Madrigal Pharmaceuticals Provides Corporate Updates and Reports Fourth Quarter and Full Year 2023 Financial Results

February 28, 2024

- *Announced appointment of Mardi C. Dier as Chief Financial Officer*
- *Anticipates resmetirom to become the first medicine approved for NASH; PDUFA date March 14, 2024*
- *Reports year-end 2023 cash, cash equivalents and marketable securities of $634 million*

CONSHOHOCKEN, Pa., Feb. 28, 2024 (GLOBE NEWSWIRE) -- Madrigal Pharmaceuticals, Inc. (NASDAQ:MDGL), a clinical-stage biopharmaceutical company pursuing novel therapeutics for nonalcoholic steatohepatitis (NASH), today provides a summary of corporate updates and reports fourth quarter and full year 2023 financial results.

Bill Sibold, Chief Executive Officer of Madrigal, stated “As we approach the March PDUFA date for resmetirom, we remain focused on advancing key regulatory, operational and commercial activities in preparation for a potential U.S. launch. Our goal is to establish resmetirom as the foundational therapy for NASH with significant fibrosis, a serious disease with significant unmet need that represents a high burden to patients, their families and the healthcare system.”

Recent Corporate Updates

- On February 28, 2024, the Company announced that Mardi Dier will join Madrigal as Chief Financial Officer. Ms. Dier has spent over 20 years in executive financial leadership roles in biotechnology companies, with deep experience in operational and strategic decision making, capital raising, financial planning and accounting (FP&A), global supply chain management, investor relations and business development. She has held CFO positions at Portola Pharmaceuticals, Ultragenyx, and Acelyrin.
- Additional appointments were made to the Madrigal leadership team since fourth quarter of 2023, including Carole Huntsman to Chief Commercial Officer, Ronald Fillipo to Chief Information Officer, Clint Wallace to Chief Human Resources Officer, Mark Barrett to Chief Business Officer and Tina Ventura to Chief Investor Relations Officer.
- On February 8, 2024, positive results from the 52-week pivotal Phase 3 MAESTRO-NASH trial were published in the *New England Journal of Medicine*, including detailed analyses that reinforce the safety and efficacy profile of resmetirom. MAESTRO-NASH is a multicenter, randomized, double-blind, placebo-controlled Phase 3 study of resmetirom in patients with liver biopsy-confirmed NASH.
- Five Madrigal health economic abstracts were presented at the NASH-TAG conference, which took place January 4-6, 2024 in Park City, Utah. Abstracts highlighted the serious clinical burden of uncontrolled NASH and identified opportunities to improve patient care.
- New data from the pivotal Phase 3 MAESTRO-NASH trial demonstrating broad treatment effects of resmetirom on noninvasive measures of liver health were presented at the American Association for the Study of Liver Disease (AASLD) Liver Meeting ®, which took place November 10-14, 2023 in Boston. Multiple additional Madrigal abstracts at the conference examined resmetirom safety and efficacy in NASH with significant fibrosis and NASH with compensated cirrhosis.

Financial Results for the Three and Twelve Months Ended December 31, 2023

As of December 31, 2023, Madrigal had cash, cash equivalents and marketable securities of $634.1 million, compared to $358.8 million at December 31, 2022. The increase in cash and marketable securities was primarily from proceeds from our October 2023 public offering partially offset by funding of operations.

Operating expenses were $117.2 million and $380.5 million for the three and twelve month periods ended December 31, 2023, compared to $85.3 million and $293.6 million in the comparable prior year periods.

Research and development expenses for the three and twelve month periods ended December 31, 2023, were $70.6 million and $272.4 million, compared to $70.7 million and $245.4 million in the comparable prior year periods. The increases are attributable primarily to a scale up of manufacturing activities to prepare for the launch of resmetirom as well as an increase in R&D personnel.

General and administrative (G&A) expenses for the three and twelve month periods ended December 31, 2023 were $46.5 million and $108.1 million, compared to $14.6 million and $48.1 million in the comparable prior year periods. The increases are attributable primarily to commercial activities in preparation for the expected approval and launch of resmetirom. We expect our G&A expenses to further increase as we expand our operating activities associated with the commercialization of resmetirom.

Interest income for the three and twelve month periods ended December 31, 2023, was $9.0 million and $19.6 million, compared to $1.1 million and $2.2 million in the comparable prior year periods. The increases in interest income for the latest three and

twelve month periods were due primarily to a higher average principal balance in our investment account as well as higher average interest rate in 2023.

Interest expense for the three and twelve month periods ended December 31, 2023 was $4.0 million and $12.7 million, compared to $1.7 million and $4.0 million in the comparable prior year periods. The increase in interest expense was as a result of the higher outstanding principal balances during the period under the company's loan facility as well as higher average interest rate in 2023.

About NASH

Nonalcoholic steatohepatitis (NASH) is a more advanced form of nonalcoholic fatty liver disease (NAFLD). NASH is a leading cause of liver-related mortality and an increasing burden on healthcare systems globally. Additionally, patients with NASH, especially those with more advanced metabolic risk factors (hypertension, concomitant type 2 diabetes), are at increased risk for adverse cardiovascular events and increased morbidity and mortality.

Once patients progress to NASH with significant fibrosis (consistent with fibrosis stages 2 and 3), the risk of adverse liver outcomes increases dramatically. NASH is rapidly becoming the leading cause of liver transplantation in the U.S.

Madrigal estimates that approximately 1.5 million patients have been diagnosed with NASH in the U.S., of which approximately 525,000 have NASH with significant fibrosis. Madrigal plans to focus on approximately 315,000 diagnosed patients with NASH with significant fibrosis under the care of the liver specialist physicians during the launch of resmetirom.

There are currently no FDA-approved therapies available for the treatment of NASH. NASH is also known as "metabolic dysfunction-associated steatohepatitis (MASH)" following a change in disease nomenclature introduced by hepatology medical societies in 2023.

About Madrigal Pharmaceuticals

Madrigal Pharmaceuticals, Inc. (Nasdaq: MDGL) is a clinical-stage biopharmaceutical company pursuing novel therapeutics for nonalcoholic steatohepatitis (NASH), a liver disease with high unmet medical need. Madrigal's lead candidate, resmetirom, is a liver-directed oral therapy that is designed to target key underlying causes of NASH. For more information, visit www.madrigalpharma.com.

Forward Looking Statements

This communication includes "forward-looking statements" made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, that are based on Madrigal's beliefs and assumptions and on information currently available to it, but are subject to factors beyond its control. Forward-looking statements reflect management's current knowledge, assumptions, judgment and expectations regarding future performance or events. Forward-looking statements include: all statements that are not historical facts; statements referenced by forward-looking statement identifiers, including the examples in the paragraph below; estimates of patients diagnosed with NASH; the relationship between NASH progression and adverse patient outcomes; the estimated clinical burden of uncontrolled NASH; analyses for patients with NASH with significant fibrosis concerning potential progression to cirrhosis, decompensated cirrhosis, liver transplant or death; cardiovascular risks, comorbidities and outcomes; health economics assessments or projections; resmetirom's potential to be the first specialty therapy for NASH patients with significant liver fibrosis; projections or objectives for obtaining accelerated or full approval for resmetirom, including all statements concerning potential clinical benefit to support accelerated approval and/or potential accelerated approval; and statements or references concerning - the potential efficacy and safety of resmetirom for noncirrhotic NASH patients and cirrhotic NASH patients, possible or assumed future results of operations and expenses, business strategies and plans (including ex-US. Launch/partnering plans), research and development activities, and the timing and results associated with the future development of resmetirom, the timing and completion of projected future clinical milestone events, including enrollment, additional studies, top-line data and open label projections, Madrigal's primary and key secondary study endpoints for resmetirom and the potential for achieving such endpoints and projections, the potential to support an additional indication for resmetirom in patients with well-compensated NASH cirrhosis, optimal dosing levels for resmetirom and projections regarding potential NASH or NAFLD and potential patient benefits with resmetirom, including future NASH resolution, safety, fibrosis treatment, cardiovascular effects, lipid treatment, and/or biomarker effects with resmetirom, and strategies, objectives and commercial opportunities, including potential prospects or results.

Forward-looking statements can be identified by terms such as "accelerate," "achieve," "allow," "anticipates," "appear," "be," "believes," "can," "confidence," "continue," "could," "demonstrates," "design," "estimates," "expectation," "expects," "forecasts," "future," "goal," "help," "hopeful," "inform," inform," "intended," "intends," "may," "might," "on track," "planned," "planning," "plans," "positions," "potential," "powers," "predicts," "predictive," "projects," "seeks," "should," "will," "will achieve," "will be," "would" or similar expressions and the negatives of those terms.

Forward-looking statements are subject to a number of risks and uncertainties including, but not limited to: the assumptions underlying the forward-looking statements; risks of obtaining and maintaining regulatory approvals, including, but not limited to, potential regulatory delays or rejections; risks associated with meeting the objectives of Madrigal's clinical studies, including, but not limited to Madrigal's ability to achieve enrollment objectives concerning patient numbers (including an adequate safety database), outcomes objectives and/or timing objectives for Madrigal's studies; any delays or failures in enrollment, and the

occurrence of adverse safety events; risks related to the effects of resmetirom's mechanism of action; the achievement of enrollment objectives concerning patient number, safety database and/or timing for Madrigal's studies; enrollment and trial conclusion uncertainties; market demand for and acceptance of our products; the potential inability to raise sufficient capital to fund ongoing operations as currently planned or to obtain financings on terms similar to those arranged in the past; the ability to service indebtedness and otherwise comply with debt covenants; outcomes or trends from competitive studies; future topline data timing or results; our ability to prevent and/or mitigate cyber attacks, unauthorized exfiltration of data or other security incidents; the risks of achieving potential benefits in studies that includes substantially more patients, and patients with different disease states, than prior studies; the timing and outcomes of clinical studies of resmetirom; the uncertainties inherent in clinical testing; and uncertainties concerning analyses or assessments outside of a controlled clinical trial. 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 with the U.S. Securities and Exchange Commission, or SEC, 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. Madrigal specifically discusses these risks and uncertainties in greater detail in the sections appearing in Part I, Item 1A of its Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 28, 2024, and as updated from time to time by Madrigal's 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)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Total revenues	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	70,640	70,742	272,350	245,441
General and administrative	46,536	14,557	108,146	48,130
Total operating expenses	117,176	85,299	380,496	293,571
Loss from operations	(117,176)	(85,299)	(380,496)	(293,571)
Interest income, net	8,953	1,076	19,578	2,185
Interest expense	(3,971)	(1,682)	(12,712)	(3,964)
Net loss	$ (112,194)	$ (85,905)	$ (373,630)	$ (295,350)
Basic and diluted net loss per common share	$ (5.68)	$ (4.98)	$ (19.99)	$ (17.23)
Basic and diluted weighted average number of common shares outstanding	19,760,842	17,237,517	18,687,774	17,137,201

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

	December 31, 2023	December 31, 2022
Assets		
Cash, cash equivalents and marketable securities	$ 634,131	$ 358,774

Other current assets		3,150		2,595
Other non-current assets		3,266		1,203
Total assets	$	640,547	$	362,572
Liabilities and Equity				
Current liabilities	$	118,548	$	115,894
Long-term liabilities		116,666		49,289
Stockholders' equity		405,333		197,389
Total liabilities and stockholders' equity	$	640,547	$	362,572

Source: Madrigal Pharmaceuticals, Inc.