Madrigal Pharmaceuticals Provides Business and Clinical Updates and Reports 2021 Fourth Quarter and Full Year Financial Results

February 24, 2022

CONSHOHOCKEN, Pa., Feb. 24, 2022 (GLOBE NEWSWIRE) -- Madrigal Pharmaceuticals, Inc. (NASDAQ:MDGL), a clinical-stage biopharmaceutical company pursuing novel therapeutics for non-alcoholic steatohepatitis (NASH), today provides a summary of corporate accomplishments and reports its fourth quarter and full year 2021 financial results.

Paul Friedman, M.D., Chief Executive Officer of Madrigal, stated, “2021 was a year of significant progress for Madrigal as we continued to advance our industry-leading NASH clinical development program, setting up two critical readouts from our Phase 3 MAESTRO trials in 2022, one of which we have already delivered. Additionally, we expanded our leadership team, deepened relationships with the NASH community and enhanced our capabilities to support the commercialization of resmetirom.”

Becky Taub, M.D., Chief Medical Officer and President of Research & Development at Madrigal stated, “The positive MAESTRO-NAFLD-1 safety study results we announced in January support our conviction that resmetirom has the potential to be the first medication approved for the treatment of patients with NASH. The data reinforce our expectation that the second Phase 3 trial of resmetirom, the MAESTRO-NASH liver biopsy study, will also produce positive safety and efficacy data later this year.”

Clinical Trial Results and Updates

Primary and key secondary endpoints from the double-blind placebo-controlled 969-patient MAESTRO-NAFLD-1 safety study were achieved and demonstrate that resmetirom:

- Was safe and well-tolerated at 80 and 100 mg in patients treated for 52 weeks;
- Provided significant and, we believe, clinically relevant reductions in liver fat as measured by magnetic resonance imaging proton density fat-fraction (MRI-PDFF);
- Significantly reduced atherogenic lipids, including LDLc, apolipoprotein B and triglycerides.

Adverse events were generally mild to moderate in severity. The frequency of serious adverse events was similar across placebo and active treatment arms and discontinuation for adverse events was low. Serious adverse events occurred at expected rates based on the patient population.

Madrigal will continue to generate safety and efficacy data from the MAESTRO-NAFLD-1 trial and intends to provide at least one additional public disclosure prior to publication/presentation at a major medical meeting.

The Phase 3 MAESTRO-NASH trial continues to progress with the Subpart H cohort patients scheduled to complete the 52-week dosing regimen on time. Based on more conservative timeline assumptions for analysis of biopsies and other data from the trial, topline results are now expected in Q4 2022.

Leadership Team Expanded

Dominic F. Labriola, PhD, has joined Madrigal as Chief Data and Analytics Officer. Dr. Labriola has 35 years of experience in clinical development overseeing the global registration of 20 medicines. He spent more than 20 years at Bristol Myers Squibb as Head of Global Biometric Sciences where he was responsible for the team overseeing the company’s NASH program among many other programs. Prior to joining Bristol Myers Squibb, he held positions of increasing responsibility at DuPont Pharmaceutical Company, managing biostatisticians and programmers for multiple therapeutic areas. Dr. Labriola began his career as a research biostatistician at Memorial Sloan Kettering Cancer Center and earned his Ph.D. in Mathematical Statistics from the University of Delaware.

Sunil Kadam, PhD, has joined Madrigal as Senior Vice President of Global Regulatory Affairs. Dr. Kadam has successfully built and directed Global Regulatory Affairs teams at both large and emerging biopharmaceutical companies. Most recently, he was Senior Vice President of Global Regulatory Affairs at Telix Pharmaceuticals Limited. As the Regulatory Affairs lead for gastroenterology at Shire/Takeda, he led FDA Advisory Committee and secured FDA approval for Motegrity (prucalopride). As the Head of Regulatory Affairs for Takeda’s endocrine and metabolic rare disease products, he managed the global development of multiple pipeline projects. Prior to joining Takeda, he led Regulatory Affairs teams at IQVIA and Eli Lilly & Company.

Financial Results for the Three and Twelve Months Ended December 31, 2021

As of December 31, 2021, Madrigal had cash, cash equivalents and marketable securities of $270.3 million, compared to $284.1 million at December 31, 2020. The decrease in cash and marketable securities resulted primarily from cash used in operations of $183.9 million.

Operating expenses were $64.6 million and $242.5 million for the three and twelve month periods ended December 31, 2021, compared to $59.6 million and $206.7 million in the comparable prior year periods.

Research and development expenses for the three and twelve month periods ended December 31, 2021 were $52.9 million and $205.2 million, compared to $53.4 million and $184.8 million in the comparable prior year periods. The increases are primarily attributable to additional activities related to the Phase 3 clinical trials, an increase in manufacturing costs to support ongoing clinical trials and to prepare for commercialization, and an

increase in head count and related expenses.

General and administrative expenses for the three and twelve month periods ended December 31, 2021 were $11.7 million and $37.3 million, compared to $6.1 million and $21.9 million in the comparable prior year periods. The increases are primarily attributable to an increase in non-cash stock compensation from stock option awards, head count and consulting costs.

Interest income for the three and twelve month periods ended December 31, 2021 was $0.1 million and $0.4 million, compared to $0.4 million and $4.3 million in the comparable prior year periods. The decreases in interest income for the latest three and twelve month periods were due primarily to lower average principal balances in our investment accounts in 2021, and decreased interest rates.

About Madrigal Pharmaceuticals

Madrigal Pharmaceuticals, Inc. (Nasdaq: MDGL) is a clinical-stage biopharmaceutical company pursuing novel therapeutics for non-alcoholic steatohepatitis (NASH), a liver disease with high unmet medical need. Madrigal's lead candidate, resmetirom, is a once daily, oral, thyroid hormone receptor (THR)-β selective agonist that is designed to target key underlying causes of NASH in the liver. Resmetirom is currently being evaluated in two Phase 3 clinical studies, MAESTRO-NASH and MAESTRO- NAFLD-1, designed to demonstrate multiple benefits in patients with NASH. 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 but are subject to factors beyond our control. Forward-looking statements include but are not limited to statements or references concerning: our clinical trials, including the anticipated timing of disclosure, presentations of data from, or outcomes from our trials; research and development activities; market size and patient treatment estimates for NASH and NAFLD patients; 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; plans, objectives and timing for making a Subpart H (Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses) submission to FDA; optimal dosing levels for resmetirom; projections regarding potential future NASH resolution, safety, fibrosis treatment, cardiovascular effects, lipid treatment and/or biomarker effects with resmetirom; the potential efficacy and safety of resmetirom for non-cirrhotic NASH patients and cirrhotic NASH patients; ex-U.S. launch/partnering plans; the predictive power of liver fat reduction, as measured by non-invasive tests, on NASH resolution with fibrosis reduction or improvement; the predictive power of liver fat, liver volume changes or MAST scores for NASH and/or NAFLD patients; the effects of resmetirom's mechanism of action; the achievement of enrollment objectives concerning patient number, safety database and/or timing for our studies; the predictive power of NASH resolution and/or liver fibrosis reduction or improvement with resmetirom using non-invasive tests, including the use of ELF, FibroScan, MRE and/or MRI-PDFF; the ability to develop clinical evidence demonstrating the utility of non-invasive tools and techniques to screen and diagnose NASH and/or NAFLD patients; the predictive power of non-invasive tests generally, including for purposes of diagnosing NASH, monitoring patient response to resmetirom, or recruiting a NASH clinical trial; potential NASH or NAFLD patient risk profile benefits with resmetirom; the potential for resmetirom to become the best-in-class and/or first-to-market treatment option for patients with NASH and liver fibrosis; and 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 "allow," "anticipates," "be," "believes," "continue," "could," "demonstrate," "design," "estimates," "expectation," "expects," "forecasts," "future," "goal," "hopeful," "inform," "intends," "may," "might," "planned", "plans," "positions," "potential," "powers," "predicts," "predictive," "projects," "seeks," "should," "will," "will be," "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, generally and in relation to COVID-19-related measures that may be continued for an uncertain period of time or implemented; outcomes or trends from competitive studies; future topline data timing or results; the risks of achieving potential benefits in studies that include substantially more patients, and patients with different disease states, than our prior studies; limitations associated with early stage or non-placebo controlled study data; 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 submissions filed or furnished 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 our Annual Report on Form 10-K for the year ended December 31, 2021, 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,	
	2021	2020	2021	2020
Revenues:				
Total revenues	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	52,889	53,429	205,164	184,809
General and administrative	11,712	6,126	37,318	21,864
Total operating expenses	64,601	59,555	242,482	206,673
Loss from operations	(64,601)	(59,555)	(242,482)	(206,673)
Interest income, net	52	432	363	4,329
Other income	-	-	273	100
Net loss	$ (64,549)	$ (59,123)	$ (241,846)	$ (202,244)
Basic and diluted net loss per common share	$ (3.78)	$ (3.82)	$ (14.63)	$ (13.09)
Basic and diluted weighted average number of common shares outstanding	17,074,543	15,475,291	16,535,188	15,446,638

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

	December 31, 2021	December 31, 2020
Assets		
Cash, cash equivalents and marketable securities	$ 270,346	$ 284,149
Other current assets	1,338	1,014
Other non-current assets	1,648	1,832
Total assets	$ 273,332	$ 286,995
Liabilities and Equity		
Current liabilities	$ 76,838	$ 46,557
Long-term liabilities	387	468
Stockholders' equity	196,107	239,970
Total liabilities and stockholders' equity	$ 273,332	$ 286,995

Source: Madrigal Pharmaceuticals, Inc.