Madrigal Pharmaceuticals Provides Corporate Updates and Reports Third Quarter 2023 Financial Results

November 6, 2023

- *Priority Review of resmetirom new drug application underway in the U.S.*
- *Bill Sibold appointed Chief Executive Officer of Madrigal in September 2023*
- *$500 million financing provides Madrigal with funds to support a potential first-to-market launch of resmetirom in the U.S.*
- *Multiple resmetirom abstracts from the Phase 3 MAESTRO program to be presented at the American Association for the Study of Liver Diseases (AASLD) Liver Meeting®*

CONSHOHOCKEN, Pa., Nov. 06, 2023 (GLOBE NEWSWIRE) -- Madrigal Pharmaceuticals, Inc. (NASDAQ:MDGL), a clinical-stage biopharmaceutical company pursuing novel therapeutics for nonalcoholic steatohepatitis (NASH), today provides a summary of recent corporate accomplishments, previews new Phase 3 MAESTRO study data scheduled for presentation at the AASLD Liver Meeting, and reports third quarter 2023 financial results.

Bill Sibold, Chief Executive Officer of Madrigal, stated, “Over the last several months, the Madrigal team has made significant progress advancing key regulatory and commercial activities in preparation for a potential approval of resmetirom in March 2024. Our New Drug Application is supported by the largest and most advanced development program in NASH and our commercial strategy is grounded in resmetirom’s profile as a liver-directed oral therapy that treats the underlying drivers of the disease. The $500 million financing we closed in October provides Madrigal with the resources necessary to execute a first-to-market launch of resmetirom in the U.S.”

Becky Taub, M.D., Chief Medical Officer and President of Research & Development of Madrigal, stated, “In addition to advancing our regulatory strategy, we are focused on sharing new data and insights to help clinicians manage patients in the real world setting following a potential approval of resmetirom. At the AASLD Liver Meeting next week, we will present a comprehensive analysis of noninvasive tests and imaging from the MAESTRO-NASH trial. Resmetirom demonstrated a broad and consistent treatment response across a range of noninvasive measures, including simple biomarkers that are widely available to clinicians.”

Recent Corporate Highlights

- Madrigal announced that the FDA accepted its New Drug Application and granted Priority Review for resmetirom for the treatment of adult patients with NASH with liver fibrosis. The FDA assigned a Prescription Drug User Fee Act date for resmetirom of March 14, 2024. The Agency noted that it is not currently planning to hold an advisory committee meeting to discuss the application.
- Bill Sibold was appointed Chief Executive Officer of Madrigal, succeeding Dr. Paul Friedman, who served as Madrigal’s CEO since 2016 and continues to serve on the Board of Directors. Mr. Sibold was previously Executive Vice President, Specialty Care of Sanofi and President, Sanofi North America, where he led a global organization of approximately 10,000 employees across five specialty therapeutic areas and served as a member of the Sanofi Executive Committee. While at Sanofi, Mr. Sibold led the launch of Dupixent, a first-in-class therapy which has grown into an industry-leading medicine.
- Madrigal executed a public offering that generated gross proceeds of $500 million to be used for clinical and commercial activities in preparation for a potential launch of resmetirom in the U.S. and for general corporate purposes.
- Positive results from the Phase 3 MAESTRO-NAFLD-1 safety study were published in *Nature Medicine*. MAESTRO-NAFLD-1 was a 52-week multicenter, randomized, placebo-controlled, double-blind Phase 3 study of resmetirom in ~1,200 patients with NAFLD, presumed NASH.

Resmetirom Data Presentations at AASLD

Multiple Madrigal abstracts have been accepted at the AASLD Liver Meeting, taking place November 10-14 in Boston:

- Oral presentation: “Relationship of Non-Invasive Measures with Histological Response in Patients with Nonalcoholic Steatohepatitis and Fibrosis: 52-Week Data from the Phase 3 MAESTRO-NASH Trial” [Monday, November 13 at 8:30 AM. Presenter: Rohit Loomba]
- Oral presentation: “Artificial Intelligence to Measure Fibrosis Change on Liver Biopsy in MAESTRO-NASH: A Phase 3 Serial Liver Biopsy Study in 966 Patients with NASH Treated with Resmetirom or Placebo” [Sunday, November 12 at 11:00 AM. Presenter: Stephen Harrison]
- Late-Breaking poster: “Artificial Intelligence-Based Measurement of NASH Histology (AIM-NASH) Recapitulates Primary Results from Phase 3 Study of Resmetirom for Treatment of NASH/MASH” [Presenter: Janani Iyer]
- Poster of Distinction: “Resmetirom Treatment Helps Restore Thyroid Hormone Levels in Patients with Nonalcoholic Steatohepatitis: 52-Week Data from the Phase 3 MAESTRO-NASH Trial” [Presenter: Stephen Harrison]
- Poster: “Resmetirom Improves the Atherogenic Lipid/Lipoprotein Profile in Patients with Nonalcoholic Steatohepatitis: 52-Week Data from the Phase 3 MAESTRO-NASH Trial” [Presenter: Naim Alkhouri]

- Poster: “The Next Generation of HepQuant Tests Measure Reduction in Risk for Clinical Events in Compensated NASH Cirrhosis Subjects Treated with Resmetirom” [Presenter: Michael McRae]
- Poster: “Understanding the Incremental Costs of Nonalcoholic Steatohepatitis and Diabetes Using Electronic Health Records and Closed Claims Data” [Presenter: Jesse Fishman]
- Poster: “Characterizing the Management of Patients with NASH (With Versus Without Cirrhosis) in Real-World Clinical Practice: Rare Assessment by Hepatologists and Low Frequency of Imaging” [Presenter: Christina Qian]

Financial Results for the Nine Months Ended September 30, 2023

As of September 30, 2023, Madrigal had cash, cash equivalents and marketable securities of $232.4 million, compared to $358.8 million at December 31, 2022. In October 2023, we completed a public offering and received an additional $472.0 million in net cash proceeds.

Operating expenses were $98.5 million and $263.3 million for the three month and nine month periods ended September 30, 2023, compared to $80.4 million and $208.3 million in the comparable prior year periods.

Research and development expenses for the three and nine month periods ended September 30, 2023 were $71.0 million and $201.7 million, compared to $68.3 million and $174.7 million in the comparable prior year periods. The increase is attributable primarily to additional activities related to the Phase 3 clinical trials, and an increase in head count.

General and administrative expenses for the three and nine month periods ended September 30, 2023 were $27.6 million and $61.6 million, compared to $12.1 million and $33.6 million in the comparable prior year periods. The increase is due primarily to increases in commercial preparation activities, including an increase in headcount and an increase in non-cash stock compensation.

Interest income for the three and nine month periods ended September 30, 2023 was $3.3 million and $10.6 million, compared to $0.7 million and $1.1 million in the comparable prior year periods. These increases in interest income were due primarily to higher average interest rates in 2023.

Interest expense for the three and nine month periods ended September 30, 2023 was $3.5 million and $8.7 million, compared to $1.5 million and $2.3 million in the comparable prior year periods.

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 (F2/F3), the risk of adverse liver outcomes increases dramatically. NASH is rapidly becoming the leading cause of liver transplantation in the U.S. 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; resmetirom’s potential to be the first specialty therapy for NASH patients with significant liver fibrosis; statements concerning 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, plans, objectives, timing and support for making for making a Subpart H (Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses) submission to FDA, projections or objectives for obtaining accelerated or full approval for resmetirom, Madrigal’s primary and key secondary study endpoints for resmetirom and the potential for achieving such endpoints and projections, demonstrating clinical benefit to support

accelerated approval, 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.

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; 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 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, 2022, filed with the SEC on February 23, 2023, as amended by our Form 10-K/A filed with the SEC on March 3, 2023, and Part II, Item 1A of its Quarterly Reports on Form 10-Q for the quarters ended June 30, 2023 and September 30, 2023, 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)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Total revenues	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	70,951	68,271	201,710	174,699
General and administrative	27,583	12,141	61,610	33,573
Total operating expenses	98,534	80,412	263,320	208,272
Loss from operations	(98,534)	(80,412)	(263,320)	(208,272)
Interest income	3,298	717	10,625	1,109
Interest expense	(3,504)	(1,502)	(8,741)	(2,282)
Net loss	$ (98,740)	$ (81,197)	$ (261,436)	$ (209,445)

Basic and diluted net loss per common share	$ (5.34)	$ (4.75)	$ (14.27)	$ (12.25)
Basic and diluted weighted average number of common shares outstanding	18,476,414	17,103,395	18,326,154	17,103,395

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

	September 30, 2023	December 31, 2022
Assets		
Cash, cash equivalents and marketable securities	$ 232,351	$ 358,774
Other current assets	3,118	2,595
Other non-current assets	2,495	1,203
Total assets	$ 237,964	$ 362,572
Liabilities and Equity		
Current liabilities	$ 99,665	$ 115,894
Long-term liabilities	116,050	49,289
Stockholders' equity	22,249	197,389
Total liabilities and stockholders' equity	$ 237,964	$ 362,572

Source: Madrigal Pharmaceuticals, Inc.