Madrigal Pharmaceuticals Reports 2019 Second Quarter Financial Results and Highlights

August 7, 2019

-- Phase 3 MAESTRO-NASH Program Continues to Progress --

-- Jim Daly Added to Board of Directors and Becky Taub Promoted to President of R&D --

-- Madrigal Presentations Selected for the Liver Meeting® AASLD 2019 in Boston, November 2019 --

CONSHOHOCKEN, Pa., Aug. 07, 2019 (GLOBE NEWSWIRE) -- Madrigal Pharmaceuticals, Inc. (NASDAQ:MDGL) today announced its second quarter 2019 financial results and highlights:

“Madrigal has continued to progress on several important fronts during the second quarter. We have moved forward with our 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 were also fortunate to add Jim Daly to our Board of Directors. Jim’s deep commercial expertise will be invaluable as we move forward with development of resmetirom in NASH and Non-Alcoholic Fatty Liver Disease (NAFLD). In addition, in recognition of our clinical development progress and corresponding growth of the Company, we promoted Becky Taub, M.D., to President of R&D.”

Becky Taub, M.D.,CMO, President, Research & Development of Madrigal, added, “Madrigal is enrolling patients in our MAESTRO-NASH Phase 3 clinical study, and although it’s early in the process, we are encouraged by the rate of site openings and patient screening numbers. We are also pleased to announce that 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 at the Liver Meeting® AASLD 2019 in Boston, November 2019. A 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 at AASLD meeting.”

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 Six Months Ended June 30, 2019

As of June 30, 2019, Madrigal had cash, cash equivalents and marketable securities of $466.4 million, compared to $483.7 million at December 31, 2018. Cash used in operating activities during the first six months of 2019 was $18.0 million.

Operating expenses were $22.7 million and $40.8 million for the three and six month periods ended June 30, 2019, compared to $7.8 million and $14.9 million in the comparable prior year periods.

Research and development expenses for the three and six month periods ended June 30, 2019 were $15.6 million and $28.0 million compared to $5.1 million and $10.3 million in the comparable prior year periods. The increase is 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 six month periods ended June 30, 2019 were $7.1 million and $12.9 million compared to $2.7 million and $4.6 million in the comparable prior year periods. The increase is due primarily to higher non-cash stock compensation expense from stock option awards.

Interest income for the three and six month periods ended June 30, 2019 was $3.0 million and $6.0 million compared to $1.2 million and $1.9 million in the comparable prior year periods. 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 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. 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, 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	Six Months Ended

	June 30,		June 30,	
	2019	2018	2019	2018
Revenues:				
Total revenues	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	15,594	5,109	27,967	10,307
General and administrative	7,110	2,717	12,856	4,588
Total operating expenses	22,704	7,826	40,823	14,895
Loss from operations	(22,704)	(7,826)	(40,823)	(14,895)
Interest income (expense), net	3,005	1,166	6,044	1,871
Other income	-	200	-	200
Net loss	$ (19,699)	$ (6,460)	$ (34,779)	$ (12,824)
Basic and diluted net loss per common share	$ (1.28)	$ (0.45)	$ (2.26)	$ (0.90)
Basic and diluted weighted average number of common shares outstanding	15,368,986	14,383,720	15,366,738	14,256,501

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

	June 30, 2019	December 31, 2018
Assets		
Cash, cash equivalents and marketable securities	$ 466,396	$ 483,718
Other current assets	2,389	1,483
Other non-current assets	1,037	227
Total assets	$ 469,822	$ 485,428
Liabilities and Equity		
Current liabilities	$ 12,316	$ 8,444
Long-term liabilities	520	-
Stockholders' equity	456,986	476,984
Total liabilities and stockholders' equity	$ 469,822	$ 485,428

Source: Madrigal Pharmaceuticals, Inc.