Madrigal Pharmaceuticals Reports Third-Quarter 2024 Financial Results and Provides Corporate Updates

October 31, 2024

- *Third-quarter 2024 net sales of $62.2 million*
- *Rezdiffra™ (resmetirom) coverage goal achieved early, with more than 80 percent of commercial lives covered; less than 5 percent of Rezdiffra-covered lives require biopsy*
- *Completed enrollment of clinical outcomes study of Rezdiffra in patients with compensated NASH/MASH cirrhosis*
- *Reports cash, cash equivalents, restricted cash and marketable securities of $1.0 billion at September 30, 2024*
- *Company to host conference call today, October 31, 2024, at 8 a.m. EDT*

CONSHOHOCKEN, Pa., Oct. 31, 2024 (GLOBE NEWSWIRE) -- Madrigal Pharmaceuticals, Inc. (NASDAQ:MDGL), a biopharmaceutical company focused on delivering novel therapeutics for nonalcoholic steatohepatitis (NASH)/metabolic dysfunction-associated steatohepatitis (MASH), today reports third-quarter 2024 financial results and provides corporate updates.

Bill Sibold, Chief Executive Officer of Madrigal, stated, “Our U.S. launch of Rezdiffra is progressing exceptionally well driven by the outstanding execution of our team. Growing adoption by prescribers, broader payer coverage and an increasing number of patients on therapy each contributed to the strong performance. This early success highlights the critical need for effective treatments for moderate to advanced NASH/MASH, which is expected to become the leading cause of liver transplants in the U.S.”

Sibold continued, “We’ve also advanced our pipeline, completing enrollment in our clinical outcomes study for patients with compensated NASH/MASH cirrhosis. This milestone is key, as positive results could lead to full approval and a broader indication for Rezdiffra.”

Third Quarter and Recent Corporate Updates

- **Rezdiffra U.S. launch update**
  - Madrigal is continuing to execute the U.S. launch of Rezdiffra by educating healthcare providers and patients on the risks of NASH and the potential clinical benefits of Rezdiffra. The Company is also supporting the creation of care pathways for patients at physician offices, driving breadth and depth of Rezdiffra prescribers, engaging with payers to increase Rezdiffra coverage and supporting patient access to therapy.
  - As of September 30, coverage for Rezdiffra was in place for more than 80 percent of commercial lives covered by health insurance in the U.S. The Company achieved its 80 percent commercial coverage goal one quarter ahead of schedule. Less than 5 percent of Rezdiffra-covered lives require biopsy for diagnosis and instead accept noninvasive tests, or NITs, in line with current standard of care.
- **Completed enrollment in MAESTRO-NASH OUTCOMES trial**
  - In October, the Company announced that it completed enrollment in its MAESTRO-NASH OUTCOMES trial evaluating Rezdiffra for the treatment of patients with compensated NASH cirrhosis. Positive results from this study could result in Rezdiffra becoming the first medicine approved for patients with compensated cirrhosis, expanding its eligible patient population, and could support full approval in noncirrhotic NASH.
- **Appointed Dr. Michael Charlton to Senior Vice President of Clinical Development**
  - In October, the Company announced the appointment of Michael Charlton, M.B.B.S., F.R.C.P., as Senior Vice President, Clinical Development. Dr. Charlton has more than 30 years of leadership experience in hepatology, gastroenterology and liver transplantation, with an expertise in NASH. His extensive research in the pathophysiology and treatment of NASH has resulted in over 200 publications, making him a key figure in both clinical and academic hepatology.
- **Rezdiffra quality of life data published in journal of Hepatology**
  - In September, positive health-related quality of life data from the Phase 3 MAESTRO-NASH trial of Rezdiffra was published in the journal *Hepatology*. Results demonstrated that patients with MASH/NASH treated with Rezdiffra experienced clinically meaningful and statistically significant improvements in emotional well-being and health distress.
- **Madrigal to have strong presence at upcoming AASLD Liver Meeting**
  - Madrigal expects to have a significant presence at the upcoming American Association for the Study of Liver Diseases (AASLD) Liver Meeting taking place Nov. 15 -19 in San Diego. More than ten Madrigal abstracts have been accepted for presentation at the meeting, including two oral presentations of new analyses from the Phase 3 MAESTRO-NASH study of Rezdiffra.
- **Driving future growth through European expansion**
  - Rezdiffra is currently under evaluation with the European Medicines Agency’s (EMA) Committee for Medicinal Products for Human Use (CHMP) and has the potential to become the first therapy for patients with NASH/MASH liver fibrosis to receive approval in Europe.

- The Company plans to directly commercialize resmetirom in Europe in the event of a positive decision from the EMA on the Marketing Authorization Application (MAA). The EMA's decision is expected mid-year 2025.

Third-Quarter 2024 Financial Results

- **Total revenues:** The Company generated third-quarter 2024 net revenues of $62.2 million. No product sales were recognized during the comparable prior year period.
- **Operating Expenses:** Third-quarter 2024 operating expenses were $178.5 million, compared to $98.5 million in the comparable prior year period.
  - **Cost of sales:** Third-quarter 2024 cost of sales were $2.2 million. Cost of sales were not recognized during the comparable prior year period given that no product sales were recorded.
  - **R&D Expense:** Third-quarter 2024 R&D expense was $68.7 million, compared to $71.0 million in the comparable prior year period. The decrease was primarily due to the change in accounting for inventory costs following FDA approval of Rezdiffra in March 2024, partially offset by increases in headcount.
  - **SG&A Expense:** Third-quarter 2024 SG&A expense was $107.6 million, compared to $27.6 million in the comparable prior year period. The increase was primarily due to the commercial launch activities for Rezdiffra, including a corresponding increase in headcount, and an increase in stock compensation expense.
- **Interest Income:** Third-quarter 2024 interest income was $13.0 million, compared to $3.3 million in the comparable prior year period. The increase in interest income was due primarily to higher principal balances and interest rates in 2024.
- **Interest Expense:** Third-quarter 2024 interest expense was $3.7 million, compared to $3.5 million in the comparable prior year period. The increase in interest expense was primarily the result of a higher average outstanding principal balance during the period under the Company's loan facility.
- **Cash, Cash Equivalents, Restricted Cash and Marketable Securities:** As of September 30, 2024, Madrigal had cash, cash equivalents, restricted cash and marketable securities of $1.0 billion, compared to $634.1 million at December 31, 2023.

Conference Call and Webcast
At 8 a.m. EDT today, October 31, 2024, the Company will host a webcast to review its financial and operating results and provide a general business update. To access the webcast, please visit the investor relations section of the Madrigal website or click here to register. An archived webcast will be available on the Madrigal website following the event.

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 moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis), the risk of adverse liver outcomes increases dramatically. NASH is expected to become the leading cause of liver transplants 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 moderate to advanced liver fibrosis. Madrigal is focusing on approximately 315,000 diagnosed patients with NASH with moderate to advanced liver fibrosis under the care of the liver specialist physicians during the launch of Rezdiffra.

NASH is also known as metabolic dysfunction associated steatohepatitis (MASH). In 2023, global liver disease medical societies and patient groups came together to rename the disease, with the goal of establishing an affirmative, non-stigmatizing name and diagnosis. Nonalcoholic fatty liver disease (NAFLD) was renamed metabolic dysfunction-associated steatotic liver disease (MASLD); NASH was renamed MASH; and an overarching term, steatotic liver disease (SLD), was established to capture multiple types of liver diseases associated with fat buildup in the liver. In addition to liver disease, patients with MASH have at least one related comorbid condition (e.g., obesity, hypertension, dyslipidemia, or type 2 diabetes).

About Madrigal Pharmaceuticals
Madrigal Pharmaceuticals, Inc. (Nasdaq: MDGL) is a biopharmaceutical company focused on delivering therapeutics for nonalcoholic steatohepatitis (NASH), a liver disease with high unmet medical need. Madrigal's medication, Rezdiffra (resmetirom), is a once-daily, oral, liver-directed THR-β agonist designed to target key underlying causes of NASH. For more information, visit www.madrigalpharma.com.

Forward Looking Statements
This press release 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; and statements regarding: Rezdiffra (resmetirom) and its expected use for treating NASH with moderate to advanced fibrosis; potential future growth of Rezdiffra sales; projections or objectives for obtaining approval from EMA for Rezdiffra (resmetirom) and expected commercialization of Rezdiffra (resmetirom) in Europe; expectations regarding payer coverage; the potential impact of positive results from the MAESTRO-NASH OUTCOMES trial expected presence at the AASLD 2024 Liver Meeting; the U.S. opportunity for Rezdiffra in patients with NASH with moderate to advanced liver fibrosis; the competitive landscape and market dynamics; estimates of patients diagnosed with NASH and

market opportunities; 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", "future" 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; the challenges with the commercial launch of a new product, particularly for a company that does not have commercial experience; our history of operating losses and the possibility that we may never achieve or maintain profitability; 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 Rezdiffra's (resmetirom's) mechanism of action; enrollment and trial conclusion uncertainties; market demand for and acceptance of Rezdiffra; the potential inability to raise sufficient capital to fund ongoing operations as currently planned or to obtain financing on acceptable terms; 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; the timing and outcomes of clinical studies of Rezdiffra (resmetirom); the uncertainties inherent in clinical testing; uncertainties concerning analyses or assessments outside of a controlled clinical trial; and changes in laws and regulations applicable to our business and our ability to comply with such laws and regulations. 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 Part II, Item 1A of its Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, filed with the SEC on October 31, 2024, and as updated from time to time by Madrigal's other filings with the SEC.

Investor Contact
Tina Ventura, IR@madrigalpharma.com

Media Contact
Christopher Frates, media@madrigalpharma.com

(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,	
	2024	2023	2024	2023
Revenues:				
Product revenue, net	$ 62,175	$ -	$ 76,813	$ -
Operating expenses:				
Cost of sales	2,152	-	2,788	-
Research and development	68,742	70,951	211,070	201,710
Selling, general and administrative	107,585	27,583	293,834	61,610
Total operating expenses	178,479	98,534	507,692	263,320
Loss from operations	(116,304)	(98,534)	(430,879)	(263,320)
Interest income, net	13,019	3,298	35,575	10,625
Interest expense	(3,679)	(3,504)	(11,172)	(8,741)
Net loss	$ (106,964)	$ (98,740)	$ (406,476)	$ (261,436)
Basic and diluted net loss per common share	$ (4.92)	$ (5.34)	$ (19.31)	$ (14.27)

Basic and diluted weighted average number of common shares outstanding	21,745,929	18,476,414	21,052,544	18,326,154

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

	September 30, 2024	December 31, 2023
Assets		
Cash, cash equivalents, restricted cash, and marketable securities	$ 1,003,627	$ 634,131
Trade receivables, net	30,463	-
Other current assets	29,576	3,150
Other non-current assets	9,599	3,266
Total assets	$ 1,073,265	$ 640,547
Liabilities and Equity		
Current liabilities	$ 177,847	$ 118,548
Long-term liabilities	118,263	116,666
Stockholders' equity	777,155	405,333
Total liabilities and stockholders' equity	$ 1,073,265	$ 640,547

Source: Madrigal Pharmaceuticals, Inc.