net	3,039	705
Net loss	$ (15,080)	$ (6,364)
Basic and diluted net loss per common share	$ (0.98)	$ (0.45)
Basic and diluted weighted average number of common shares outstanding	15,364,465	14,127,868

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

	March 31, 2019	December 31, 2018
Assets		
Cash, cash equivalents and marketable securities	$ 477,825	$ 483,718
Other current assets	565	1,483
Other non-current assets	1,170	227
Total assets	$ 479,560	$ 485,428
Liabilities and Equity		
Current liabilities	$ 10,456	$ 8,444
Long-term liabilities	598	-
Stockholders' equity	468,506	476,984
Total liabilities and stockholders' equity	$ 479,560	$ 485,428

Source: Madrigal Pharmaceuticals, Inc.