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

May 7, 2024 at 7:00 AM EDT

- *On March 14, 2024, received U.S. FDA approval of Rezdiffra™ (resmetirom) for the treatment of patients with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis*
- *In April 2024, product shipped and first patients received Rezdiffra, the first and only medication approved by the FDA for the treatment of NASH (also known as "MASH")*
- *On March 5, 2024, announced validation of European Medicines Agency marketing application for resmetirom*
- *Raised $690 million in gross proceeds from upsized public offering and full over-allotment exercise*
- *Reports cash, cash equivalents and marketable securities of $1.1 billion at March 31, 2024*
- *Company to host conference call today, May 7, 2024, at 8 a.m. EDT*

CONSHOHOCKEN, Pa., May 07, 2024 (GLOBE NEWSWIRE) -- Madrigal Pharmaceuticals, Inc. (NASDAQ:MDGL), a biopharmaceutical company focused on delivering novel therapeutics for nonalcoholic steatohepatitis (NASH), today reports first-quarter 2024 financial results and provides corporate updates.

Bill Sibold, Chief Executive Officer of Madrigal, stated, "Madrigal is the first company to deliver an approved therapy for patients with NASH, which we believe will give us a strong competitive advantage for many years to come. As a once-daily, well-tolerated, liver-directed, oral medicine that has demonstrated unprecedented efficacy in a pivotal Phase 3 trial, Rezdiffra is well positioned to become the foundational therapy for this serious disease." He continued, "We are focused on executing this first-in-disease launch, where our expert team is partnering with the NASH community to establish treatment pathways for patients, laying the groundwork for our long-term leadership. I'm highly encouraged by the enthusiasm we're seeing for Rezdiffra across our key stakeholders in these early weeks of launch."

Rezdiffra Launch Update

On March 14, 2024, the Company received U.S. Food and Drug Administration (FDA) approval for Rezdiffra for the treatment of patients with noncirrhotic NASH with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). Rezdiffra is a once-daily, oral, liver-directed, THR-β agonist designed to target key underlying causes of NASH.

- **Rezdiffra positioned to address significant patient need as first-ever medicine approved for NASH.** NASH with moderate to advanced liver fibrosis is a serious and progressive liver disease, and Rezdiffra is the first and only FDA-approved therapy for the condition. 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 focused on the approximately 315,000 diagnosed patients with NASH with moderate to advanced liver fibrosis under the care of specialist physicians.
- **Strong label positions Rezdiffra as a foundational therapy for NASH.** The accelerated approval of Rezdiffra was based on results from the Phase 3 MAESTRO-NASH trial, which was published in *The New England Journal of Medicine* in February 2024. This includes data demonstrating Rezdiffra stops or improves fibrosis in more than 80% of patients. The Rezdiffra prescribing information includes simple, weight-based dosing, does not include a liver biopsy requirement for diagnosis, contains no contraindications, no boxed warnings and no monitoring requirements beyond standard of care.
- **Experienced team executing on U.S. specialty launch.** Madrigal built an expert team across sales, medical affairs, market access and patient support that is executing on the Rezdiffra launch. The sales team is engaging with healthcare providers to educate on NASH and Rezdiffra and activate offices to process prescriptions with the support from Madrigal patient services. The market access team is meeting with national and regional payers to establish coverage and increase patient access to Rezdiffra. Rezdiffra started shipping to customers in April.
- **Expanding access to Rezdiffra outside of the U.S.** In March, the Company announced that its Marketing Authorization Application (MAA) for resmetirom for the treatment of NASH/MASH with liver fibrosis was validated and under evaluation with the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP). Resmetirom has the potential to become the first therapy for patients with NASH/MASH with liver fibrosis to receive approval in Europe.

First Quarter and Recent Corporate Updates

- **Raised $690 million from upsized public offering and full over-allotment option exercise.** On March 21, 2024, the Company closed an upsized public offering, which generated gross proceeds of $600 million. On April 2, 2024, the Company closed the underwriters' exercise in full of their option to purchase additional shares for an additional $90 million gross proceeds. Total net proceeds were $660 million after deducting fees and commissions. These proceeds further strengthen the Company's balance sheet and fully resource the Rezdiffra launch.

- **New appointment to the Madrigal leadership team.** On February 28, 2024, the Company announced the appointment of Mardi C. Dier as Chief Financial Officer (CFO). Ms. Dier has spent more than 20 years in executive financial leadership roles in biotechnology companies, including CFO positions at Portola Pharmaceuticals, Ultragenyx, and Acelyrin.
- **MAESTRO-NASH results published in *NEJM*.** On Feb. 8, 2024, positive results from the 52-week pivotal Phase 3 MAESTRO-NASH were published in *The New England Journal of Medicine*, including detailed analyses that reinforce the safety and efficacy profile of Rezdiffra. MAESTRO-NASH is a multicenter, randomized, double-blind, placebo-controlled Phase 3 study of Rezdiffra in patients with liver biopsy-confirmed NASH.
- **Health economic abstracts presented at NASH-TAG.** 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.

First-Quarter 2024 Financial Results

- **Total revenues:** The Company shipped Rezdiffra beginning in April. No revenue was booked in the first quarter.
- **Operating Expenses:** First-quarter 2024 operating expenses were $152.0 million, compared to $78.3 million in the comparable prior year period. The increase is primarily attributable to expenses incurred related to commercial preparation activities.
- **R&D Expense:** First-quarter 2024 R&D expense was $71.2 million, compared to $62.2 million in the comparable prior year period. The increase is primarily attributable to an increase related to timing of manufacturing, headcount and stock compensation expense.
- **SG&A Expense:** First-quarter 2024 SG&A expense was $80.8 million, compared to $16.2 million in the comparable prior year period. The increase is primarily attributable to increases in commercial preparation activities for the launch of Rezdiffra, including significant commercial headcount expansion and stock compensation expense.
- **Interest Income:** First-quarter 2024 interest income was $8.3 million, compared to $3.8 million in the comparable prior year period. The increase in interest income is due primarily to a higher average principal balance in our investment account as well as higher average interest rate.
- **Interest Expense:** First-quarter 2024 interest expense was $3.8 million, compared to $2.3 million in the comparable prior year period. The increase in interest expense was a result of the higher outstanding principal balances during the period under the Company's loan facility as well as higher average interest rate.
- **Cash, Cash Equivalents and Marketable Securities:** As of March 31, 2024, Madrigal had cash, cash equivalents and marketable securities of $1.1 billion, compared to $634.1 million at Dec. 31, 2023. The increase in cash and marketable securities was attributable to the March 2024 public offering partially offset by funding of operations.

Conference Call and Webcast

At 8 a.m. EDT today, May 7, 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 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 moderate to advanced liver fibrosis. Madrigal plans to focus 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 pursuing novel 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; the initiation of the commercial launch of Rezdiffra, including statements regarding commercial insurance and the anticipated time to fill prescriptions; estimates of

patients diagnosed with NASH and market opportunities; the relationship between NASH progression and adverse patient outcomes; the estimated clinical burden of uncontrolled NASH; analyses for patients with NASH with moderate to advanced fibrosis concerning potential progression to cirrhosis, decompensated cirrhosis, liver transplant or death; cardiovascular risks, comorbidities and outcomes; health economics assessments or projections; indicating Rezdiffra has been shown to improve the fibrosis that is associated with progression to cirrhosis and its complications and resolve the underlying inflammation that drives the disease; projections or objectives for obtaining full approval for Rezdiffra (resmetirom), including those concerning potential clinical benefit to support potential full approval; regarding post-approval requirements and commitments; reduced risk of progression to cirrhosis, liver failure, need for liver transplant and premature mortality; treatment paradigm; improved liver enzymes, fibrosis biomarkers and imaging tests; the potential efficacy and safety of Rezdiffra (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, the timing and results associated with the future development of Rezdiffra (resmetirom), the timing and completion of projected future clinical milestone events, including enrollment, additional studies, the potential to support an additional indication for Rezdiffra (resmetirom) in patients with well-compensated NASH cirrhosis; optimal dosing levels for Rezdiffra (resmetirom); potential NASH or NAFLD and potential patient benefits with Rezdiffra (resmetirom), including future NASH resolution, safety, fibrosis treatment, cardiovascular effects, lipid treatment, and/or biomarker effects with Rezdiffra (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," "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; the challenges with the commercial launch of a new product, particularly for a company that does not have commercial experience; 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 our product; 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; the timing and outcomes of clinical studies of Rezdiffra (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 Part II, Item 1A of its Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, filed with the SEC on May 7, 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)
(unaudited)

	Three Months Ended March 31,	
	2024	**2023**
Revenues:		
Total revenues	$ -	$ -
Operating expenses:		
Research and development	71,237	62,154
Selling, general and administrative	80,800	16,182
Total operating expenses	152,037	78,336
Loss from operations	(152,037)	(78,336)
Interest income, net	8,334	3,776

Interest expense		(3,838)		(2,336)
Net loss	$	(147,541)	$	(76,896)
Basic and diluted net loss per common share	$	(7.38)	$	(4.23)
Basic and diluted weighted average number of common shares outstanding		20,001,569		18,187,924

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

		March 31, 2024		December 31, 2023
Assets				
Cash, cash equivalents and marketable securities	$	1,059,063	$	634,131
Other current assets		14,889		3,150
Other non-current assets		8,328		3,266
Total assets	$	1,082,280	$	640,547
Liabilities and Equity				
Current liabilities	$	114,341	$	118,548
Long-term liabilities		117,180		116,666
Stockholders' equity		850,759		405,333
Total liabilities and stockholders' equity	$	1,082,280	$	640,547

Source: Madrigal Pharmaceuticals, Inc.