Madrigal Pharmaceuticals Reports First-Quarter 2025 Financial Results and Provides Corporate Updates

- *First-quarter 2025 Rezdiffra™ (resmetirom) net sales of $137.3 million*
- *As of March 31, 2025, more than 17,000 patients on Rezdiffra*
- *Two-year compensated MASH cirrhosis (F4c) data from MAESTRO-NAFLD-1 trial selected as oral late-breaker at EASL Congress (May 7-10)*
- *Appointed David Soergel, M.D., to Chief Medical Officer; Rebecca Taub, M.D., named Senior Scientific and Medical Advisor*
- *Appointed Jacqualyn Fouse, Ph.D., to Board of Directors*
- *Reports cash, cash equivalents, restricted cash and marketable securities of $848.1 million at March 31, 2025*
- *Company to host conference call today, May 1, 2025, at 8 a.m. EDT*

CONSHOHOCKEN, Pa., May 1, 2025 – Madrigal Pharmaceuticals, Inc. (NASDAQ: MDGL), a biopharmaceutical company focused on delivering novel therapeutics for metabolic dysfunction-associated steatohepatitis (MASH), today reports first-quarter 2025 financial results and provides corporate updates.

Bill Sibold, Chief Executive Officer of Madrigal, stated, “Since Rezdiffra’s approval last year, we’ve executed an exceptional launch. We introduced the first FDA-approved treatment for MASH, launched with a best-case label, built a strong foundation with healthcare providers and payers, and delivered Rezdiffra to more than 17,000 patients. What’s most gratifying is the positive feedback we’re hearing from healthcare providers – they’re seeing meaningful improvements in the measures that matter most to patients, including liver stiffness, liver fat, liver enzymes, LDL and triglycerides, which are exceeding their expectations.”

Sibold continued, “We’re building on our leadership in MASH, and we believe Rezdiffra is on track to become the foundational therapy across F2 to F4c MASH. Later this month at the EASL Congress, we’ll share new Rezdiffra F4c late-breaking data from our MAESTRO-NAFLD-1 trial that shows its effect on the risk of clinically significant portal hypertension – a major consequence of cirrhosis that’s responsible for its most severe complications. In addition, we’re awaiting a regulatory decision from the European Medicines Agency expected mid-year that, if positive, would make Rezdiffra the first MASH therapy approved for patients in Europe.”

First Quarter 2025 and Recent Corporate Updates

- **Marked the one-year approval anniversary of Rezdiffra on March 14, 2024; more than 17,000 patients on Rezdiffra as of March 31, 2025**
- **Reported two-year F4c data from MAESTRO-NAFLD-1 trial**
  - In February, Madrigal announced two-year results from the active-treatment open-label compensated MASH cirrhosis (F4c) arm of its Phase 3 MAESTRO-NAFLD-1 trial (n=101):
    - Patients achieved a mean 6.7 kPa reduction in liver stiffness as measured by vibration-controlled transient elastography (VCTE). This reduction was statistically significant as compared to baseline.
    - 51% of patients achieved a ≥ 25% reduction in liver stiffness as measured by VCTE. A reduction of this magnitude has been associated with reduced progression to end-stage liver disease.

    - Rezdiffra's safety and tolerability profile was consistent with other Rezdiffra clinical trials with a low discontinuation rate due to adverse events.
  - The results further support the potential benefit of Rezdiffra in patients with compensated MASH cirrhosis and the potential success of the ongoing MAESTRO-NASH OUTCOMES trial, a double blind, placebo-controlled, event-driven trial in F4c, for which data are anticipated in 2027.
- **Strong presence at upcoming European Association for the Study of Liver (EASL) Congress being held May 7-10, 2025**
  - Six Madrigal abstracts were accepted by the EASL Congress, which will take place from May 7-10, 2025, in Amsterdam, the Netherlands. The abstracts include a late-breaking oral presentation with detailed two-year data from the active-treatment open-label compensated MASH cirrhosis (F4c) arm of the Phase 3 MAESTRO-NAFLD-1 trial. The presentation will focus on the impact of Rezdiffra on liver stiffness, fibrosis biomarkers and the risk of clinically significant portal hypertension, a major consequence of cirrhosis that's responsible for its most severe complications, such as ascites, variceal bleeding and hepatic encephalopathy.
- **Madrigal will host an investor webcast to review the F4c two-year data on May 13, 2025**
  - At 8 a.m. EDT May 13, 2025, Madrigal will host a webcast to review the detailed two-year data from the active-treatment open-label compensated MASH cirrhosis (F4c) arm of the Phase 3 MAESTRO-NAFLD-1 trial. To access the webcast, please visit the investor relations section of the Madrigal website or click here to register.
- **Appointed David Soergel, M.D., as Chief Medical Officer; named Rebecca Taub, M.D., to Senior Scientific and Medical Advisor**
  - In April, the Company announced that David Soergel, M.D., was appointed to Chief Medical Officer, succeeding Rebecca Taub, M.D., who moved to the role of Senior Scientific and Medical Advisor. Dr. Taub founded Madrigal in 2011; her pioneering research in academia and industry led to the first FDA-approved therapy for patients with MASH.
  - Dr. Soergel brings more than 20 years of leadership experience in metabolic and cardiovascular disease drug development, most recently as Executive Vice President and Global Head of Cardiovascular, Renal and Metabolism Development at Novartis.
- **Appointed Jacqualyn ("Jackie") Fouse, Ph.D. to Board of Directors**
  - In March 2025, Jackie Fouse, Ph.D., was appointed to Madrigal's Board of Directors.
  - Dr. Fouse is an accomplished biotech executive, with more than 30 years of biopharmaceutical and financial leadership experience. Dr. Fouse has served in executive leadership roles as a CEO, CFO and COO across multiple biotechnology companies, including Agios Pharmaceuticals and Celgene Corporation.

First-Quarter 2025 Financial Results

- **Total revenues:** The Company generated first-quarter 2025 net revenues of $137.3 million. No product sales were recognized during the comparable prior year period.
- **Operating Expenses:** First-quarter 2025 operating expenses were $216.6 million, compared to $152.0 million in the comparable prior year period.
  - **Cost of sales:** First-quarter 2025 cost of sales was $4.5 million. Cost of sales was not recognized during the comparable prior year period given that no product sales were recorded.
  - **R&D Expense:** First-quarter 2025 R&D expense was $44.2 million, compared to $71.2 million in the comparable prior year period. Research and development expenses decreased by $27.1 million primarily due the change in accounting for inventory costs

following FDA approval of Rezdiffra in March 2024 and a reduction in clinical trial expense.
    - **SG&A Expense:** First-quarter 2025 SG&A expense was $167.9 million compared to $80.8 million in the comparable prior year period. Selling, general and administrative expenses increased by $87.1 million due primarily to increases for commercial launch activities for Rezdiffra, including a corresponding increase in headcount, and an increase in stock compensation expense.
- **Interest Income:** First-quarter 2025 interest income was $9.4 million compared to $8.3 million in the comparable prior year period. The increase in interest income was due primarily to higher principal balances.
- **Interest Expense:** First-quarter 2025 interest expense was $3.3 million compared to $3.8 million in the comparable prior year period. The decrease of $0.5 million was primarily the result of lower interest rates in 2025.
- **Cash, Cash Equivalents, Restricted Cash and Marketable Securities:** As of March 31, 2025, Madrigal had cash, cash equivalents, restricted cash and marketable securities of $848.1 million, compared to $931.3 million at December 31, 2024. This decrease was attributable to funding of operations.

Conference Call and Webcast
At 8 a.m. EDT today, May 1, 2025, Madrigal 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 MASH
Metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), is a serious liver disease that can progress to cirrhosis, liver failure, liver cancer, need for liver transplantation, and premature mortality. MASH is expected to become the leading cause of liver transplantation in the U.S. and is already the leading cause of liver transplantation among women.

Once patients progress to MASH with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis), the risk of adverse liver outcomes increases dramatically. These patients have a 10 to 17 times higher risk of liver-related mortality as compared to patients without fibrosis. Those who progress to cirrhosis face a 42 times higher risk of liver-related mortality, underscoring the need to treat MASH before complications of cirrhosis develop. MASH is also an independent driver of cardiovascular disease, the leading cause of mortality for patients.

An estimated 1.5 million patients have been diagnosed with MASH in the U.S., and Madrigal is focused on reaching approximately 315,000 patients with moderate to advanced fibrosis who are under the care of liver specialists. As MASH disease awareness improves and disease prevalence increases, the number of diagnosed patients with MASH with moderate to advanced fibrosis is expected to grow.

About Rezdiffra
What is Rezdiffra?
Rezdiffra is a prescribed medicine used along with diet and exercise to treat adults with nonalcoholic steatohepatitis (NASH) with moderate to advanced liver scarring (fibrosis), but not with cirrhosis of the liver.
It is not known if Rezdiffra is safe and effective in children (under 18 years old).

This indication is approved based on improvement of NASH and liver scarring (fibrosis). There are ongoing studies to confirm the clinical benefit of Rezdiffra.

Before you take Rezdiffra, tell your healthcare provider about all of your medical conditions, including if you:

- have any liver problems other than NASH.
- have gallbladder problems or have been told you have gallbladder problems, including gallstones.
- are pregnant or plan to become pregnant. It is not known if Rezdiffra will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Rezdiffra passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take Rezdiffra.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

- Rezdiffra and other medicines may affect each other, causing side effects. Rezdiffra may affect the way other medicines work, and other medicines may affect how Rezdiffra works.
- Especially tell your healthcare provider if you take medicines that contain gemfibrozil to help lower your triglycerides, or cyclosporine to suppress your immune system, because Rezdiffra is not recommended in patients taking these medicines.
- Tell your healthcare provider if you are taking medicines such as clopidogrel to thin your blood or statin medicines to help lower your cholesterol.
- Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

What are the possible side effects of Rezdiffra?

Rezdiffra may cause serious side effects, including:

- liver injury (hepatotoxicity). Stop taking Rezdiffra and call your healthcare provider right away if you develop the following signs or symptoms of hepatotoxicity: tiredness, nausea, vomiting, fever, rash, your skin or the white part of your eyes turns yellow (jaundice), pain or tenderness in the upper middle or upper right area of your stomach (abdomen).
- gallbladder problems. Gallbladder problems such as gallstones, inflammation of the gallbladder, or inflammation of the pancreas from gallstones can occur with NASH and may occur if you take Rezdiffra. Call your healthcare provider right away if you develop any signs or symptoms of these conditions including nausea, vomiting, fever, or pain in your stomach area (abdomen) that is severe and will not go away. The pain may be felt going from your abdomen to your back and the pain may happen with or without vomiting.

The most common side effects of Rezdiffra include: diarrhea, nausea, itching, stomach (abdominal) pain, vomiting, dizziness, constipation.

These are not all the possible side effects of Rezdiffra. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Madrigal at 1-800-905-0324.

Please see the full Prescribing Information, including Patient Information, for Rezdiffra.

About Madrigal

Madrigal Pharmaceuticals, Inc. (Nasdaq: MDGL) is a biopharmaceutical company focused on delivering novel therapeutics for metabolic dysfunction-associated steatohepatitis (MASH), 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 MASH. Rezdiffra is the first and only medication approved by the FDA for the treatment of MASH with moderate to advanced fibrosis (consistent with stages F2 to F3). An ongoing Phase 3 outcomes trial is evaluating Rezdiffra for the treatment of compensated MASH cirrhosis (consistent with stage F4c). 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, as amended, including statements related to Madrigal's aspirations to be the leading company in the MASH sector and Rezdiffra's role as a foundational therapy, the timing and potential impact of results from the MAESTRO-NASH OUTCOMES trial, the potential benefit of Rezdiffra in patients with compensated MASH cirrhosis, the timing for a regulatory decision by the European Commission and the planned launch of Rezdiffra in Europe. 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 related to obtaining and maintaining regulatory approvals, including, but not limited to, potential regulatory delays or rejections; 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 trials, 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 trials; 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; 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; our ability to service indebtedness and otherwise comply with debt covenants; outcomes or trends from competitive trials; future topline data timing or results; our ability to prevent and/or mitigate cyber-attacks; the timing and outcomes of clinical trials 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("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, 2024, filed with the SEC on February 26, 2025, and Part II, Item 1A of its Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, filed with the SEC on May 1, 2025, and as updated from time to time by Madrigal's other filings with the SEC.

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Madrigal Pharmaceuticals, Inc.
Condensed Consolidated Statement of Operations
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2025	2024
Revenues:		
Product revenue, net	$ 137,250	$ -
Operating expenses:		
Cost of sales	4,513	-
Research and development	44,172	71,237
Selling, general and administrative	167,876	80,800
Total operating expenses	216,561	152,037
Loss from operations	(79,311)	(152,037)
Interest income	9,370	8,334
Interest expense	(3,297)	(3,838)
Net loss	$ (73,238)	$ (147,541)
Basic and diluted net loss per common share	$ (3.32)	$ (7.38)
Basic and diluted weighted average number of common shares outstanding	22,091,314	20,001,569

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

	March 31, 2025	December 31, 2024
Cash, cash equivalents, restricted cash and marketable securities	$ 848,068	$ 931,251
Trade receivables, net	61,428	53,822
Other current assets	78,483	47,854
Other non-current assets	8,650	9,320
Total assets	$ 996,629	$ 1,042,247
Liabilities and Equity		
Current liabilities	$ 167,237	$ 169,277
Long-term liabilities	118,755	118,587
Stockholders' equity	710,637	754,383
Total liabilities and stockholders' equity	$ 996,629	$ 1,042,247